SAMHSA SUBRECIPIENT AGREEMENT

BETWEEN

THE CITY OF COLUMBIA, MISSOURI,

AND

THE CURATORS OF THE UNIVERSITY OF MISSOURI

THIS AGREEMENT is entered into on the date of the last signatory noted below (the "Effective Date"), between the City of Columbia, Missouri, a municipal corporation (hereinafter "City") and The Curators of the University of Missouri, a body politic, organized in the State of Missouri with authority to transact business within the State of Missouri (hereinafter "Subrecipient"), is hereby entered into as of the date of the last party to execute the Agreement (the "Effective Date").

WITNESSETH:

WHEREAS, the City of Columbia received a grant from the U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (hereinafter "SAMHSA")to establish the Boone County Community Paramedic Program (hereinafter "Project");

WHEREAS, the City identified a need for a subrecipient to carry out part of the program;

WHEREAS, Subrecipient represents and warrants that Subrecipient is equipped, competent, and able to provide all of the work for the Project in accordance with the terms of this Agreement; and

NOW, THEREFORE, in consideration of the mutual covenants set out in this Agreement and for other good and valuable consideration (the receipt and sufficiency of which is hereby acknowledged), the Parties agree as follows.

1. Project Scope and Approved Budget:
   a. The Project Scope and Approved Budget are set forth in Exhibit F.
   b. Prior Approval for Changes: Subrecipient may not transfer allocated funds among cost categories within the approved budget without the prior written approval of the City's Designated Representative; nor shall Subrecipient make any changes, directly or indirectly, to program design, Approved Activities, or Approved Budget without the prior written approval of City. All changes must be in accordance with the Grant Requirements, and may require approval by the federal agency.
   c. This is a cost-reimbursement Agreement. Disbursement of the funding for the Project under this Agreement may be requested only for necessary, reasonable, and allowable costs of the Project in accordance with the Approved

Budget during the period of performance which begins on the Effective Date of the Agreement.

2. Term(s) and Amount of Funding

a. Initial Term: Subject to the availability of funds, City shall provide funding to Subrecipient in the amount of four hundred fifty-four thousand, three hundred forty-nine dollars ($454,349.00). The Initial Term is for a period from the September 30, 2024 until September 29, 2025.

b. Renewal Terms: Subject to the availability of funds, City may renew the Agreement for up to two, additional consecutive terms of one year. The total amount funding for each renewal term shall not exceed four hundred fifty-four thousand, three hundred forty-nine dollars ($454,349.00) or the amount of federal funding provided for the renewal term, whichever is less.

c. The amount of Funds, however, is subject to reduction by the City if a substantial change is made in the Approved Activities that affects this Agreement, if the amount of federal funding is reduced, or if this Agreement is terminated prior to the expiration of the Agreement.

d. If unspent grant funding from the initial period of the grant (9/30/23-9/29/24) is determined to be available and SAMHSA agrees in writing to allow the unspent grant funding from the initial period (9/30/23-9/29/24) to be used in either the Initial Term or Renewal Terms (as those terms are defined in Sections 2(a) and (b) above, the City's Public Health and Human Services Department Director may authorize in writing an increase in the amounts set forth above. Any approved increase shall be no higher than the unspent amount from the initial period of the grant that SAMHSA has determined may be utilized as additional funding in either the Initial Term or any Renewal Term.

3. City's Subaward Obligations Contingent on Federal Funding and Subrecipient Compliance: The payment of funds to Subrecipient under the terms of this Agreement shall be contingent on the receipt of such funds by City pursuant to the SAMHSA grant and shall be subject to Subrecipient's continued eligibility to receive funds under the applicable provisions of state and federal laws. If the amount of funds that City receives from the SAMHSA grant is reduced, City may reduce the amount of funds awarded under this Agreement or terminate this Agreement. City also may deny payment for Subrecipient's expenditures for Approved Activities where invoices or other reports are not submitted by the deadlines specified in this Agreement or for failure of Subrecipient to comply with the terms and conditions of this Agreement.

4. Compliance with Grant Requirements: Subrecipient acknowledges federal grant funds are being used for this Project. Subrecipient agrees to familiarize itself and comply with all conditions and requirements for utilization of such grant funds, including, but not limited to those set forth or referenced herein, or attached hereto. Subrecipient shall perform all Approved Activities funded by this Agreement in accordance with this

Agreement, and the award agreement/requirements between City and the US Department of Health and Human Services, and all applicable federal, state and local requirements, including all applicable statutes, rules, regulations, executive orders, directives or other requirements. Such requirements may be different from Subrecipient's current policies and practices. Subrecipient remains responsible for ensuring its compliance with all applicable requirements.

5. Restriction on Disbursements: The funding for this Project shall not be disbursed to Subrecipient except pursuant to the conditions of this Agreement. Disbursements may be suspended or terminated under this Agreement upon Subrecipient's refusal to accept any additional conditions that may be imposed by the City at any time or if the federal funding granted to the City is suspended or terminated.

6. The following regulations apply to this Agreement:

a. Uniform Guidance, 2 Code of Federal Regulations (CFR) Section 200 as codified by the US Department of Health and Human Services at 45 CFR Section 75;

b. Department of Health and Human Services (HHS) Grant Policy Statement at https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf (Exhibit E);

c. SAMHSA Additional Directives at https://www.samhsa.gov/grants/grants-management/policies-regulations/additional-directives (Exhibit D);

d. Standard Terms and Conditions for the fiscal year in which the grant was awarded at: https://www.samhsa.gov/grants/grants-management/notice-award-noa/standard-terms-conditions (Exhibit B).

7. Additional Grant Requirements: Subrecipient shall comply with the grant requirements contained in the Notice of Award in Exhibits A, B, C. D, and E.

8. Funding Limitations: Subrecipient is responsible for ensuring that costs allocated to the grant award are reasonable and allowable in accordance with the Notice of Funding opportunity and all applicable policies and regulations. The Cost Principles that delineate the allowable and unallowable expenditures are described in the Code of Federal Regulations. Subrecipient must exercise proper stewardship over federal funds and ensure that costs charged to awards are allowable, allocable, reasonable, necessary and consistently applied regardless of the source of funds according to the "Factors affecting allowability of costs per 2 CFR Section 200.403 and the "Reasonable Costs" considerations per 2 CFR Section 200.404. All costs incurred prior to the award issue date and costs not consistent with the funding opportunity, 45 CFR Section 75 and the HHS Grants Policy Statement, are not allowable under this award. See also, Exhibit C, including, Appendices I and L.

9. Supplanting. Subrecipient must not use grant funding to supplant current funding of existing activities.

10. Treatment of Program Income. Subrecipient will add program income to funds committed to the project to further eligible project objectives, in accordance with the Notice of Award, contained in Exhibit A.

11. System for Award Management. Subrecipient must comply with the reporting and regulatory requirements that are applicable as set forth in Exhibit A, B, and C.

12. Disclosure of Lobbying Activities: Subrecipient must not use the funds for publicity or propaganda purposes or for the preparation, distribution or use of information designed to support or defeat legislation pending before Congress or state legislatures. Subrecipient must comply with the requirements set forth in Exhibit B, Section 22.

13. Failure to Comply with Award Terms and Conditions: Failure to comply with the terms and conditions may result in actions in accordance with 45 CFR 75.371. Remedies for non-compliance and 45 CFR 75.372 Termination. This may include withholding payment, disallowance of costs, suspension and debarment, termination of the award, or denial of future funding.

14. Improper Payments: Any item of expenditure by Subrecipient under the terms of this Agreement which is found by auditors, investigators, and other authorized representatives of the City, the US Department of Health and Human Services, the State of Missouri Treasurer, or other federal or state instrumentality to be improper, unallowable, in violation of federal or state law, or the terms of this Agreement, or involving any fraudulent, deceptive, or misleading representations or activities of Subrecipient, shall become Subrecipient's liability, and shall be paid solely by Subrecipient, immediately upon notification of such, from funds other than those provided by City under this Agreement or any other agreements between City and Subrecipient. This provision shall survive the expiration or termination of this Agreement.

15. Reimbursement Requests and Invoices:

a. To obtain reimbursement for such costs, Subrecipient must submit a request for reimbursement to the City using the form required by the City. On or before the fifteenth (15th) day of each month and in any event no later than sixty (60) days after the earlier of the expiration or termination of this Agreement, Subrecipient shall submit invoices and associated receipts, in a format dictated by City, for the most recent month ended, to City's Director of Public Health and Human Services setting forth actual expenditures of Subrecipient in accordance with this Agreement. Within ten (10) working days from the date it receives such

invoice, City may disapprove the requested reimbursement claim. If the reimbursement claim is so disapproved, City shall notify Subrecipient as to the disapproval. If City approves payment, then City will disburse the funds without further notice.

b. Upon request, Subrecipient shall submit documentation showing to City's satisfaction that the expenditure is an appropriate intended use of the grant funds and compliance with this Agreement and the federal grant requirements. Such documentation shall include, but is not limited to, contract(s) entered into by Subrecipient, or agreements between a contractor and the Subrecipient, for the work; an agency payment voucher; a copy of the signed check with which the payment was made; any invoices, receipts and/or bills from vendors; and related payroll reports. City reserves the right to request further supporting documentation as necessary to ensure compliance with the federal legislation, its implementing regulations, 2 CFR Part 200, and the terms of this Agreement.

c. Subrecipient shall also submit the Duplication of Benefits Certification with each request for reimbursement.

16. Reporting Requirements: Subrecipient shall comply with the Reporting Requirements set forth herein and in Exhibits A, B, and C, including but not limited to Integrity and Performance Matters. Subrecipient shall timely provide data on activities and progress reports to City on a schedule provided by City's Designated Representative so that City may provide reporting to the federal agency. These requirements extend to all years of the grant program.

17. Certification Statement: Subrecipient certifies that proper financial management controls and accounting systems, to include policies and procedures have been established to adequately administer the Federal awards and funds drawn down. Subrecipient certifies that it will comply with all terms and conditions of the award including:

a. Terms and conditions included in the HHS Grants Policy Statement in effect at the time of a new, non-competing continuation, or renewal award, including the requirements of HHS grants administration regulations including but not limited to all flow down Public Policy Requirements (see Exhibits)

b. Requirements of the authorizing statutes and implementing regulations for the program under which the award is funded;

c. Applicable requirements or limitations in the appropriations act; and

d. Requirements specific to the particular award specified in the program policy and guidance, the Notice of Funding Opportunity (NOFO) (Exhibit C), or the Notice of Award (NOA) (Exhibit A).

18. Award Expectations: Subrecipient must comply with the performance goals, milestones, outcomes, and performance data collection as reflected in the NOFO (Exhibit C) and related policy and guidance. Additional terms and / or conditions may

be applied if outstanding financial and programmatic compliance issues are identified by SAMHSA or the City.

19. Future Spending: Funding is subject to the availability of Federal funds, satisfactory progress and continued funding is in the best interest of the Federal government.

20. Conflicts of Interest Policy: Subrecipient must establish written policies and procedures to prevent employees, consultants, and others (including family, business or other ties) involved in grant supported activities, from involvement in actual or perceived conflicts of interest. The policies and procedures must meet the requirements set forth in Exhibit B.

21. Administrative and National Policy Requirements: Subrecipient must ensure that their activities comply with all applicable federal regulations set forth in the HHS Grants Policy Statement.

22. Marijuana Restriction: Subrecipient must not use grant funds to purchase, prescribe, or provide marijuana or treatment using marijuana.

23. Promotional Items: Subrecipient must not use grant funds for Promotional Items in accordance with the HHS Policy on the Use of Appropriated Funds for Promotional Items as set forth in Section 14 of Exhibit B.

24. Financial Accountability and Transparency Act (FFATA): Subrecipient shall comply with the requirements of the FFATA as set forth in Section 16 of Exhibit B.

25. Acknowledgement of Federal Funding in Communications and Contracting: Subrecipient must comply with the requirements set forth in Exhibit B, Section 18.

26. Acknowledgement of Federal Funding at Conferences and Meetings. Subrecipient must comply with the requirements set forth in Exhibit B, Section 19.

27. Rights in Data and Publications: Subrecipient must comply with the requirements set forth in Exhibit B, Section 20; and in Exhibit C.

28. Mandatory Disclosures: Subrecipient must comply with the requirements set forth in Exhibit B, Section 21. Subrecipient must disclose, in a timely manner, in writing to the City, all information related to violations of federal criminal law involving fraud, bribery or gratuity violations potentially affecting the federal award. Failure to make required disclosures can result in any of the remedies decribed in 45 CFR 75.371 Remedies for noncompliance; including suspension of debarment (See 2 CFR parts 180 & 376 and 31 U.S.C. 3321. See also Exhibit C.

29. Drug Free Workplace: Subrecipient shall comply with the Drug-Free Workplace Act of 1988, as set forth in Exhibit B, Section 23.

30. Civil Rights Laws that Prohibit Discrimination: Subrecipient shall comply with the Civil Rights Laws that Prohibit Discrimination, regulations, rules and guidance as set forth in Exhibit B, Section 24.

31. Confidentiality of Alcohol and Drug Abuse Patient Records: To the extent applicable, Subrecipient must comply with the requirements set forth in Exhibit B, Section 26. Subrecipient's Emergency Medical Services shall maintain patient records in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as described in Section 54.

32. Healthy People 2020: Subrecipient acknowledges that the federal agency is leading a national initiative which sets priorities for all SAMHSA programs. See Exhibit B, Section 27.

33. Accessibility Provisions: Subrecipient must administer the program in compliance with Federal civil rights laws and shall ensure equal access to the program without regard to a person's race, color, national origin, disability, age, and in some circumstances, sex and religion. This includes ensuring programs are accessible to persons with limited English proficiency, with culturally and linguistically appropriate services in health and health care, and persons with disabilities, consistent with the requirements set forth in Exhibit B, Section 28; and Exhibit C.

34. Data Collection and Performance Measurement: Subrecipient must collect and report evaluation data to ensure the effectiveness and efficiency of tis programs under the Government Performance and Results Modernization Act of 2010 (P.L. 102-62). Subrecipients must comply with the performance goals, milestones, and expected outcomes as reflected in the NOFO and as set forth in Exhibits A and B.

35. Legislative Mandates: Subrecipient shall comply with all legislative mandates that limit the use of grants funds, as may be included in specific appropriation language. See Exhibit B, Section 30.

36. Executive Order 13410: Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs: To the extent applicable to Subrecipient, Subrecipient shall comply with Executive Order 13410, as set forth in Exhibit B, Section 31.

37. Ad Hoc Submissions: Should SAMHSA determine that a grant requires submission of additional information beyond the standard deliverables including but not

limited to those items listed in Exhibit B, Section 33, Subrecipient must timely provide the additional information.

38. Risk Assessment: Should City or SAMHSA determine that there are material weaknesses or other financial management concerns, grant funding may be restricted in accordance with 45 CFR Section 75/2 CFR Section 200, as applicable.

39. 120 Day Reconciliation and Liquidation Period: In accordance with 2 CFR Section 200.344, recipient must liquidate all obligations incurred under the award not later than 120 days after the end of the award's obligation and expenditure period (the project period). Unless extended by City's Designated Representative, Subrecipient shall provide all necessary and requested information for the City to liquidate all obligations no later than 90 days after the end of the award's obligation and expenditure period.

40. Cancel Year: For information on the cancel year, see Exhibit B, Section 37.

41. Termination: This award may be terminated in whole or in part,

a. By SAMHSA or the City, if the City or the Subrecipient fails to comply with the terms and conditions of the federal award;

b. By SAMHSA or City for cause;

c. By SAMHSA or City with the consent of the Subrecipient, as set forth in Exhibit B, Section 38;

d. By Subrecipient upon sending to SAMHSA and the City written notification setting forth the reasons for such termination, the effective date, and in the case of partial termination, the portion to be terminated. However, if the federal agency or City determines in the case of partial termination that the reduced or modified portion of the federal award or subaward will not accomplish the purposes for which the federal award was made, SAMHSA or City may terminate the funding in its entirety.

42. Termination for Cause: In the event that Subrecipient fails to comply with any term of this Agreement, the City may suspend or terminate this Agreement, in whole or in part, or take other remedial action in accordance with 2 CFR § 200.339 through 200.343. Should the City desire to terminate this Agreement for noncompliance, it shall first give written notice of the reason for proposed termination. The notice shall set forth the following: (a) Reasonable description of the default/reason for termination; (b) Demand for a cure; and (c) Statement of reasonable time within which a cure must be effected. Such reasonable time will be presumed to be not less than five, nor more than fifteen, business days. Such times shall be measured from the actual receipt of said notice. In the event of termination of this Agreement by the City, when termination is due to Subrecipient noncompliance as set forth above, Subrecipient shall forfeit to the City all unexpended monies provided under the Agreement. At the City's discretion,

Subrecipient may also be required to refund all the funding awarded during the period of this Agreement that have already been spent by Subrecipient and reimbursed by the City. If Subrecipient cures the default within the reasonable period of time set forth in the notice, or as otherwise agreed between the parties, the City shall not terminate the Agreement and the written notice of proposed termination shall be deemed revoked, null and void.

43. Termination for Convenience: City shall have the right at any time by written notice to Subrecipient to terminate and cancel this Agreement, without cause, for the convenience of City, and Subrecipient shall immediately stop work. In such event City shall not be liable to Subrecipient except for payment for actual work performed prior to such notice in an amount proportionate to the completed contract price and for the actual costs of preparations made by Subrecipient for the performance of the cancelled portions of the Agreement, including a reasonable allowance of profit applicable to the actual work performed and such preparations. In the event of termination for convenience, City, at its sole option, may purchase, for just and equitable compensation any and all finished or unfinished documents, data, studies, and reports or other materials prepared by Subrecipient under this Agreement. Any reuse of any satisfactory work completed prior to the termination for convenience shall be at City's own risk and without any liability to Subrecipient. Anticipatory profits and consequential damages shall not be recoverable by Subrecipient.

44. Termination by Mutual Agreement: City and Subrecipient may agree to terminate this Agreement for their mutual convenience. The Parties will state the effective date of the termination and the procedures for proper closeout of the Agreement, which shall be documented in writing and signed by both parties.

45. Termination for Insufficient Funding: In the event that sufficient funds are not appropriated, or the event that the federal agency reduces the funding amount for any reason, this Agreement may be terminated in whole or in part, at the sole discretion of the City, with fifteen business days' written notice to Subrecipient. Subrecipient understands and agrees that the City shall not be liable for any costs or injuries caused by or related to such reduction in funds.

46. Imposition of Sanctions: The City reserves the right to impose sanctions on Subrecipient for the violation of any terms of this Agreement, failure to comply with any terms of this Agreement, or failure to undertake the Project in a timely manner. Sanctions may include, but are not necessarily limited to, suspension of the funding operations until corrective measures are implemented, withholding any and all project funds, termination of the Agreement, requiring the Subrecipient to return funds already received, or barring the Subrecipient from future funding. No sanction may be imposed pursuant to this paragraph unless the City complies with requirements of Section 43 and

Subrecipient fails to cure the alleged default within the reasonable period of time provided for in the notice or as otherwise agreed between the parties.

47. Other Remedial Actions and Reservation of Rights:

a. The City reserves the right to impose additional conditions or requirements on Subrecipient's receipt of this funding, as the City deems necessary or advisable, in order to facilitate compliance with any existing or additional conditions or requirements imposed upon the City by the federal agency.

b. The City also reserves the right to seek recoupment or repayment of this funding in whole or in part, in the event that the federal agency seeks recoupment or repayment of payments made to the City, for reasons relating to Subrecipient's acts or omissions respecting this funding.

c. These reservations are expressed without limitation to any other rights the City may hold, either to impose additional conditions or requirements on Subrecipient's receipt of this funding or to recoup this funding in whole or in part, under this Agreement or other applicable law.

48. Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment: Subrecipient shall comply with the prohibitions on certain telecommunications and video surveillance services as set forth in 2 CFR Section 200.216, and in Exhibit B, Section 39; and Exhibit C.

49. Quality of Services: The funding is for services or practices that have a demonstrated evidence base and that are appropriate for the population of focus. Subrecipient must implement high quality programs, practices and policies that are recovery-oriented, trauma-informed, and equity-based as a means of improving behavioral health and recovery. See Exhibit C, Sections 5 and 7.

50. Tobacco and Nicotine Free Policy: SAMHSA encourages all recipients to adopt a tobacco/nicotine inhalation (vaping) product-free facility/grounds policy and to promote abstinence from all tobacco products (except in regard to accepted tribal traditions and practices).

51. Pro-Children Act of 1994: Subrecipient must comply with the Pro-Children Act of 1994.

52. Reimbursement for the Provision of Services: Subrecipient must utilize third party reimbursements and other revenue realized from the provision of services to the extent possible and use SAMHSA funds only for services to individuals who are not covered by public or commercial health insurance programs, individuals for whom coverage have been formally determined to be unaffordable, or for services that are not sufficiently covered by an individual's health insurance plan. Subrecipients are responsible for making the detmination of affordability and insurance coverage and

must have policies and procedures in place to address these areas. Subrecipients are also expected to facilitate the health insurance application process for eligible uninsured clients. Subrecipient should also consider other systems from which a potential service recipient may be eligible for services, if appropriate for and desired by that individual to meet his/her/their needs. Additionally, Subrecipient is required to implement policies and procedures that ensure other sources of funding are utilized first when available for the individual. Subrecipient shall also address the behavioral health needs of active duty military service members, returning veterans, and military families in designing and developing their programs and to consider prioritizing this population for services where appropriate. Additionally, Subrecipient must address the behavioral needs of the LGBTQI+ population in designing and developing their programs and to consider prioritizing this population for services, where appropriate.

53. Confidentiality and SAMHSA Participant Protection / Human Subject Guidelines: Subrecipient must comply with the Confidentiality and SAMHSA Participant Protection / Human Subject Guidelines, and any SAMHSA approved requirements that are applicable to this funding. To the extent applicable, Subrecipient must comply with Human Subjects Regulations (45 CFR 46), and related guidance.

54. Health Insurance Portability and Accountability Act of 1996 (HIPAA): Subrecipient shall comply with HIPAA, the Privacy Rule, and any other rules, regulations, and guidance related to protection of protected health information. To the extent required by law, the Subrecipient shall keep patient protected health information confidential for as long as the data is maintained. This clause shall survive termination of the Agreement and shall continue to be in effect for as long as Subrecipient maintains the protected health information.

55. Trafficking in Persons: Subrecipient must comply with Trafficking Victims Protection Act of 2000, and with the administrative and national policy requirements related to Human Trafficking, see Exhibit C.

56. Additional Directives: Subrecipient must comply with SAMHSA's additional directives which are set forth in Exhibit D.

57. Record Retention and Access: Subrecipient must retain financial and programmatic records, supporting documents, statistical records, and all other records that are required by the terms of the grant, or may reasonably be considered pertinent to the grant for a period of time set forth in the Grant Requirements (Exhibits A, B, C, and D) or for the applicable Missouri state record retention requirement, whichever is longer. If there is a claim, litigation, or an audit started, the records must be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken. Subrecipient agrees to ensure, to the greatest extent possible, the cooperation of its agents, employees and board members in such monitoring and evaluation efforts. Subrecipient shall make all records, books, papers, data and other

documents that relate to this Agreement available at all reasonable times for inspection, review and audit by the authorized representatives of the City, the Missouri State Auditor, the US Department of Treasury, the US Government Accountability Office, the U.S. Inspector General, and any other authorized state or federal oversight office. This clause shall survive termination of the Agreement.

58. Audit Requirements: Subrecipient shall comply with the audit requirements set forth in Exhibit D.

59. Certification Regarding Lobbying: Subrecipient shall comply with all requirements of 31 U.S.C. 1352 that is incorporated herein as if fully set forth. Subrecipient certifies by signing and submitting this Agreement, to the best of its knowledge and belief, that:

a. No Federal appropriated funds have been paid or will be paid, by or on behalf of the Subrecipient, to any person for influencing or attempting to influence an officer or employee of an Subrecipient, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

b. If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any Subrecipient, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the Subrecipient shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.

c. The Subrecipient shall require that the language of this certification be included in the award documents for all sub-awards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all sub-recipients shall certify and disclose accordingly.

d. This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

60. Debarment; Suspension:

a. Subrecipient certifies that neither it nor its principals are presently debarred or suspended by any Federal department or Subrecipient from participation in this transaction.

b. Subrecipient, by administering each lower tier subcontract that exceeds $25,000 as a "covered transaction", must verify each lower tier participant of a "covered transaction" under the project is not presently debarred or otherwise disqualified from participation in this federally assisted project. The Subrecipient will accomplish this by: (i) Checking the System for Award Management at website: http://www.sam.gov.; (ii) Collecting a certification statement similar to the Certification of Subrecipient Regarding Debarment above; (iii) Inserting a clause or condition in the covered transaction with the lower tier contract.

c. If the federal agency later determines that a lower tier participant failed to disclose to a higher tier participant that it was excluded or disqualified at the time it entered into the covered transaction, the federal agency may pursue any available remedies, including suspension and debarment of the non-compliant participant.

61. Non-Municipal Personnel and Services: Subrecipient will secure, at Subrecipient's own expense, all personnel required to perform the services called for under this Agreement by Subrecipient. Such personnel shall not be employees of or have any contractual relationship with the City except as employees or independent contractors of Subrecipient. All of the services required hereunder will be performed by Subrecipient or under Subrecipient's direct supervision, and all personnel engaged in the services shall be fully qualified and shall be authorized under state and local law to perform such services.

62. Subrecipient's Representations and Responsibilities:

a. Subrecipient hereby certifies and warrants that it has the institutional, managerial, and financial capability to ensure proper planning, management, and completion of the Project in accordance with the contract documents and all federal requirements. Subrecipient shall provide all work and all services for the Project in a satisfactory and proper manner as determined by the City and in accordance with the terms set forth in this Agreement

b. Subrecipient agrees that costs to resolve or ameliorate any non-compliance by Subrecipient which are noted by governmental representatives shall not be reimbursed by the City and shall be the sole responsibility of Subrecipient.

63. Governing Law and Venue: This Agreement shall be governed, interpreted, and enforced in accordance with the laws of the State of Missouri and/or the laws of the United States, as applicable. The venue for all litigation arising out of, or relating to this contract document, shall be in Boone County, Missouri. The Parties hereto irrevocably agree to submit to the exclusive jurisdiction of such courts in the State of Missouri. The Parties agree to waive any defense of forum non conveniens.

64. General Laws: Subrecipient shall comply with all applicable laws, ordinances, codes, and regulations of the United States, State of Missouri, and the City of Columbia, including but not limited to Section 190.098 RSMo, and City Code Chapter 12.

65. Licenses, Certifications, Permits, Accreditation. Subrecipient shall obtain and keep current any license, certification, permit, or accreditation required by federal, state, or local law and shall submit to City proof of any licensure, certification, permit or accreditation upon request.

66. Section 285.530 RSMo: Subrecipient shall comply with Missouri State Statute Section 285.530 in that Subrecipient shall not knowingly employ, hire for employment, or continue to employ an unauthorized alien to perform work within the State of Missouri. As a condition for the award of this contract, Subrecipient shall, by sworn affidavit and provision of documentation, affirm its enrollment and participation in a federal work authorization program with respect to the employees working in connection with the contracted services. Subrecipient shall also sign an affidavit affirming that it does not knowingly employ any person who is an unauthorized alien in connection with the contracted services. Subrecipient shall require each contractor to affirmatively state in its contract with Subrecipient that the contractor shall not knowingly employ, hire for employment or continue to employ an unauthorized alien to perform work within the State of Missouri. Subrecipient shall also require each subcontractor to provide Subrecipient with a sworn affidavit under the penalty of perjury attesting to the fact that the subcontractor's employees are lawfully present in the United States.

67. Section 34.600 RSMo: If applicable and to the extent not in violation of the state or federal constitution, Subrecipient hereby certifies that Subrecipient is not currently engaged in a boycott of goods or services from the State of Israel; companies doing business in or with Israel, or authorized by, licensed by, or organized under the laws of Israel; or persons or entities doing business in the State of Israel.

68. Americans With Disabilities Act: Subrecipient shall comply with all applicable provisions of the Americans with Disabilities Act and the regulations implementing the Act, including those regulations governing employment practices. Subrecipient shall make the services, programs, and activities governed by this Contract accessible to persons with disabilities as required by the Americans with Disabilities Act and its implementing regulations.

69. Missouri Sunshine Law (Section 610 RSMo): City is subject to the Missouri Sunshine Law. The Parties agree that the Agreement shall be interpreted in accordance with the provisions of the Missouri Sunshine Law, as amended. Subrecipient shall maintain the confidentiality of information and records which are not subject to public disclosure under the Sunshine Law. Subrecipient shall not disclose to

any third party or use for any purpose inconsistent with this Agreement any confidential information it receives in connection with its performance of the services.

70. Subcontracting; Third Party Contracts; Subawards: In executing this Agreement, Subrecipient may not enter a subaward, subcontract or third party contract without prior written approval from City's Designated Representative.

71. Assignments: This Agreement shall inure to the benefit of and be binding upon the Parties and their respective successors and permitted assigns. Neither Party shall assign this Agreement or any of its rights or obligations hereunder without the prior written consent of the other Party.

72. Amendment: No amendment, addition to, or modification of any provision hereof shall be binding upon the Parties, and neither Party shall be deemed to have waived any provision or any remedy available to it unless such amendment, addition, modification or waiver is in writing and signed by a duly authorized officer or representative of the applicable Party or Parties.

73. Independent Contractor: This Agreement does not create an employee/employer relationship between the parties. It is the parties' intention that the Subrecipient will be an independent contractor and not the City's employee for all purposes, including, but not limited to: the application of the Fair Labor Standards Act minimum wage and overtime payments, Federal Insurance Contribution Act, the Social Security Act, the Federal Unemployment Tax Act, the provisions of the Internal Revenue Code, Missouri revenue and taxation laws, Missouri workers' compensation and unemployment insurance laws. The Subrecipient will retain sole and absolute discretion in the judgment of the manner and means of carrying out the Subrecipient's activities and responsibilities hereunder. The Subrecipient agrees that it is a separate and independent enterprise from the City, that it has a full opportunity to find other work, that it has made its own investment in its business, and that it will utilize a high level of skill necessary to perform the services. This Agreement shall not be construed as creating any joint employment relationship between the Subrecipient and the City, and the City will not be liable for any obligation incurred by the Subrecipient, including but not limited to unpaid minimum wages and/or overtime premiums.

74. No Third Party Beneficiary: No provision of the Agreement is intended to nor shall it in any way inure to the benefit of any other third party, so as to constitute any such Person a third-party beneficiary under the Agreement.

75. HOLD HARMLESS:

a. To the fullest extent not prohibited by law and without waiving sovereign immunity, Subrecipient shall indemnify and hold harmless the federal agency, the City of Columbia, their directors, officers, agents, and employees from and against all claims, damages, losses, and expenses for bodily injury and/or

property damage arising by reason of any act or failure to act, negligent or otherwise, of Subrecipient, of any contractor or subcontractor (meaning anyone, including but not limited to consultants having a contract with Subrecipient or a subcontractor for part of the services), of anyone directly or indirectly employed by Subrecipient or by any subcontractor, or of anyone for whose acts the Subrecipient or its contractor or subcontractor may be liable, in connection with providing these services or work on this Project.

b. To the fullest extent not prohibited by law and without waiving sovereign immunity, Subrecipient shall indemnify and hold the federal agency and the City harmless from all wages or overtime compensation due Subrecipient's employees in rendering services pursuant to this Agreement, including payment of costs in the defense of any claim made under the Fair Labor Standards Act or any other federal or state law

c. This provision does not, however, require the Subrecipient to indemnify, hold harmless, or defend the City of Columbia or federal agency from their own negligence.

d. This section survives termination of the Agreement.

76. Debts Owed:

a. Any funds paid to Subrecipient (1) in excess of the amount to which Subrecipient is finally determined to be authorized to retain under the terms of this agreement; (2) that are determined by a federal agency or the City of Columbia to have been misused; or (3) that are determined by a federal agency or the City of Columbia to be subject to a repayment obligation and have not been repaid by Subrecipient shall constitute a debt to the federal government and/or to the City.

b. Any debts determined to be owed to the federal government or the City must be paid promptly by the Subrecipient. A debt is delinquent if it has not been paid by the date specified in City's or federal agency's initial written demand for payment, unless other satisfactory arrangements have been made. If the Subrecipient knowingly or improperly retains funds that are a debt as defined herein, the federal agency or the City may take any actions available to it to collect such a debt.

c. This section shall survive termination of this Agreement.

77. Insurance: Subrecipient shall maintain, on a primary basis and at its sole expense, at all times during the life of the Agreement the following insurance coverages, limits, including endorsements described herein. The requirements contained herein, as well as the City's review or acceptance of insurance maintained by Subrecipient is not intended to, and shall not in any manner limit or qualify the liabilities or obligations assumed by Subrecipient under the Agreement. Coverage to be provided as follows by a carrier with A.M. Best minimum rating of A- VIII or through a self-insurance program.

a. Workers' Compensation & Employers Liability. Subrecipient shall maintain Workers' Compensation in accordance with Missouri State Statutes or provide evidence of monopolistic state coverage. Employers Liability with the following limits: $500,000 for each accident, $500,000 for each disease for each employee, and $500,000 disease policy limit.

b. Commercial General Liability. Subrecipient shall maintain Commercial General Liability at a limit of not less than $2,000,000 Each Occurrence, $3,000,000 Annual Aggregate. Coverage shall not contain any endorsement(s) excluding nor limiting Product/Completed Operations, Contractual Liability or Cross Liability.

c. Business Auto Liability. Subrecipient shall maintain Business Automobile Liability at a limit not less than $2,000,000 Each Occurrence. Coverage shall include liability for Owned, Non-Owned & Hired automobiles. In the event Subrecipient does not own automobiles, Subrecipient agrees to maintain coverage for Hired & Non-Owned Auto Liability, which may be satisfied by way of endorsement to the Commercial General Liability policy or separate Business Auto Liability policy.

d. Professional Liability and Medical Malpractice. If the Approved Activities requires the work of a licensed professional, Subrecipient agrees to maintain Professional (Errors & Omissions) Liability and Medical Malpractice coverage at a limit of liability not less than $2,000,000 per occurrence and $3,000,000 aggregate. For policies written on a "Claims-Made" basis, Subrecipient agrees to maintain a Retroactive Date prior to or equal to the Effective Date of this contract. In the event the policy is canceled, non-renewed, switched to an Occurrence Form, retroactive date advanced; or any other event triggering the right to purchase a Supplemental Extended Reporting Period (SERP) during the life of this contract, Subrecipient agrees to purchase a SERP with a minimum reporting period not less than two (2) years. The requirement to purchase a SERP shall not relieve Subrecipient of the obligation to provide replacement coverage.

e. Subrecipient may satisfy the minimum liability limits required for Commercial General Liability or Business Auto Liability under an Umbrella or Excess Liability policy. There is no minimum per occurrence limit of liability under the Umbrella or Excess Liability; however, the Annual Aggregate limit shall not be less than the highest "Each Occurrence" limit for either Commercial General Liability or Business Auto Liability. Subrecipient agrees to endorse the City and the federal agency as an Additional Insured on the Umbrella or Excess Liability, unless the Certificate of Insurance state the Umbrella or Excess Liability provides coverage on a "Follow-Form" basis.

f. A certificate of insurance evidencing all coverage required is to be provided at least 10 days prior to the Effective Date of the Agreement between the Subrecipient and the City. Subrecipient is required to maintain coverages as stated and required to notify the City of a Carrier Change or cancellation within two (2) business days. The City reserves the right to request a copy of the policy.

g. The Parties understand and agree that the City and federal agency are relying on and do not waive or intend to waive by any provision of this Agreement, any monetary limitations or any other rights, immunities, and protections provided by state or federal law, as from time to time amended, or otherwise available to the federal agency and the City or their elected officials and or employees.

h. Failure to maintain the required insurance in force may be cause for termination of the Agreement. In the event Subrecipient fails to maintain and keep in force the required insurance or to obtain coverage from its subcontractors, the City shall have the right to cancel and terminate the Agreement without notice.

i. The insurance required by the provisions of this article is required in the public interest and the City and federal agency do not assume any liability for acts of the Subrecipient and/or their employees and/or their subcontractors in the performance of this Agreement.

78. Notices and Designation of Representatives: Any notice, demand, request, or communication required or authorized by the Agreement shall be delivered either by hand, facsimile, overnight courier or mailed by certified mail, return receipt requested, with postage prepaid, to the Designated Representatives listed below:

If to City:
City of Columbia
Public Health and Human Services Department
P.O. Box 6015
Columbia, MO 65205-6015
ATTN: Director

If to Subrecipient:
The Curators of the University of Missouri
Sponsored Programs Administration
601 Turner Avenue
Turner Avenue Garage, Room 201
Columbia, MO 65211-0001
ATTN: Hannah Brune

The designation and titles of the person to be notified or the address of such person may be changed at any time by written notice. Any such notice, demand, request, or communication shall be deemed delivered on receipt if delivered by hand or facsimile and on deposit by the sending party if delivered by courier or U.S. mail.

79. No Waiver of Immunities: In no event shall the language of this Agreement constitute or be construed as a waiver or limitation for either party's rights or defenses

with regard to each party's applicable sovereign, governmental, or official immunities and protections as provided by federal and state constitutions or laws.

80. Nature of City's Obligations: All obligations of the City under this Agreement, which require the expenditure of funds, are conditional upon the availability of funds budgeted and appropriated for that purpose. Subrecipient further understands and agrees that neither the City nor the federal agency shall be liable for any costs or injuries caused by or related to a lack of funds, insufficient appropriations, or withholdings.

81. Required Provisions Deemed Inserted: Each and every provision of law and clause required by law or the grant agreement to be inserted in this Agreement shall be deemed to be inserted herein and the Agreement shall be read and enforced as though it were included herein, and if through mistake or otherwise any such provision is not inserted, or is not correctly inserted, then upon the application of either party the contract shall forthwith be physically amended to make such insertion of correction.

82. Interpretation: In this Agreement, unless the context otherwise reasonably requires:

a. Headings are for reference purposes only and shall not alter the interpretation of this Agreement;

b. Words importing the singular may include the plural and vice versa, as reasonably required by the context;

c. References to any document include references to such document as amended, novated, supplemented, varied or replaced from time to time;

d. References to a statute, regulation, federal notice or executive order means such statute, regulation, federal notice or executive order as amended from time to time;

e. References to a party to this Agreement includes that Party's legal successors (including but not limited to executors and administrators) and permitted assigns; and

f. Any ambiguity shall be resolved in a manner which allows the parties to comply with laws and grant requirements.

83. Electronic Signature: This Agreement may be signed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same document. Faxed signatures, or scanned and electronically transmitted signatures, on this Agreement or any notice delivered pursuant to this Agreement, shall be deemed to have the same legal effect as original signatures on this Agreement.

84. Contract Documents: This Agreement includes the following exhibits, which are incorporated herein by reference:

Exhibit A	Notice of Award
Exhibit B	Fiscal Year 2023 Award Standard Terms
Exhibit C	Department of Health and Human Services Substance Abuse and Mental Health Services Administration FY 2023 First Responders-Comprehensive Addiction and Recovery Act Notice of Funding Opportunity (NOFO) No. TI-23-012
Exhibit D	SAMHSA Additional Directives
Exhibit E	HHS Grants Policy Statement
Exhibit F	Project Scope and Approved Subrecipient Budget
Exhibit G	Subrecipient Notice of Award

In the event of a conflict between the terms of an exhibit and the terms of this Agreement, the terms of this Agreement control. In the event of a conflict between the terms of the exhibits, the exhibits control in the order listed above.

85. Entire Agreement: This Agreement represents the entire and integrated Agreement between the Parties relative to the Project herein. All previous or contemporaneous agreements, representations, promises and conditions relating to Subrecipient's services described herein are superseded.

{Signatures on Following Page}

IN WITNESS WHEREOF, the Parties have hereunto executed this Agreement the day and the year of the last signatory noted below.

SUBRECIPIENT

The Curators of the University of Missouri

By: C. Megan Faulkner

Name and Title: C. Megan Faulkner, Pre-Award Manager, Auth. Signer

Date: 09/16/2024

ATTEST:

Hannah Brune

Name and Title: Assoc. Director, Pre-Award Services

Approved as to Legal Form
Sep 16 2024

APPROVED AS TO FORM:

Jon McGough, Senior Counsel

CITY OF COLUMBIA, MISSOURI SKB

By: _____

De'Carlon Seewood, City Manager

Date: _____

ATTEST:

_____

Sheela Amin, City Clerk

APPROVED AS TO FORM:

_____

Nancy Thompson, City Counselor/rw

CERTIFICATION: I hereby certify that the above expenditure is within the purpose of the appropriation to which it is charged, Account No. 11003030 504990, and that there is an unencumbered balance to the credit of such appropriation sufficient to pay therefor.

By: _____

Director of Finance

Department of Health and Human Services
Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Treatment

Exhibit A
Notice of Award
FAIN# H79TI086392
Federal Award Date
08/07/2023

Recipient Information

1. Recipient Name
THE CITY OF COLUMBIA INC
701 E BROADWAY
COLUMBIA, MO 65201

2. Congressional District of Recipient
04

3. Payment System Identifier (ID)
1436000810A5

4. Employer Identification Number (EIN)
436000810

5. Data Universal Numbering System (DUNS)
071989024

6. Recipient's Unique Entity Identifier
WZR4KM9CBTV3

7. Project Director or Principal Investigator
Michelle Shikles

grants@como.gov
573-441-5591

8. Authorized Official
Mr. Andrew Wyatt
grants@como.gov
573-441-5591

Federal Agency Information

9. Awarding Agency Contact Information
Linda Kim
Grants Specialist
linda.kim@samhsa.hhs.gov
240-276-1865

10. Program Official Contact Information

Federal Award Information

11. Award Number
1H79TI086392-01

12. Unique Federal Award Identification Number (FAIN)
H79TI086392

13. Statutory Authority
Section 546 of the PHS Act, (42 USC 290ee-1), as amended

14. Federal Award Project Title
Boone County Community Paramedic Program

15. Assistance Listing Number
93.243

16. Assistance Listing Program Title
Substance Abuse and Mental Health Services_Projects of Regional and National Significance

17. Award Action Type
New Competing

18. Is the Award R&D?
No

Summary Federal Award Financial Information

19. Budget Period Start Date 09/30/2023 – **End Date** 09/29/2024	
20. Total Amount of Federal Funds Obligated by this Action	$499,784
20a. Direct Cost Amount	$499,784
20b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$499,784
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$499,784
26. Project Period Start Date 09/30/2023 – **End Date** 09/29/2027	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$499,784

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Rosalie Vega

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

First Responders CARA (FR-CARA) **Issue Date:** 08/07/2023
Department of Health and Human Services
Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Treatment

Award Number: 1H79TI086392-01
FAIN: H79TI086392
Program Director: Michelle Shikles

Project Title: Boone County Community Paramedic Program

Organization Name: THE CITY OF COLUMBIA INC

Authorized Official: Mr. Andrew Wyatt

Authorized Official e-mail address: grants@como.gov

Budget Period: 09/30/2023 – 09/29/2024
Project Period: 09/30/2023 – 09/29/2027

Dear Grantee:

The Substance Abuse and Mental Health Services Administration hereby awards a grant in the amount of $499,784 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to THE CITY OF COLUMBIA INC in support of the above referenced project. This award is pursuant to the authority of Section 546 of the PHS Act, (42 USC 290ee-1), as amended and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Award recipients may access the SAMHSA website at www.samhsa.gov (click on "Grants" then SAMHSA Grants Management), which provides information relating to the Division of Payment Management System, HHS Division of Cost Allocation and Postaward Administration Requirements. Please use your grant number for reference.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

If you have any questions about this award, please contact your Grants Management Specialist and your Government Project Officer listed in your terms and conditions.

Sincerely yours,
Rosalie Vega
Grants Management Officer
Division of Grants Management

See additional information below

SECTION I – AWARD DATA – 1H79TI086392-01

Award Calculation (U.S. Dollars)

Other	$499,784
Direct Cost	$499,784
Approved Budget	$499,784
Federal Share	$499,784
Cumulative Prior Awards for this Budget Period	$0
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$499,784

SUMMARY TOTALS FOR ALL YEARS	
YR	**AMOUNT**
1	$499,784
2	$499,784
3	$499,784
4	$499,784

Note: Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project.

Fiscal Information:

CFDA Number:	93.243
EIN:	1436000810A5
Document Number:	23TI86392A
Fiscal Year:	2023

IC	CAN	Amount
TI	C96N708	$499,784

IC	CAN	2023	2024	2025	2026
TI	C96N708	$499,784	$499,784	$499,784	$499,784

TI Administrative Data:
PCC: FRCARA23 / **OC:** 4145

SECTION II – PAYMENT/HOTLINE INFORMATION – 1H79TI086392-01

Payments under this award will be made available through the HHS Payment Management System (PMS). PMS is a centralized grants payment and cash management system, operated by the HHS Program Support Center (PSC), Division of Payment Management (DPM). Inquiries regarding payment should be directed to: The Division of Payment Management System, PO Box 6021, Rockville, MD 20852, Help Desk Support – Telephone Number: 1-877-614-5533.

The HHS Inspector General maintains a toll-free hotline for receiving information concerning fraud, waste, or abuse under grants and cooperative agreements. The telephone number is: 1-800-HHS-TIPS (1-800-447-8477). The mailing address is: Office of Inspector General, Department of Health and Human Services, Attn: HOTLINE, 330 Independence Ave., SW, Washington, DC 20201.

SECTION III – TERMS AND CONDITIONS – 1H79TI086392-01

This award is based on the application submitted to, and as approved by, SAMHSA on the above-title project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. The restrictions on the expenditure of federal funds in appropriations acts to the extent those restrictions are pertinent to the award.
c. 45 CFR Part 75 as applicable.
d. The HHS Grants Policy Statement.
e. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

Treatment of Program Income:
Use of program income – Additive: Recipients will add program income to funds committed to the project to further eligible project objectives. Sub-recipients that are for-profit commercial organizations under the same award must use the deductive alternative and reduce their subaward by the amount of program income earned.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75.

SECTION IV – TI SPECIAL TERMS AND CONDITIONS – 1H79TI086392-01

REMARKS

New Award

This Notice of Award (NoA) is issued to inform your organization that the application submitted through the funding opportunity # TI-23-012 *(First Responders – Comprehensive Addiction and Recovery Act) (FR-CARA)* has been selected for funding.

The purpose of this program is to support first responders and members of other key community sectors to administer a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for emergency reversal of known or suspected opioid overdose. Recipients will train and provide resources to first responders and members of other key community sectors at the state, tribal, and local levels on carrying and administering a drug or device approved or cleared under the FD&C Act for emergency treatment of known or suspected opioid overdose. Recipients will also establish processes, protocols, and mechanisms for referral to appropriate treatment and recovery support services, safety around fentanyl, carfentanil, other synthetic opioids (CDC) and other licit and illicit drugs associated with overdoses. The FR-CARA program is authorized under Section 546 of the Public Health Service Act, (42 USC 290ee-1), as amended.

Policies and Regulations
Accepting a grant award or cooperative agreement requires the recipient organization to comply with the terms and conditions of the NoA, as well as all applicable Federal Policies and

Regulations. This award is governed by the Uniform Guidance 2 Code of Federal Regulations (CFR) § 200 as codified by HHS at 45 CFR § 75; Department of Health and Human Services (HHS) Grants Policy Statement; SAMHSA Additional Directives; and the Standard Terms and Conditions for the fiscal year in which the grant was awarded.

Key Personnel

Key personnel are organization staff members or consultants/subrecipients who must be part of the project regardless of whether they receive a salary or compensation from the project. These individuals must make a substantial contribution to the execution of the project.

Key Personnel for this program are the **Project Director with at least 50 percent level of effort** (person responsible for overseeing, monitoring, and managing the award), **and the Evaluator with at least 20 percent level of effort** (organization or assigned individual within the organization) responsible for evaluating processes and outcomes of the award, and oversight of reporting in SPARS.

The Key Personnel identified in your application have not been approved by SAMHSA. Your assigned GPO will confirm approval via eRA Correspondence within 60 days of receipt of this NoA. If SAMHSA's review of the Key Personnel results in the proposed individual not being approved or deemed not qualified for the position, the organization will be required to submit a qualified candidate for the Key Personnel position. SAMHSA will not be liable for any related costs incurred on this grant award.
The identified PD for this program is listed in item #7 "Project Director or Principal Investigator" on the cover page of the NoA. If the individual identified on the NoA is incorrect, you must notify your assigned Government Project Officer (GPO) and Grants Management Specialist (GMS) via email immediately and plan to submit a post award amendment for a change in key personnel via eRA Commons. Key personnel or other grant-supported staff may not exceed 100% level of effort across all federal and non-federal funding sources.

Any changes to key staff, including level of effort involving separation from the project for more than three months or a 25 percent reduction in time dedicated to the project, requires prior approval, and must be submitted as a post-award amendment in eRA Commons. Refer to SAMHSA's website for more information on submitting a key personnel change. See SAMHSA PD Account Creation Instructions for a quick step-by-step guide and SAMHSA Grantee PD Account Creation Slides for additional information on the eRA Commons registration process for the PD.

Funding Limitations

SAMHSA reserves the right to disallow costs under this grant award at any time during the award project period. Award recipients are responsible for ensuring that costs allocated to the grant award are reasonable and allowable in accordance with the Notice of Funding Opportunity and all applicable Policies & Regulations.

The Cost Principles that delineate the allowable and unallowable expenditures for HHS recipients are described in the Code of Federal Regulations.

Funding Limitations and Restrictions are listed in the Notice of Funding Opportunity
You may also reference the SAMHSA grantee guidelines on Financial Management Requirements.

Unallowable Costs

Recipients must exercise proper stewardship over Federal funds and ensure that costs charged to awards are allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds according to the "Factors affecting allowability of costs" per 2 CFR § 200.403 and the "Reasonable costs" considerations per 2 CFR § 200.404. A cost is reasonable if, in its nature and amount, it does not exceed that which would be incurred by a prudent person under the circumstances prevailing at the time the decision was made to incur the cost.

Supplanting
"Supplement Not Supplant" grant funds may be used to supplement existing activities. Grant funds may not be used to supplant current funding of existing activities. "Supplant" is defined as replacing funding of a recipient's existing program with funds from a federal grant.

Award Payments
Payments under this award will be made available through the HHS Payment Management System (PMS). PMS is a centralized grants payment and cash management system, operated by the HHS Program Support Center (PSC), Division of Payment Management (DPM). First time PMS users must obtain access to view available funds, request funds, or submit reports. Users will need to request permission and be approved by PSC. Inquiries regarding payments should be directed to PMS by emailing the helpdesk at PMSSupport@psc.hhs.gov or call 1-877-614-553. You should also visit the PSC website for more information about their services - https://pms.psc.gov/.

Special Terms & Conditions of Award
There may be special terms and conditions associated with your grant award. Recipients must address all special terms and conditions by the reflected due date. See the Special Terms of Award and Special Conditions of Award sections below for the specific terms and conditions associated with your grant award. A recipient's failure to comply with the terms and conditions of award, may cause SAMHSA to take one or more actions, depending on the severity and duration of the non-compliance. SAMHSA will undertake any such action in accordance with applicable statutes, regulations, and policies.

Responding to Award Terms & Conditions
All responses to award terms and conditions must be submitted as .pdf documents in eRA Commons. For more information on how to respond to tracked terms and conditions or how to submit a post award amendment request please refer to Training Materials under the heading "Grant Management Reference Materials for Grantees."

Prior Approval Requirements
Prior approval is required for the following changes to your grant award: Changes in the status of the Project Director, or other key personnel named in the NoA; Changes in scope; Significant re-budgeting and Transfer of substantive programmatic work; Carryover of unobligated balances; Change of grantee organization; Deviation from award terms and conditions; No-cost extension and Transfer of substantive programmatic work. A full list of actions requiring prior approval can be found on page II-49 of the HHS Grants Policy Statement Exhibit 5 (Summary of Actions Requiring OPDIV Prior Approval). All prior approval actions must be submitted as post award amendment requests in eRA Commons.

Post Award Amendments
If information on the NoA needs to be changed, it will require approval from the federal agency before the grant recipient can implement the modification. Please refer to the SAMHSA website for specific SAMHSA guidance on how to submit a Post Award Amendments in eRA Commons:

Primary Contacts
- For technical support, contact eRA Service Desk at 866-504-9552 (Press 6 for SAMHSA Grantees).
- For budget and grants management related questions, contact your assigned GMS.
- For programmatic questions, contact your assigned GPO.

**Contact information for the GMS and GPO are listed on the last page of this NoA.*

Training & Resources – Visit the following pages on our website for more information on implementation, monitoring and reporting on your new grant award:
- Grants Management

- Training & Resources for recipients
- eRA Commons

SPECIAL TERMS

Risk Assessment

The Office of Financial Advisory Services (OFAS), SAMHSA may perform an administrative review of your organization's financial management systems, policies, procedures and records. If the review discloses material weaknesses or other financial management concerns, grant funding may be restricted in accordance with 45 CFR 75/2 CFR 200, as applicable. The restriction will affect your organization's ability to withdraw funds from the Payment Management System account, until the concerns are addressed.

Funding Limitations/Restrictions

The funding restrictions for this project are as follows:

- Recipients may use up to 20 percent of the total award for the budget period for data collection, performance measurement, and performance assessment.
- Recipients may use up to 10 percent of the total award for the budget period for state, tribal, or local governmental administrative costs.
- Recipients may use up to 15 percent of the total award for infrastructure development to support the direct service expansion of the project.
- SAMHSA award funds must not be used for the same activities that are funded by the Health Resources Services Administration (HRSA), CDC, or other SAMHSA programs.
- Only drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose may be purchased with FR-CARA funds.

SAMHSA recipients must also comply with SAMHSA's standard funding restrictions, which are included in Appendix I (Standard Funding Restrictions).

Disparity Impact Statement (DIS)

By **November 29, 2023**, submit via eRA Commons.
The DIS should be consistent with information in your application regarding access, *service use and outcomes for the program and include three components as described below. Questions about the DIS should be directed to your GPO. Examples of DIS can be found on the SAMHSA website at: https://www.samhsa.gov/grants/grants-management/disparity-impact-statement. *Service use is inclusive of treatment services, prevention services as well as outreach, engagement, training, and/or technical assistance activities.

The disparity impact statement consists of three components:

1. Proposed number of individuals to be served and/or reached by subpopulations in the grant implementation area should be provided in a table that covers the entire grant period. The disparate population(s) should be identified in a narrative that includes a description of the population and rationale for how the determination was made.
2. A quality improvement plan for how you will use your program (GPRA) data on access, use and outcomes to monitor and manage program outcomes by race, ethnicity and LGBT status, when possible. The quality improvement plan should include strategies for how processes and/or programmatic adjustments will support efforts to reduce disparities for the identified sub-populations.
3. The quality improvement plan should include methods for the development and implementation of policies and procedures to ensure adherence to the Enhanced Culturally and

Linguistically Appropriate Services (CLAS) Standards and the provision of effective care and services that are responsive to:

a. Diverse cultural health beliefs and practices;
b. Preferred languages; and
c. Health literacy and other communication needs of all sub-populations within the proposed geographic region.

All responses to award terms and conditions must be submitted as .pdf documents in eRA Commons. For more information on how to respond to tracked terms and conditions please refer to **https://www.samhsa.gov/grants/grants-training-materials** under heading **How to Respond to Terms and Conditions.**

SPECIAL CONDITIONS

Participant Protection (PPC)

By **10/30/2023**, submit via eRA Commons your response to the following Participant Protection concerns raised by
SAMHSA's Initial Review Group.

The Committee reviewed the applicant organization's plans for ensuring confidentiality and SAMHSA participant protection and had comments about the inadequacy of the discussion of the following elements:

Data collection

• The applicant organization does not address data collection procedures.

Maintenance of privacy and confidentiality

• The applicant organization does not adequately address how paper copies of information will be stored and how EMS will obtain critical information.

Consent policies, procedures, and forms

• The applicant organization does not include a release of information.

All responses to award terms and conditions must be submitted as .pdf documents in eRA Commons. For more information on how to respond to tracked terms and conditions please refer to **https://www.samhsa.gov/grants/grants-training-materials** under heading **How to Respond to Terms and Conditions.**

Please also email, with the grant number in the Subject line, the response to your assigned Government Project Officer and Participant Protection Officers, Candece Griffin at candece.griffin@samhsa.hhs.gov and Devin Sweat at devin.sweat@samhsa.hhs.gov.

All grant funds are available for this project except for those funds directly related to Participant Protection issues as outlined in the NOFO. Currently, only activities that do not directly involve Participant Protection issues (i.e., are clearly severable and independent from those activities that do involve Participant Protection issues) may be conducted under this award. This restriction of funds will only be lifted if the Participant Protection issues noted above is appropriately addressed by you as the grantee and resolved to the satisfaction of your designated Government Project Officer and a SAMHSA/CSAP Participant Protection Officer.

Marginal or Unacceptable (Marginal Rating)

By ***10/30/2023***, submit via eRA Commons.

Your organization received a marginal rating for Section D: Staff and Organizational Experience. Reviewers noted the following:

• The applicant organization does not detail its experience with similar projects, as it proposes to secure sub-contractors to facilitate the program.
• The applicant organization has not identified staff to fill positions and omits critical requirements.

By **October 30, 2023**, you must submit a response to the following to ensure that you meet an acceptable standard for this section:
o Provide a detailed narrative describing how your organization will identify and secure sub-contractors to facilitate the program;
o Provide a detailed narrative describing how your organization will staff each position and include the descriptions of roles, levels of effort, and qualifications.

All responses to award terms and conditions must be submitted as .pdf documents in eRA Commons. For more information on how to respond to tracked terms and conditions please refer to **https://www.samhsa.gov/grants/grants-training-materials** under heading **How to Respond to Terms and Conditions.**

Revised Detailed Budget/Narrative Justification

By **10/30/2023**, submit via eRA Commons, using the SAMHSA budget template.

Per the NOFO, your budget/narrative justification must be concrete and specific, demonstrating costs as necessary, reasonable and allocable to the grant. You must justify the basis for each proposed cost and how that cost was calculated. Budget/narrative details must be aligned with your programmatic narrative, referencing activities, resources, staff and other items.

All Key Personnel (per the NOFO) must be identified in the budget, including names, salaries and Level of Effort (LOE), even if the positions are filled at no cost/in-kind to SAMHSA. In addition, your budget must address the funding limitations/restrictions specified in Section IV-5 of the NOFO as these expenses must be identified in your proposed budget.

Links to the SAMHSA Budget Template and Guidance are as follows:
o **SAMHSA Budget Template (PDF | 1.2 MB)** – If you need accessibility assistance when using this file, please contact terry.valladares@samhsa.hhs.gov.
o **SAMHSA Budget Template Guidance (PDF | 453 KB)**

All responses to award terms and conditions must be submitted as .pdf documents in eRA Commons. For more information on how to respond to tracked terms and conditions please refer to **https://www.samhsa.gov/grants/grants-training-materials** under heading **How to Respond to Terms and Conditions.**

Revised SF424

By **10/30/2023**, submit in eRA.

The proposed Project Director, as listed in your budget/narrative, must be registered in eRA Commons and the Commons ID of the proposed Project Director must be stated on **Section #4** of the SF-424. In addition, **Section #8f** must reflect the Project Director contact information.

- Revise **Section #8f** of your SF424, keeping all other details the same (see link to the SF424 template).

All responses to award terms and conditions must be submitted as .pdf documents in eRA Commons. For more information on how to respond to tracked terms and conditions please refer to **https://www.samhsa.gov/grants/grants-training-materials** under heading **How to Respond to Terms and Conditions.**

SMA 170 Charitable Choice Form

By **10/30/2023**, submit in eRA.

The SMA 170 Charitable Choice form was not included with application.

- https://www.samhsa.gov/sites/default/files/charchoice_assurance.pdf

** If your organization is not faith-based, indicate "Not Applicable" on the form (no need to sign) and submit.*

All responses to award terms and conditions must be submitted as .pdf documents in eRA Commons. For more information on how to respond to tracked terms and conditions please refer to **https://www.samhsa.gov/grants/grants-training-materials** under heading **How to Respond to Terms and Conditions.**

Disclosure of Lobbying Activities (SF-LLL) Form

The Disclosure of Lobbying Activities (SF-LLL) form was not included with application.

By **10/30/2023**, submit in eRA.

- SF-LLL form

Federal law prohibits the use of appropriated funds for publicity or propaganda purposes or for the preparation, distribution, or use of the information designed to support or defeat legislation pending before Congress or state legislatures. For SAMHSA to determine whether or not your organization participates in lobbying activities, a signed copy of the SF-LLL form must be submitted." If your organization does not participate in lobbying activities, indicate "Not Applicable" on the form.

All responses to award terms and conditions must be submitted as .pdf documents in eRA Commons. For more information on how to respond to tracked terms and conditions please refer to https://www.samhsa.gov/grants/grants-training-materials under heading ***How to Respond to Terms and Conditions.***

STANDARD TERMS AND CONDITIONS

Standard Terms for Awards

Your organization must comply with the Standard Terms and Conditions for the Fiscal Year in which your grant was awarded. The Fiscal Year for your award is identified on Page 3 of your Notice of Award. SAMHSA's Terms and Conditions Webpage is located at: https://www.samhsa.gov/grants/grants-management/notice-award-noa/standard-terms-conditions.

Reasonable Costs for consideration

Recipients must exercise proper stewardship over Federal funds and ensure that costs charged to awards are allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds according to "Reasonable Costs" consideration per 2 CFR § 200.404 and the "Factors affecting allowability of costs" per 2 CFR § 200.403. A cost is reasonable if, in its nature and amount, it does not exceed that which would be incurred by a prudent person under the circumstances prevailing at the time the decision was made to incur the cost.

Consistent Treatment of Costs
Recipients must treat costs consistently across all federal and non-federal grants, projects and cost centers. Recipients may not direct-charge federal grants for costs typically considered indirect in nature, unless done consistently. If part of the indirect cost rate, then it may not also be charged as a direct cost. Examples of indirect costs include (administrative salaries, rent, accounting fees, utilities, office supplies, etc.). If typical indirect cost categories are included in the budget as direct costs, it is SAMHSA's understanding that your organization has developed a cost accounting system adequate to justify the direct charges and to avoid an unfair allocation of these costs to the federal government. Also, note that all awards are subject to later review in accordance with the requirements of 45 CFR 75.364, 45 CFR 75.371, 45 CFR 75.386 and 45 CFR Part 75, Subpart F, Audit Requirements.

Compliance with Award Terms and Conditions
FAILURE TO COMPLY WITH THE ABOVE STATED TERMS AND CONDITIONS MAY RESULT IN ACTIONS IN ACCORDANCE WITH 45 CFR 75.371, REMEDIES FOR NON-COMPLIANCE AND 45 CFR 75.372 TERMINATION. THIS MAY INCLUDE WITHHOLDING PAYMENT, DISALLOWANCE OF COSTS, SUSPENSION AND DEBARMENT, TERMINATION OF THIS AWARD, OR DENIAL OF FUTURE FUNDING.

All previous terms and conditions remain in effect until specifically approved and removed by the Grants Management Officer.

Reporting Requirements

FR CARA grantees are required to collect and report certain data so that SAMHSA can meet its obligations under the Government Performance and Results (GPRA) Modernization Act of 2010. Recipients are required to report performance data quarterly on the fiscal quarter.

These GPRA data are collected and reported using SAMHSA's Performance Accountability and Reporting System (SPARS). SPARS is an online data entry, reporting, and training system that supports grantee recipients in reporting timely and accurate data to SAMHSA. A username and password are required to gain access to SPARS system, https://spars.samhsa.gov. Your assigned Government Project Officer will provide additional information about these reporting requirements after award. Grantees will be required to submit these data quarterly:

- Submit data on activities from October 1 through December 31 by January 31
- Submit data on activities from January 1 through March 30 by April 30
- Submit data on activities from April 1 through June 30 by July 31
- Submit data on activities from July 1 through September 30 by October 31

**The approved Quarter 4 report must be uploaded into eRA Commons by December 28, 2024.*

This requirement extends to all years of the grant program. Grantees are also required to complete SPARS training by **November 30, 2023**. Information on SPARS training will be shared by your GPO.

Programmatic Progress Report

By **04/30/2024** & **12/28/2024**, submit via eRA Commons:
Grantees will be required to submit a progress report on project performance **at the midpoint of Year -01** *within 30 days of the end of the second quarter* and **annually** *within 90 days of the end of each 12-month budget period* (two reports will be required in Year 1 and one report will be required at the completion of each year thereafter). The report must discuss:

- Progress achieved in the project which should include qualitative and quantitative data (GPRA) to demonstrate programmatic progress to include updates on required activities, successes, challenges, and changes or adjustments that have been made to the project;
- Progress addressing quality care of underserved populations related to the Disparity Impact Statement (DIS);

- Barriers encountered, including challenges serving populations of focus;
- Efforts to overcome these barriers;
- Evaluation activities for tracking DIS efforts.

A final performance report must be submitted within 120 days after the end of the project period. The final performance report must be cumulative and report on all activities during the entire project period. These reports will be entered into eRA as a .pdf to the View Terms Tracking Details page in the eRA Commons System.

Note: Recipients must also comply with the GPRA requirements that include the collection and periodic reporting of performance data as specified in the FOA or by the Grant Program Official (GPO). This information is needed in order to comply with PL 102-62, which requires that Substance Abuse and Mental Health Services Administration (SAMHSA) report evaluation data to ensure the effectiveness and efficiency of its programs.

The response to this term must be submitted as .pdf documents in eRA Commons. Please contact your Government Program Official (GPO) for program specific submission information.
For more information on how to respond to tracked terms and conditions please refer to https://www.samhsa.gov/grants/grants-training-materials under heading **How to Respond to Terms and Conditions.**

Additional information on reporting requirements is available at https://www.samhsa.gov/grants/grants-management/reporting-requirements.

Annual Federal Financial Report (FFR or SF-425)

All financial reporting for recipients of Health and Human Services (HHS) grants and cooperative agreements will be consolidated through a single point of entry, which has been identified as the Payment Management System (PMS). The Federal Financial Report (FFR or SF-425) initiative ensures all financial data is reported consistently through one source; shares reconciled financial data to the HHS grants management systems; assists with the timely financial monitoring and grant closeout; and reduces expired award payments. The FFR should reflect cumulative amounts. Additional guidance to complete the FFR can be found at http://www.samhsa.gov/grants/grants-management/reporting-requirements.

Your organization is required to submit an FFR for this grant funding as follows:

- No later than **12/28/2024.**

Effective January 1, 2021, recipients can connect seamlessly from the eRA Commons FFR Module to PMS by clicking the Manage FFR button on the Search for Federal Financial Report (FFR) page.

- Recipients who do not have access to PMS may use the following instructions on how to update user permission: https://pms.psc.gov/grant-recipients/access-newuser.html.
- Recipients who currently have access to PMS and are submitting or certifying the FFR on behalf of their organization, should login to PMS and update their permissions to request access to the FFR Module using the following instructions: https://pms.psc.gov/grant-recipients/access-changes.html.
- Instructions on how to submit a FFR via PMS are available at https://pmsapp.psc.gov/pms/app/help/ffr/ffr-grantee-instructions.html (**Must be logged**

into PMS to access link)

If you have questions about how to set up a PMS account for your organization, please contact the PMS Help Desk at PMSSupport@psc.hhs.gov or 1-877-614-5533. Note: Recipients will use PMS to report all financial expenditures, as well as to drawdown funds; SAMHSA recipients will continue to use the eRA Commons for all other grant-related matters including submitting progress reports, requesting post-award amendments, and accessing grant documents such as the Notice of Award.

Staff Contacts:

Linda Kim, Grants Specialist
Phone: 240-276-1865 **Email:** linda.kim@samhsa.hhs.gov

Exhibit B

Fiscal Year 2023 Award Standard Terms

1. Acceptance of the Terms of an Award

By drawing or otherwise obtaining funds from the Health and Human Services (HHS) Payment Management System, the recipient acknowledges acceptance of the terms and conditions of the award and is obligated to perform in accordance with the requirements of the award. If the recipient cannot accept the terms, the recipient should notify the Grants Management Officer (GMO) within thirty (30) days of receipt of this award notice. Once an award is accepted by a recipient, the contents of the Notice of Award (NoA) are binding on the recipient unless and until modified by a revised NoA signed by the GMO.

Certification Statement: By drawing down funds, the recipient certifies that proper financial management controls and accounting systems, to include personnel policies and procedures, have been established to adequately administer Federal awards and funds drawn down. Recipients of Department of Health and Human Services' (DHHS) grants or cooperative agreement awards must comply with all terms and condition of their awards, including: (a) terms and conditions included in the HHS Grants Policy Statement in effect at the time of a new, non-competing continuation, or renewal award, including the requirements of HHS grants administration regulations; (b) requirements of the authorizing statutes and implementing regulations for the program under which the award is funded; (c) applicable requirements or limitations in appropriations acts; and (d) any requirements specific to the particular award specified in program policy and guidance, the Notice of Funding Opportunity (NOFO), or the Notice of Award (NoA).

2. Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards

The NoA issued is subject to the administrative requirements, cost principles, and audit requirements that govern Federal monies associated with this award, as applicable, in the Uniform Guidance – 2 Code of Federal Regulations (CFR) § 200 as codified by HHS at 45 CFR § 75.

3. Award Expectations

The eligibility and program requirements originally outlined in the NOFO must continue to be adhered to as the funded project is implemented. Recipients must comply with the performance goals, milestones, outcomes, and performance data collection as reflected in the NOFO and related policy and guidance. Additional terms and/or conditions may be applied to this award if outstanding financial or programmatic compliance issues are identified by Substance Abuse and Mental Health Services Administration (SAMHSA).

4. Flow down of requirements to sub-recipients

The recipient, as the awardee organization, is legally and financially responsible for all aspects of this award including funds provided to sub-recipients, in accordance with 45 CFR § 75.351 – 75.352, Sub-recipient monitoring and management.

5. Future Spending

As indicated in the NoA, recommended future support reflects total costs (direct plus indirect). Funding is subject to the availability of Federal funds, satisfactory progress and continued funding is in the best interest of the Federal government.

6. Non-Supplant

Federal award funds must supplement, not replace (supplant) non-federal funds. All recipients who receive awards under programs that prohibit supplanting by law must ensure that federal funds do not supplant funds that have been budgeted for the same purpose through non-federal sources. Applicants or award recipients may be required to demonstrate and document that a reduction in non-federal resources occurred for reasons other than the receipt of expected receipt of federal funds.

7. Unallowable Costs

All costs incurred prior to the award issue date and costs not consistent with the funding opportunity, 45 CFR § 75, and the HHS Grants Policy Statement, are not allowable under this award.

8. Conflicts of Interest Policy

Consistent with 45 CFR § 75.112, recipients must establish written policies and procedures to prevent employees, consultants, and others (including family, business, or other ties) involved in grant-supported activities, from involvement in actual or perceived conflicts of interest. The policies and procedures must:

- address conditions under which outside activities, relationships, or financial interest are proper or improper;
- provide for advance disclosure of outside activities, relationships, or financial interest to a responsible organizational official;
- include a process for notification and review by the responsible official of potential or actual violations of the standards; and
- specify the nature of penalties that may be imposed for violations.

9. Administrative and National Policy Requirements

Public policy requirements are requirements with a broader national purpose than that of the Federal sponsoring program or award that an applicant/recipient must adhere to as a prerequisite to and/or condition of an award. Public policy requirements are established by statute, regulation, or Executive order. In some cases, they relate to general activities, such as preservation of the environment, while, in other cases they are integral to the purposes of the award-supported activities. An application funded with the release of federal funds through a grant award does not constitute or imply compliance with federal statute and regulations. Funded organizations are responsible for ensuring that their activities comply with all applicable federal regulations, refer to Part II of the HHS Grants Policy Statement.

10. Carryover - Expanded Authority for Unobligated Balances from One Budget Period to Any Subsequent Budget Period

Federal administrative requirements allow agencies to provide recipients with expanded authorities, which waive certain cost-related and administrative prior approvals under certain conditions.

Per 45 CFR § 75.308 (d)(3), SAMHSA has extended expanded authority to recipients requesting carryover of unobligated balances (UOB) up to 25% or less of the current budget period (year when the funds are needed) provided that recipients are not on drawdown restriction.

Recipients requesting a carryover greater than 25% of the current budget period award cannot exercise this expanded authority.

Recipients who exercise expanded authority may include an Intent to Carryover statement in the Remarks section (box 12) of the annual Federal Financial Report (FFR).

Expanded authority may be overridden by other special terms or conditions of the award. Recipients must carefully review the Notice of Award to determine if a particular authority is withheld for a specific award.

Recipients must exercise proper stewardship over Federal funds and ensure that costs charged to awards are allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds.

Additional Guidance: https://www.samhsa.gov/grants/grants-management/post-award-amendments#carryover

11. Marijuana Restriction

SAMHSA grant funds may not be used to purchase, prescribe, or provide marijuana or treatment using marijuana. See, e.g., 45 CFR § 75.300(a) (requiring HHS to ensure that Federal funding is expended in full accordance with U.S. statutory and public policy requirements); 21 U.S.C. 812(c)(10) and 841 (prohibiting the possession, manufacture, sale, purchase or distribution of marijuana).

12. Prior Approval

SAMHSA anticipates that the recipient may need to modify the recipient's award budget or other aspects of its approved application during performance to accomplish the award's programmatic objectives. In general, recipients are allowed a certain degree of latitude to re-budget within and between budget categories to meet unanticipated needs and to make other types of post-award changes, provided that the changes still meet the statutory program requirements and the regulatory requirements under 45 CFR § 75, as applicable.

Items that require prior approval (i.e., formal written approval) from the GMO, as indicated in either 45 CFR § 75 or the HHS Grants Policy Statement, must be submitted in writing to the GMO. Based on the nature, extent, and timing of the request, the SAMHSA GMO may approve, deny, or request additional material to further document and evaluate your request.

Only an amended NoA signed by the GMO is considered valid. Verbal authorization is not approval and is not binding on SAMHSA. Recipients who proceed do so at their own risk.

Prior approval is required for but is not limited to: Changes in Key Personnel and Level of Effort, Budget Revisions, Changes in Scope, Carryover Requests (that fall outside the term for the Expanded Authority for Carryover), and No Cost Extensions. A summary of activities that require prior approval is listed in the HHS Grants Policy Statement under Exhibit 5, Page II-49.

SAMHSA instructions regarding requests for prior approval are available at:
https://www.samhsa.gov/grants/grants-management/post-award-amendments

13. Executive Pay

The Consolidated Appropriations Act, 2023 (Public Law No: 117-328), signed into law on December 29, 2022, restricts the amount of direct salary to Executive Level II of the Federal Executive Pay scale. Effective January 1, 2023, the salary limitation for Executive Level II is $212,100.

For awards issued prior to this change, if adequate funds are available in active awards, and if the salary cap increase is consistent with the institutional base salary, recipients may re-budget

to accommodate the current Executive Level II salary level. However, no additional funds will be provided to these grant awards.

14. Promotional Items

SAMHSA grant funds may not be used for Promotional Items. Promotional items include but are not limited to clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags.

HHS Policy on the Use of Appropriated Funds for Promotional Items:

https://www.hhs.gov/grants/contracts/contract-policies-regulations/spending-on-promotional-items/index.html

15. Universal Identifier and SAM Requirements

This award is subject to requirements as set forth in 2 CFR § 25 – Universal Identifier and System of Award Management (SAM) Requirements.

A. Requirement for System of Award Management

Unless you are exempted from this requirement under 2 CFR § 25.110, you, as the recipient, must maintain the currency of your information in the SAM, until you submit the final financial report required under this award or receive the final payment, whichever is later. This requires that you review and update the information at least annually after the initial registration, and more frequently if required by changes in your information or another award term.

B. Requirement for unique entity identifier if you are authorized (reference project description) to make subawards under this award, you:

1. Must notify potential subrecipients that no entity (see definition in paragraph C of this award term) may receive a subaward from you, unless the entity has provided its unique entity identifier to you; and

2. May not make a subaward to an entity, unless the entity has provided its unique entity identifier to you.

C. Definitions.

For purposes of this award term:

1. System of Award Management (SAM) means the Federal repository into which an entity must provide information required for the conduct of business as a recipient.

Additional information on SAM registration procedures may be found at: https://www.sam.gov.

2. Unique entity identifier means the identifier required for SAM registration to uniquely identify business entities.

3. Entity, as it is used in this award term, means all of the following, as defined at 2 CFR § 25, subpart D:

   - A governmental organization, which is a state, local government, or Indian Tribe;
   - A foreign public entity;
   - A domestic or foreign nonprofit organization;
   - A domestic or foreign for-profit organization; and
   - A Federal agency, but only as a subrecipient under an award or subaward to a non-Federal entity.

4. Subaward:

   - This term means a legal instrument to provide support for the performance of any portion of the substantive project or program for which you received this award and that you as the recipient award to an eligible subrecipient;
   - The term does not include your procurement of property and services needed to carry out the project or program (for further explanation, see 2 CFR § 200.1 and 2 CFR § 200.331).
   - A subaward may be provided through any legal agreement, including an agreement that you consider a contract.

5. Subrecipient means an entity that:

   - receives a subaward from you under this award; and
   - is accountable to you for the use of the Federal funds provided by the subaward.

16. Financial Accountability and Transparency Act (FFATA)

The Federal Funding Accountability and Transparency Act (FFATA) was signed on September 26, 2006. The FFATA Subaward Reporting System (FSRS) is the reporting tool federal prime awardees (i.e. prime contractors and prime grants recipients) must use to capture and report subaward and executive compensation data regarding their first-tier subawards to meet the FFATA reporting requirements.

Prime contract awardees must report against sub-contracts awarded. Prime grant awardees will report against sub-grants awarded. The sub-award information you enter in FSRS will display on USASpending.gov associated with the prime award.

17. SAM.gov Responsibility Qualification (R/Q) – Recipient Integrity and Performance

Reporting of Matters Related to Recipient Integrity and Performance

1. General Reporting Requirement

If the total value of your currently active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds $10,000,000 for any period of time during the period of performance of this Federal award, then you as the recipient during that period of time must maintain the currency of information reported to the System for Award Management (SAM) that is made available in the designated integrity and performance system (formerly the Federal Awardee Performance and Integrity Information System (FAPIIS) now called Responsibility/Qualification (R/Q) on SAM.gov about civil, criminal, or administrative proceedings described in paragraph 2 of this award term and condition. This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available.

2. Proceedings About Which You Must Report

Submit the information required about each proceeding that:

- Is in connection with the award or performance of a grant, cooperative agreement, or procurement contract from the Federal Government;
- Reached its final disposition during the most recent five-year period; and
- If one of the following:
    - A criminal proceeding that resulted in a conviction, as defined in paragraph 5 of this award term and condition;
    - A civil proceeding that resulted in a finding of fault and liability and payment of a monetary fine, penalty, reimbursement, restitution, or damages of $5,000 or more;
    - An administrative proceeding, as defined in paragraph 5 of this award term and condition, that resulted in a finding of fault and liability and your payment of

either a monetary fine or penalty of $5,000 or more or reimbursement, restitution, or damages in excess of $100,000; or

- Any other criminal, civil, or administrative proceeding if:
  - It could have led to an outcome described in paragraph 2.c.(1), (2), or (3) of this award term and condition;
  - It had a different disposition arrived at by consent or compromise with an acknowledgement of fault on your part; and
  - The requirement in this award term and condition to disclose information about the proceeding does not conflict with applicable laws and regulations.

3. Reporting Procedures

Enter in the SAM Entity Management area the information that SAM requires about each proceeding described in paragraph 2 of this award term and condition. You do not need to submit the information a second time under assistance awards that you received if you already provided the information through SAM because you were required to do so under Federal procurement contracts that you were awarded.

4. Reporting Frequency

During any period of time when you are subject to this requirement in paragraph 1 of this award term and condition, you must report proceedings information through SAM for the most recent five-year period, either to report new information about any proceeding(s) that you have not reported previously or affirm that there is no new information to report. Recipients that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $10,000,000 must disclose semiannually any information about the criminal, civil, and administrative proceedings.

5. Definitions

For purposes of this award term and condition:

- Administrative proceeding means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (e.g., Securities and Exchange Commission Administrative proceedings, Civilian Board of Contract Appeals proceedings, and Armed Services Board of Contract Appeals proceedings). This includes proceedings at the Federal and State level but only in connection with performance of a

Federal contract or grant. It does not include audits, site visits, corrective plans, or inspection of deliverables.

- Conviction, for purposes of this award term and condition, means a judgment or conviction of a criminal offense by any court of competent jurisdiction, whether entered upon a verdict or a plea, and includes a conviction entered upon a plea of nolo contendere.

- Total value of currently active grants, cooperative agreements, and procurement contracts includes—

    - Only the Federal share of the funding under any Federal award with a recipient cost share or match; and

    - The value of all expected funding increments under a Federal award and options, even if not yet exercised

[2 CFR Appendix XII to Part 200 - Award Term and Condition for Recipient Integrity and Performance Matters]

18. Acknowledgement of Federal Funding in communications and contracting

For each publication that results from HHS grant-supported activities, recipients must include an acknowledgment of grant support using one of the following statements:

"This publication was made possible by Grant Number _____ from _____."

"The project described was supported by Grant Number _____ from _____."

Recipients also must include a disclaimer stating the following:

"Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the [SAMHSA]."

If the recipient plans to issue a press release concerning the outcome of HHS grant-supported activities, it should notify SAMHSA in advance to allow for coordination. One copy of each publication resulting from work performed under an HHS grant-supported project must accompany the annual or final progress report submitted to SAMHSA.

19. Acknowledgement of Federal Funding at Conferences and Meetings

A conference is defined as a meeting, retreat, seminar, symposium, workshop or event whose primary purpose is the dissemination of technical information beyond the non-Federal entity and is necessary and reasonable for successful performance under the Federal award.

Allowable conference costs paid by the non-Federal entity as a sponsor or host of the conference may include rental of facilities, speakers' fees, costs of meals and refreshments, local transportation, and other items incidental to such conferences unless further restricted by the terms and conditions of the Federal award. As needed, the costs of identifying, but not providing, locally available dependent-care resources are allowable. Conference hosts/sponsors must exercise discretion and judgment in ensuring that conference costs are appropriate, necessary and managed in a manner that minimizes costs to the Federal award. The HHS awarding agency may authorize exceptions where appropriate for programs including Indian tribes, children, and the elderly. See also 45 CFR §§75.438, 75.456, 75.474, and 75.475.

Disclaimer for Conference/Meeting/Seminar Materials: If a conference/meeting/seminar is funded by a grant, cooperative agreement, sub-grant and/or a contract, the recipient must include the following statement on conference materials, including promotional materials, agenda, and internet sites:

"Funding for this conference was made possible (in part) by SAMHSA. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services, nor does the mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government."

20. Rights in Data and Publications

As applicable, recipients agree to the requirements for intellectual property, rights in data, access to research data, publications, and sharing research tools, and intangible property and copyrights as described in 45 CFR § 75.322 and the HHS Grants Policy Statement.

Recipients may copyright any work that is subject to copyright and was developed, or for which ownership was acquired, under a Federal award. SAMHSA reserves a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so.

21. Mandatory Disclosures

Consistent with 45 CFR § 75.113, applicants and recipients must disclose in a timely manner, in writing to the HHS Office of Inspector General (OIG), all information related to violations, or suspected violations, of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. Subrecipients must disclose, in a timely manner, in writing to the prime recipient (pass through entity) and the HHS OIG, all information related to violations, or suspected violations, of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. Disclosures must be sent in writing to the awarding agency and to the HHS OIG at the following addresses:

U.S. Department of Health and Human Services

Office of Inspector General ATTN: Mandatory Grant Disclosures, Intake Coordinator 330 Independence Avenue, SW, Cohen Building, Room 5527, Washington, DC 20201

Fax: (202) 205-0604 (Include "Mandatory Grant Disclosures" in subject line) or email: MandatoryGranteeDisclosures@oig.hhs.gov

Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371 – Remedies for noncompliance, including suspension or debarment (see 2 CFR §§ 180 & 376 and 31 U.S.C. 3321).

22. Lobbying Restrictions

Per 45 CFR §75.215, Recipients are subject to the restrictions on lobbying as set forth in 45 CFR § 93.

Lobbying with appropriated moneys, U.S. Code 18 § 1913 (2021), No part of the money appropriated by any enactment of Congress shall, in the absence of express authorization by Congress, be used directly or indirectly to pay for any personal service, advertisement, telegram, telephone, letter, printed or written matter, or other device, intended or designed to influence in any manner a Member of Congress, a jurisdiction, or an official of any government, to favor, adopt, or oppose, by vote or otherwise, any legislation, law, ratification, policy, or appropriation, whether before or after the introduction of any bill, measure, or resolution proposing such legislation, law, ratification, policy, or appropriation; but this shall not prevent officers or employees of the United States or of its departments or agencies from communicating to any such Member or official, at his/her request, or to Congress or such official, through the proper official channels, requests for any legislation, law, ratification, policy, or appropriations which they deem necessary for the efficient conduct of the public business, or from making any communication whose prohibition by this section might, in the opinion of the Attorney General, violate the Constitution or interfere with the conduct of foreign policy, counter-intelligence, intelligence, or national security activities.

Violations of this section shall constitute as a violation of section 1352 (a) of Title 31.

23. Drug-Free Workplace

The Drug-Free Workplace Act of 1988 (41 U.S.C. § 701 et seq.) requires that all organizations receiving grants from any Federal agency agree to maintain a drug-free workplace. You as the recipient must comply with drug-free workplace requirements in Subpart B (or Subpart C, if the recipient is an individual) of part 382, which adopts the Governmentwide implementation (2 CFR §182) of sec. 5152-5158 of the Drug-Free Workplace Act of 1988 (Pub. L. 100-690, Title V, Subtitle D; 41 U.S.C. 701-707). By signing the application, the AOR agrees that the recipient will

provide a drug-free workplace and will comply with the requirement to notify SAMHSA if an employee is convicted of violating a criminal drug statute. Failure to comply with these requirements may be cause for debarment. Government wide requirements for Drug-Free Workplace for Financial Assistance are found in 2 CFR § 182; HHS implementing regulations are set forth in 2 CFR § 382.400.

24. Civil Right Laws that prohibit discrimination

You must administer your project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html.

- You must take reasonable steps to ensure that your project provides meaningful access to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.

- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and taking appropriate steps to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.

- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.

- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

25. Trafficking Victims Protection Act of 2000 (22 U.S.C. 7104(G)), as amended, and 2 CFR § 175

The Trafficking Victims Protection Act of 2000 authorizes termination of financial assistance provided to a private entity, without penalty to the Federal government, if the recipient or subrecipient engages in certain activities related to trafficking in persons. SAMHSA may unilaterally terminate this award, without penalty, if a private entity recipient, or a private entity subrecipient, or their employees:

- Engage in severe forms of trafficking in persons during the period of time that the award is in effect;
- Procure a commercial sex act during the period of time that the award is in effect; or,
- Use forced labor in the performance of the award or subawards under the award.

The text of the full award term is available at 2 CFR § 175.15(b).

26. Confidentiality of Alcohol and Drug Abuse Patient Records

The regulations (42 CFR § 2) are applicable to any information about alcohol and other drug abuse patients obtained by a "program" (42 CFR § 2.11), if the program is federally assisted in any manner (42 CFR § 2.12b). Accordingly, all project patient records are confidential and may be disclosed and used only in accordance with 42 CFR § 2. The recipient is responsible for assuring compliance with these regulations and principles, including responsibility for assuring the security and confidentiality of all electronically transmitted patient material.

27. Healthy People 2020

Healthy People 2020 is a national initiative led by HHS that set priorities for all SAMHSA programs. The initiative has two major goals: (1) increase the quality and years of a healthy life; and (2) eliminate our country's health disparities. The program consists of 28 focus areas and 467 objectives. SAMHSA has actively participated in the work groups of all the focus areas and is committed to the achievement of the Healthy People 2020 goals. Healthy People 2010 and the conceptual framework for the forthcoming Healthy People 2020 process can be found online at: http://www.healthypeople.gov/

28. Accessibility Provisions

Recipients of Federal financial assistance (FFA) from HHS must administer their programs in compliance with Federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin,

disability, age, and in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency.

The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see: http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html.

Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see- http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html. Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under Federal civil rights laws at https://www.hhs.gov/civil-rights/index.html or call 1-800-368-1019 or TDD 1-800-537-7697.

Also note that it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=1&lvlid=6.

29. Data Collection and Performance Measurement

All SAMHSA recipients are required to collect and report evaluation data to ensure the effectiveness and efficiency of its programs under the Government Performance and Results (GPRA) Modernization Act of 2010 (P.L. 102-62). Recipients must comply with the performance goals, milestones, and expected outcomes as reflected in the NOFO and are required to submit data via SAMHSA's data-entry and reporting system.

Please contact your Government Program Official for additional submission information.

30. Legislative Mandates

Certain statutory provisions under P.L. 115-245, Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019, Division B, Title V, Title II, General Provisions limit the use of funds on SAMHSA grants, cooperative agreements, and contract awards. Such provisions are subject to change annually based on specific appropriation language that restricts the use of grant funds. The full text of P.L. 115-245 is available at https://www.congress.gov/bill/115th-congress/house-bill/6157/text?Format=txt.

31. Executive Order 13410: Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs

This EO promotes efficient delivery of quality health care through the use of health information technology, transparency regarding health care quality and price, and incentives to promote the widespread adoption of health information technology and quality of care. Accordingly, all recipients that electronically exchange patient level health information to external entities where national standards exist must:

- Use recognized health information interoperability standards at the time of any HIT system update, acquisition, or implementation, in all relevant information technology systems supported, in whole or in part, through this agreement/contract. Please consult www.healthit.gov for more information, and
- Use Electronic Health Record systems (EHRs) that are certified by agencies authorized by the Office of the National Coordinator for Health Information Technology (ONC), or that will be certified during the life of the grant.

32. Audits

Non-Federal recipients that expend $750,000 or more in federal awards during the recipient's fiscal year must have a single or program-specific audit conducted for that year in accordance with the provisions of 45 CFR § 75.501. Guidance on determining Federal awards expended is provided in 45 CFR §75.502.

Recipients are responsible for submitting their Single Audit Reports and the Data Collections Forms (SF-FAC) electronically to the to the Federal Audit Clearinghouse Visit disclaimer page (FAC) within the earlier of 30 days after receipt or nine months after the FY's end of the audit period. The FAC operates on behalf of the OMB.

For specific questions and information concerning the submission process:

- Visit the Federal Audit Clearinghouse at https://harvester.census.gov/facweb
- Call FAC at the toll-free number: (800) 253-0696

33. Ad Hoc Submissions

Throughout the project period, SAMHSA may determine that a grant requires submission of additional information beyond the standard deliverables. This information may include, but is not limited to, the following:

- Payroll

- Purchase orders
- Contract documentation
- Proof of project implementation

34. Submitting Responses to Conditions and Reporting Requirements

Unless otherwise identified in the special terms and conditions of award and post award requests, all responses to special terms and conditions of award and post award requests must be submitted through the eRA Commons system.

35. Risk Assessment

SAMHSA may perform an administrative review of your organization's financial management system. If the review discloses material weaknesses or other financial management concerns, grant funding may be restricted in accordance with 45 CFR § 75/2 CFR § 200, as applicable. The restriction will affect your organization's ability to withdraw funds from the Payment Management Services account, until the concerns are addressed.

36. 120-day Reconciliation and Liquidation Period

In accordance with 2 CFR § 200.344, recipients must liquidate all obligations incurred under an award not later than one hundred and twenty (120) days after the end of award's obligation and expenditure period (i.e., the project period). After one hundred and twenty (120) days, letter of credit accounts are locked. SAMHSA does not approve extensions to the one hundred and twenty (120) day post-award reconciliation/liquidation period. Therefore, recipients are expected to complete all work and reporting within the approved project period and the aforementioned 120-day post-award reconciliation/liquidation period. Recipients (late) withdrawal requests occurring after the aforementioned periods will be denied.

37. Cancel Year

31 U.S.C. 1552(a) Procedure for Appropriation Accounts Available for Definite Periods states the following: On September 30th of the 5th fiscal year after the period of availability for obligation of a fixed appropriation account ends, the account shall be closed and any remaining balances (whether obligated or unobligated) in the account shall be canceled and thereafter shall not be available for obligation or expenditure for any purpose.

38. Termination

Termination (45 CFR § 75.372) applies to this award and states, in part, the following:

This award may be terminated in whole or in part:

- By the HHS awarding agency (SAMHSA) or pass-through entity, if a non-Federal entity fails to comply with the terms and conditions of a Federal award;

- By the HHS awarding agency (SAMHSA) or pass-through entity for cause;

- By the HHS awarding agency (SAMHSA) or pass-through entity with the consent of the non-Federal entity, in which case the two parties must agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated;

- By the non-Federal entity upon sending to the HHS awarding agency or pass-through entity written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the Federal awarding agency or pass-through entity determines in the case of partial termination that the reduced or modified portion of the Federal award or subaward will not accomplish the purposes for which the Federal award was made, the HHS awarding agency or pass-through entity may terminate the Federal award in its entirety.

39. Prohibition on certain tele-communications and video surveillance services or equipment

As described in 2 CFR § 200.216, recipients and subrecipients are prohibited to obligate or spend grant funds (to include direct and indirect expenditures as well as cost share and program) to:

- Procure or obtain;

- Extend or renew a contract to procure or obtain; or

- Enter into contract (or extend or renew contract) to procure or obtain equipment, services, or systems that use covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. As described in Pub. L. 115- 232, section 889, covered telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).

    - For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).

- Telecommunications or video surveillance services provided by such entities or using such equipment.

- Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise, connected to the government of a covered foreign country.

Exhibit C

Department of Health and Human Services

Substance Abuse and Mental Health Services Administration

FY 2023 First Responders-Comprehensive Addiction and Recovery Act

(Short Title: FR-CARA)

(Initial Announcement)

Notice of Funding Opportunity (NOFO) No. TI-23-012

Assistance Listing Number: 93.243

Key Dates:

Application Deadline	**Applications are due by March 14, 2023.**
Intergovernmental Review (E.O. 12372)	**Applicants must comply with E.O. 12372 if their state(s) participate(s). Review process recommendations from the State Single Point of Contact (SPOC) are due no later than 60 days after application deadline.**
Public Health System Impact Statement (PHSIS)/Single State Agency Coordination	**Applicants must send the PHSIS to appropriate state and local health agencies by the administrative deadline. Comments from the Single State Agency are due no later than 60 days of the application deadline.**

Table of Contents

EXECUTIVE SUMMARY

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Prevention (CSAP), is accepting applications for the fiscal year (FY) 2023 First Responders-Comprehensive Addiction and Recovery Act program (Short Title: FR-CARA). The purpose of this program is to support first responders and members of other key community sectors to administer a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for emergency reversal of known or suspected opioid overdose. Recipients will train and provide resources to first responders and members of other key community sectors at the state, tribal, and local levels on carrying and administering a drug or device approved or cleared under the FD&C Act for emergency treatment of known or suspected opioid overdose. Recipients will also establish processes, protocols, and mechanisms for referral to appropriate treatment and recovery support services, safety around fentanyl, carfentanil, other synthetic opioids (CDC) and other licit and illicit drugs associated with overdoses. With this program, SAMHSA aims to support First Responder's efforts to mitigate the overdose epidemic across the nation and provide targeted resources to populations disproportionately impacted by opioid use relative (relative to national averages).

Funding Opportunity Title:	First Responders – Comprehensive Addiction and Recovery Act (Short Title: FR-CARA)
Funding Opportunity Number:	TI-23-012
Due Date for Applications:	March 14, 2023
Estimated Total Available Funding:	Up to $17,200,000 (approximately $6.3M will be awarded to applicants serving rural communities with high rates of opioid use disorder)
Estimated Number of Awards:	34
Estimated Award Amount:	Tribes/Tribal Organizations up to $250,000 per year Local Government entities up to $500,000 per year States up to $800,000 per year
Cost Sharing/Match Required:	No
Anticipated Project Start Date:	September 30, 2023
Anticipated Award Date:	August 31, 2023

Length of Project Period:	Up to 4 years
Eligible Applicants:	Eligibility for this program is statutorily limited to States, local governmental entities, and Indian tribes and tribal organizations. [See Section III-1 for complete eligibility information.]
Authorizing Statute:	The First Responders-Comprehensive Addiction and Recovery Act is authorized under Section 546 of the Public Health Service Act, (42 USC 290ee-1), as amended.

Be sure to check the SAMHSA website periodically for any updates on this program.

All applicants MUST register with NIH's eRA Commons in order to submit an application. This process takes up to six weeks. If you believe you are interested in applying for this opportunity, you MUST start the registration process immediately. Do not wait to start this process.

WARNING: BY THE DEADLINE FOR THIS NOFO YOU MUST HAVE SUCCESSFULLY COMPLETED THE FOLLOWING TO SUBMIT AN APPLICATION:

- **The applicant organization MUST be registered in NIH's eRA Commons; AND**
- **The Project Director MUST have an active eRA Commons account (with the PI role) affiliated with the organization in eRA Commons.**

No exceptions will be made.

Applicants also must register with the System for Award Management (SAM) and Grants.gov (see Appendix A of this NOFO for all registration requirements).

DO NOT WAIT UNTIL THE LAST MINUTE TO SUBMIT THE APPLICATION. If you wait until the last minute, there is a strong possibility that the application will not be received without errors by the deadline.

I. PROGRAM DESCRIPTION

1. PURPOSE

The purpose of this program is to support first responders and members of other key community sectors to administer a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for emergency reversal of known or suspected opioid overdose. Recipients will train and provide resources to first responders and members of other key community sectors at the state, tribal, and local levels on carrying and administering a drug or device approved or cleared under the FD&C Act for emergency treatment of known or suspected opioid overdose. Recipients will also establish processes, protocols, and mechanisms for referral to appropriate treatment and recovery support services, safety around fentanyl, carfentanil, other synthetic opioids, and other licit and illicit drugs associated with overdoses. The population of focus are: 1) populations disproportionately impacted (relative to national averages) by opioid use as evidenced by high rates of opioid and other drug-related overdose, 2) primary treatment admissions, and 3) populations with high overdose rates. Applicant organizations must document that their population of focus is

underserved as demonstrated by a lack of accessibility to treatment providers, emergency medical services, and recovery and other psychosocial support services (CDC Urban-Rural Differences) https://www.cdc.gov/nchs/products/databriefs/db403.htm.

For the purposes of this NOFO, first responders include firefighters, law enforcement officers, paramedics, emergency medical technicians, mobile crisis providers or other legally organized and recognized volunteer organizations that respond to adverse opioid related incidents.

Applicants may use the following resources to document that their proposed target population has been disproportionately impacted by overdose:

- Applicable demographic, geographic, and socioeconomic data from the National Survey on Drug Use and (NSDUH)
- Applicable mortality data from the Centers for Disease Control and Prevention Wide-ranging Online Data for Epidemiological (CDC WONDER)
- Applicable Centers for Disease Control (CDC) data on differences in urban and rural overdose death rates (CDC Death Rates)
- Applicable local- and county-level data on drug overdose deaths, including provisional counts from the National Vital Statistics System (NVSS)
- Applicable data regarding social stigma, discrimination, and other challenges encountered by lesbian, gay, bisexual, transgender, and queer (LGBTQ) people(NIDA/NIH Data)

SAMHSA's Guidelines for Selecting Rural Communities of High Need

The FR-CARA program statutorily requires that no less than 20 percent of the funding be made to applicant organizations providing services to rural communities with high rates of opioid use disorder.

Applicants proposing to serve rural communities must be able to identify a catchment area defined as a nonmetropolitan statistical area; an area designated as a rural area by any law or regulation of a State; or a rural census tract of a metropolitan statistical area (Rural Urban Commuting Areas (RUCAs)) https://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx

Applicants proposing to provide training in a rural community must provide a written statement in **Attachment 9** certifying that the project will be implemented in a community not located in a metropolitan statistical area and specify whether this is a community of high need.

This program is authorized under Section 546 of the Public Health Service Act, (42 USC 290ee-1), as amended.

2. KEY PERSONNEL

Key personnel are staff members who must be part of the project regardless of whether or not they receive a salary or compensation from the project. These staff members must make a substantial contribution to the execution of the project and should reflect SAMHSA's expectation of diversity, equity, and inclusion in the selection of staff.

Key Personnel for this program are the Project Director with at least 50 percent level of effort (person responsible for overseeing, monitoring, and managing the award), **and the Evaluator** with at least 20 percent level of effort (organization or assigned individual within the organization) responsible for evaluating processes and outcomes of the award, and oversight of reporting in SPARS.

If awarded, recipients will be notified by SAMHSA about whether the individuals designated for these positions have been approved. If recipients need to replace a Key Personnel during the project period, the individual proposed for the vacant position requires prior approval by SAMHSA after review of credentials of the staff member and the job description.

3. REQUIRED ACTIVITIES

Required activities are the activities that every award recipient must implement. They must be reflected in the Project Narrative of your application. This is in response to Section V of this NOFO.

Project implementation is expected to begin by the fourth month of the award. This time frame may be extended if necessary. Upon award, further directions will be provided to recipients.

In the Project Narrative (B.1), applicants must indicate the total number of unduplicated individuals that will be served each year of the award and over the total project period. Award recipients are expected to achieve the numbers that are proposed.

Award recipients must use SAMHSA's funds to support direct services primarily. This includes the following activities:

- Provide resources to support the purchase and distribution of FD&C Act approved or cleared devices for emergency reversal of known or suspected opioid overdose by first responders and members of other key community sectors in the targeted catchment area. Note: These resources may include the purchase and distribution of FDA-approved overdose reversal drugs (e.g., naloxone).
- Train and provide resources for first responders and members of other key community sectors (including direct service providers) on the following:

- Carrying and administering a device approved or cleared under the FD&C Act for emergency reversal of known or suspected opioid overdose.
- Education and safety measures around fentanyl, carfentanil, other synthetic opioids, and other licit and illicit drugs associated with overdoses.
- Establishing policies and procedures for the implementation of evidence-based trauma-informed care practices.

- Establish processes, protocols, and mechanisms for referral to appropriate treatment, which may include an outreach coordinator, peer support specialist or team, or mobile crisis services to connect individuals receiving opioid overdose reversal drugs to follow-up services.
- Develop a Naloxone Education and Distribution Plan and submit the plan in SPARS within the first 6 months of the award.
- Form or join an established advisory committee that meets the following requirements of the award. If the recipient chooses to join an established advisory committee, the recipient must establish a memorandum of understanding (MOU) with the existing committee that ensures that the FR-CARA requirements will be met.
  - The advisory committee must include representatives from the Office of the Governor or Chief Executive Officer, tribal council, or office of the local chief executive, as applicable; and a core group of agencies identified by the recipient that must include agencies currently engaged in efforts to prevent drug overdose and overdose-related deaths. This may include: first responders, entities that distribute FDA-approved overdose reversal drugs, and representatives of agencies and organizations responsible for substance use disorder (SUD) prevention, treatment, mental health, recovery support, and harm reduction services.
  - Members of other key community sectors are also encouraged to be a part of the advisory committee, such as emergency medical services agencies, agencies and organizations working with prison and jail populations, offender reentry programs, physical and behavioral health care providers, including community health centers, community mental health centers, federally qualified health centers, and Certified Community Behavioral Health Clinics (CCBHCs), harm reduction agencies, organizations providing housing support, pharmacies, cultural support resources appropriate to the population of focus, family and children's support services (including school systems), LGBT centers, and other local psychosocial support providers. The advisory committee should provide ongoing advice and guidance to the program throughout the four years of the award and create workgroups to monitor progress and ensure that the goals of the project are being met.
- Hire staff that represent the population of the community (see Culturally and Linguistically Appropriate Services in Health and Health Care (CLAS Standard 3);

- Translate tools and resources available to recipients of services (see CLAS Standards 5-8).
- Develop strategies to provide, increase, or enhance access to services for people of all racial/ethnic/marginalized groups in the community.
- Create conflict and grievance resolutions processes that are culturally and linguistically appropriate (CLAS standard 14).

4. ALLOWABLE ACTIVITIES

Allowable activities are an allowable use of funds but are not required. Allowable activities may include:

- Develop and implement tobacco cessation programs, activities, and/or strategies.
- Support efforts to reduce alcohol misuse for those at risk.
- Provide training on behavioral health implementation for the national CLAS standards, supporting providers in their desire to increase awareness and acknowledgment of differences in language, age, culture, racial and ethnic disparities, socio-economic status, religious beliefs, sexual orientation and gender identity, and life experiences in order to improve the inclusiveness of the service delivery environment and ultimately improve behavioral health outcomes.
- Provide activities that address behavioral health disparities and the social determinants of health.
- Implement efforts aligned to the award that may expand diversity, equity, inclusion, and accessibility.
- Use data to understand who is served and disproportionately served (e.g., overserved or underserved).
- Develop and implement outreach and referral pathways that engage/target all demographic groups representative of your community.
- Collaborate with health care providers to educate them on overdose dangers and recommend that they consider providing resources to individuals at risk of experiencing or being impacted by overdose, including information on treatment, recovery, and other support services.
- Provide public education on any applicable "Good Samaritan" laws, such as those that permit bystanders to alert emergency responders to an overdose or to administer FDA-approved overdose reversal drugs without fear of civil or criminal penalties.
- Provide community first aid or cardiopulmonary resuscitation (CPR) training that may include appropriate use of naloxone by laypersons (non-direct services providers) such as caregivers and family members of those with opioid use disorder.
- Facilitate field initiation of low-threshold buprenorphine or other appropriate medication intended to reduce the risk of withdrawal symptoms and overdose

death and initiate treatment, per applicable local, state, and Federal regulations; and make warm-handoff referrals to community-based treatment, recovery, and other psychosocial supports as appropriate.

- Applicants proposing to implement this allowable activity will be required to:
  - Submit a written statement certifying in **Attachment 9** that the applicant is aware of all applicable local, state, and federal laws and regulations governing the distribution and/or provision of buprenorphine and any other medication intended to reduce the risk of withdrawal symptoms and overdose death, and that their proposed program falls within all applicable legal and restrictions.
  - Submit Letters of Commitment in **Attachment 1** from any direct service provider organizations (including First Responders) who will be providing and/or administering field-initiated buprenorphine or other medication intended to reduce the risk of withdrawal symptoms and overdose death.
  - Demonstrate that individuals who receive field-initiated buprenorphine or other medication intended to reduce the risk of withdrawal symptoms and overdose death are also initiated into time-limited comprehensive support services, which may include but are not limited to: engagement with peer support services (e.g., linkages to certified peer support professionals, referrals to recovery housing programs, etc.,); case management, patient, and health system navigation services; referral to behavioral health and/or other treatment/clinical services; referral to housing, employment, insurance/medical, and other assistance services; and other forms of psychosocial support.
  - Provide or facilitate the provision of appropriate training to direct service provider organizations (including First Responders as defined by the legislation) who will be providing and/or administering field-initiated buprenorphine or other medication intended to reduce the risk of withdrawal symptoms and overdose death. Training curriculums should be developed with input from the population of focus and should include, at minimum: best practices for interacting with individuals who have experienced a known or suspected overdose; culturally-informed best practices for interacting with the population of focus; evidence-based and/or evidence-informed education on the physical and psychological impact of overdose on the individual; and specific guidance on locally-available resources for treatment, recovery, and psychosocial support.

- Provision of comprehensive support services, as appropriate, which may include, but are not limited to, engagement with peer recovery support

professionals; case management, patient, and health system navigation services; referral to behavioral health and/or other treatment services; referral to housing, employment, insurance/medical, and other assistance services; and other forms of psychosocial support.

- Facilitate immediate overdose follow-up support, including warm handoff referrals to treatment, recovery, and other psychosocial support resources as appropriate.
- Facilitate access to fentanyl test strips, where legally accessible.

Infrastructure Development (maximum 15 percent of the total award for the budget period)

Although funds must be used primarily for the provision of training, SAMHSA recognizes that infrastructure changes may be needed to implement the training or improve its effectiveness. You may use no more than 15 percent of the total award for the types of infrastructure development listed below, if necessary, to support the direct service expansion of the project. You must describe in Section B of your Project Narrative the use of funds for infrastructure activities which may include:

- Developing partnerships with other service providers for service delivery and stakeholders serving the population of focus.
- Training/workforce development to help project staff gain skills necessary to utilize new computer system/management information system/EHRs, etc. funded through this award.
    - Note: Computer systems/management information systems/ EHRs, health information technology (HIT), and other IT systems are considered administrative costs, which are not recoverable directly from grants, but rather must be allocated to all awards, projects, and cost centers over an entire cost accounting period through a federally negotiated indirect cost rate or an approved de minimis rate (if eligible). For more information on the requirements of implementing, acquiring, or upgrading HIT, see: (a) https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-B; (b) HITECH Act; (c) https://www.healthit.gov/topic/certification-ehrs/certification-health-it; and (d) https://www.healthit.gov/isa/.
- Training/workforce development to help your staff or other providers in the community identify mental health or substance abuse issues or provide effective services consistent with the purpose of the program.
- Policy development to support needed service system improvements (e.g., rates setting activities, establishment of standards of care, adherence to the Behavioral Health Guide for the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care, development/revision of

credentialing, licensure, or accreditation requirements)[1]

5. USING EVIDENCE-BASED PRACTICES

SAMHSA's awards for the provision of services are intended to fund services or practices that have a demonstrated evidence base and that are appropriate for the population(s) of focus. An evidence-based practice (EBP) refers to approaches to prevention, treatment, or recovery that are validated by documented research evidence. Applicants are encouraged to visit the SAMHSA Evidence-Based Practice Resource Center (www.samhsa.gov/ebp-resource-center) and SAMHSA's National Network to Eliminate Disparities in behavioral health (NNED) (https://nned.net/) to identify evidence-informed and culturally appropriate mental illness and substance use prevention and treatment practices that can be implemented in your project.

Both researchers and practitioners recognize that EBPs are essential to improving the effectiveness of treatment and prevention services. While SAMHSA realizes that EBPs have not been developed for all populations and/or service settings, application reviewers will closely examine proposed interventions for evidence base and appropriateness for the population of focus. If an EBP(s) exists for the population(s) of focus and types of problems or disorders being addressed, the expectation is that EBP(s) will be utilized. If one does not exist but there are evidence-informed and/or culturally promising practices that are appropriate or can be adapted, these interventions may be implemented in the delivery of services.

In your Project Narrative, in response to Section C of Section V of this NOFO, you will need to identify the evidence-based practice(s) and/or interventions that are evidence-informed and/or culturally promising that are appropriate or can be adapted to meet the needs of your specific population(s) of focus. You must discuss the population(s) for which the practice(s) has (have) been shown to be effective and document that it is (they are) appropriate for your population(s) of focus. You must also address how these interventions will improve outcomes and address how you will monitor and ensure fidelity of EBPs and other appropriate interventions. In situations where an EBP is appropriate but requires additional culturally-informed engagement practices, this should be discussed in the application.

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[1] For purposes of this NOFO efforts do not include activities designed to influence the enactment of legislation, appropriations, regulations, administrative actions, or Executive Orders ("legislation and other orders") proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, and awardees may not use federal funds for such activities. This restriction extends to both grassroots lobbying efforts and direct lobbying. However, for state, local, and other governmental recipients, certain activities falling within the normal and recognized executive-legislative relationships or participation by an agency or officer of a state, local, or tribal government in policymaking and administrative processes within the executive branch of that government are not considered impermissible lobbying activities and may be supported by federal funds.

6. DATA COLLECTION/PERFORMANCE MEASUREMENT AND PROJECT PERFORMANCE ASSESSMENT

Data Collection/Performance Measurement

All SAMHSA recipients are required to collect and report certain data so that SAMHSA can meet its obligations under the Government Performance and Results (GPRA) Modernization Act of 2010. You must document your plan for data collection and reporting in your Project Narrative in response to Section E: Data Collection and Performance Measurement in Section V of this NOFO.

Recipients are required to report performance quarterly including the following GPRA measures:

1. The number of drug or device approved or cleared under the FD&C Act for emergency reversal of known or suspected opioid overdose purchased through award funding.

2. The number of drug or device approved or cleared under the FD&C Act for emergency reversal of known or suspected opioid overdose purchased through award funding and distributed to first responders and members of other key community sectors. An example of this measure would include the quantity of FDA-approved naloxone kits distributed through your program.

3. The number of first responders and members of other key community sectors receiving training to use a drug or device approved or cleared under the FD&C Act for emergency treatment of known or suspected opioid overdose.

4. The number of opioid and heroin overdoses reversed by first responders and members of other key community sectors who received supplies of a drug or device approved or cleared under the FD&C Act for emergency treatment of known or suspected opioid overdose through award funding. SAMHSA currently requires the reporting of outcomes for administration events associated with: (A) a person who received award-funded training to use a drug or device for emergency treatment of known or suspected opioid overdose and (B) a person who utilized an award-funded drug or device for emergency treatment of known or suspected opioid overdose. Possible outcomes for an administration event include:

- Overdose reversal
- Death
- Not an opioid overdose
- Unknown.

5. The total number of overdose deaths in the targeted geographic area.

6. The number of responses to requests for services by the entity or subgrantee related to opioid and heroin overdose.

7. The extent to which overdose victims and families receive information about treatment services and available data describing treatment admissions;

This information will be gathered using a uniform data collection tool provided by SAMHSA. Recipients are required to submit data via SAMHSA's Performance Accountability and Reporting System (SPARS); and access will be provided upon award. An example of the required data collection tool (i.e., National Outcome Measures (NOMs) or NOMS client level services tool) can be found at: https://spars.samhsa.gov/https://spars.samhsa.gov/ Data will be collected quarterly.,

The collection of these data enables SAMHSA to report on key outcome measures relating to the program. In addition to these outcomes, performance measures collected by recipients will be used to demonstrate how SAMHSA's programs are reducing disparities in behavioral health access, retention, service use, and outcomes nationwide.

Performance data will be reported to the public as part of SAMHSA's Congressional Budget Justification.

Recipients will also be required to conduct a local evaluation, including developing an evaluation plan and submitting annual evaluation reports, and to develop a Naloxone Education and Distribution plan. Naloxone Education and Distribution Work Plans and evaluation plans and reports will also be submitted via the SPARS system.

An additional evaluation may be required to build the evidence base for this program. If an evaluation is required, recipients are required to participate fully in all aspects of the evaluation. This may include collection of additional client-level data and participation of sub-recipients. Details on the evaluation, including type of evaluation and research questions, will be provided upon award if such an evaluation will be required.

Project Performance Assessment

In addition, recipients are required to report on their progress addressing the goals and objectives identified in your Project Narrative. Recipients must periodically review the performance data they report to SAMHSA (as required above), assess their progress, and use this information to improve the management of their project. The project performance assessment should be designed to help you determine whether you are achieving the goals, objectives, and outcomes you intend to achieve and whether adjustments need to be made to your project.

Performance assessments should be used to determine whether your project is having/will have the intended impact on behavioral health disparities. Recipients should

also review the behavioral health Disparities Impact Statement (DIS) submitted within the first two months of the award. See Section VI.3 for information on required progress reports.

Note: See Appendix E and Appendix F of this NOFO for more information on responding to this section.

7. OTHER EXPECTATIONS

SAMHSA Values That Promote Positive Behavioral Health

SAMHSA expects recipients to use funds to implement high quality programs, practices, and policies that are recovery-oriented, trauma-informed, and equity-based as a means of improving behavioral health.[2]

Recovery is a process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential. Recovery oriented recipients promote partnerships with people in recovery from mental and substance use disorders and their family members to guide the behavioral health system and promote individual, program, and system-level approaches that foster: *Health*—managing one's illnesses or symptoms and making informed healthy choices that support physical and emotional wellbeing; *Home*—a stable and safe place to live; *Purpose*—meaningful daily activities such as a job or school; and *Community*—supportive relationships with families, friends and peers. Recovery oriented systems of care embrace recovery as: emerging from hope; person-driven; occurring via many pathways; holistic; supported by peers and allies; culturally based and informed; supported through relationship and social networks; involving individual, family, and community strengths and responsibility; supported by addressing trauma; and based on respect.

Trauma-informed Approaches recognize and intentionally respond to the lasting adverse effects of experiencing traumatic events. SAMHSA defines a trauma-informed approach through six key principles:

- *Safety*: participants and staff feel physically and psychologically safe;
- *Peer support:* peer support and mutual self-help are key as vehicles for establishing safety and hope, building trust, enhancing collaboration, and utilizing their lived experience to promote recovery and healing;

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[2] "Behavioral health" means the promotion of mental health, resilience and wellbeing; the treatment of mental and substance use disorders; and the support of those who experience and/or are in recovery from these conditions, along with their families and communities.

- *Trustworthiness and Transparency*: Organizational decisions are conducted with the goal of building and maintaining trust with participants and staff;
- *Collaboration and Mutuality:* importance is placed on partnering and leveling power differences between staff and service participants;
- *Cultural, Historical, & Gender Issues*: culture and gender-responsive services are offered while moving beyond stereotypes/biases;
- *Empowerment, Voice and Choice*: organizations foster a belief in the primacy of the people who are served to heal and promote recovery from trauma.[3]

It is critical recipients promote the linkage to recovery and resilience for those individuals and families impacted by trauma.

Behavioral health equity is the right to access high quality and affordable health care services and supports for all populations regardless of the individual's race, age, ethnicity, gender (including gender identity), disability, socioeconomic status, sexual orientation, or geographical location. By improving access to behavioral health care, promoting quality behavioral health programs and practice, and reducing persistent disparities in mental health and substance use services for underserved populations and communities, recipients can ensure that everyone has a fair and just opportunity to be as healthy as possible. In conjunction with promoting access to high quality services, behavioral health disparities can be further reduced by addressing social determinants of health, such as social exclusion, unemployment, adverse childhood experiences, and food and housing insecurity.

Language Access Provision. Per Title VI of the Civil Rights Act of 1964, recipients of Federal financial assistance must take reasonable steps to make their programs, services, and activities accessible by eligible persons with limited English Proficiency. Recipients must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). (See Appendix K)

Behavioral Health Disparities

If your application is funded, you will be expected to develop a behavioral health Disparity Impact Statement (DIS) no later than 60 days after your award. (See Appendix H –Addressing Behavioral Health Disparities). Progress and evaluation of DIS activities will be reported in annual progress reports (see Section VI.3 Reporting Requirements).

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[3] https://ncsacw.samhsa.gov/userfiles/files/SAMHSA_Trauma.pdf

The DIS is a data-driven, quality improvement approach to advance equity for all, and to identify racial, ethnic, sexual and gender minority, and rural populations at highest risk for experiencing behavioral health disparities as part of their projects. The purpose of the DIS is for recipients to identify and address health disparities[4] and to develop and implement an action plan with a disparity reduction, quality improvement process to close the identified gap(s). The aim is to achieve targeted behavioral health equity[5] for disparate populations and improve systems.

The behavioral health disparity impact statement is in alignment with the expectations related to Executive Order 13985 "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government."

Tribal Behavioral Health Agenda

SAMHSA, working with tribes, the Indian Health Service, and National Indian Health Board developed the first collaborative National Tribal Behavioral Health Agenda (TBHA). Tribal applicants are encouraged to briefly cite the applicable TBHA foundational element(s), priority(ies), and strategies that are addressed by their application. The TBHA can be accessed at http://nihb.org/docs/12052016/FINAL%20TBHA%2012-4-16.pdf.

Tobacco and Nicotine Free Policy

SAMHSA strongly encourages all recipients to adopt a tobacco/nicotine inhalation (vaping) product-free facility/grounds policy and to promote abstinence from all tobacco products (except in regard to accepted tribal traditions and practices).

Reimbursements for the Provision of Services

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[4] Healthy People 2030 defines a health disparity as a "particular type of health difference that is closely linked with social, economic, and/or environmental disadvantage. Health disparities adversely affect groups of people who have systematically experienced greater obstacles to health based on their racial or ethnic group; religion; socioeconomic status; gender; age; disability; mental health; cognitive, sensory, or physical disability; sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion."

[5] Behavioral health equity the right to access high quality and affordable health care services and supports for all populations regardless of the individual's race, age, ethnicity, gender (including gender identity), disability, socioeconomic status, sexual orientation, or geographical location. Advancing behavioral health equity involves ensuring that everyone has a fair and just opportunity to be as healthy as possible. In conjunction with quality services, this involves addressing social determinants of health, such as employment and housing stability, insurance status, proximity to services, and culturally responsive care – all of which have an impact on behavioral health outcomes.

Recipients must utilize third party reimbursements and other revenue realized from the provision of services to the extent possible and use SAMHSA funds only for services to individuals who are not covered by public or commercial health insurance programs, individuals for whom coverage have been formally determined to be unaffordable, or for services that are not sufficiently covered by an individual's health insurance plan. Recipients are responsible for making the determination of affordability and insurance coverage and must have policies and procedures in place to address these areas. Recipients are also expected to facilitate the health insurance application and enrollment process for eligible uninsured clients. Recipients should also consider other systems from which a potential service recipient may be eligible for services (for example, the Veterans Health Administration or senior services), if appropriate for and desired by that individual to meet his/her needs. In addition, recipients are required to implement policies and procedures that ensure other sources of funding are utilized first when available for that individual.

Behavioral Health for Military Service Members and Veterans

SAMHSA encourages all recipients to address the behavioral health needs of active-duty military service members, returning veterans, and military families in designing and developing their programs and to consider prioritizing this population for services, where appropriate.

Behavioral Health for Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, and Intersex (LGBTQI+) Individuals

In line with the Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals (E.O. 14075) and the behavioral health disparities that the LGBTQI+ population face, SAMHSA encourages all recipients to address the behavioral health needs of the LGBTQI+ population in designing and developing their programs and to consider prioritizing this population for services, where appropriate.

8. RECIPIENT MEETINGS

Recipient meetings will be held virtually, and recipients are expected to fully participate in these meetings. If SAMHSA elects to hold an in-person meeting, budget revisions may be permitted.

II. FEDERAL AWARD INFORMATION

1. GENERAL INFORMATION

Funding Mechanism: Grant Award

Estimated Total Available Funding:	Up to $17,200,000
Estimated Number of Awards:	34 Awards
Estimated Award Amount:	Tribes/Tribal Organizations up to $250,000 per year Local Government entities up to $500,000 per year States up to $800,000 per year
Length of Project Period:	Up to 4 years
Anticipated Start Date	September 30, 2023

Proposed budgets cannot exceed $250,000 - $800,000 in total costs in total costs (direct and indirect) in any year of the proposed project. Annual continuation awards will depend on the availability of funds, recipient progress in meeting project goals and objectives, timely submission of required data and reports, and compliance with all terms and conditions of award.

III. ELIGIBILITY INFORMATION

1. ELIGIBLE APPLICANTS

Eligibility for this program is statutorily limited (Section 546 of the Public Health Service Act [42 USC 290ee-1], as amended) to the following entities:

- State governments: The District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau are also eligible to apply;

- Federally recognized American Indian/Alaska Native (AI/AN) tribes, tribal organizations, Urban Indian Organizations, and consortia of tribes or tribal organizations; and

- Local governmental entities including, but not limited to, municipal corporations, counties, cities, boroughs, incorporated towns, and townships.

Tribal organization means the recognized body of any AI/AN tribe; any legally established organization of AI/ANs which is controlled, sanctioned, or chartered by such governing body, or which is democratically elected by the adult members of the Indian community to be served by such organization and which includes the maximum participation of AI/ANs in all phases of its activities. Consortia of tribes or tribal organizations are eligible to apply, but each participating entity must indicate its approval. A single tribe in the consortium must be the legal applicant, the recipient of the award, and the entity legally responsible for satisfying the award requirements.

Urban Indian Organization (UIO) (as identified by the Indian Health Service Office of Urban Indian Health Programs through active Title V awards/contracts) means a non-profit corporate body situated in an urban center governed by an urban Indian-controlled board of directors, and providing for the maximum participation of all interested Individuals and groups, which body is capable of legally cooperating with other public and private entities for the purpose of performing the activities described in 503(a) of 25 U .S.C. § 1603. UIOs are not tribes or tribal governments and do not have the same consultation rights or trust relationship with the federal government.

FR-CARA recipients who received their initial funding in 2020 under TI-19-004, in 2021 under TI-21-009, or in 2022 under TI-22-008 are not eligible to apply. Grants to Prevent Prescription Drug/Opioid Overdose-Related Deaths (PDO) recipients who received funding in 2021 under the PDO NOFO (SP-21-002) are not eligible to apply.

An organization may submit more than one application; however, each application must focus on a different population of focus or a different geographic/catchment area(s).

It is recommended that you review information on eligibility in Appendix C of this NOFO.

2. COST SHARING AND MATCHING REQUIREMENTS

Cost sharing/match is not required in this program.

3. OTHER REQUIREMENTS

- The Project Narrative must not exceed 10 pages. If the Project Narrative is over 10 pages, the application will not be considered for review.

IV. APPLICATION AND SUBMISSION INFORMATION

1. ADDRESS TO REQUEST APPLICATION PACKAGE

The application forms package specific to this funding opportunity can be accessed through Grants.gov Workspace or eRA ASSIST. Due to difficulties with internet access, SAMHSA understands that applicants may have a need to request paper copies of materials, including forms and required documents. See Appendix A for more information obtaining an application package.

2. CONTENT AND FORM OF APPLICATION SUBMISSION

REQUIRED APPLICATION COMPONENTS:

The standard and supporting documents that must be submitted with the application are outlined below and in Appendix A - 2.2 Required Application Components of this NOFO.

All files uploaded as part of the application must be in Adobe PDF file format. See Appendix B of this NOFO for formatting and validation requirements.

SAMHSA will not accept paper applications except under very special circumstances. If you need special consideration, SAMHSA must approve the waiver of this requirement in advance. See Appendix A - 3.2 Waiver of Electronic Submission of this NOFO.

- **SF-424** – Fill out all Sections of the SF-424.
  - In **Line #4** (i.e., Applicant Identifier), input the Commons Username of the PD/PI.
  - In **Line #17** input the following information: (Proposed Project Date: a. Start Date: 9/30/2023; b. End Date: 9/29/2027).

    New applicants should review the sample of a completed SF-424.

- **SF-424A BUDGET INFORMATION FORM –** Fill out all Sections of the SF-424A using instructions below. **The totals in Sections A, B, and D must match.**

  - **Section A –** Budget Summary: If cost sharing/match is **not required**, use the first row only (Line 1) to report the total federal funds (e) and non-federal funds (f) requested for the **first year** of your project only. If cost sharing/match **is required**, use the **second row** (Line 2) to report the total non-federal funds (f) for the **first year** of your project only.

  - **Section B** – Budget Categories: If cost sharing/match is **not required**, use the first column only (Column 1) to report the budget category breakouts (Lines 6a through 6h) and indirect charges (Line 6j) for the total funding requested for the **first year** of your project only. If cost sharing/match is required, you must use the second column (Column 2) to report the budget category breakouts for the **first year** of your project only.

  - **Section C –**If cost sharing/match is **not required** leave this section blank. If cost sharing/match **is required** use the second row (line 9) to report non-federal match for the **first year** only.

  - **Section D** – Forecasted Cash Needs: Input the total funds requested, broken down by quarter, only for **Year 1** of the project period. Use the first row for federal funds and the second row (Line 14) for **non-federal** funds.

  - **Section E** – Budget Estimates of Federal Funds Needed for the Balance of the Project: Enter the total funds requested for the out years (e.g., Year 2, Year 3, and Year 4). For example, if you are requesting funds for four years in total, enter the requested budget amount for each budget period in columns b, c, and d (i.e., 3 out years) - (b) First column is the budget for the second

budget period; (c) Second column is the budget for the third budget period; (d) Third column is the budget for the fourth budget period. Use Line 16 for federal funds and Line 17 for non-federal funds.

See Appendix B of this NOFO to review common errors in completing the SF-424 and the SF-424A. These errors will prevent your application from being successfully submitted.

The following pdfs are samples of completed SF-424A forms:

- Sample SF-424A (No Match Required)

A link to a sample budget form and justification is provided in Appendix L of this NOFO. **It is highly recommended that you use this sample budget format. This will expedite review of your application.**

- **PROJECT NARRATIVE – (Maximum 10 pages total)**
  The Project Narrative describes your project. It consists of Sections A through E. **[Note: change these letters, as appropriate, based on the sections that are required in the Project Narrative. No more than five sections can be included in the Project Narrative.]** (Remember that if your Project Narrative starts on page 5 and ends on page 15, it is 11 pages long, not 10 pages.) More detailed instructions for completing each section of the Project Narrative are provided in Section V.1 – Application Review Information.

- **BUDGET JUSTIFICATION AND NARRATIVE**
  The budget justification and narrative must be submitted as a file entitled "BNF" (Budget Narrative Form) when you submit your application into Grants.gov. (See Appendix A – 2.2 Required Application Components.)

- **ATTACHMENTS 1 THROUGH 10**

  Use only the attachments listed below. If your application includes any attachments not required in this document, they will be disregarded.

  Do not use attachments to extend or replace any of the sections of the Project Narrative. Reviewers will not consider them if you do.

  Label the attachments as: Attachment 1, Attachment 2, etc. (Use the Other Attachments Form if applying with Grants.gov Workspace or Other Narrative Attachments if applying with eRA ASSIST.)

  - ***Attachment 1: Letters of Commitment***

Letters of Commitment from any direct service provider organization (including First Responders) who will be providing and/or administering field-initiated buprenorphine or other medication intended to reduce the risk of withdrawal symptoms and overdose death and/or any other organizations participating in the project. **(Do not include any letters of support. Reviewers will not consider them if you do.)**

- ***Attachment 2: Data Collection Instruments/Interview Protocols***
  If you are using standardized data collection instruments/interview protocols, you do not need to include these in your application. Instead, provide a web link to the appropriate instrument/protocol. If the data collection instrument(s) or interview protocol(s) is/are not standardized, you must include a copy in Attachment 2.

- ***Attachment 3: Sample Consent Forms***
  Forms to be submitted include, as appropriate, sample consent forms that provide for: (1) informed consent for participation in service intervention; (2) informed consent for participation in the data collection component of the project; and (3) informed consent for the exchange (releasing or requesting) of confidential information.

- ***Attachment 4: Project Timeline***
  This attachment is scored by reviewers. Maximum of 2 pages. See instructions in Section V, B.3 of this NOFO.

- ***Attachment 5: Biographical Sketches and Position Descriptions***
  See Appendix G of this NOFO for information on completing biographical sketches and job descriptions. Position descriptions should be no longer than one page each and biographical sketches should be two pages or less.

- ***Attachment 6: Letter to the Single State Agency (SSA)***
  See Appendix J of this NOFO for Intergovernmental Review (E.O. 12372) Requirements, if applicable.

- ***Attachment 7: Confidentiality and SAMHSA Participant Protection/ Human Subjects Guidelines***
  This attachment is in response to Appendix D of this NOFO and is **a required attachment.**

- ***Attachment 8: Documentation of Non-profit Status***
  All non-profit entities must submit documentation of their non-profit status. Any of the following is acceptable documentation:

- A reference to the applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in section 501(c)(3) of the IRS Code;
- A copy of a currently valid Internal Revenue Service tax exemption certificate;
- A statement from a State taxing body, State Attorney General, or other appropriate state official certifying the applicant organization has a non-profit status;
- A certified copy of the organization's certificate of incorporation or similar document that clearly establishes non-profit status; or
- Any of the above proof for a state or national parent organization and a statement signed by the parent organization that the applicant organization is a local non-profit affiliate.

- ***Attachment 9: Statements of Certification***
  - You must provide a written statement certifying that the project will be implemented in a community not located in a metropolitan statistical area and specify whether this is a community of high need. If the project will not be implemented in a community not located in a metropolitan statistical area, you do not need to submit this attachment.
  - If you plan to facilitate field initiation of low-threshold buprenorphine or other appropriate medications to reduce the risk of withdrawal symptoms and overdose death, you must submit a written statement certifying that you are aware of all applicable local, state, and federal laws and regulations governing the distribution and/or provision of these medications and that your proposed program falls within all applicable legal guidelines and restrictions.

- ***Attachment 10: Form SMA 170 – Assurance of Compliance with SAMHSA Charitable Choice Statutes and Regulations.***
  You are required to complete Form SMA 170 if your project is offering substance use prevention or treatment services. This form is posted on SAMHSA's website at http://www.samhsa.gov/grants/applying/forms-resources.

3. UNIQUE ENTITY IDENTIFIER AND SYSTEM FOR AWARD MANAGEMENT

See Appendix A for information about the three registration processes that must be completed including obtaining a Unique Entity Identifier and registering with the System for Award Management (SAM). You must continue to maintain an active SAM registration with current information during the period of time your organization has an active federal award or an application under consideration by an agency (unless you are an individual or federal agency that is exempted from those

requirements under 2 CFR § 25.110(b) or (c), has an exception approved by the agency under 2 CFR § 25.110(d)).

4. APPLICATION SUBMISSION REQUIREMENTS

Applications are due by **11:59 PM** (Eastern Time) on **March 14, 2023.** If an organization is submitting more than one application, the project title should be different for each application.

If you have been granted permission to submit a paper copy, the application must be received by the above date and time. See Appendix A of this NOFO for information on how to submit the application.

All applicants MUST register with NIH's eRA Commons in order to submit an application. This process takes up to six weeks. If you believe you are interested in applying for this opportunity, you MUST start the registration process immediately. Do not wait to start this process.

WARNING: BY THE DEADLINE FOR THIS NOFO YOU MUST HAVE SUCCESSFULLY COMPLETED THE FOLLOWING TO SUBMIT AN APPLICATION:

- **The applicant organization MUST be registered in NIH's eRA Commons; AND**
- **The Project Director MUST have an active eRA Commons account (with the PI role) affiliated with the organization in eRA Commons.**

No exceptions will be made.

Applicants must also register with SAM and Grants.gov (see Appendix A for all registration requirements).

DO NOT WAIT UNTIL THE LAST MINUTE TO SUBMIT THE APPLICATION. If you wait until the last minute, there is a strong possibility that the application will not be received without errors by the deadline.

5. FUNDING LIMITATIONS/RESTRICTIONS

The funding restrictions for this project are below. Be sure to identify these expenses in your proposed budget.

- Recipients may use up to 20 percent of the total award for the budget period for data collection, performance measurement, and performance assessment.

- Recipients may use up to 10 percent of the total award for the budget period for state, tribal, or local governmental administrative costs.
- Recipients may use up to 15 percent of the total award for infrastructure development to support the direct service expansion of the project.
- SAMHSA award funds must not be used for the same activities that are funded by the Health Resources Services Administration (HRSA), CDC, or other SAMHSA programs.
- Only drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose may be purchased with FR-CARA funds.

SAMHSA recipients must also comply with SAMHSA's standard funding restrictions, which are included in Appendix I – Standard Funding Restrictions.

6. INTERGOVERNMENTAL REVIEW (E.O. 12372) REQUIREMENTS

All SAMHSA programs are covered under Executive Order (EO) 12372, as implemented through Department of Health and Human Services (HHS) regulation at 45 CFR Part 100. Under this Order, states may design their own processes for reviewing and commenting on proposed federal assistance under covered programs. See Appendix J for additional information on these requirements as well as requirements for the Public Health System Impact Statement (PHSIS).

7. OTHER SUBMISSION REQUIREMENTS

See Appendix A for specific information about submitting your application.

V. APPLICATION REVIEW INFORMATION

1. EVALUATION CRITERIA

The Project Narrative describes what you intend to do with your project and includes the Evaluation Criteria in Sections A-E below. Your application will be reviewed and scored according to your response to the requirements in Sections A-E.

In developing the Project Narrative section of your application, use these instructions, which have been tailored to this program.

- The Project Narrative (Sections A-E) together may be no longer than **10 pages.**
- You must use the five sections/headings listed below in developing your Project Narrative. **You must indicate the Section letter and number in your**

response, i.e., type "A-1", "A-2", etc., before your response to each question. You do not need to type the full criterion in each section. You only need to include the letter and number of the criterion. You may not combine two or more questions or refer to another section of the Project Narrative in your response, such as indicating that the response for B.2 is in C.1. **Only information included in the appropriate numbered question will be considered by reviewers.** Your application will be scored according to how well you address the requirements for each section of the Project Narrative.

- The number of points after each heading is the maximum number of points a review committee may assign to that section of your Project Narrative. Although scoring weights are not assigned to individual questions, each question is assessed in deriving the overall Section score.

- Any cost sharing proposed in your application will not be a factor in the evaluation of your response to the Evaluation Criteria.

SECTION A: Population of Focus and Statement of Need (10 points – approximately 1 page)

1. Identify and describe your population(s) of focus and the geographic catchment area where services will be delivered that aligns with the intended population of focus of this program. Provide a demographic profile of the population of focus in terms of race, ethnicity, federally recognized tribe (if applicable), language, sex, gender identity, sexual orientation, age, and socioeconomic status.

2. Describe the extent of the problem in the catchment area, including service gaps, disparities, and document the extent of the need (i.e., current prevalence rates or incidence data) for the population(s) of focus identified in your response to A.1 as it relates to the program. Identify the source of the data.

SECTION B: Proposed Implementation Approach (Up to 30 points – approximately 5 pages not including Attachment 4 – Project Timeline)

1. Describe the goals and measurable objectives (see Appendix E) of the proposed project and align them with the Statement of Need described in A.2. Provide the following table:

Number of Unduplicated Individuals to be Served with Award Funds				
Year 1	Year 2	Year 3	Year 4	Total

2. Describe how you will implement all of the Required Activities in Section I. **An additional 5 points will be awarded to applicants who provide specific information about how they plan to demonstrate outreach to minorities and/or serve communities and demographic groups with high prevalence rates of opioid use or misuse and overdose and/or a lack of adequate treatment and recovery support services.** This plan must align with data presented in A.2. If you plan to use funds for infrastructure development, describe how those funds will be used.

3. Applicants proposing to implement field initiation of low-threshold buprenorphine or other appropriate medication intended to reduce the risk of withdrawal symptoms and overdose death and initiate the individual into treatment and recovery must include a description how they plan to implement this allowable activity. Specify if you do not plan to implement this activity.

4. In **Attachment 4**, provide a chart or graph depicting a realistic timeline for the entire four years of the project period showing dates, key activities, and responsible staff. These key activities must include the requirements outlined in Section I **[NOTE:** Be sure to show that the project can be implemented, and service delivery can begin as soon as possible and no later than **four months** after award. **The timeline cannot be more than two pages and should be submitted in Attachment 4.]** The recommendation of pages for this section does not include the timeline.

SECTION C: Proposed Evidence-Based Service/Practice (25 points approximately 2 pages)

1. Identify the Evidence-Based Practice(s) (EBPs), evidence-informed, and/or culturally promising practices that will be used. Discuss how each intervention chosen is appropriate for your population(s) of focus and the outcomes you want to achieve. Describe any modifications (e.g., cultural) that will be made to the EBP(s) and the reason the modifications are necessary. If you are not proposing any modifications, indicate so in your response.

2. Describe how you will monitor and ensure fidelity of EBPs, evidence-informed and/or promising practices that will be implemented.

SECTION D: Staff and Organizational Experience (15 points – approximately 1 page)

1. Describe the experience of your organization with similar projects and/or providing services to the population(s) of focus for this NOFO. Identify other organization(s) that you will partner with in the proposed project. Describe their experience providing services to the population(s) of focus, and their specific roles and responsibilities for this project. If applicable, Letters of Commitment

from each partner must be included **Attachment 1** of your application. If you are not partnering with any other organization(s), indicate so in your response.

2. Provide a complete list of staff positions for the project, including the Key Personnel (Project Director and Evaluator) and other significant personnel. For each staff member describe their:
    - Role,
    - Level of Effort, and
    - Qualifications, to include their experience providing services to the population(s) of focus and familiarity with their culture(s) and language(s).

SECTION E: Data Collection and Performance Measurement (20 points – approximately 1 page)

1. Provide specific information about how you will collect the required data for this program and how such data will be utilized to manage, monitor, and enhance the program (See Appendix F). Describe your quality improvement efforts and explain how you will use the data to address your identified behavioral health disparity(ies) and close the gap(s).

2. BUDGET JUSTIFICATION, EXISTING RESOURCES, OTHER SUPPORT (Other federal and non-federal sources)

You must provide a narrative justification of the items included in your proposed budget. You must also provide a narrative description of existing resources and other support you expect to receive for the proposed project as a result of cost matching. Other support is defined as funds or resources, non-federal, or institutional, in direct support of activities through fellowships, gifts, prizes, in-kind contributions, or non-federal means. (This should correspond to Item #18 on your SF-424, Estimated Funding.) Other sources of funds may be used for unallowable costs, e.g., meals, sporting events, entertainment.

Although non-federal share may not be required, if an applicant proposes non-federal resources in their budget, they will be held to submission of the non-federal resources. These must be reported on the financial reports. If recipients fail to meet their proposed amount or percentage, that could be grounds for a cost disallowance.
An illustration of a budget and narrative justification is included in Appendix L – Sample Budget and Justification. **It is highly recommended that you use this sample budget format.** Your proposed budget must reflect the funding limitations/restrictions specified in Section IV-5. **Specifically identify the items associated with these costs in your budget.**

3. REVIEW AND SELECTION PROCESS

The Project Narratives of SAMHSA applications are peer-reviewed according to the evaluation criteria listed above.

Decisions to fund an award are based on:

The strengths and weaknesses of the application as identified by peer reviewers. The results of the peer review are advisory in nature.

The program office and approving official make the final determination for funding based on the following:

- When the individual award is over $250,000, approval by the Center for Substance Abuse Treatment National Advisory Council.
- Availability of funds;
- Equitable distribution of awards in terms of geography (including urban, rural, and remote settings) and balance among populations of focus and program size;
- FR-CARA recipients who received their initial funding in FY 2020 under the TI-19-004) in FY 2021 under TI-21-009, or in FY 2022 under TI-22-008 are not eligible to apply. In addition, Grants to Prevent Prescription Drug/Opioid Overdose-Related Deaths (PDO) recipients who received funding in 2021 under the SP-21-002 are not eligible to apply.
- SAMHSA may select awards for funding that best reach underserved communities and/or populations;
- Submission of any required documentation that must be submitted prior to making an award;
- SAMHSA is required to review and consider any information about your organization that is in the Federal Award Performance and Integrity Information System (FAPIIS). In accordance with 45 CFR 75.212, SAMHSA reserves the right not to make an award to an entity if that entity does not meet the minimum qualification standards as described in section 75.205(a)(2). If SAMHSA chooses not to award a fundable application in accordance with 45 CFR 75.205(a)(2), SAMHSA must report that determination to the designated integrity and performance system accessible through the System for Award Management (SAM) [currently, FAPIIS]. You may review and comment on any information about your organization that a federal awarding agency previously entered. SAMHSA will consider your

comments, in addition to other information in FAPIIS in making a judgment about your organization's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed as described in 45 CFR 75.205 HHS Awarding Agency Review of Risk Posed by Applicants.

VI. FEDERAL AWARD ADMINISTRATION INFORMATION

1. FEDERAL AWARD NOTICES

You will receive an email from SAMHSA, via NIH's eRA Commons, that will describe the process for how you can view the general results of the review of your application, including the score that your application received.

If your application is approved for funding, a Notice of Award (NoA) will be emailed to the following: 1) the BO's email address identified in the Authorized Representative section email field on page 3 of the SF-424; and 2) the email associated with the Commons account for the Project Director (section 8 Item f on page 1 of the SF-424). Hard copies of the NoA will no longer be mailed via postal service. The NoA is the sole obligating document that allows you to receive federal funding for work on the project. Information about what is included in the NoA can be found at: https://www.samhsa.gov/grants/grants-management/notice-award-noa.

If your application is not funded, you will receive a notification from SAMHSA, via NIH's eRA Commons.

2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS

If your application is funded, you must comply with all terms and conditions of the NoA. SAMHSA's standard terms and conditions are available on the SAMHSA website - . https://www.samhsa.gov/grants/grants-management/notice-award-noa/standard-terms-conditions. See Appendix K for specific information about administrative and national policy requirements.

3. REPORTING REQUIREMENTS

You will be required to submit a progress report on project performance at the midpoint of Year 1 (within 30 days of the end of the second quarter) and annually within 90 days of the end of each budget period (two reports will be required in Year 1 and one report will be required at the completion of each year thereafter). The report must discuss:

- Progress achieved in the project which should include qualitative and quantitative data (GPRA) to demonstrate programmatic progress to include updates on required activities, successes, challenges, and changes or adjustments that have been made to the project;

- Progress addressing quality care of underserved populations related to the Disparity Impact Statement (DIS);
- Barriers encountered, including challenges serving populations of focus;
- Efforts to overcome these barriers;
- Evaluation activities for tracking DIS efforts; and
- A revised quality improvement plan if the DIS does not meet quality of care requirements as stated in the DIS.

A final performance report must be submitted within 120 days after the end of the project period. The final performance report must be cumulative and report on all activities during the entire project period.

Management of Award:

Successful applicants must also comply with the following standard award management reporting requirements at https://www.samhsa.gov/grants/grants-management/reporting-requirements, unless otherwise noted in the NOFO or NoA.

VII. AGENCY CONTACTS

For program related and eligibility questions contact:

Anthony Bethea
Center for Substance Abuse Prevention
Substance Abuse and Mental Health Services Administration
DTPFRCARA@samhsa.hhs.gov

For fiscal/budget related questions contact:

Office of Financial Resources, Division of Grants Management
Substance Abuse and Mental Health Services Administration
(240) 276-1400
FOACSAP@samhsa.hhs.gov

For review process and application status questions contact:

Stephanie Boyd
Office of Financial Resources, Division of Grant Review
Substance Abuse and Mental Health Services Administration
(240) 276-1451
stephanie.boyd@samhsa.hhs.gov

Appendix A – Application and Submission Requirements

1. GET REGISTERED

You are required to complete three **(3) registration processes:**

1.1) System for Award Management (SAM);
1.2) Grants.gov; and
1.3) eRA Commons.

If you have already completed registrations for SAM and Grants.gov, you need to ensure that your accounts are still active, and then register in **eRA Commons (see 1.3).**

You must register in eRA Commons and receive a Commons Username in order to have access to electronic submission, receive notifications on the status of your application, and retrieve award information.

WARNING: If your organization is not registered and does not have an active eRA Commons PI/PD account by the deadline, the application will not be accepted. No exceptions will be made.

1.1 System for Award Management Registration

You must register your organization with the System for Award Management (SAM). A Unique Entity Identifier (UEI) will be assigned as part of the registration process. (The UEI replaced the Dun and Bradstreet Number (DUNS Number). If your organization is currently registered in SAM.gov, the UEI has already been assigned and is viewable in SAM.gov. This includes inactive registrations. The Unique Entity Identifier is currently located below the DUNS Number on your entity registration record. You must be signed in to your SAM.gov account to view entity records.

You must continue to maintain active SAM registration with current information during the period of time your organization has an active federal award or an application under consideration by an agency (unless you are an individual or federal agency that is exempted from those requirements under 2 CFR § 25.110(b) or (c), has an exception approved by the agency under 2 CFR § 25.110(d)). To create a SAM user account, Register/Update your account, and/or Search Records, go to https://www.sam.gov. It takes 7-10 business days for a new SAM entity registration to become active.

It is important to initiate this process well before the application deadline. You will receive an email alerting you when your registration is active.

It is also highly recommended that you renew your account prior to the expiration date. **SAM information must be active and up-to-date and should be updated at least every 12 months to remain active (for both recipients and sub-recipients).** Once you update your record in SAM, **it will take 48 to 72 hours to complete the validation** processes. **Grants.gov rejects electronic submissions from applicants with expired registrations.**

If your SAM account expires, the renewal process requires the same validation with IRS and DoD (Cage Code) as required for a new account.

1.2 Grants.gov Registration

Grants.gov is an online portal for submitting federal award applications. It requires a one-time registration to submit applications. eRA Commons registration is separate but can be done concurrently. You can register to obtain a Grants.gov username and password at http://www.grants.gov/web/grants/register.html.

If you have already completed Grants.gov registration and ensured your **Grants.gov and SAM accounts are up-to-date and/or renewed**, go to the eRA Commons registration steps noted below. If this is your first time submitting an application through Grants.gov, registration information can be found at the Grants.gov "Applicants" tab.

The person submitting your application must be properly registered with Grants.gov as the Authorized Organization Representative (AOR) for the specific UEI number cited on the SF-424 (first page). See the Organization Registration User Guide for details at the following Grants.gov link: http://www.grants.gov/web/grants/applicants/organization-registration.html.

1.3 eRA Commons Registration

eRA Commons is an online data platform managed by NIH that allows applicants, award recipients, and federal staff to securely share, manage, and process award-related information. It is strongly recommended that you start the eRA Commons registration process **at least six (6) weeks** prior to the application due date. Organizations applying for SAMHSA funding must register in eRA Commons. This is a one-time registration separate from Grants.gov registration. Note: Grants.gov and eRA Commons Registration may occur concurrently. In addition to the organization registration, the Business Official (BO) named in the Authorized Representative section field on page 3 of the SF-424 and the Project Director details entered in the Applicant Information item f on page 1 of the SF-424 (Name and contact information of the person to be contacted on matters involving this application) must have accounts in eRA Commons and receive a Commons ID in order to have access to electronic submission and retrieval of application/award information. **If your organization is not registered and does not have an active eRA Commons PI account by the deadline, the application will not be accepted.**

For organizations registering with eRA Commons for the first time, the BO named in the Authorized Representative section of the SF-424 must complete the online Institution Registration Form. Instructions on how to complete the online Institution Registration Form is provided on the eRA Commons Online Registration Page.

[Note: You must have a valid and verifiable UEI number to complete the eRA Commons registration.]

After the BO named as the Authorized Representative completes the online Institution Registration Form and clicks Submit, the eRA Commons will send an e-mail notification from era-notify@mail.nih.gov with the link to confirm the email address. Once the e-mail address is verified, the registration request will be reviewed and confirmed via email. If your request is denied, the representative will receive an email detailing the reason for the denial. If the request is approved, the BO will receive an email with an eRA Commons User ID for the Signing Official account (SO) role. The representative will receive a separate email pertaining to this SO account containing a temporary password to be used for the first-time log in. The representative will need to log into eRA Commons with the temporary password, at which time the system will provide prompts to change the temporary password to one of their choosing. Once the BO/SO signs the registration request, the organization will be active in eRA Commons. The BO/SO can then create additional accounts for the organization as needed. Organizations can have multiple user accounts with the SO role, and any user with the SO role will be able to create and maintain additional accounts for the organization's staff, including accounts for those designated as Project Director/Principal Investigator (PD/PI) and other Signing Officials.

Important: The eRA Commons requires organizations to identify at least one BO/SO, who is the BO entered in the Authorized Representative section on the SF-424, and a PD/PI in order to submit an application. The primary BO/SO must create the account for the PD/PI listed as the person to contact regarding the application on page 1 of the SF-424 assigning that person the 'PI' role in eRA Commons. Note that you must also enter the PD/PI's Commons Username into the 'Applicant Identifier' field of the SF-424 document (Line 4). **The individual designated as the BO cannot also be a PD.**

You can find additional information about the eRA Commons registration process at https://era.nih.gov/reg_accounts/register_commons.cfm.

2. WRITE AND COMPLETE APPLICATION

SAMHSA strongly encourages you to sign up for Grants.gov email notifications regarding this NOFO. If the NOFO is cancelled or modified, individuals who sign up with Grants.gov for updates will be automatically notified.

2.1 Obtaining Paper Copies of Application Materials

If your organization has difficulty accessing high-speed internet and cannot download the required documents, you may request a paper copy of the application materials.

Contact the Division of Grant Review at dgr.applications@samhsa.hhs.gov for additional information on obtaining paper copies.

2.2 Required Application Components

After downloading and retrieving the required application components and completing the registration processes, it is time to write and complete your application. All files uploaded with the Grants.gov application **MUST** be in **Adobe PDF** file format. Directions for creating PDF files can be found on the Grants.gov website. See Appendix B **for all** application formatting and validation requirements.

Standard Application Components

Applications must include the following required application components listed in the table below. This table consists of a full list of standard application components, a description of each required component, and where you can find each document.

#	Standard Application Components	Description	Where to Find Document
1	SF-424 (Application for Federal Assistance) Form	This form must be completed by applicants for all SAMHSA awards. The names and contact information for Project Director (PD) and Business Official (BO) are required for SAMHSA applications and are to be entered on the SF-424 form. • The PD must have an eRA Commons account: the PD's Commons Username must be entered in field **4. Applicant Identifier**; and the PD's name, phone number and email address must be entered in Section **8. APPLICANT INFORMATION**: **item f. Name and contact information of person to be contacted on matters involving this application.** The PD listed in the SF-424 must match the PD in the Personnel Costs section in the budget. • The BO name, title, email address and phone number must be entered in the **Authorized Representative** section fields on page three of the SF 424. The organization mailing address is required in section 8. **APPLICANT INFORMATION** item **d. Address.** All SAMHSA Notices of Award (NoAs) will be emailed by SAMHSA via NIH's eRA Commons to the Project Director/Principal Investigator (PD/PI), and the Signing Official/Business Official (SO/BO).	Grants.gov/forms
2	SF-424 A (Budget Information – Non-Construction Programs) Form	Use SF-424A. Fill out Sections A, B, D and E of the SF-424A. Section C should only be completed if applicable. **It is highly recommended that you use the budget template. (See Section IV.2)**	Grants.gov/forms
3	Project/Performance Site Location(s) Form	The purpose of this form is to collect physical location information on the site(s) where work funded under this announcement will be performed. The address cannot be a P.O. Box.	Grants.gov/forms

#	Standard Application Components	Description	Where to Find Document
4	Project Abstract Summary	It is recommended the abstract is no more than one page. It should include the project name, population(s) to be served (demographics and clinical characteristics), strategies/interventions, project goals and measurable objectives, including the number of people to be served annually and throughout the lifetime of the project, etc. In the first five lines or less of your abstract, write a summary of your project that can be used, if your project is funded, in publications, reports to Congress, or press releases.	
5	Project Narrative Attachment	The Project Narrative is your response to the Evaluation Criteria found at Section V.1 of this NOFO. It cannot be longer than 10 pages. You must attach the Project Narrative file (Adobe PDF format only) inside the Project Narrative Attachment Form.	
6	Budget Justification and Narrative Attachment	You must include a detailed Budget Narrative in addition to Budget Form SF-424A. In preparing the budget, adhere to any existing federal award or agency guidelines which prescribe how and whether budgeted amounts should be separately shown for different functions or activities within the program. The budget justification and narrative must be submitted as file name **"BNF"** when you submit your application into Grants.gov.	SAMHSA Website
7	SF-424 B (Assurances for Non-Construction) Form	You must read the list of assurances provided on the SAMHSA website and check the box marked 'I Agree' before signing the first page (SF-424) of the application.	SAMHSA Website
8	Disclosure of Lobbying Activities (SF-LLL) Form	Federal law prohibits the use of appropriated funds for publicity or propaganda purposes or for the preparation, distribution, or use of the information designed to support or defeat legislation pending before Congress or state legislatures. **For SAMHSA to determine whether or not your organization participates in lobbying activities, a signed copy of the SF-LLL form must be submitted.**" If your organization does not participate in lobbying activities, indicate "Not Applicable" on the form.	Grants.gov/forms
9	Other Attachments Form	Refer to the Supporting Documents below. Use the Other Attachments Form to attach all required additional/supporting documents listed in the table below.	

Supporting Documents

In addition to the Standard Application Components listed above, the following supporting documents are necessary for the review of your application. Supporting documents must be attached to your application. **For each of the following application components, attach each document (Adobe PDF format only) using the Other Attachments Form in ASSIST, Workspace, or other S2S provider.**

#	Supporting Documents	Description	Where to Find Document
1	HHS 690 Form	Every applicant must have a completed HHS 690 form (PDF | 291 KB) on file with the Department of Health and Human Services.	SAMHSA Website
2	Charitable Choice Form SMA 170 (Attachment 10)	See Section IV-1 of the NOFO to determine if you are required to submit Charitable Choice Form SMA 170.	SAMHSA Website
3	Biographical Sketches and Job Descriptions (Attachment 5)	See Appendix G of this document for additional instructions for completing these sections. Formatting requirements outlined in Appendix B are not applicable for these documents.	Appendix G of this document.
4	Confidentiality and SAMHSA Participant Protection/Human Subjects (Attachment 7)	See the NOFO for requirements related to confidentiality, participant protection, and the protection of human subject's regulations.	Appendix D of this document.
5	Additional Documents in the NOFO	The NOFO will indicate the attachments you need to include in your application.	NOFO: Section IV.

2.3 Additional Documents for Submission (SAMHSA Website)

You will find additional materials you will need to complete your application on the SAMHSA website at http://www.samhsa.gov/grants/applying/forms-resources.

3. SUBMIT APPLICATION

3.1 Electronic Submission (eRA ASSIST, Grants.gov Workspace, or other S2S provider)

After completing all required registration and application requirements, SAMHSA requires applicants to **electronically submit** using eRA ASSIST, Grants.gov

Workspace, or another system to system (S2S) provider. Information on each of these options is below:

1) **ASSIST** – The Application Submission System and Interface for Submission Tracking (ASSIST) is an NIH sponsored online interface used to prepare applications using the SF-424 form set, submit electronically through Grants.gov to SAMHSA and other participating agencies, and track applications. [Note: ASSIST requires an eRA Commons ID to access the system]

2) **Grants.gov Workspace –** You can use the shared, online environment of the Grants.gov Workspace to collaboratively work on different forms within the application.

The specific actions you need to take to submit your application will vary by submission method as listed above. The steps to submit your application are as follows:

To submit to Grants.gov using ASSIST: eRA Modules, User Guides, and Documentation | Electronic Research Administration (eRA)

To submit to Grants.gov using the Grants.gov Workspace:

http://www.grants.gov/web/grants/applicants/workspace-overview.html

Regardless of the option you use, your application will be subject to the same registration requirements, completed with the same data items, routed through Grants.gov, validated against the same agency business rules, assembled in a consistent format for review consideration, and tracked in eRA Commons. All applications that are successfully submitted must be validated by Grants.gov before proceeding to the NIH eRA Commons system and validations.

3.2 Waiver from Electronic Submission

SAMHSA will not accept paper applications except under very special circumstances. If you need special consideration, SAMHSA must approve the waiver of this requirement in advance.

If you do not have the technology to apply online, or your physical location has no Internet connection, you may request a waiver of electronic submission. **You must send a written request to the Division of Grant Review at least 15 calendar days before the application due date.**

Direct any questions regarding the submission waiver process to the Division of Grant Review at dgr.applications@samhsa.hhs.gov.

3.3 Deadline

On-time submission requires that electronic applications be error-free and made available to SAMHSA for processing from the NIH eRA system on or before the application due date and time. Applications must be submitted to and validated successfully by Grants.gov and eRA Commons no later than 11:59 PM Eastern Time on the application due date. Applications submitted in Grants.gov after the application due date will not be considered for review.

You are strongly encouraged to allocate additional time prior to the submission deadline to submit your application and to correct errors identified in the validation process. You are also encouraged to check the status of your application submission to determine if the application is complete and error-free.

3.4 Resources for Assistance

If you encounter problems when submitting your application in Grants.gov, you must attempt to resolve them by contacting the Grants.gov Service Desk at the following:

- By e-mail: support@grants.gov
- By phone: (toll-free) 1-800-518-4726 (1-800-518-GRANTS). The Grants.gov Contact Center is available 24 hours a day, 7 days a week, excluding federal holidays.

Make sure you receive a case/ticket/reference number that documents the issues/problems with Grants.gov.

Additional support is also available from the NIH eRA Service desk at:

- To submit a service request ticket: http://grants.nih.gov/support/index.html
- By phone: 301-402-7469 or (toll-free) 1-866-504-9552. (Press menu option 6 for SAMHSA). The NIH eRA Service desk is available Monday – Friday, 7 a.m. to 8 p.m. Eastern Time, excluding federal holidays.

If you experience problems accessing or using ASSIST (see below), you can:

- Access the ASSIST Online Help Site at: https://era.nih.gov/erahelp/assist/
- Or contact the NIH eRA Service Desk

SAMHSA highly recommends that you submit your application 24-72 hours before the submission deadline. Many submission issues can be fixed within that time and you can attempt to re-submit.

4. AFTER SUBMISSION

4.1 System Validations and Tracking

After you complete and comply with all registration and application requirements and submit your application, the application will be validated by Grants.gov. You will receive a notification that your application is being processed. You will receive two additional e-mails from Grants.gov within the next 24-48 hours (one notification email will confirm receipt of the application in Grants.gov, and the other notification email will indicate that the application was either successfully validated by the Grants.gov system or rejected due to errors). It is important that you retain this Grants.gov tracking number. **Receipt of the Grants.gov tracking number is the only indication that Grants.gov has successfully received and validated your application.** If you do not receive a Grants.gov tracking number, you may want to contact the Grants.gov help desk for assistance (see Resources for Assistance in Section 3.4).

If Grants.gov identifies any errors and rejects your application with a "Rejected with Errors" status, you must address all errors and resubmit. If no problem is found, Grants.gov will allow the eRA system to retrieve the application and check it against its own agency business rules (eRA Commons validations). If you use ASSIST to complete your application, you can validate your application and fix errors before submission.

After you successfully submit your application through Grants.gov, your application will go through eRA Commons validations. If no errors are found, the application will be assembled in eRA Commons. At this point, you can view your application in eRA Commons. It will then be forwarded to SAMHSA as the receiving institution for further review.

If errors are found during eRA Commons validation, you will receive a System Error and/or Warning notification regarding the problems found in the application (see 4.2 below). You must take action to make the required corrections and resubmit the application through Grants.gov before the application due date and time **(See 4.4 below).** Do not assume that if your application passes the Grants.gov validations that it will successfully pass eRA validations and will be received by SAMHSA. You must check your application status in eRA Commons to ensure that no errors were identified. It is critical that you allow for sufficient time to resubmit the application if errors are detected.

You are responsible for viewing and tracking your applications in the eRA Commons after submission through Grants.gov to ensure accurate and successful submission. Once you can access your application in the eRA Commons, be sure to review it carefully as this is what reviewers will see.

4.2 eRA Commons: Warning vs. Error Notifications

You may receive a System Warning and/or Error notification after submitting an application. Take note that there is a distinction between System Errors and System Warnings.

Warnings – If you receive a Warning notification after the application is submitted, you are not required to resubmit the application. The reason for the Warning will be identified in the notification. It is at your discretion to choose to resubmit, but if the application was successfully received, it does not require any additional action.

Errors – If you receive an Error notification after the applications is submitted, you must correct and resubmit the application. The word Error is used to characterize any condition which causes the application to be deemed unacceptable for further consideration.

4.3 System or Technical Issues

If you encounter a system error that prevents you from completing the application submission process on time, the BO from your organization will receive an email notification from eRA Commons. SAMHSA highly recommends contacting the eRA Service Desk and submitting a web ticket to document your good faith attempt to submit your application and determining next steps. See Section 3.4 for more information on contacting the eRA Service Desk.

4.4 Resubmitting a Changed/Corrected Application

If SAMHSA does not receive your application by the application due date as a result of a failure in the SAM, Grants.gov, or NIH's eRA Commons systems, you must contact the Division of Grant Review within **one business day after the official due date at:** dgr.applications@samhsa.hhs.gov and provide the following:

- A case number or email from SAM, Grants.gov, and/or NIH's eRA system that allows SAMHSA to obtain documentation from the respective entity for the cause of the error.

SAMHSA will consider the documentation to determine **if** you followed Grants.gov and NIH's eRA requirements and instructions, met the deadlines for processing paperwork within the recommended time limits, met NOFO requirements for submission of electronic applications, and made no errors that caused submission through Grants.gov or NIH's eRA to fail. No exceptions for submission are allowed when user error is involved. Note that system errors are extremely rare.

[Note: When resubmitting an application after revisions have been made, ensure that the **Project Title is identical to the Project Title in the originally submitted application** (i.e., no extra spacing) as the Project Title is a free-text form field.] In addition, check the Changed/Corrected Application box in #1.

Appendix B - Formatting Requirements and System Validation

1. SAMHSA FORMATTING REQUIREMENTS

SAMHSA's goal is to review all applications submitted for funding. However, this goal must be balanced against SAMHSA's obligation to ensure equitable treatment of applications. For this reason, SAMHSA has established certain formatting requirements for its applications. See below for a list of formatting requirements required by SAMHSA:

- Text must be legible. Pages must be typed in black, single-spaced, using a font of Times New Roman 12, with all margins (left, right, top, bottom) at least one inch each. You may use Times New Roman 10 only for charts or tables.

- **You must submit your application and all attached documents in Adobe PDF format, or your application will not be forwarded to eRA Commons and will not be reviewed. See Section 3 below for more details on PDF requirements.**

- To ensure equity among applications, the 10-page limit for the Project Narrative cannot be exceeded. If an application exceeds the 10-page limit, the application will not be reviewed.

- Citations can be put in an Attachment. They do not have to be placed in the Project Narrative.

- Black print should be used throughout your application, including charts and graphs (no color).

- If you are submitting more than one application under the same announcement number, you must ensure that the Project Title in Field 15 of the SF-424 is unique for each submission.

2. GRANTS.GOV FORMATTING AND VALIDATION REQUIREMENTS

- Grants.gov allows the following list of UTF-8 characters when naming your attachments: A-Z, a-z, 0-9, underscore, hyphen, space, and period. Other UTF-8 characters should not be used as they will not be accepted by NIH's eRA Commons, as indicated in item #9 in the table below.

- Scanned images must be scanned at 150-200 dpi/ppi resolution and saved as a PDF file. Using a higher resolution setting or different file type will result in a larger file size, which could result in rejection of your application.

- Any files uploaded or attached to the Grants.gov application must be PDF file format and must contain a valid file format extension in the filename. In addition, the use of compressed file formats such as ZIP, RAR or Adobe Portfolio will not be accepted.

3. eRA COMMONS FORMATTING AND VALIDATION REQUIREMENTS

The following are formatting requirements and system validations required by eRA Commons and will result in errors if not met. The application must be 'error free' to be processed through the eRA Commons. There may be additional validations which will result in Warnings, but these will not prevent the application from processing through the submission process. (See Appendix A, Section 4.2)

ASSIST File Formatting Requirements

The eRA system contains file formatting requirements for uploading documents in ASSIST. The only accepted file type for submission is PDF and each file may be no larger than 6 MB. Fillable forms must be 'flattened' and saved as a PDF prior to upload. Adobe Portfolio file types will not be accepted.

Files for Upload to ASSIST must be:

- ☑ PDF Format
- ☑ Under 6MB in File Size
- ☑ 8.5 x 11 Page Size
- ☑ Flat *(No Fillable/Editable Fields)*

Files must **NOT** contain:

- ☒ Password-Protection
- ☒ Live hyperlinks *(only plain text URLs)*
- ☒ Bookmarks or Signature Boxes
- ☒ A filename exceeding 50 Characters *(including spaces)*

Flatten Fillable Forms Prior to Upload in ASSIST

A completed fillable form (an electronic document that can be filled out and edited digitally—also called fillable, dynamic, or interactive forms) should not only be saved as a PDF; it must also be flattened to remove the interactive fields so that the final answers are saved. Flattening a form is not the same as "locking" it; locking a form restricts access to editing, printing, and copying the document.

Flattening a PDF document:

- **Keeps form values permanent.** When an interactive PDF is uploaded or emailed, every field remains open to accidental or deliberate revision. Flattening the form ensures that only the completed version of the form is visible.
- **Removes values on drop down lists.** A flattened document will show only the selected text or value, no other values and options are shown and there is no indication that options were present.
- **Simplifies the PDF.** Interactive forms are larger than normal files, which may prevent upload for submission. Flattening reduces the file size which makes it easier to render and view.

To flatten a file, follow the steps below.

1. Ensure that the form is completed, and the information is correct. Go to the print settings by selecting **File > Print.**
2. On the pull-down menu of printer options, choose Adobe PDF or Microsoft Print to PDF, then click OK.
3. After clicking **OK,** a pop-up will open with options to save the PDF. Be sure to select a specific location to save the document where it can easily be found and give it a unique file name. Use a file name that clearly differentiates the completed form from the original fillable form. File names cannot exceed 50 characters.
4. The flattened form should appear in the new location with the new file name. Open it to check once more for any changes and to confirm that the conversion worked.

If you do not adhere to these requirements, you will receive an email notification from era-notify@mail.nih.gov to take action and adhere to the requirements so that your application can be processed successfully. It is highly recommended that you submit your application 24-72 hours before the submission deadline to allow for sufficient time to correct errors and resubmit the application. If you experience any system validation or technical issues after hours on the application due date, contact the eRA Service Desk and submit a Web ticket to document your good faith attempt to submit your application.

eRA Commons Validation Table

The following table shows formatting requirements and system validations required by eRA Commons and will result in errors if not met.

eRA Validations	eRA Error Messages
#1: Applicant Identifier (Item 4 on the SF-424):	
The PD/PI Credentials must be provided	The Commons Username must be provided in the Applicant Identifier field for the PD/PI.
Username provided must be a valid Commons account	The Commons Username provided in the Applicant Identifier is not a recognized Commons account.
Username must be affiliated with the organization submitting the application and/or have the PI role	The Commons account provided in the Applicant Identifier field for the PD/PI is either not affiliated with the applicant organization or does not hold the PI role. Check with your Commons Account Administrator to make sure your account affiliation and roles are set-up correctly.
#2. The UEI number provided must include valid characters (12 numbers)	The UEI number provided has invalid characters (other than 12 numbers)
#3. The documentation (forms) required for the NOFO must be submitted	The format of the application does not match the format of the NOFO. Contact the eRA Service Desk for assistance.
(#4 If a change or correction is made to address an error, "Changed/Corrected" must be selected. Item #1 on the SF-424). Refer to Appendix A II-4.4 for more information on resubmission criteria.	This application has been identified as a duplicate of a previous submission. The 'Type of Submission' should be set to Changed/Corrected if you are addressing errors/warnings.
#5. The application cannot exceed 1.2GB.	The application did not follow the agency-specific size limit of 1.2 GB. Resize the application to be no larger than 1.2 GB before submitting.
#6. The correct Notice of Funding Opportunity (NOFO) number must be provided	The Funding Opportunity Announcement number does not exist.
#7 All documents and attachments must be submitted in PDF format.	"The <attachment> attachment is not in PDF format. All attachments must be provided to the agency in PDF format with a .pdf extension. Help with PDF attachments can be found at http://grants.nih.gov/grants/ElectronicReceipt/pdf_guidelines.htm."

eRA Validations	eRA Error Messages
#8. All attachments must comply with the following formatting requirements: PDF attachments cannot be empty (0 bytes).	The {attachment} attachment was empty. PDF attachments cannot be empty, password protected or encrypted.
All PDF attachments cannot have Meta data missing, cannot be encrypted, password protected or secured documents.	The <attachment> attachment contained formatting or features not currently supported by NIH: <condition returned>.
The size of PDF attachments cannot be larger than 8.5 x 11 inches (horizontally or vertically). [Note: It is recommended that you limit the size of attachments to 35 MB.]	Filename <file> cannot be larger than U.S. standard letter paper size of 8.5 x 11 inches. See the PDF guidelines at http://grants.nih.gov/grants/ElectronicReceipt/pdf_guidelines.htm
PDF attachments must have a valid file name. Valid file names must include the following UTF-8 characters: A-Z, a-z, 0-9, underscore (_), hyphen (-), space, period.	The <attachment> attachment filename is invalid. Valid filenames may only include the following characters: A-Z, a-z, 0-9, underscore (_), hyphen (-), space, or period. No special characters (including brackets) can be part of the filename.
#9. The email addresses for the Contact Person (SF-424 Section F) and the Authorized Representative (SF-424 below Section 21) must contain a '@', with at least 1 and at most 64 chars preceding and following the '@'. Control characters (ASCII 0 through 31 and 127), spaces and special chars < > ( ) [ ] \ , ; : are not valid.	The submitted e-mail address for the person to be contacted {email address}, is invalid. Must contain a '@', with at least 1 and at most 64 chars preceding and following the '@'. Control characters (ASCII 0 through 31 and 127), spaces and special chars < > ( ) [ ] \ , ; : are not valid.
#10. Congressional district code of applicant (after truncating) must be valid. (SF-424, item 16 a and b)	Congressional district <Congressional District> is invalid. To locate your district, visit http://www.house.gov/

Budget Errors	
eRA Validations	**eRA Error Messages**
SF424-A: Section A – Budget Summary The total fields at the end of rows or at the bottom of columns must equal the sum of the elements for that row or column	Ensure that the sum of Grant Program Function or Activity (a) elements entered equals the total amounts in the Total field
SF424-A: Section B – Budget Categories The Total in Section B (Column 5 - Row k) must equal the Total in Section A – Budget Summary: (Row 5, Column g).	Ensure that the TOTALS Total (row k, column 5) equals the Budget Summary Totals in section A, row 5 column g.
SF424-A: Section D – Forecasted Cash Needs The Federal Total for the 1st Year (Line 13) must equal the Total in Section A (Row 5, Column g) The Non-Federal Total for 1st Year sum must equal Estimated Unobligated Funds Non-Federal Totals in Section A (d-5) + New or Revised Budget Non-Federal Totals (f-5)	Ensure that the Federal Total for 1st year, in Section D- Forecasted Needs equals the Section A, New or Revised Budget Federal Totals (e-5) amount. Ensure that the Non-Federal Total for 1st year equals the sum of Estimated Unobligated Funds Non-Federal Totals (d-5) and New or Revised Budget Non-Federal Totals (f-5) on Section A.
The Total for 1st Year TOTAL in Section D must equal the Total (Row 5, Column G) in Section A	Ensure that the Forecasted Cash Needs: 15 TOTAL equals to SECTION A – Budget Summary: Line 5. Totals, Column (g).
SF424-A: Section E – Budget Estimates of Federal Funds Needed for Balance of The Project The number of budget years/periods must match the span of the project. The number of years in the project period in Block 17 on the SF-424 must align with the future funding periods.	Ensure that the project period years on the SF 424 block 17 matches the provided budget periods in the SF-424A. Enter data for the first budget period in Section D and enter future budget periods in Section E.

Appendix C – General Eligibility Information

Determining whether you are eligible to apply for and receive a SAMHSA award is very important. If you are not legally eligible for a specific funding opportunity, you would spend considerable time and money completing the application process when you cannot receive the award.

There are many types of organizations generally eligible to apply for SAMHSA funding opportunities. However, eligibility is strictly tied to the statutory authority governing this award. Please be sure to double check the NOFO for eligibility. Eligibility for this NOFO may include the following:

Government Organizations

State governments and territories
County governments
City or township governments
Special district governments
Native American tribal governments (federally recognized)
Native American tribal governments (other than federally recognized)
State-Recognized Tribes

Other Tribal Entities

Tribal organizations
Consortia of tribes or tribal organizations
Urban Indian Organizations

Education Organizations

Independent school districts
Public and state-controlled institutions of higher education
Private institutions of higher education
Education agencies/authorities serving children and youth residing in federally recognized American Indian/Alaska Native (AI/AN) tribes

Non-profit Organizations

Non-profits having a 501(c)(3) status with the Internal Revenue Service (IRS), other than institutions of higher education
Non-profits that do not have a 501(c)(3) status with the IRS, other than institutions of higher education, including entities with 501(c)(4) status (civic leagues, social welfare organizations, and local associations of employees) and 501(c)(5) status (labor organizations).

Please note: For-profit organizations and foreign entities are not eligible to apply for SAMHSA awards.

Appendix D – Confidentiality and SAMHSA Participant Protection/Human Subjects Guidelines

CONFIDENTIALITY AND PARTICIPANT PROTECTION:

It is important to have safeguards protecting individuals from risks associated with their participation in SAMHSA projects. **As part of Attachment 7 of the application, all applicants (including those who plan to obtain Institutional Review Board (IRB) approval) must address all of the elements below.** If some elements are not applicable to the proposed project, explain why the element(s) is not applicable.

In addition to addressing these elements, you will need to determine if the section below titled "Protection of Human Subjects Regulations" applies to your project. If so, you must submit the required documentation as described below. There are no page limits for your response to the elements in this appendix.

1. Protect Participants and Staff from Potential Risks

- Identify and describe the foreseeable physical, medical, psychological, social, and legal risks or potential adverse effects **participants** may be exposed to because of the project.
- Identify and describe the foreseeable physical, medical, psychological, social, and legal risks or potential adverse effects **staff** may be exposed to as a result, of the project.
- Describe the procedures you will follow to minimize or protect participants and staff against potential risks, including risks to confidentiality.
- Identify your plan to provide guidance and assistance in the event there are adverse effects to participants and/or staff.

Responses that will be considered unacceptable or incomplete:

- *Indicating that there are **no risks** to participants. If services are being delivered as part of the project, it is **very unlikely** that there will be no foreseeable physical, medical, psychological, social, or legal risks or potential adverse effects as a result of their involvement in the project.*
- *Addressing potential risks to participants but not addressing risks to staff*
- *Neglecting to describe how the organization will provide guidance and assistance in the event there are adverse effects to participants and whether alternative treatments will be available to participants.*

2. Fair Selection of Participants

- Explain how you will recruit and select participants ensuring all populations have equitable opportunities to participate in the program.
- Identify any individuals in the geographic catchment area where services will be delivered who will be excluded from participating in the project and explain the reasons for this exclusion.

Responses that will be considered unacceptable or incomplete:

- *Not explaining reasons for including or excluding participants*
- *Not identifying how participants will be selected*

3. Absence of Coercion

- If you plan to compensate participants, state how participants will be awarded incentives (e.g., gift cards, bus passes, gifts, etc.) If you plan to implement a contingency management program, specify the evidence-based model you will use and briefly justify its use with your population(s) of focus. If you have included funding for incentives in your budget, you **must** address this item. (For specific information about incentives, see https://www.samhsa.gov/grants/grants-management/policies-regulations/additional-directives)
- Provide justification that the use of incentives is appropriate, judicious, and conservative and that incentives do not provide an "undue inducement" that removes the voluntary nature of participation.
- Describe how you will inform participants in a culturally competent manner that they may receive services even if they choose to not participate in or complete the data collection component of the project.

Responses that will be considered unacceptable or incomplete:

- *Indicating that you do not plan to compensate participants, such as through incentives, but including funding for incentives in the budget or describing the use of incentives in the Project Narrative.*
- *Not specifying how participants will be told that they may receive services even if they choose not to participate in the data collection component of the project.*

4. Data Collection

- Identify from whom you will collect data (e.g., participants, clients, family members, teachers, others).
- Describe the data collection procedures and specify the sources for obtaining data (e.g., school records, interviews, psychological assessments, questionnaires, observation, or other sources). Identify what type of specimens (e.g., urine, blood) will be used, if any. State if the specimens will be used for purposes other than evaluation.
- In **Attachment 2**, "Data Collection Instruments/Interview Protocols," you **must** provide copies of all available data collection instruments and interview protocols that you plan to use (unless you are providing the web link to the standardized instrument(s)/protocol(s). Include any culturally adapted data collection instruments and interview protocols.

Responses that will be considered unacceptable or incomplete:

- *Not clearly identifying all the entities from which data will be collected.*
- *Describing the use of drug testing in the Project Narrative but not providing the requested information about specimen collection.*
- *Not including data collection instruments/interview protocols (or links to websites for the instruments) in Attachment 2.*
- *Not including how the data collection will occur (i.e., paper surveys versus electronic survey links; at a school setting or at the organization's clinic, etc.).*

5. Privacy and Confidentiality

- Explain how you will ensure privacy and confidentiality. Describe:
  - Where data will be stored,
  - Who will have access to the data collected, and
  - How the identity of participants will be kept private, for example, using a coding system on data records, limiting access to records, or storing identifiers separately from data.
- **NOTE:** Recipients must maintain the confidentiality of substance use disorder client records according to the provisions of **Title 42 of the Code of Federal Regulations, Part II, Subpart B.**

Responses that will be considered unacceptable or incomplete:

- *Not providing detailed information about where data is stored and how the identity of participants will be kept confidential.*
- *Not clearly identifying the individuals who will have access to the data.*
- *Not specifying that you agree to maintain the confidentiality of substance use disorder client records according to the provisions of Title 42 of the Code of Federal Regulations, Part II.*

6. Adequate Consent Procedures

- Include, as appropriate, sample consent forms* that provide for:

  1. informed consent for participation in service intervention;
  2. informed consent for participation in the data collection component of the project, including information that participants are informed that they may receive services even if they choose not to participate in or complete this component of the project; and
  3. informed consent for the exchange (releasing or requesting) of confidential information.
  4. Informed consent for youth participants.

  *Consent forms should be written at no higher than 8th grade reading level.

- The sample forms must be included in **Attachment 3, "Sample Consent Forms"**, of your application. If needed, provide translated forms.
- Explain how you will obtain consent for youth, the elderly, people with limited reading skills, and people who do not use English as their first language. Describe how the consent will be documented. For example: Will you read the consent forms? Will you ask prospective participants questions to be sure they understand the forms? Will you give them copies of what they sign?

  NOTE: The consent forms should never imply that the participant waives or appears to waive any legal rights. The forms should also not imply that individuals cannot end involvement with the project or that your project or its agents will be released from liability for negligence.

Responses that will be considered unacceptable or incomplete:

- *Not providing copies of sample consent forms in Attachment 3.*

- *Not providing details on how consent/assent will be obtained for youth participants.*
- *Not providing details on how consent will be obtained for non-English speaking priority populations identified in the application.*

7. Risk/Benefit Discussion

- Discuss why the risks you have identified in **Element 1. Protect Participants and Staff from Potential Risks** are reasonable compared to the anticipated benefits to participants involved in the project.

Responses that will be considered unacceptable or incomplete:

- *Indicating there are no risks to participants in the first element and noting that this element is therefore not applicable.*
- *Not mentioning any anticipated benefits to participants involved in the project.*

PROTECTION OF HUMAN SUBJECTS REGULATIONS

SAMHSA expects that most recipients funded under this announcement will not have to comply with the Protection of Human Subjects Regulations (45 CFR 46), which requires Institutional Review Board (IRB) approval. However, in some instances, the applicant's proposed project may meet the regulation's criteria for research involving human subjects. Although IRB approval is not required at the time of award, you are required to provide the documentation below prior to enrolling participants into your project.

In addition to the elements above, applicants whose projects must comply with the Human Subjects Regulations must:

- Describe the process for obtaining IRB approval for your project.
- Provide documentation that an Assurance of Compliance is on file with the Office for Human Research Protections (OHRP).
- Provide documentation that IRB approval has been obtained for your project prior to enrolling participants.

General information about Human Subjects Regulations can be obtained through OHRP at http://www.hhs.gov/ohrp or (240) 453-6900. SAMHSA–specific questions should be directed to the program contact listed in Section VII of this announcement.

Appendix E – Developing Goals and Measurable Objectives

To be able to effectively evaluate your project, it is critical that you develop realistic goals and measurable objectives. This appendix provides information on developing goals and objectives for use in your Project Narrative. It also provides examples of well-written goals and measurable objectives.

GOALS

Definition – a goal is a broad statement about the long-term expectation of what should happen because of your program (the desired result). It serves as the foundation for developing your program objectives. Goals should align with the statement of need that is described. Goals should only be one sentence.

The characteristics of effective goals include:

- Goals address outcomes, not how outcomes will be achieved.
- Goals describe the behavior or condition in the community expected to change.
- Goals describe who will be affected by the project.
- Goals lead clearly to one or more measurable results.
- Goals are concise.

Examples

Unclear Goal	Critique	Improved Goal
Increase the substance use and HIV/AIDS prevention capacity of the local school district	This goal could be improved by *specifying an expected program effect in reducing a health problem*	Increase the capacity of the local school district to reduce high-risk behaviors of students that may contribute to substance use and/or HIV/AIDS
Decrease the prevalence of marijuana, alcohol, and prescription drug use among youth in the community by increasing the number of schools that implement effective policies, environmental change, intensive training of teachers, and educational approaches to address high-risk behaviors, peer pressure, and tobacco use.	This goal is not concise	Decrease youth substance use in the community by implementing evidence-based programs within the school district that address behaviors that may lead to the initiation of use.

OBJECTIVES

Definition – Objectives describe the results to be achieved and the manner in which they will be achieved. Multiple objectives are generally needed to address a single goal. Well-written objectives help set program priorities and targets for progress and accountability. It is recommended that you avoid verbs that may have vague meanings to describe the intended outcomes, like "understand" or "know" because it may prove difficult to measure them. Instead, use verbs that document action, such as: "By the end of 2020, 75% of program participants will be *placed* in permanent housing. To be effective, objectives should be clear and leave no room for interpretation.

SMART is a helpful acronym for developing objectives that are ***specific, measurable, achievable, realistic, and time-bound***:

Specific –
Includes the "who" and "what" of program activities. Use only one action verb to avoid issues with measuring success. For example, "Outreach workers will administer the HIV risk assessment tool to at least 100 injection drug users in the population of focus" is a more specific objective than "Outreach workers will use their skills to reach out to drug users on the street."

Measurable –
How much change is expected. It must be possible to count or otherwise quantify an activity or its results. It also means that the source of and mechanism for collecting measurement data can be identified and that collection of the data is feasible for your program. A baseline measurement is required to document change (e.g., to measure the percentage of increase or decrease). If you plan to use a specific measurement instrument, it is recommended that you incorporate its use into the objective. Example: By 9/20 increase by 10% the number of 8th, 9th, and 10th grade students who disapprove of marijuana use as measured by the annual school youth survey.

Achievable –
Objectives should be attainable within a given time frame and with available program resources. For example, "The new part-time nutritionist will meet with seven teenage mothers each week to design a complete dietary plan" is a more achievable objective than "Teenage mothers will learn about proper nutrition."

Realistic –
Objectives should be within the scope of the project and propose reasonable programmatic steps that can be implemented within a specific time frame. For example, "Two ex-gang members will make one school presentation each week for two months to raise community awareness about the presence of gangs" is a more realistic objective than "Gang-related violence in the community will be eliminated."

Time-bound –
Provide a time frame indicating when the objective will be measured or a time by when the objective will be met. For example, "Five new peer educators will be recruited by

the second quarter of the first funding year" is a better objective than "New peer educators will be hired."

Examples:

Non-SMART Objective	Critique	SMART Objective
Teachers will be trained on the selected evidence-based substance use prevention curriculum.	The objective is not SMART because it is not *specific, measurable*, or *time-bound*. It can be made SMART by *specifically* indicating who is responsible for training the teachers, how many will be trained, who they are, and by when the trainings will be conducted.	***By June 1, 2022, LEA supervisory staff*** will have trained ***75% of health education*** teachers ***in the local school district*** on the selected, evidence-based substance use prevention curriculum.
90% of youth will participate in classes on assertive communication skills.	This objective is not SMART because it is not *specific* or *time-bound.* It can be made SMART by indicating *who* will conduct the activity, *by when*, and *who* will participate in the lessons on assertive communication skills.	By the ***end of the 2022 school year, district health educators*** will have conducted classes on assertive communication skills for 90% of youth ***in the middle school*** receiving the ***substance use and HIV prevention curriculum.***
Train individuals in the community on the prevention of prescription drug/opioid overdose-related deaths.	This objective is not SMART as it is not *specific, measurable* or *time-bound.* It can be made SMART by specifically indicating *who* is responsible for the training, *how many* people will be trained, *who* they are, and by *when* the training will be conducted.	***By the end of year two of the project***, the ***Health Department*** will have trained ***75% of EMS staff in the County Government*** on the selected curriculum addressing the prevention of prescription drug/opioid overdose-related deaths.

Appendix F – Developing the Plan for Data Collection and Performance Measurement

Information in this Appendix should be taken into consideration when developing a response for criteria in Section E of the Project Narrative.

Data Collection:

In describing your plan for data collection, consider addressing the following points:

- Electronic data collection software that will be used
- Frequency of data collection?
- Organizational processes that will be implemented to ensure the accurate and timely collection and input of data.
- Staff that will be responsible for collecting and recording the data.
- Data source and data collection instruments that will be used to collect the data.
- How well the data collection methods will take into consideration the language, norms, and values of the population(s) of focus.
- Processes and policies to keep data secure.
- If applicable, the data collection procedures to ensure that confidentiality is protected and that informed consent is obtained.
- If applicable, data collection procedures from partners and/or sub-recipients.

It is not necessary to provide information related to data collection and performance measurement in a table, but the following samples may give you some ideas about how to display the information.

Table 1 *[provides an example of how information for the required performance measures could be displayed]*

Performance Measures	Data Source	Data Collection Frequency	Responsible Staff for Data Collection	Method of Data Analysis

Table 2 *[provides an example of how information could be displayed for the data that will be collected to measure the objectives that are included in B.1]*

Objective	Data Source	Data Collection Frequency	Responsible Staff for Data Collection	Method of Data Analysis
Objective 1.a				

Objective	Data Source	Data Collection Frequency	Responsible Staff for Data Collection	Method of Data Analysis
Objective 1.b				

Data Management and Performance Monitoring

Points to consider:

- Data protection policies and procedures, including information about storage, retention, and access.
- Frequency of reviews and monitoring of performance data
- Staff conducting data analysis, including evaluation.
- Data analysis methods and how you will use data to monitor and evaluate activities and processes.
- Staff responsible for completing reports.
- How data will be reported to staff, stakeholders, SAMHSA, an Advisory Board, and other relevant project partners.

How Data Will Be Used to Enhance the Project/Quality Improvement (QI):

Points to consider:

- If applicable, the QI model that will be used.
- How will the QI process be used to track progress?
- Staff responsible for overseeing QI processes.
- Details of how to implement any needed changes to project implementation and/or project management.
    - What decision-making processes will be used??
    - When and by whom will decisions be made concerning project improvement?
    - What are the thresholds for determining that changes need to be made?
    - Will the Advisory Board have a role in the QI process?
    - How will the changes be communicated to staff and/or partners/sub-recipients?

Appendix G – Biographical Sketches and Position Descriptions

Include position descriptions and biographical sketches for all project staff as supporting documentation to the application. The formatting requirements outlined in Appendix B are not applicable for these documents.

Biographical Sketch

Existing curricula vitae of project staff members may be used if they are updated and contain all items of information requested below. You may add any information items listed below to complete existing documents. For development of new curricula vitae include items below in the most suitable format:

1. Name of staff member
2. Educational background: school(s), location, dates attended, degrees earned (specify year), major field of study
3. Professional experience
4. Recent relevant publications

Position Description

1. Title of position
2. Description of duties and responsibilities
3. Qualifications for position
4. Supervisory relationships
5. Skills and knowledge required
6. Amount of travel and any other special conditions or requirements
7. Salary range
8. Hours per day or week

Appendix H – Addressing Behavioral Health Disparities

SAMHSA expects recipients to submit a Behavioral Disparity Impact Statement (DIS) within 60 days of receiving the award.

SAMHSA's Behavioral Health Disparity Impact Statement (DIS) is a data-driven, quality improvement approach to advance equity for all, and to identify racial, ethnic, sexual and gender minority, and rural populations at highest risk for experiencing behavioral health disparities as part of their projects. The purpose of the DIS is for recipients to identify and address health disparities[6] and to develop and implement an action plan with a disparity reduction quality improvement process to close the identified gap(s). The aim is to achieve targeted behavioral health equity[7] for disparate populations and improve systems.

SAMHSA provides a DIS Worksheet that award recipients are expected to use to respond to this special condition of award.

The main components of the DIS are:

- Identify and describe the scope of the problem (i.e., behavioral health disparity) related to the program and the population(s) of focus that experience disparate access, use, and outcomes. Identify data sources that will be used to inform the DIS (this should be in alignment with the information provided in your application). Complete a table that includes this information at the individual/client, organizational or systemic level as it relates to the data collection requirements: NOMS, IPP, or both, in relation to access, use, and outcomes.

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[6] Healthy People 2030 defines a health disparity as a "particular type of health difference that is closely linked with social, economic, and/or environmental disadvantage. Health disparities adversely affect groups of people who have systematically experienced greater obstacles to health based on their racial or ethnic group; religion; socioeconomic status; gender; age; disability; mental health; cognitive, sensory, or physical disability; sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion."

[7] Behavioral health equity is the right to access high quality and affordable health care services and supports for all populations regardless of the individual's race, age, ethnicity, gender (including gender identity), disability, socioeconomic status, sexual orientation, or geographical location. Advancing behavioral health equity involves ensuring that everyone has a fair and just opportunity to be as healthy as possible. In conjunction with quality services, this involves addressing social determinants of health, such as employment and housing stability, insurance status, proximity to services, and culturally responsive care – all of which have an impact on behavioral health outcomes.

- Identify Social Determinant of Health (SDOH) domain(s) that your organization will work to address and improve for the identified population(s) of focus using the NOFO. Visit Healthy People 2030 for more information on the five (5) domains. Using the Behavioral Health Implementation Guide, identify Culturally and Linguistically Appropriate Services (CLAS) standards that your organization plans to meet, expand, or improve through this funding opportunity. Review the Behavioral Health Implementation Guide for full explanations of the overarching themes and 15 CLAS Standards with behavioral health related samples, strategies, and examples.

- Develop and implement a disparity reducing quality improvement action plan to address the behavioral health disparity(ies) experienced by underserved population differences based on the GPRA data on access, use, and outcomes of activities. The plan should include realistic goals and SMART objectives (see Appendix E), the activities that will be implemented to address disparities, the intended impact, timeline, measurement, and evaluation. Ensure documentation of the processes, progress, and outcomes on how the identified behavioral health disparity(ies) have improved.

Recipients are expected to provide, at a minimum, an annual update on the DIS (e.g., what worked, what did not work, what modifications were made) as part of the programmatic progress reports per the NOFO.

Examples of a DIS are available on the SAMHSA website at http://www.samhsa.gov/grants/grants-management/disparity-impact-statement

DIS Related Terminology and Resources

Definition of Health Disparities

Healthy People 2030 defines a health disparity as a "particular type of health difference that is closely linked with social, economic, and/or environmental disadvantage. Health disparities adversely affect groups of people who have systematically experienced greater obstacles to health based on their racial or ethnic group; religion; socioeconomic status; gender; age; disability; mental health; cognitive, sensory, or physical disability; sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion."

Social Determinants of Health (SDOH)

SDOH are the conditions in the environment where people are born, live, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. SDOH can be grouped into 5 domains:

- Economic Stability

- Education Access and Quality
- Health Care Access and Quality
- Neighborhood and Built Environment
- Social and Community Context

For more information about SDOH Z codes and how SDOH are being used to narrow the health disparities gaps, see https://www.cms.gov/files/document/zcodes-infographic.pdf; https://www.cms.gov/files/document/cms-omh-january2020-zcode-data-highlightpdf.pdf; and https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6207437/pdf/18-095.pdf

Definition of Equity

Equity is the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality. Addressing issues of equity should include an understanding of intersectionality and how multiple forms of discrimination impact individuals' lived experiences. Individuals and communities often belong to more than one group that has been historically underserved, marginalized, or adversely affected by persistent poverty and inequality. Individuals at the nexus of multiple identities often experience unique forms of discrimination or systemic disadvantages, including in their access to needed services.

Definition of Health Equity

Health equity is the attainment of the highest level of health for all people. Achieving health equity requires valuing everyone equally with focused and ongoing societal efforts to address avoidable inequalities, historical and contemporary injustices, and the elimination of health and health care disparities. Behavioral health equity is the right to access quality health care for all populations regardless of the individual's race, ethnicity, gender, socioeconomic status, sexual orientation, or geographical location. This includes access to prevention, treatment, and recovery services for mental and substance use disorders.

Underserved populations

SAMHSA applicants are routinely asked to define the population they intend to serve given the focus of a particular program (e.g., adults with opioid use disorders at risk of overdose; adults with serious mental illness [SMI]; adolescents engaged in underage drinking; populations at risk for contracting HIV/AIDS, etc.). Within these populations of focus are *underserved populations* that may have unequal access to, use of, or

outcomes from provided services. These disparities may be the result of differences in race, ethnicity, language, culture, and/or socioeconomic factors specific to that underserved population. For instance, Latino adults with opioid use disorder may be at heightened risk for overdoses due to lack of in-language prevention campaigns and treatment; African Americans with an SMI may more likely to terminate treatment prematurely due to lack of providers with whom they can develop a therapeutic relationship; Native American youth may have an increased incidence of underage drinking due to coping patterns related to historical trauma; and African American women may be at greater risk for contracting HIV/AIDS due to lack of access to education on risky sexual behaviors in urban low-income communities, etc. While these factors might not be pervasive among the general population served by a recipient, they may be predominant among underserved populations or groups vulnerable to disparities. It is imperative that recipients understand who is being served, who is underserved, and who is not being served within their community in order to provide outreach and care that will yield positive outcomes, per the focus of the award. For organizations to attend to the potentially disparate impact of their award efforts, recipients are asked to address access, use and outcomes, disaggregated by underserved populations. Underserved populations can be defined by the following factors:

- By race
- By ethnicity
- By gender identity (including transgender populations)
- By sexual orientation (including lesbian, gay and bisexual populations)

Access refers to which populations/underserved populations are being served/reached by the program. Use refers to what interventions/services are received by the various populations. Outcomes refers to the outcome measures stipulated by the award and examined across underserved populations.

Culturally and Linguistically Appropriate Services in Health and Health Care (CLAS Standards)

The ability to address the quality of care provided to underserved populations served within SAMHSA's programs is enhanced by programmatic alignment with the federal National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (CLAS Standards).

The CLAS Standards are comprised of 15 Standards that provide a blueprint for health and health care organizations to implement culturally and linguistically appropriate, respectful, and responsive services that will advance health equity, improve quality, and help eliminate health care disparities.

The CLAS Standards are grouped into a Principal Standard and three themes focused on

1) Governance and Leadership.
2) Communication and Language Assistance.
3) Engagement, Continuous Improvement and Accountability.

Widely embraced by States and health care systems, the National CLAS Standards are more recently being promoted in behavioral health care, which includes a Behavioral Health CLAS Implementation Guide at https://www.minorityhealth.hhs.gov/Assets/PDF/clas%20standards%20doc_v06.28.21.pdf. You can learn more about the CLAS mandates, guidelines, and recommendations at: http://ThinkCulturalHealth.hhs.gov.

Guidelines for behavioral health implementation of the CLAS Standards can be found at https://thinkculturalhealth.hhs.gov/clas. This document addresses the importance of improving access to behavioral health care, promoting quality behavioral health programs and practice, and ultimately reducing persistent disparities in mental health and substance use prevention, treatment, and recovery for underserved, minority populations and communities.

Appendix I – Standard Funding Restrictions

HHS codified the *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards*, 45 CFR Part 75. In Subpart E, cost principles are described and allowable/unallowable expenditures for HHS recipients are delineated. 45 CFR Part 75 is available at https://ecfr.federalregister.gov/current/title-45/subtitle-A/subchapter-A/part-75. Unless superseded by program statute or regulation, follow the cost principles in 45 CFR Part 75 and the standard funding restrictions below.

Guidelines for recipients on financial management requirements are available at https://www.samhsa.gov/grants/grants-management/policies-regulations/financial-management-requirements.

SAMHSA funds may not be used to:

- Purchase, prescribe, or provide marijuana or treatment using marijuana. See, e.g., 45 CFR. 75.300(a) (requiring HHS to ensure that Federal funding is expended in full accordance with U.S. statutory and public policy requirements); 21 U.S.C. 812(c)(10) and 841 (prohibiting the possession, manufacture, sale, purchase, or distribution of marijuana).

- Purchase, procure, or distribute pipes or cylindrical objects intended to be used to smoke or inhale illegal scheduled substances.

- Pay for promotional items including, but not limited to, clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags. (See 45 CFR 75.421(e)(3))

- Pay for the purchase or construction of any building or structure to house any part of the program. Minor alterations and renovations (A&R) may be authorized for up to 25% of a given budget period or $150,000 (whichever is less) for existing facilities, if necessary and appropriate to the project. Minor A&R may not include a structural change (e.g., to the foundation, roof, floor, or exterior or loadbearing walls of a facility, or extension of an existing facility) to achieve the following: Increase the floor area; and/or, change the function and purpose of the facility. All minor A&R must be approved by SAMHSA.

- Provide inpatient treatment or hospital-based detoxification services. Residential services are not considered to be inpatient or hospital-based services.

- Pay for housing other than recovery housing which includes application fees and security deposits.

- Make direct payments to individuals to enter treatment or continue to participate in prevention or treatment services (See 42 U.S.C. § 1320a-7b).

  Note: A recipient or treatment or prevention provider may provide up to $30 non-cash incentive to individuals to participate in required data collection follow-up. This amount may be paid for participation in each required follow-up interview. For programs including contingency management as a component of the treatment program, each individual contingency must be $15 or less in value and clients may not receive contingencies totaling more than $75 per budget period.

- Meals are generally unallowable unless they are an integral part of a conference award or specifically stated as an allowable expense in the NOFO (See https://www.hhs.gov/grants/contracts/contract-policies-regulations/spending-on-food/index.html)

- Purchase firearms.

- General Provisions under Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act Public Law 116-260, Consolidated Appropriations Act, 2021, Division H, Title V, Section 527, notwithstanding any other provision of this Act, no funds appropriated in this Act shall be used to purchase sterile needles or syringes for the hypodermic injection of any illegal drug. Provided, that such limitation does not apply to the use of funds for elements of a program other than making such purchases if the relevant State or local health department, in consultation with the Centers for Disease Control and Prevention, determines that the State or local jurisdiction, as applicable, is experiencing, or is at risk for, a significant increase in hepatitis infections or an HIV outbreak due to injection drug use, and such program is operating in accordance with state and local law.

- **Salary Limitation**: The Consolidated Appropriations Act, 2021 (Public Law 116-260), Division H, Title II, Section 202, provides a salary rate limitation. The law limits the salary amount that may be awarded and charged to SAMHSA awards and cooperative agreements. Award funds may not be used to pay the salary of an individual at a rate in excess of Executive Level II, which is **$203,700.** This amount reflects an individual's base salary exclusive of fringe and any income that an individual may be permitted to earn outside of the duties to your organization. This salary limitation does not apply to consultants but does apply to subrecipients under a SAMHSA award or cooperative agreement . Note that these or other salary limitations will apply in the following fiscal years, as required by law.

Appendix J – Intergovernmental Review (E.O. 12372) Requirements

States with SPOCs

All SAMHSA programs are covered under Executive Order (EO) 12372, as implemented through Department of Health and Human Services (DHHS) regulation at 45 CFR Part 100. Under this Order, states may design their own processes for reviewing and commenting on proposed federal assistance under covered programs. Certain jurisdictions have elected to participate in the EO process and have established State Single Points of Contact (SPOCs). Information on the SPOC for participating states can be found at: https://www.whitehouse.gov/wp-content/uploads/2020/04/SPOC-4-13-20.pdf

This requirement does not apply to American Indian/Alaska Native tribes or tribal organizations. If your state participates, contact your SPOC as early as possible to alert him/her to the prospective application(s) and to receive any necessary instructions on the state's review process. For proposed projects serving more than one state, you are advised to contact the SPOC of each affiliated state.

The SPOC should send any state review process recommendations to the following address within 60 days of the application deadline:

Director, Division of Grants Management
Office of Financial Resources,
ATTN: SPOC – Funding Announcement No.TI-23-012
Substance Abuse and Mental Health Services Administration,
5600 Fishers Lane, Room 17E20
Rockville, MD 20857

States without SPOCs

If your state does not have a SPOC and you are a community-based, non-governmental service provider, you must submit a Public Health System Impact Statement (PHSIS)[8] to the head(s) of appropriate state and local health agencies in the area(s) to be affected no later than the application deadline. The PHSIS is intended to keep state and local health officials informed of proposed health services applications submitted by

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[8] Approved by OMB under control no. 0920-0428; Public reporting burden for the Public Health System Reporting Requirement is estimated to average 10 minutes per response, including the time for copying the first page of SF-424 and the abstract and preparing the letter for mailing. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0920-0428. Send comments regarding this burden to CDC Clearance Officer, 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0428).

community-based, non-governmental organizations within their jurisdictions. If you are a state or local government or American Indian/Alaska Native tribe or tribal organization, you are not subject to these requirements.

The PHSIS consists of the following information:

- A copy of the first page of the application (SF-424); and
- A summary of the project, no longer than one page in length that provides: 1) a description of the population to be served; 2) a summary of the services to be provided; and 3) a description of the coordination planned with appropriate state or local health agencies.

For SAMHSA awards, the appropriate state agencies are the Single State Agencies (SSAs) for substance abuse and mental health. A listing of the SSAs for substance abuse and the SSAs for mental health can be found on SAMHSA's website at http://www.samhsa.gov/grants/applying/forms-resources. If the proposed project falls within the jurisdiction of more than one state, you should notify all representative SSAs.

Review Section IV of the NOFO carefully to determine if you must include an attachment with a copy of a letter transmitting the PHSIS to the SSA. The letter must notify the state that, if it wishes to comment on the proposal, its comments should be sent no later than 60 days after the application deadline to the following address:

Director of Grants Management
Office of Financial Resources,
ATTN: SSA – Funding Announcement No TI-23-012
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane, Room 17E20
Rockville, MD 20857

In addition, applicants may request that the SSA send them a copy of any state comments. The applicant must notify the SSA within 30 days of receipt of an award.

Appendix K – Administrative and National Policy

If your application is funded, you must comply with all terms and conditions of the NoA. SAMHSA's standard terms and conditions are available on the SAMHSA website.

HHS Grants Policy Statement (GPS)

If your application is funded, you are subject to the requirements of the HHS Grants Policy Statement (GPS) that are applicable based on recipient type and purpose of award. This includes any requirements in Parts I and II of the HHS GPS that apply to the award. The HHS GPS is available at http://www.samhsa.gov/grants/grants-management/policies-regulations/hhs-grants-policy-statement. The general terms and conditions in the HHS GPS will apply as indicated unless there are statutory, regulatory, or award-specific requirements to the contrary (as specified in the NoA).

HHS Award Regulations

If your application is funded, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions. For more information see the SAMHSA website at http://www.samhsa.gov/grants/grants-management/policies-regulations/requirements-principles.

Additional Terms and Conditions

Depending on the nature of the specific funding opportunity and/or your proposed project as identified during review, SAMHSA may negotiate additional terms and conditions with you prior to award. These may include, for example:

- actions required to be in compliance with confidentiality and participant protection/human subjects requirements.
- requirements relating to additional data collection and reporting.
- requirements relating to participation in a cross-site evaluation.
- requirements to address problems identified in review of the application or the budget and narrative justification.

Performance Goals and Objectives

If your application is funded, you will be held accountable for the information provided in the application relating to performance targets. SAMHSA program officials will consider your progress in meeting goals and objectives, as well as your failures and strategies for overcoming them, when making an annual recommendation to continue the award and the amount of any continuation award. In addition, you must relate financial data and accomplishments to the performance goals and objectives of the award. Failure to

meet stated goals and objectives may result in suspension or termination (see 2 CFR 200.202, 2 CFR 200.301 and 2 CFR 200.329) of the award, or in reduction or withholding of continuation awards.

Termination of Federal Award

Note that the OMB revisions to Guidance for Grants and Agreements termination provisions located at 2 CFR § 200.340 - Termination apply to all federal awards effective August 13, 2020.

Accessibility Provisions for All Award Application Packages and Funding Opportunity Announcements

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS will be required to complete an HHS Assurance of Compliance form (HHS 690) in which you agree, as a condition of receiving the grant, to administer your programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, age, sex, and disability, and agreeing to comply with federal conscience laws, where applicable. This includes ensuring that entities take meaningful steps to provide meaningful access to persons with limited English proficiency; and ensuring effective communication with persons with disabilities. Where applicable, Title XI and Section 1557 prohibit discrimination on the basis of sexual orientation, and gender identity, the HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html.

You will administer your project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. You will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws require taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html.

- For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.

- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see https://www.hhs.gov/ocr/civilrights/understanding/disability/index.html

- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.

- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated antidiscrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

Acknowledgement of Federal Funding

As required by HHS appropriations acts, all HHS recipients must acknowledge Federal funding when issuing statements, press releases, publications, requests for proposal, bid solicitations, and other documents, such as toolkits, resource guides, websites, and presentations describing the projects or programs funded in whole or in part with HHS federal funds. The recipient must clearly state: 1) the percentage and dollar amount of the total costs of the program or project funded with federal money; and 2) the percentage and dollar amount of the total costs of the project or program funded by non-governmental sources.

Supplement Not Supplant

Funds may be used to supplement existing activities. Award funds may not be used to supplant current funding of existing activities. "Supplant" is defined as replacing funding of a recipient's existing program with funds from a federal award (2 CFR Part 200, Appendix XI).

Mandatory Disclosures

A term may be added to the NoA which states: Consistent with 45 CFR 75.113, applicants and recipients must disclose in a timely manner, in writing to the HHS awarding agency, all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Sub-recipients must disclose, in a timely manner, in writing to the prime recipient (pass through entity), all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Disclosures must be sent in writing to SAMHSA at the following address:

SAMHSA

Attention: Office of Financial Advisory Services
5600 Fishers Lane
Rockville, MD 20857

You may also submit a complaint via the OIG Hotline online form (see https://oig.hhs.gov/fraud/report-fraud/), by phone (1-800-447-8477), or by mail to the following address:

U.S. Dept. of Health and Human Services
Office of the Inspector General
ATTN: OIG Hotline Operations
P.O. Box 23489
Washington, DC 20026

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance; including suspension or debarment (See 2 CFR parts 180 & 376 and 31 U.S.C. 3321)."

System for Award Management (SAM) Reporting

A term may be added to the NoA that states: "In accordance with the regulatory requirements provided at 45 CFR 75.113, 2 CFR 25, and Appendix XII to 45 CFR Part 75, recipients that have currently active federal awards and procurement contracts with cumulative total value greater than $10,000,000, must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a federal award that reached final disposition within the most recent five-year period. The recipient also must make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75."

Drug-Free Workplace

A term may be added to the NoA that states: "You as the recipient must comply with drug-free workplace requirements in Subpart B of part 382, which adopts the Government-wide implementation (2 CFR part 182) of section 5152-5158 of the Drug-Free Workplace Act of 1988 (Pub. L. 100-690, Title V, Subtitle D; 41 U.S.C. 701-707)."

Smoke-Free Workplace

The Public Health Service strongly encourages all award recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. Further, 20 USC 6081 et seq., the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in

some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

Standards for Financial Management

Recipients and subrecipients are required to meet the standards and requirements for financial management systems set forth in 45 CFR part 75 Subpart D. The financial systems must enable the recipient and subrecipient to maintain records that adequately identify the sources of funds for federally assisted activities and the purposes for which the award was used, including authorizations, obligations, unobligated balances, assets, liabilities, outlays or expenditures, and any program income. The system must also enable the recipient and subrecipient to compare actual expenditures or outlays with the approved budget for the award. SAMHSA funds must retain their award/subaward-specific identity and may not be commingled with non-federal funds or other federal funds. "Commingling funds" typically means depositing or recording funds in a general account without the ability to identify each specific source of funds with related expenditures. Common mistakes related to comingling are outlined below:

- ***Commingling of Cost Centers***: Every business activity constitutes a cost center. Examples of cost centers include: a federal award, a state award, a private award, matching costs for a specific award, a self-funded project, fundraising activities, membership activities, lines of business, unallowable costs, indirect costs, etc. Recipients and subrecipients must establish a unique account(s) in the accounting system to capture and accumulate expenditures of each cost center, apart from other cost centers.
- ***Commingling of Cost Categories***: Recipients and subrecipients must avoid budget fluctuations that violate programmatic restrictions. They must also avoid applying indirect cost rates to prohibited cost categories, such as equipment, participant support costs and subcontracts/subawards in excess of $25,000. As a result, recipients must establish unique object codes in the accounting system to capture and 59 accumulate costs by budget category (i.e., salaries, fringe benefits, consultants, travel, participant support costs, subcontracts, etc.).
- ***Commingling of Time Worked and Not Worked***: Recipients and subrecipients may not directly charge an award for employees' time not spent working on the award. Therefore, Paid Time Off (PTO), such as vacation, holiday, sick and other paid leave, is not recoverable directly from awards, but rather must be allocated to all awards, projects, and cost centers over an entire cost accounting period through either an indirect cost or fringe benefit rate.
- ***Unsupported Labor Costs***: To support charges for direct and indirect salaries and wages, recipients and subrecipients maintaining hourly timesheets must ensure that timesheets encompass all hours worked and not worked on a daily basis. The timesheet should identify the: (a) award, project or cost center being worked on; (b) number of hours worked on each; (c) description of work performed; and (d) Paid Time Off (PTO) hours. The total hours recorded each

day should coincide with an individual's employment status in accordance with established policy (i.e., fulltime employees work 8 hours each day, etc.).

- ***Inconsistent Treatment of Costs***: Recipients and subrecipients must treat costs consistently across all federal and non-federal awards, projects, and cost centers. For example, recipients and subrecipients may not direct-charge federal awards for costs typically considered indirect in nature, unless done consistently. Examples of indirect costs include administrative salaries, office rent, accounting fees, utilities, etc. Additionally, in most cases, the cost to develop an accounting system adequate to justify direct charging of the aforementioned items outweighs the benefits. As a result, use of an indirect cost rate is the most effective mechanism to recover these costs and not violate federal financial requirements of consistency, allocability and allowability. If typical indirect cost categories are included in the budget as direct costs, it is SAMHSA's understanding that the recipient or subrecipient has developed a cost accounting system that can withstand audit scrutiny and therefore the system must be adequate to justify the direct charges and to avoid an unfair allocation of these costs to the federal government. All costs are subject to subsequent agency review and/or audit scrutiny in accordance with awards' terms and conditions.

Trafficking in Persons

Awards issued by SAMHSA are subject to the requirements of 2 CFR part 175 and 22 USC 7104(g). For the full text of the award term, go to http://www.samhsa.gov/grants/grants-management/notice-award-noa/standard-terms-conditions.

NOTE: The signature of the AOR on the application serves as the required certification of compliance for your organization regarding the administrative and national policy requirements.

Publications

Recipients are required to notify the Government Project Officer (GPO) of any materials based on the SAMHSA-funded project that are accepted for publication. In addition, SAMHSA requests that recipients:

- Provide the GPO with advance copies of publications.
- Include acknowledgment of the SAMHSA program as the source of funding for the project.
- Include a disclaimer stating that the views and opinions contained in the publication do not necessarily reflect those of SAMHSA or the U.S. Department of Health and Human Services and should not be construed as such.

SAMHSA reserves the right to issue a press release about any publication deemed by SAMHSA to contain information of program or policy significance to the substance use treatment/substance use prevention/mental health services community.

Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment

As described in 2 CFR 200.216, recipients and subrecipients are prohibited to obligate or spend award funds (to include direct and indirect expenditures as well as cost share and program) to:

(1) Procure or obtain,

(2) Extend or renew a contract to procure or obtain; or

(3) Enter into contract (or extend or renew contract) to procure or obtain equipment, services, or systems that use covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. As described in Pub. L. 115-232, section 889, covered telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).

i. For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).

ii. Telecommunications or video surveillance services provided by such entities or using such equipment.

iii. Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise, connected to the government of a covered foreign country.

Appendix L – Sample Budget and Justification

All applications must have a detailed budget justification and narrative that explains the federal and the non-federal expenditures broken out by the object class cost categories listed on SF-424A – Section B (Budget Category) for non-construction awards.

- The detailed budget must match the costs identified on the SF-424A and the total costs on the SF-424.
- The Budget Narrative and justification must be consistent with and support the Project Narrative.
- The Budget Narrative and justification must be concrete and specific. It must provide a justification for the basis of each proposed cost in the budget and how that cost was calculated. Examples to consider when justifying the basis of your estimates can be ongoing activities, market rates, quotations received from vendors, or historical records. The proposed costs must be reasonable, allowable, allocable, and necessary for the supported activity.
- NOFOs invite applications for periods of performance of one to up to five years. Generally, awards, on a competitive basis, will be for a one-year budget period but the period of performance may be up to five years. Submission and SAMHSA approval of the progress report(s) and any other required submission or reports is the basis for the budget period renewal and release of subsequent year funds. Funding beyond the one-year budget period but within the multi-year period of performance is subject to availability of funds and satisfactory progress of the recipient. Progress will be evaluated by submission of data on required performance measures, satisfactory achievement of identified goals and objectives, providing services to the projected number of individuals specified in the application, and satisfactory resolution of barriers and challenges that arise in the implementation of the project.
- Refer to the program specific Funding Restrictions/Limitations and the Standard Funding Restrictions in the NOFO, as well as to 45 CFR Part 75 (https://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75, for applicable administrative requirements and cost principles.

SAMHSA Budget Template

To expedite review of your application, it is highly recommended you use the following PDF budget template to complete the Detailed Budget and Narrative Justification for submission with your application:

- The budget template can be found on the SAMHSA Forms and Resources webpage – scroll down to "**SAMHSA Budget Template**" section. You **must**

download the budget template PDF to your computer first before opening it directly in Adobe Acrobat or Acrobat Reader (not your internet browser):

1. Right-click the link "**SAMHSA Budget Template (PDF)**"
2. Select "save link as" and save to a location on your computer
3. Go to the saved location and open the "SAMHSA Budget Template (PDF)" using Adobe Acrobat or Acrobat Reader.

Guidance

The following documents provide guidance on using the budget template:

- Key Features of the Budget Template
- Budget Template Users Guide
- Budget Review Checklist – use this checklist to review your detailed budget and narrative justification before submission to SAMHSA.

Note: For SAMHSA to view all of your budget data, you must convert the PDF to a non-editable format by **PRINTING TO PDF** before submission.

Sample Budgets

The following PDFs are samples of detailed budgets and narrative justification:

- Sample SF-424 - New Awards (PDF | 1.3 KB)
- Sample Budget – NON-MATCH (PDF | 697 KB)
- Sample Budget – MATCH (PDF |729 KB)

Completing the SF-424A (see Section IV)

Budget Cost Categories

Personnel Costs: Explain personnel costs by listing each staff member who will be working directly on the award by name (if possible), position title, percentage level of effort or proposed hours and annual salary. Award funds may not be used to pay the salary of an individual at a rate in excess of Executive Level II or **$203,700**. An individual's base salary, per se, is NOT constrained by the statutory provision for a limitation of salary. The rate limitation simply limits the amount that may be awarded and charged to SAMHSA awards and cooperative agreements. The salary limitation does not apply to consultants but does apply to all subawards and subcontracts.

Note: If an organization is selected for an award and chooses to move forward with hiring an individual for a Key Personnel position before receiving SAMHSA's formal approval, this will be done at the organization's own risk. If SAMHSA's review of the Key Personnel request results in the proposed individual not being approved or deemed not qualified for the position, the expectation is that the organization must submit a qualified candidate to be placed in the Key Personnel position. SAMHSA will not be liable for any costs incurred or pay for salaries of a Key Personnel that is not approved or deemed not qualified for the program.

Fringe Benefits: Fringe benefits typically include items, such as health insurance, taxes, unemployment insurance, life insurance, retirement plans, tuition reimbursement and paid absences. Fringe benefits are recoverable in accordance with an organization's federally approved indirect cost rate agreement, if applicable, or the organization's accounting practices, provided those practices are consistent with federal cost principles and result in a fair and equitable allocation of fringe benefits.

Travel: List travel costs according to local and long-distance travel. For local travel, outline the mileage rate, number of miles, reason for travel and staff member/consumers completing the travel. The budget should also reflect the travel expenses (e.g., airfare, lodging, parking, per diem, etc.) for each person and trip associated with participating in meetings and other proposed trainings or workshops. Name the traveler(s) if possible, describe the purpose of the travel, provide number of trips involved, the destinations, and the number of individuals for whom funds are requested.

Equipment: List equipment costs and provide justification for the need of the equipment to carry out the program's goals. Extensive justification and a detailed status of current equipment must be provided when requesting funds for the purchase of items that meet the definition of equipment (a unit cost of $5,000 or more and a useful life of one or more years). For example, large items of medical equipment.

Supplies: Include the programmatic items necessary to implement the proposed project (e.g., examination gloves, etc.). Conversely, general office supplies (e.g., paper, pencils, etc.) should be recovered through a federally approved indirect cost rate or de minimis rate.

Per 45 CFR § 75.321, property will be classified as supplies if the acquisition cost is under $5,000. Note that items such as laptops, tablets, and desktop computers are classified as a supply if the value is under the $5,000 equipment threshold.

Vendor Contracts/Subawards & Subcontracts/Consortiums/Consultants: Provide a clear explanation as to the purpose, the basis for how costs were estimated, and the specific deliverables. You are responsible for ensuring that your organization has adequate procurement and merit review systems with fully developed written procedures for awarding and monitoring vendor contracts and subawards/subcontracts, respectively.

Recipients must notify potential subrecipients to register in SAM and provide the recipient with their UEI number (see 2 CFR part 25). For consultant services, list the total costs for all consultant services. In the budget narrative, identify each consultant, the services he/she will perform, total number of days, travel costs, and total estimated costs.

Note: To assist with classifying costs and relationships, note that vendor contracts are for the purpose of obtaining goods and services (i.e., examination gloves provided by a medical supply company). Conversely, subawards/subcontracts are for the purpose of carrying out a portion of a federal award (i.e., a health care clinic providing substance use treatment services directly to patients). Your organization must ensure proper classification of costs and relationships. For subrecipient relationships, your organization must ensure written subaward/subcontract agreements are in place. These written agreements must require that subrecipients comply with the same terms and conditions as the prime recipient, as applicable (i.e., financial management requirements, audit requirements, etc.) In other words, the requirements imposed on the prime recipient must "flow down" to subrecipients. Written agreements should also describe the scope of work, deliverables, etc.

Other: Include all costs that do not fit into any other category and provide an explanation of each cost in this category (e.g., provider licenses, dedicated space rental, etc.).

Indirect Costs: Indirect costs are those costs incurred for common or joint objectives which cannot be readily and specifically identified with a particular project or program but are necessary to the operations of the organization, e.g., the cost of operating and maintaining facilities, depreciation, and administrative salaries. For some institutions, the term "facilities and administration" (F&A) is used to denote indirect costs.

Applicants may request full indirect costs, subject to statutory and regulatory limitations.

Applicants may request full indirect costs, subject to statutory and regulatory limitations, and submission of an approved Negotiated Indirect Cost Rate Agreement (NICRA) established by the cognizant Federal agency (typically the agency that provides the most funds). If indirect costs are claimed, a copy of the NICRA must be submitted with the application. If unable to obtain a NICRA from the cognizant agency at the time of application, the applicant may elect to recover indirect costs using a de minimis rate as explained below. Otherwise, the applicant may only be reimbursed for allowable direct costs. Violation of cost accounting principles is not permitted when re-budgeting or charging costs to awards. Rather, costs must be consistently charged as either indirect or direct costs.

Applicants may elect a 10% de minimis indirect cost rate, subject to statutory and regulatory limitations.

Applicants who cannot obtain a NICRA from their cognizant Federal agency at the time of application may elect a 10% de minimis rate, subject to statutory and regulatory limitations.

The 10% *de minimis* rate may be used indefinitely and should be applied to Modified Total Direct Costs (MTDC). MTDC means all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and up to the first $25,000 of each subaward (regardless of the period of performance of the subawards under the award.) MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward in excess of $25,000. Violation of cost accounting principles is not permitted when charging costs to awards. Rather, costs must be consistently charged as either direct or indirect costs. Additionally, once elected, the 10% *de minimis* rate must be applied to all existing awards. If the cognizant agency issues a NICRA subsequent to the award, the negotiated rate may *not* be retroactively applied.

Waived Indirect Costs – An applicant may elect *not* to request recovery of indirect costs. If so, the applicant should write *None Requested* in the same space allotted for Item J of the budget sheet.

Exhibit D

SAMHSA

Substance Abuse and Mental Health Services Administration

Additional Directives

All grantees must abide by the Trafficking Victims Protection Act, follow funding prohibitions against ACORN, and review SAMHSA's incentive policies.

Trafficking Victims Protection Act of 2000

The Trafficking Victims Protection Act of 2000 is a comprehensive federal law that was enacted to protect victims of trafficking or to prosecute their traffickers.

All SAMHSA grantees are required to abide by the award term that implements Section 106 (g) of the Trafficking Victims Protection Act of 2000, as amended (22 USC 7104). The award term is now located at 2 CFR Part 175.

Association of Community Organizations for Reform Now (ACORN)

In accordance with guidance provided by the Department of Health and Human Services, funding prohibitions regarding the Association of Community Organizations for Reform Now (ACORN) and related entities remain in effect pending further litigation as to ACORN's First Amendment and due process claims.

All SAMHSA grantees are required to abide by these prohibitions (PDF | 1 MB).

Incentives

"Incentives" refer to any monetary or service benefit that you provide to program participants to attract and retain them in the service or

prevention program. The dictionary defines "incentive" as "something that encourages or motivates somebody to do something."

SAMHSA discretionary grant funds may be used for non-cash incentives.

Only Non-Cash Incentives Before and After Programs

Non-cash incentives to participants in treatment and prevention programs are essential to retain individuals and to encourage attendance and attainment of treatment or prevention goals. You must build all the non-cash incentives into the program design, and they should be of minimal cash value.

Do not use discretionary grant funds to make direct cash payments to individuals during the treatment or prevention program.

SAMHSA policy supports the appropriate, judicious, and conservative use of incentives in discretionary grant programs. Incentives should be the minimum amount necessary to meet the program and evaluation goals of the grant, **up to $30**. You should determine the minimum amount to be effective as follows:

Before the Program: You may not use discretionary grant funds to make direct payments to individuals to induce them to enter treatment or prevention programs.

During the Program: You may use discretionary grant funds for "wrap-around services" (non-clinical supportive services) that intend to:

- Improve an individual's access to and retention in treatment that is deemed essential to meeting program goals as they relate to the target population
- Improve access to and retention in prevention programs
- Meet abstinence benchmarks

After the program: SAMHSA allows for discretionary grant funds to be used for incentives (not to exceed a cash value of $30) for individuals to participate in required data collection follow-up.
Last Updated: 10/06/2022

Source: https://www.samhsa.gov/grants/grants-management/policies-regulations/additional-directives

Exhibit E

HHS

Grants Policy Statement

U.S. Department of Health and Human Services
Office of the Assistant Secretary for Resources and Technology
Office of Grants

January 1, 2007

Introduction

The Department of Health and Human Services Grants Policy Statement (HHS GPS) is intended to make available in a single document the general terms and conditions of HHS discretionary grant and cooperative agreement awards. These general terms and conditions are common across all HHS Operating Divisions (OPDIVs)[1] and apply as indicated in the HHS GPS unless there are statutory, regulatory, or award-specific requirements to the contrary (as specified in individual Notices of Award). The HHS awarding offices are components of the OPDIVs and Staff Divisions (hereafter "OPDIVs") that have grant-awarding authority.

This document also is designed to be useful to those interested in the HHS grants process by providing information about that process and its associated authorities and about responsibilities. The HHS GPS is available online from the HHS home page at http://www.hhs.gov/grantsnet.

HHS GPS Organization

The HHS GPS has four parts and an appendix, which allow general information, application information, and other types of reference material to be separated from legally binding terms and conditions:

- *Part I: HHS Grants Process.* Part I describes the OPDIVs, their role, and the roles of other HHS organizations in HHS grants; specifies recipient and HHS staff responsibilities; outlines the grant application and review processes; and explains the various resources available to those interested in the HHS grants process.

- *Part II: Terms and Conditions of HHS Grant Awards.* Part II includes generally applicable terms and conditions. This part also specifies the terms and conditions that apply to particular types of grants, recipients, and activities that differ from, supplement, or elaborate on the general terms and conditions.

- *Part III: Points of Contact.* Part III lists pertinent offices and officials with their addresses and telephone numbers.

- *Part IV: OPDIV-Specific Information and Terms and Conditions.* Part IV, which supplements Parts I, II, and III for a given OPDIV, contains any OPDIV supplementary information and OPDIV-specific terms and conditions of award. This includes statutory, regulatory, or public policy requirements that apply only to that OPDIV or its programs. OPDIV-specific terms and conditions in Part IV take precedence if they conflict with requirements in Part II of the HHS GPS.

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[1] As indicated under "Applicability," the National Institutes of Health (NIH) maintains its own Grants Policy Statement. While the requirements of both policy statements are equivalent, the NIH GPS addresses only research and research-related matters as well as requirements that apply only to NIH.

- *Appendices:* The appendices include all abbreviations and a glossary of terms used throughout the HHS GPS for ease of reference.

Supersession and Applicability

Supersession

Applicants for HHS grants and recipients have historically relied on a variety of sources for information about the grants processes and requirements of HHS and its component OPDIVs. For the recipients of grants from the OPDIVs constituting the Public Health Service (PHS), the primary source of information for recipients was the *Public Health Service Grants Policy Statement*. This HHS GPS supersedes in its entirety the *Public Health Service Grants Policy Statement*, dated April 1, 1994, and addendum, dated January 24, 1995.

Applicability

This policy statement applies only to HHS discretionary grant programs and only to awards to organizational entities made by OPDIVs other than the National Institutes of Health (NIH). It does not apply to awards under mandatory grant programs (e.g., entitlement programs) or to awards made directly to individuals (e.g., scholarships). In 1998 (and with subsequent updates), NIH issued its own NIH Grants Policy Statement. Until further notice, NIH will continue to issue and maintain its own Grants Policy Statement in lieu of the HHS GPS.[2]

Recipients are not directly subject to the requirements of HHS Grants Policy Directives and implementing HHS Grants Administration Manuals (or any predecessor OPDIV manuals), which are internal documents guiding HHS operations. If an OPDIV implements a requirement in an internal document that does affect recipients, it will not do so by citing that document; rather, the requirement is placed on the recipient through explicit coverage in the NoA.

Cooperative Agreements

The Federal Grant and Cooperative Agreement Act of 1977, 31 U.S.C. 6301, defines the cooperative agreement as an alternative assistance instrument to be used in lieu of a grant whenever substantial Federal involvement with the recipient during performance is anticipated. The difference between grants and cooperative agreements is the degree of Federal programmatic involvement rather than the type of administrative requirements imposed. Therefore, statutes, regulations, policies, and the information contained in this policy statement that are applicable to grants also apply to cooperative agreements, unless the award itself provides otherwise.

[2] This HHS GPS is issued as a preliminary step by HHS to standardize and streamline award terms and conditions. Once there are government-wide changes under the Federal Financial Assistance Management Improvement Act of 1999, 31 U.S.C. 6101 note, HHS will use this document to reflect those changes.

Subrecipients and Contractors under Grants

The information contained in this policy statement applies directly to the primary recipients of HHS funds. The HHS GPS indicates in Part II whether requirements must be applied to or "flowed down" to subawards or contracts under grants. Recipients are responsible for specifying those requirements in subawards (which includes consortium agreements) or contracts, as applicable.

Effective Date

This document is effective for all new, competing continuation, and non-competing continuation HHS grant and cooperative agreement awards with beginning dates on or after January 1, 2007. This document reflects current HHS requirements as specified in 45 CFR parts 74 and 92.

The information in this document is subject to change following its issuance due to changes in statutes, regulations, or policies adopted subsequent to its effective date. To ensure that applicants and recipients are aware of changes, recipients should refer to the *Federal Register* and Code of Federal Regulations (Titles 45 and 42). These documents are available online at http://www.gpoaccess.gov/.

Conventions

Certain conventions are followed throughout this document. The term "grant" is used to mean both grants and cooperative agreements; however, for clarity, certain sections mention both grants and cooperative agreements. The term "recipient" generally is used to refer to the organization to which an OPDIV makes a grant or cooperative agreement award. However, depending on the context, the terms "grantee" may be used rather than "recipient." "HHS" may be used in this document to refer to the entire organization or to its component organizations, or else to contrast an action by an OPDIV with an action by a recipient or other organization. A reference to Part I, II, III, or IV without further elaboration means the corresponding part of the HHS GPS. Although most of the requirements in the HHS GPS apply to the covered activities of all OPDIVs, if a requirement applies more narrowly, the exception is explicitly noted.

Maintenance

The Office of Grants—part of the HHS Office of the Assistant Secretary for Resources and Technology—is responsible for developing and maintaining this document, which will be reissued periodically. Interim changes will be posted on the HHS and OPDIV Web sites (see Part I). Each change, including its applicability and effective date and the affected sections of the HHS GPS specified, will be described, and the necessary language to implement it as a term or condition of award will be provided. The Office of Grants welcomes comments and suggestions for future versions of the HHS GPS.

Table of Contents

Part I: HHS Grants Process

General Information

This section provides information about how HHS is organized to award and administer grants and cooperative agreements. This section describes the roles of organizations within HHS with responsibilities for the HHS grants process, as well as organizations external to HHS that have a role in that process.

HHS is the Federal government's principal agency for protecting the health of Americans and providing essential human services, especially for those who are least able to help themselves. In support of its mission, HHS awards grants under more than 300 programs, making it the largest grant-awarding agency in the Federal government.

HHS Grant-Awarding Operating Divisions (OPDIVs)

HHS grant programs are the responsibility of 12 OPDIVs (see Exhibit 1).

Exhibit 1. OPDIVs with Responsibilities for HHS Grant Programs

OPDIV	Mission
Administration for Children and Families	ACF is responsible for programs that promote the economic and social well-being of children, families and communities. Administers the State-Federal welfare program, Temporary Assistance for Needy Families, providing assistance to an estimated 5 million people, including 4 million children. Administers the national child support enforcement system. Administers the Head Start program, serving more than 900,000 preschool children. Provides funds to assist low-income families in paying for child care, and supports State programs to support foster care and provide adoption assistance. Funds programs to prevent child abuse and domestic violence. http://www.acf.dhhs.gov/
Administration on Aging	AoA supports a nationwide aging network, providing services to the elderly, especially to enable them to remain independent. Supports close to 240 million meals for the elderly each year, including home-delivered "meals on wheels." Helps provide transportation and at-home services. Supports ombudsman services for the elderly, and provides policy leadership on aging issues. http://www.aoa.dhhs.gov
Agency for Healthcare Research and Quality	AHRQ supports research to improve the quality, safety, efficiency, and effectiveness of health care for all Americans. http://www.ahrq.gov
Office of the Assistant Secretary for Planning and Evaluation	The ASPE is the principal advisor to the Secretary of HHS on policy development and is responsible for major activities in policy coordination, legislation development, strategic planning, policy research, evaluation, and economic analysis. http://aspe.hhs.gov/_/index.cfm

Exhibit 1. OPDIVs with Responsibilities for HHS Grant Programs

OPDIV	Mission
Centers for Disease Control and Prevention	Working with States and other partners, CDC provides a system of health surveillance to monitor and prevent disease outbreaks (including bioterrorism), implement disease prevention strategies, and maintain national health statistics. Provides for immunization services, workplace safety, and environmental disease prevention. Working with the World Health Organization, CDC also guards against international disease transmission, with personnel stationed in more than 25 foreign countries. CDC helps prevent exposure to hazardous substances from waste sites on the U.S. Environmental Protection Agency's National Priorities List, and develops toxicological profiles of chemicals at these sites through the Agency for Toxic Substances and Disease Registry. http://www.cdc.gov
Centers for Medicare and Medicaid Services	CMS administers the Medicare and Medicaid programs, which provide health care to about one in every four Americans. Medicare provides health insurance for more than 41 million elderly and disabled Americans. Medicaid, a joint Federal-State program, provides health coverage for some 44 million low-income persons, including 19 million children, and nursing home coverage for low-income elderly. CMS also administers the State Children's Health Insurance Program that covers more than 4.2 million children. http://www.medicare.gov, http://www.cms.gov
Food and Drug Administration	FDA ensures the safety of foods and cosmetics, and the safety and efficacy of pharmaceuticals, biological products, and medical devices, products which represent almost 25 cents out of every dollar in U.S. consumer spending. http://www.fda.gov
Health Resources and Services Administration	HRSA provides access to essential health care services for people who are low-income, uninsured, or live in rural areas or urban neighborhoods where access to or availability of health care is limited. HRSA-funded health centers provide medical care to more than 13 million patients each year at more than 3,600 sites nationwide. HRSA also helps prepare the nation's health care system and providers to respond to bioterrorism and other public health emergencies, is responsible for the National Health Service Corps, and helps build the health care workforce through many training and education programs. HRSA administers a variety of programs to improve the health of mothers and children and serves people living with HIV/AIDS through the Ryan White CARE Act programs. HRSA also oversees the nation's organ transplantation system. http://www.hrsa.gov
Indian Health Service	IHS is the principal Federal health care provider and health advocate for Indian people, and its goal is to raise their health status to the highest possible level. http://www.ihs.gov
National Institutes of Health	NIH is the world's premier medical research organization. Its mission is to improve human health by increasing scientific knowledge related to disease and health. NIH carries out its mission through the conduct of intramural and extramural support of biomedical and behavioral research, research training, research infrastructure, and communications. NIH makes extramural awards though its Institutes and Centers. http://www.nih.gov

Exhibit 1. OPDIVs with Responsibilities for HHS Grant Programs

OPDIV	Mission
Office of Public Health and Science	OPHS is located within the Office of the Assistant Secretary for Health, who is the primary adviser to the Secretary, HHS on matters involving the nation's public health and oversees the U.S. Public Health Service (PHS). OPHS includes several offices—Office of Minority Health, Office of Population Affairs, and Office of Disease Prevention and Health Promotion. http://www.osophs.dhhs.gov/ophs/
Substance Abuse and Mental Health Services Administration	SAMHSA works to improve the quality and availability of substance abuse prevention, addiction treatment, and mental health services. Provides funding through block grants to States to support substance abuse and mental health services, including treatment for more than 650,000 Americans with serious substance abuse problems or mental health problems. Helps improve substance abuse prevention and treatment services through the identification and dissemination of best practices. Monitors prevalence and incidence of substance abuse. http://www.samhsa.gov

There are several references throughout the HHS GPS to "PHS OPDIVs." Unless otherwise specified for a specific requirement, the PHS OPDIVs include the following: AHRQ, CDC, FDA, HRSA, IHS, OPHS, and SAMHSA. NIH also is a PHS OPDIV; however, the requirements that apply to NIH grants are included in the NIH Grants Policy Statement.

Types of HHS Financial Assistance Programs

HHS financial assistance programs reflect a breadth of programmatic activity, consistent with the mission of each OPDIV. Activities are carried out under a variety of types of grants as well as by use of cooperative agreements. HHS generally classifies its financial assistance programs in two major categories of grants—discretionary and mandatory. Discretionary grants are those for which the OPDIV may exercise judgment ("discretion") in determining the recipient and the amount of the award. Discretionary grants may be further categorized by purpose (for example, research, training, services, construction, and conference support). Generally such awards are made following a competitive process. Mandatory grants are those that an OPDIV is required to award if the recipient (usually a State) submits an acceptable plan or application and meets the statutory and regulatory eligibility and compliance requirements for the program. Mandatory grants include block grants and entitlement grants.

When an OPDIV expects to be substantially involved in carrying out the project/program, it awards a cooperative agreement rather than a grant. Substantial involvement pertains to programmatic involvement rather than administrative oversight.

These distinctions help in determining the appropriate relationship between the OPDIV and the recipient and in determining which governing requirements apply. In general, discretionary grants are subject to more detailed programmatic and administrative requirements than block grants, which afford States a significant degree of programmatic and administrative discretion within broad guidelines. However, even within discretionary grants, a range of potential requirements may

apply depending on the type of recipient and the nature of the programmatic activity. For example, different requirements apply to university-based research grants than to community-based services grants. The applicable requirements are communicated to potential recipients as part of the funding opportunity announcement process and also are observed as part of the award and post-award administration processes.

Sources of Requirements

This policy statement is based on generally applicable public laws and Executive orders, OMB circulars and the HHS implementation of them, and HHS-specific policies and procedures applicable to discretionary grants and cooperative agreements. Among these are the regulations that implement OMB Circular A-102 (applicable to grants to State, local, and Indian tribal governments) and OMB Circular A-110 (applicable to grants to institutions of higher education, hospitals, and other non-profit organizations), reissued as 2 CFR part 215, and OMB circulars incorporated in them—the OMB cost principles and single audit circular. These regulations are codified at 45 CFR part 74[3] (Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Non-Profit Organizations, and Commercial Organizations) and 45 CFR part 92 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local, and Tribal Governments). These requirements provide the framework for the terms and conditions of OPDIV awards as specified in Part II and apply generally; however, where applicable, differences based on grant purpose or type of recipient will be highlighted. In addition, grants are awarded and administered under a variety of programmatic authorities (established in statute and program regulations) and under OPDIV and award-specific requirements. Part II also addresses the relationship among these differing types of requirements. Part IV includes OPDIV requirements that differ from those in Part II of the HHS GPS. The NoA includes any requirements that are specific to that award.

Roles and Responsibilities

HHS, as a Federal grantor agency, is responsible to Congress and the U.S. taxpayer for carrying out its mission cost-effectively and in compliance with applicable requirements. HHS seeks to ensure integrity and accountability in the award and administration of grants by relying on a system of checks and balances and separation of responsibilities within its own staff and by establishing a similar set of expectations for recipient organizations. The recipient's roles and responsibilities have assumed greater importance as HHS has shifted to increased reliance on systems compliance and provided greater decision-making authority to recipients.

[3] Currently, the HHS implementation of OMB Circular A-110 continues to be 45 CFR part 74 even with the publication of A-110 in Title 2 of the CFR (2 CFR part 215).

The following sections highlight the major functions and areas of responsibility of Federal and recipient offices and staffs. HHS recognizes that additional staff members in a number of different organizations may be involved in grant-related activities; however, this section details only the major participants representing the Federal government and the recipient.

Roles and Responsibilities of OPDIV Staff Members and Other HHS Offices

The roles and responsibilities of HHS participants are as follows:

- *Grants Management Officer.* The GMO is the OPDIV official whose name appears on the NoA and is the official responsible for the business management and other non-programmatic aspects of an award. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with statutes, regulations, and guidelines; negotiating awards; providing consultation and technical assistance to applicants and recipients, including interpretation of grants administration policies and provisions; and administering and closing out grants. The GMO is the focal point for receiving and acting on requests for prior approval or for changes in the terms and conditions of award. The GMO is the only official authorized to obligate the OPDIV to the expenditure of Federal funds or to change the funding, duration, or other terms and conditions of an award. OPDIVs may have one or more GMOs with responsibility for particular programs or awards. The GMO works closely with his or her counterparts at the recipient organization and with the designated HHS PO.

- *Grants Management Specialist.* The GMS is an OPDIV employee with assigned responsibility for the day-to-day management of a portfolio of OPDIV grants. The GMS performs many of the activities described above on behalf of the GMO and usually is the primary point of contact for the recipient when dealing with grant-related issues.

- *Project Officer/Program Official.* The PO is the OPDIV official responsible for the programmatic, scientific, and/or technical aspects of assigned applications and grants. The PO's responsibilities include, but are not limited to, development of programs to meet the OPDIV mission; preparation of funding opportunity announcements; provision of programmatic technical assistance; post-award monitoring of project/program performance, including review of progress reports and making site visits; and other activities complementary to those of the GMO. The PO and the GMO work as a team in many of these activities.

- *Review Administrator.* In some OPDIVs, RAs manage application review activities for discretionary grants. The RA, who may be an employee of the funding OPDIV, another OPDIV that provides review services, or a contractor, reviews applications for completeness and conformity to requirements; ensures that an adequate number of reviewers with appropriate expertise is available for application review; and assigns applications to individual reviewers.

- *Other HHS Functions.* In addition to the GMO and PO, an applicant or recipient may be required to interact with other HHS staff members or offices with respect to its organization-wide systems and/or individual transactions. These include the office responsible for negotiating indirect cost rates (known as "facilities and administrative costs" for some organizations) and research patient care rates, typically the responsible[4] DCA office or NIH's DFAS; the HHS OIG; the Assistant Secretary for Resources and Technology's Division of Financial Systems, Payment Integrity, and Audit Resolution; OHRP; OLAW; DPM; and ORI. Staff members in these offices generally coordinate with the GMO on grant-related matters, but they are responsible for discrete areas of specialization and are not required to channel their communications with the applicant or recipient through the GMO. Part III of this policy statement includes a list of these organizations and contact information.

Roles and Responsibilities of Recipients and Their Principals

HHS grant awards generally are made to organizations. The organization is legally accountable for the performance of the award and the expenditure of funds. The roles and responsibilities of designated individuals at recipient organizations, who serve as agents of the recipient, are as follows:

- *Authorized Organizational Representative.* The authorized organizational representative is the designated representative of the applicant/recipient organization with authority to act on the organization's behalf in matters related to the award and administration of grants. In signing a grant application, this individual agrees that the organization will assume the obligations imposed by applicable Federal statutes and regulations and other terms and conditions of the award, including any assurances, if a grant is awarded. These responsibilities include accountability both for the appropriate use of funds awarded and the performance of the grant-supported project or activities as specified in the approved application. Although HHS requires that the recipient organization designate such an individual, HHS does not specify the organizational location or full set of responsibilities for this individual.

- *Principal Investigator/Program or Project Director.* The PI/PD is the individual, designated by the recipient, responsible for the scientific, technical, or programmatic aspects of the grant and for day-to-day management of the project or program. The PI/PD generally is an employee of the recipient. However, because the grant, if awarded, is made to the recipient organization, if the PI/PD is not an employee of that organization, the organization must have a formal written agreement with the PI/PD that specifies an official relationship between the parties even if the relationship

[4] The responsible DCA office generally is determined on the basis of geographical location.

does not involve a salary or other form of remuneration. If the PI/PD is not an employee of the applicant organization, the OPDIV will assess whether the arrangement will result in the organization being able to fulfill its responsibilities under the grant, if awarded.

The PI/PD is a member of the recipient team responsible for ensuring compliance with the financial and administrative aspects of the award. This individual works closely with designated officials within the recipient organization to create and maintain necessary documentation, including both technical and administrative reports; prepare justifications; appropriately acknowledge Federal support in publications, announcements, news programs, and other media; and ensure compliance with other Federal and organizational requirements. The PI/PD is encouraged to maintain contact with the PO with respect to the scientific, technical, or programmatic aspects of the project or program and, as applicable, the GMO concerning the business and administrative aspects of the award.

Organizations receiving HHS grant funds, whether such funds are received directly from an OPDIV, indirectly under a contract, subaward, or as student assistance under a training grant, are responsible for and must adhere to all applicable Federal statutes, regulations, and policies, including income tax regulations. Questions concerning the applicability of income tax regulations to grant funds should be directed to the IRS. Organizations also are expected to be in compliance with applicable State and local laws and ordinances.

Fraud, Waste, and Abuse

Anyone who becomes aware of the existence (or apparent existence) of fraud, waste, or abuse related to HHS grants or use of grant funds should report this information to HHS. The HHS OIG provides several means, including toll-free numbers, for this purpose. The OIG hotline may be reached by telephone at 1-800-HHS-TIPS (1-800-447-8477) or TTY at 1-800-377-4950; by fax at 1-800-223-8164; by e-mail at HHSTips@oig.hhs.gov; or by mail at Office of the Inspector General, Department of Health and Human Services, Attn: HOTLINE, 330 Independence Avenue, SW, Washington, DC 20201. Fraud, waste, and abuse includes, but is not limited to, embezzlement, misuse, or misappropriation of grant funds or property, and false statements, whether by organizations or individuals. Examples are theft of grant funds for personal use; using funds for non-grant-related purposes; theft of federally owned property or property acquired or leased under a grant; charging inflated building rental fees for a building owned by the recipient; submitting false financial reports; and submitting false financial data in bids submitted to the recipient (for eventual payment under the grant).

Callers are not required to give their names and, if they do, their identities are kept confidential. Contact information for the OIG and the OIG hotline also is included in Part III of this policy statement. In addition, some OPDIVs have a designated point of contact within the OPDIV for receiving information from third parties about administrative or programmatic concerns relating to an application or award. These contacts may be found in Part IV or on the OPDIV's Web site.

The Federal government may pursue administrative, civil, or criminal action under a variety of statutes that relate to fraud and false statements or claims. Even if a grant is not awarded, the applicant may be subject to penalties if the information

contained in or submitted as part of an application, including its certifications and assurances, is found to be false, fictitious, or fraudulent.

The Program Fraud and Civil Remedies Act of 1986, 31 U.S.C. 3801 *et seq.*, provides for the imposition by HHS of civil penalties and assessments against people who knowingly make false, fictitious, or misleading claims to the Federal government for money, including money representing grants, loans, or benefits. A civil penalty of not more than $5,000 may be assessed for each such claim. If a grant is awarded and payment is made on a false or fraudulent claim, an assessment of not more than twice the amount of the claim, up to $150,000, may be made in lieu of damages. Regulations at 45 CFR part 79 specify the process for imposing civil penalties and assessments, including hearing and appeal rights.

The Criminal False Claims Act, 18 U.S.C. 287 and 1001, provides for criminal prosecution of a person who knowingly makes or presents any false, fictitious, or fraudulent statements, representations, or claims against the United States. Violations carry a maximum sentence of 5 years imprisonment (or 8 years for offenses involving international or domestic terrorism) and/or a fine.

The Civil False Claims Act, 31 U.S.C. 3729(a), provides for imposition of penalties and damages by the United States, through civil litigation, against any person who knowingly makes a false or fraudulent claim for payment, makes or uses a false record or false statement to get a false claim paid or approved, or conspires to defraud the Federal government to get a false claim paid. A "false claim" is any request or demand for money or property made to the United States or to a contractor, grantee, or other recipient, if the Federal government provides or will reimburse any portion of the funds claimed. Civil penalties of $5,500 to $11,000 may be imposed for each false claim, plus damages of up to three times the amount of the false claim.

Part II of this policy statement addresses the administrative remedies included in 45 CFR parts 74 and 92 that the Federal government may use after award if a recipient deliberately withholds information, submits fraudulent information, or does not comply with applicable requirements. These remedies include recovery of misspent grant funds.

Paperwork Reduction Act

OMB clearance is required for OPDIV "information collections." An information collection occurs when identical questions are posed to, or identical reporting, recordkeeping, or disclosure requirements are imposed on, 10 or more people, whether the collection is mandatory, voluntary, or required to obtain or retain a benefit. All application or reporting forms, whether paper or electronic, that an OPDIV requires an applicant or recipient to complete and submit must receive OMB approval before the OPDIV may collect the information. Information collection under a cooperative agreement award or a grant award, under specified conditions, also requires OMB clearance. See Part II of this policy statement for OMB clearance requirements under the PRA.

Sources of Information about HHS Grant Processes and Programs

The *Catalog of Federal Domestic Assistance* is a government-wide publication available to members of the public that can be used to obtain general information about assistance programs. It is updated twice a year. A listing of current entries in the CFDA is available at http://www.cfda.gov/. HHS programs are found under the prefix 93.XXX.

Grants.gov FIND is a government-wide source of information about specific funding opportunities. HHS uses detailed funding opportunity announcements to invite applications for specific funding opportunities. Synopses of these announcements are posted at Grants.gov FIND. The "Application and Review Processes" section of this policy statement provides information about Grants.gov FIND and the types of HHS funding opportunity announcements.

HHS and its individual OPDIVs maintain a number of information resources about their grant programs and activities that can be accessed through their Web sites. Some are descriptive materials that enable interested parties to learn about OPDIV grant initiatives, funding opportunities, and proposed and actual policy changes. Others provide historical data. This information is updated periodically. The HHS Web site address for grant-related materials and links to OPDIVs is http://www.hhs.gov/grantsnet/.

Application and Application Review Processes

This section provides an overview of the following:

- Funding opportunity announcements
- Types of entities generally eligible to receive grants
- Types of applications
- The application submission process (including application forms, application receipt points and deadlines, and use of information in applications)
- The objective review of applications.

Several of these areas also pertain after award. For example, an organization must remain eligible in order to continue to receive funding. In addition, post-award changes may invoke requirements that in this section are identified as "application" requirements, e.g., undertaking an activity not contemplated at the time of award that might affect a historic property.

Grants.gov and Funding Opportunity Announcements

It is HHS policy to maximize competition for discretionary grants to the greatest extent practicable. As such, OPDIVs promote the widest and earliest possible dissemination of information for potential applicants concerning the availability of competing funding opportunities. A synopsis of each new competing funding opportunity is posted at Grants.gov FIND. Grants.gov FIND (http://grants.gov/applicants_grant_opportunities.jsp) is a government-wide

electronic site that includes, in a single place, postings of available Federal grant and other financial assistance opportunities. Each synopsis includes a brief description of the funding opportunity, eligibility requirements, cost sharing or matching requirements, application deadline date, and other information that allows a potential applicant to determine whether it wants to read the funding opportunity announcement to obtain further details about the funding opportunity.

All HHS funding opportunity announcements follow the standard government-wide format and must be available on the Internet.[5] Each synopsis is required to provide an electronic link to the full funding opportunity announcement. For HHS, that link may be to the OPDIV or a program Web site, the *Federal Register*, or the *NIH Guide for Grants and Contracts*. An OPDIV also may choose to issue a notice in the *Federal Register* that indicates the availability of the funding opportunity announcement and its location (e.g., directing the reader to the OPDIV or program Web site).

In addition, if the OPDIV can identify all eligible applicants, the OPDIV may send the funding opportunity announcement directly to each eligible organization (generally the business office with a copy to the PI/PD). This may be the case if a competition is limited to a certain class or group of eligible organizations (see "Eligibility" below); for example, a program may be limited, by statute, to States, or a funding opportunity may be limited to incumbent recipients, based on a justified limitation of competition. Synopses/funding opportunity announcements generally will allow applicants a minimum of 30 days to prepare and submit applications.

There are several types of authorized exceptions to the requirements for use of Grants.gov FIND, Internet posting of an announcement, and/or the maximum time to prepare an application. The authorization is provided on a case-by-case basis according to an internal HHS justification process. The recognized exceptions include applications for single-source awards and urgent applications.

A single-source application is one resulting from an OPDIV request to only one applicant. Urgent applications are ones required to fulfill immediate needs such as public health needs after a natural disaster. For urgent awards, which may be made on a single-source or limited-competition basis, OPDIVs are required to allow the maximum feasible time for application preparation.

Because single-source (including urgent single-source) applications do not represent competitive funding opportunities, information about them is not posted at Grants.gov FIND. When an awarding office anticipates making a single-source award, the OPDIV is required to publish in the *Federal Register* a notice of its intent to make the award prior to or simultaneous with issuance of the award.

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[5] The standard government-wide format was promulgated by the Office of Federal Financial Management, OMB, on June 23, 2003 (68 FR 37370).

Eligibility

Authorizing legislation and governing programmatic regulations specify eligibility for individual grant programs. In general, HHS grants may be awarded to domestic public or private, non-profit or for-profit organizations.[6] Eligible organizations may include State, local, and Indian tribal governments; institutions of higher education; other non-profit organizations (including faith-based, community-based, and tribal organizations); and hospitals. In some cases, grants also may be made to foreign or international organizations. Eligibility for a particular funding opportunity announcement is specified in the Grants.gov FIND synopsis, with more detailed eligibility information found in the funding opportunity announcement.

On the basis of a statute or regulation or a limitation, with appropriate justification, described in a funding opportunity announcement, an OPDIV may limit eligibility to, or exclude from eligibility, classes or types of entities. Examples are limitations on the participation of foreign entities, and programs under which only small businesses are eligible applicants. In addition to organizational eligibility, an OPDIV may include responsiveness criteria in a funding opportunity announcement. Responsiveness criteria are objective criteria, such as possessing a particular certification or, if specified by the OPDIV, not exceeding a stated page limitation. These are sometimes called "go-no-go" criteria.

The applicant may be required to provide proof of its status by submitting documentation. For non-profit entities, except where the grant program's authorizing statute sets particular limits, acceptable evidence of eligibility includes the following:

- A copy of a currently valid Internal Revenue Service tax exemption certificate
- A statement from a State taxing body, State attorney general, or other appropriate State official certifying that the applicant organization has a non-profit status
- A certified copy of the organization's certificate of incorporation or similar document that clearly establishes non-profit status
- Any of the above proof for a State or national parent organization and a statement signed by the parent organization that the applicant organization is a local non-profit affiliate.

Any requirements, such as citizenship, affecting the eligibility of the PI/PD or others (e.g., trainees) will be specified in the funding opportunity announcement (which may provide a link or reference to another document in which the requirements are found). For example, for career awards, the individual to be trained must be a citizen or a non-citizen national of the United States or have been lawfully admitted for permanent residence at the time of award. A non-citizen national is a person who, although not a citizen of the United States, owes permanent allegiance to the United States. They generally are individuals born in U.S. outlying possessions (American Samoa and Swains Island)

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[6] Section 1611 of Title 2 of the U.S.C. prohibits non-profit entities organized under (501)(c)(4) of the Internal Revenue Code that engage in lobbying activities from receiving Federal grants.

- on or after the date of formal acquisition of the possession, or

- to parents who are non-citizen nationals and have had a residence in the United States or one of its outlying possessions before the birth of that individual.[7]

In most cases, individuals are required to have the appropriate citizenship status when the award is made rather than when the application is submitted. For research grants, the applicant is required to determine that individuals identified as key personnel possess visas that will allow them to remain in this country long enough for them to be productive on the research project. Recipient organizations are expected to have policies, consistently applied regardless of the source of funds, to address this area. If a grant is awarded and an individual's visa will not allow a long enough stay to be productive on the project, the grant may be terminated. Trainees must have been lawfully admitted for permanent residence at the time of appointment. This must be documented by the individual's possession of an alien registration receipt card I-151 or I-551. Individuals on temporary or student visas are not eligible to receive training grant (or fellowship) support.

Upon receipt of applications, the awarding office performs an initial screening for eligibility. Unless an applicant is required to submit proof of eligibility, the authorized organizational representative's signature on the application generally serves as assurance that the applicant is eligible to apply for and receive an award (e.g., a small business applying under the SBIR or STTR programs). However, an awarding office may independently verify the applicant's status.

If an applicant is found to be ineligible or if the applicant or application does not meet published responsiveness criteria, the OPDIV will return the application without further review. If a grant is awarded, in the post-award phase, the OPDIV monitors changes in recipient and project status to ensure continued eligibility.

[7] Title 8 Section 1101(a)(29) of the U.S.C. includes an additional criterion that is not applicable to this eligibility determination.

Suspension and Debarment

HHS regulations published in 45 CFR part 76[8] implement the government-wide debarment and suspension requirements for HHS's non-procurement transactions. "Non-procurement transactions" include grants and cooperative agreements (as well as scholarships, fellowships, and loans). Organizations or individuals that are suspended, debarred, declared ineligible, or voluntarily excluded from eligibility for covered transactions by any Federal department or agency cannot, during the period of suspension, debarment, or exclusion, receive HHS grants or be paid from HHS grant funds, whether under a primary or lower-tier transaction. Because individuals who have been debarred, suspended, declared ineligible or who have been voluntarily excluded from covered transactions may not receive Federal funds for a specified period of time, charges made to HHS grants for such individuals (e.g., salary) are unallowable.

Applicants are required to disclose if any of the following conditions apply to them or their principals, including PIs and other key personnel:

- Within the 3-year period preceding the application, they have been convicted of, or had a civil judgment rendered against them for:
  - fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction;
  - violation of a Federal or State antitrust statute;
  - embezzlement, theft, forgery, bribery, falsification, or destruction of records; or
  - false statements or receipt stolen property.
- They are presently indicted or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated above.
- Within a 3-year period preceding the application, they have had any public transaction (Federal, State, or local) terminated for cause or default.

Disclosure of unfavorable information will not necessarily cause an OPDIV to return an application. If the applicant discloses unfavorable information, the application still may undergo objective review (see "Objective Review of Applications" in this section). If appropriate, the OPDIV will consider the information as part of the determination of whether to award a grant. The OPDIV also will consider any additional information or explanation that an applicant elects to submit with the disclosed information. If an awarding office makes an award and later determines that the recipient failed to disclose relevant information, the OPDIV may void the award, terminate the award for material failure to comply with the terms and

[8] Consistent with the OMB guidance on debarment and suspension in 2 CFR part 180, the regulations at 45 CFR part 76 will be superseded, for HHS, by 2 CFR part 376.

conditions of the award, or pursue any other available remedies, including suspension and debarment.

In addition to reviewing any information submitted by the applicant, the GMO will determine whether the applicant is included on the Excluded Parties Listing System maintained by GSA.[9] This system is a centrally maintained government-wide database that includes the names of organizations and individuals that have been debarred, suspended, declared ineligible, or been voluntarily excluded; the reasons for that status; and the duration of that status.

A variety of "lower-tier" transactions also are subject to these requirements. Contracts (including individual consultants) under grants (where the contract requires the provision of goods or services that will equal or exceed $25,000) and all subawards (including consortium agreements) also are subject to these suspension and debarment rules. A recipient is required to comply with the requirements of 45 CFR 76.300 through 76.365 as a condition of its award from HHS. The recipient must include a requirement in any covered transaction at the next lower tier to comply with those same regulatory provisions. One of those provisions is that, before entering into a covered transaction, the recipient or lower-tier participant must verify that the entity is not suspended or debarred or otherwise excluded. This requirement extends to trainees under an institutional training grant before their appointment. This verification may be accomplished by checking the Excluded Parties Listing System, collecting a certification from the organization or individual, or adding a clause or condition to the covered transaction with that entity.

Delinquency on Federal Debt

Any organization or individual that is indebted to the United States, and has a judgment lien filed against it for a debt to the United States, is ineligible to receive a Federal grant. Applicants are required to indicate in their applications if they are delinquent on any Federal debt. If the applicant discloses a delinquency, HHS may not award the grant until the debt is satisfied or satisfactory arrangements are made with the agency to which the debt is owed. In addition, once the debt is repaid or satisfactory arrangements made, an OPDIV will continue to take that delinquency into account when determining whether the applicant would be responsible with respect to an HHS grant, if awarded.

Anyone who has been judged to be in default on a Federal debt and who has had a judgment lien filed against him or her should not be listed as a participant in an application for an HHS grant until the judgment is paid in full or is otherwise satisfied. No funds may be rebudgeted following an award to pay such an individual. The OPDIV will disallow costs charged to awards that provide funds to individuals in violation of this requirement.

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[9] The information contained in the Excluded Parties Listing System is available in printed and electronic formats. The printed version is published monthly. Copies may be obtained by purchasing a yearly subscription from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, or by calling the Government Printing Office Inquiry and Order Desk at 202-783-3238. The electronic version can be accessed on the Internet (http://www.epls.gov).

Lobbying

Applicants for (and recipients of) Federal grants, cooperative agreements, contracts, and loans are prohibited by 31 U.S.C. 1352, "Limitation on use of appropriated funds to influence certain Federal contracting and financial transactions," from using appropriated Federal funds to pay any person for influencing or attempting to influence any officer or employee of an agency, a member of Congress, an officer or employee of Congress, or an employee of a member of Congress with respect to the award, extension, continuation, renewal, amendment, or modification of any of these instruments. These requirements are implemented for HHS in 45 CFR part 93, which also describes types of activities, such as legislative liaison activities and professional and technical services that are not subject to this prohibition.

Applicants for HHS grants with total costs expected to exceed $100,000 are required to certify that they

- have not made, and will not make, such a prohibited payment;
- will be responsible for reporting the use of non-appropriated funds for such purposes; and
- will include these requirements in consortium agreements, other subawards, and contracts under grants that will exceed $100,000 and will obtain necessary certifications from those consortium participants and contractors.

Disclosure reporting is required after award as indicated in Part II of this policy statement.

Application Process

Types of Applications and Letters of Intent

Under the project period system, a project may be approved for a multi-year period, but generally is funded in annual increments known as "budget periods." This system provides the recipient with an indication of the OPDIV's intent to non-competitively fund the project during the approved project period as long as required information is submitted, funds are available, and certain criteria are met. For some types of projects, e.g., construction, an award covering multiple years is issued at the outset at the fully funded amount. HHS uses the following types of applications and requests for funding under the project period system:

- *New Application*—a request for financial assistance for a project or activity that is not currently receiving support, which must compete for support unless justified as a single-source application.
- *Competing Continuation Application*—a request for funding to renew, by one or more additional budget periods (described as a "competitive segment"), a project period that would otherwise expire. This type of application is sometimes referred to as "renewal." These applications must compete for support in the same manner as new applications.
- *Supplemental Application*—a request for an increase in support in a current budget period for expansion of the scope of the approved project or program

or to meet an unforeseen increase in costs. The request may specify budgetary changes required for the remainder of the project period as well as for the current budget period. Supplemental applications requesting a programmatic expansion (change in scope) must undergo objective review and generally are required to compete for support; requests for administrative supplements may be awarded without objective review or competition.

- *Revised (Amended) Application*—an unfunded application that the applicant has modified following objective review and has resubmitted for a subsequent review cycle.

- *Non-Competing Continuation Application*—a request for funding, whether the OPDIV terms the request an application or a progress or performance report, for funding the second or subsequent budget period within an approved competitive segment. A non-competing continuation application does not compete with other applications for support.

Generally, funding opportunity announcements will invite the submission of full applications at the outset. However, an OPDIV may require or encourage submission of preliminary documents before submission of applications for initial (new) support. If pre-applications are used, they must be submitted as specified by the OPDIV in the funding opportunity announcement. Pre-applications may be required as a means of screening out, through an objective review process, those applications with little or no chance for Federal funding before applicants incur significant expenditures in preparing an application.

OPDIVs may request submission of LOIs preliminary to submission of applications. LOIs generally are not required to include detailed information about a proposed project or application. Instead, LOIs are used to estimate the number of applications that may be submitted. When used in this way, potential applicants are not required to submit them, and, if an LOI is submitted, it is not binding and does not require the respondent to submit an application.

Application Forms

Exhibit 2 lists the application forms used by the OPDIVs. The forms vary by applicant or grant type and they may differ for non-competing continuation applications and other applications. These forms and associated instructions are available electronically at the specified Web site and, as appropriate, at the Grants.gov APPLY site (http://www.grants.gov/Apply). Questions about application forms and instructions may be directed to the OPDIV to which the application will be submitted.

Exhibit 2. Required Forms for Applications

Application title	Form number	Use/availability
Application for Federal Assistance	SF 424	Face page for applications from State, local, and Indian tribal governmental applicants for all types of grants, and nongovernmental applicants for construction and health services grants submitted through Grants.gov http://www.whitehouse.gov/omb/grants/grants_forms.html

Exhibit 2. Required Forms for Applications

Application title	Form number	Use/availability
Public Health Service Grant Application for Use by State and Local Government Applicants and Nongovernmental Applicants for Health Services Projects	PHS 5161-1, with budget and assurances applicable to non-construction (424-A and 424-B) or construction (424-C and 424-D)	All applications, including non-competing continuation applications, from State, local, and Indian tribal governmental applicants and non-governmental applicants for construction and health services projects http://www.hhs.gov/forms/publicuse.html
Research Grant Application	SF 424 (R&R)	Suite of forms for use as specified by the OPDIV when applying through Grants.gov
Application for a Public Health Service Grant	PHS 398	New and competing continuation applications for research project grants and cooperative agreements, program projects, centers, career awards, Kirschstein-National Research Service Awards institutional research training grants, research-related conference grants, and SBIR and STTR grants[10] Available at http://grants.nih.gov/grants/forms.htm
Application for Ruth L. Kirschstein National Research Service Award Individual Fellowship	PHS 416-1	Kirschstein-National Research Service Award fellowships http://grants.nih.gov/grants/forms.htm
Public Health Service Non-Competing Grant Progress Report	PHS 2590	Non-competing continuation applications for research project grants and cooperative agreements, program projects, centers, career awards, Kirschstein-National Research Service Awards institutional research training grants, research-related conference grants (when applicable), and SBIR and STTR grants. Available at http://grants.nih.gov/grants/forms.htm

Preparing an Application

Regardless of any preliminary documentation required or submitted, to be considered for support, an applicant must be an eligible entity and must submit a complete application that complies with OPDIV instructions. In addition to indicating the substantive information required, OPDIVs may specify page limitations or other formatting requirements, whether for hard-copy or electronic applications.

A complete new or competing continuation application typically includes a project description, detailed budget and budget justification, biographical sketches of key personnel, and other information specified in the funding opportunity announcement. The funding opportunity announcement (or related application package) may provide specific instructions for completion of these forms that differ from the standard instructions for completion.

[10] This form may continue to be used in accordance with OPDIV instructions until transition to use of Grants.gov is complete.

In preparing an application, an applicant should ensure that it addresses requirements specified (or incorporated by reference) in the funding opportunity announcement that relate to the project or program narrative, public policy requirements, and the application budget.

The same project may not be submitted concurrently to two PHS OPDIVs, a limitation that applies to the PHS OPDIVs only. Any such applications will be returned to the applicant without review.

Public Policy Requirements

Public policy requirements are requirements with a broader national purpose than that of the Federal sponsoring program or award that an applicant/recipient must adhere to as a prerequisite to and/or condition of an award. Public policy requirements are established by statute, regulation, or Executive order. In some cases they relate to general activities, such as preservation of the environment, while, in other cases they are integral to the purposes of the grant-supported project, such as protecting the welfare or identity of subjects in research projects. Some public policy requirements require an indication of intent to comply with the requirement if an award is made, others require submission of specific documentation before award (sometimes in the form of a certification or assurance or an environmental assessment), and still others require a demonstration of compliance that is an integral part of the application review for technical or scientific merit (e.g., the requirement in 45 CFR 46.111(a)(6) that, when appropriate, the research plan must make adequate provision for monitoring the data collected to ensure the safety of subjects). Applicants and recipients should take particular note of these requirements. If an applicant or recipient does not provide the required information or the information is incomplete or is otherwise not adequate, depending on the requirement the organization may be deemed ineligible for award, the award may be delayed, an award may be terminated, or other appropriate action may be taken by the OPDIV.

The signature of the authorized organizational representative on the application indicates that the organization complies, or intends to comply, with all applicable public policy requirements specified in the funding opportunity announcement, generally by reference to another document such as application instructions or a grants policy statement. Some requirements (human subjects assurance, civil rights assurance, environmental analysis) are in the form of separate documents that an applicant must have on file with the applicable HHS office before an award may be made. Other requirements may be satisfied by means of "just-in-time" documentation submitted, at OPDIV request, by those applicants being considered for award.

Part II contains general guidance to help the applicant/recipient determine which public policy requirements apply to its activities after award, including whether a requirement should be included in subawards or contracts under the grant.

Research-Related Requirements

Just-in-time procedures may be used in relation to requirements for submission of certification of IRB approval of the project's proposed use of human subjects, verification of IACUC approval of the project's proposed use of live vertebrate animals, and evidence of compliance with the requirement for education in the

protection of human research participants. Applications from organizations with approved Animal Welfare Assurances will be considered incomplete if they do not contain the information concerning the use of vertebrate animals required as part of the application (see application instructions for completing the specific points that need to be addressed). In the case of apparent or potential violation of the policy, the application may be referred back to the applicant for further IACUC review.

The funding opportunity announcement will specify the timing and nature of required just-in-time submissions. These requirements differ from any need to describe the involvement of human subjects or animals in an application, which is reviewed by the objective reviewers.

In addition, several OPDIVs have policies concerning the inclusion of women, minorities, and children as subjects in their grant-supported research. These policies, which implement Section 492B of the PHS Act, 42 U.S.C. 289 a-2, require that women and members of minority groups and their subpopulations be included in OPDIV-supported research projects involving human subjects, unless a clear and compelling rationale and justification establishes that inclusion is inappropriate with respect to the health of the subjects, the purpose of the research, or other circumstances. When these policies apply (as specified in the funding opportunity announcement), the applicant is required to address inclusion of these groups in the application narrative, and the applicant's plans will be assessed as part of the objective (peer) review process. Failure to comply with this policy or to adequately address use of human subjects and animals may adversely affect the score for technical merit, which may result in the OPDIV not making an award.

National Environmental Policy Act

NEPA, as amended, 42 U.S.C. 4331 *et seq.*, establishes national policy goals and procedures to protect and enhance the environment, including protection against natural disasters. To comply with NEPA for its grant-supported activities, HHS requires the environmental aspects of construction grants (and certain non-construction projects as specified by the OPDIV) to be reviewed and evaluated before final action on the application.

If the OPDIV determines that NEPA applies (or may apply), the OPDIV will address NEPA requirements in the funding opportunity announcement. If the OPDIV has not indicated in the funding opportunity announcement that NEPA applies, no environmental analysis is necessary, unless, in an unusual situation, the applicant anticipates a significant environmental consequence or, following receipt of an application, an OPDIV official indicates the need for an environmental analysis. In those cases, an environmental analysis must be provided with the application or as requested by the OPDIV. An environmental analysis means a written review that indicates the expected environmental effects resulting from the proposed action, defines the current and future implications of those effects, and lists any proposed actions or safeguards to avoid or reduce any negative environmental effects. If NEPA applies, the application must be accompanied by the applicant's own separately bound environmental analysis to facilitate review and evaluation for environmental concerns before approval or other action on the application.

Public Disclosure

Section 102 of NEPA, 42 U.S.C. 4332, and EO 11514 (March 5, 1970) provide for public comment and participation in the environmental impact review process. If it is determined that there is an environmental impact, applicants are required to publicly disclose the project in a newspaper or other publicly available medium and to describe its environmental impact concurrent with notification to the SPOC (see "Intergovernmental Review under Executive Order 12372" in Part I). An example of a suitable disclosure statement follows:

> Notice is hereby given that the Uptown Community Health Center proposes to construct additional space, partially utilizing Federal funds. The proposed construction project is the addition of 2,700 square feet connected to the existing Allen Building, which is located at 5333 Main Street, Downtown, Ohio.
>
> The Uptown Community Health Center has evaluated the environmental and community impact of the proposed construction. There will be construction noise and increased construction traffic during the construction period. No significant permanent environmental impacts are foreseen. All building permits and zoning approvals have been obtained. In accordance with Executive Order 11514 (March 5, 1970), which implements the National Environmental Policy Act of 1969, as amended, any individual or group may comment on, or request information concerning, the environmental implications of the proposed project. Communications should be addressed to the Uptown Community Health Center, and must be received by (date). The Federal grant application may be reviewed at 5333 Main Street, during normal working hours.

Preservation of Cultural and Historic Resources

Under Section 106 of the National Historic Preservation Act (16 U.S.C. 470 *et seq.*, agencies must consider the effect on historic properties before making a decision on whether to fund a project. Historic properties include any district, site, building, structure, or object that is listed on, or is eligible for listing on, the National Register of Historic Places (National Register). In addition, the Advisory Council on Historic Preservation must be afforded a reasonable opportunity to comment on such undertakings. The purchase, construction, or alteration/renovation of a facility with Federal funds, whether that activity is the purpose of the project or is one activity under a grant with a broader purpose (e.g., alteration of a facility under a research project), is an "undertaking" as that term is defined under 36 CFR 800.16(y). However, these are not the only activities that may result in the need to comply with Section 106. The procedures to be followed by Federal agencies in complying with Section 106 are set forth in the Council's regulations at 36 CFR part 800.

Pursuant to the regulations at 36 CFR part 800, before deciding to make an award, the OPDIV approving official for a grant-funded project or program must determine the project's or program's effect on historic properties in consultation with the involved State Historic Preservation Officers, Tribal Historic Preservation Officers, representatives of the local government, affected Indian tribes and Native Hawaiian organizations, the applicant organization, and other interested parties. In order for an OPDIV to carry out these responsibilities, applicants (and recipients) must identify to the OPDIV any property listed or eligible for listing on the National Register of Historic Places that will be affected by the award. Generally this will be at the time of application, but may not be known until after award as a result of a planned post-award change.

The term "effect" is defined under 36 CFR 800.16(i) as an "alteration to the characteristics of a historic property qualifying it for inclusion in or eligibility for the National Register." The project's impact on the property's use, character, location, and setting, including whether it will have an adverse effect, are considered when determining its effect on the historic property. The project or program will be considered to have an adverse effect if it will endanger those qualities that make the property eligible for inclusion in the National Register.

If the undertaking will have an adverse effect on a historic property, the consultation process must proceed as provided under 36 CFR 800.6 in the effort to develop either a memorandum of agreement or a programmatic agreement detailing the steps necessary to avoid, minimize, or mitigate the adverse effects. In cases where the consultation is terminated without an agreement to resolve the adverse effects, the OPDIV will follow the applicable requirements of 36 CFR 800.7. These requirements must be satisfied before approval of the application or a post-award change to an approved application.

Under the Council's regulations, applicants/recipients may initiate the Section 106 compliance consultations when authorized to do so by the OPDIV. If the OPDIV provides that authorization, it must notify the involved State Historic Preservation Officers, Tribal Historic Preservation Officers, and other consulting parties that the applicant has been given that authority. The OPDIV remains legally responsible for all findings and determinations made on its behalf. Each organization that plans to use OPDIV funds for purchase, construction, or renovation of a facility, other activity specified by the OPDIV, or activity deemed by the applicant to have an effect on a historic property must ensure that it has provided complete and accurate documentation to assist the agency with meeting its Section 106 compliance responsibilities. Failure to obtain this clearance and make this assurance will delay action on an application or change request. The State Historic Preservation Liaison Officer or the National Trust for Historic Preservation may be contacted for additional details.

Protection of Wetlands

EO 11990 provides that federally funded construction and improvements minimize the destruction, loss, or degradation of wetlands. The EO provides that, in furtherance of Section 101(b)(3) of NEPA (42 U.S.C. 4331(b)(3)), Federal agencies, to the extent permitted by law, must avoid undertaking or assisting with new construction located in wetlands unless the head of the agency finds that there is no practicable alternative to such construction, and that the proposed action includes all practicable measures to minimize harm to wetlands that may result from such use. In making this finding, the head of the agency may take into account economic, environmental, and other pertinent factors. The public disclosure requirement described above also pertains to early public review of any plans or proposals for new construction in wetlands.

Uniform Relocation Act and Real Property Acquisition Policies Act

The Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (the Uniform Relocation Act), 42 U.S.C. 4601 *et seq.*, applies to all programs or projects undertaken by Federal agencies or with Federal financial assistance that cause the displacement of any person.

The HHS requirements for complying with the Uniform Relocation Act are set forth in 49 CFR part 24. Those regulations include uniform policies and procedures regarding treatment of displaced people. They encourage entities to negotiate promptly and amicably with property owners so property owners' interests are protected and litigation can be avoided.

The Application Budget

Applicants generally will be required to prepare a detailed budget as part of the application consistent with instructions in the funding opportunity announcement and application instructions. Among other things, applicants need to understand the types of costs that are allowable under the program or award, the cost principles to which it will be subject, differences between direct and indirect costs, circumstances requiring establishment of an indirect cost rate or research patient care cost rate, and any requirement for non-Federal participation (in the form of matching or cost sharing).

In general, HHS discretionary grant awards provide for reimbursement of actual, allowable program/project costs incurred. Except for those types of awards for which HHS will not reimburse indirect costs as specified below, program/project costs consist of allowable direct costs plus the allocable portion of indirect costs of the organization, less applicable credits (as described in Part II and in the cost principles). A "direct cost" is any cost that can be specifically identified with a particular project, program, or activity or that can be directly assigned to such activities relatively easily and with a high degree of accuracy. Direct costs include, but are not limited to, salaries, travel, equipment, and supplies directly benefiting the grant-supported project or activity. Most organizations also incur costs for common or joint objectives that, therefore, cannot be readily identified with an individual project, program, or organizational activity. These costs are identified as "indirect costs" or "facilities and administrative costs." They generally include facilities operation and maintenance costs, depreciation, and administrative expenses. Organizations must have or negotiate an indirect cost rate to support a request for reimbursement of indirect costs (with limited exceptions specified below).

The various sets of government-wide (or, in the case of hospitals, HHS) cost principles establish the general standards for the allowability, including allocability, of costs and provide detailed guidance on the cost accounting treatment of costs as direct or indirect costs. Applicability of a particular set of cost principles depends on the type of organization making the expenditure. For example, if a State government recipient collaborates with a university as a contractor under the grant, the State would be subject to the cost principles for States, while the university would be subject to the cost principles for institutions of higher education. The allowability of costs also is subject to any requirements or limits established in the governing statute, program regulations, or the terms and conditions of awards. Because these considerations apply throughout the grants process, they are addressed in detail in Part II.

Indirect Costs

If indirect costs are reimbursable under an award, applicants may request indirect costs in their applications. Indirect costs should not be requested in applications for the following types of awards:

- Construction grants
- Conference grants
- Fellowships.

The following types of organizations may not request indirect costs:

- Federal institutions
- International or foreign organizations if the grant will be performed entirely outside the territorial limits of the United States (indirect costs may be paid to the American University, Beirut, which is not considered a foreign organization, and the World Health Organization).

For other types of awards and organizations, OPDIVs will not reimburse indirect costs unless the recipient has an indirect cost rate covering the applicable activities and period. Indirect cost rates are negotiated by DCA, DFAS in the Office of Acquisition Management and Policy, NIH (responsible for negotiating indirect cost rates for for-profit entities receiving awards from HHS), or other Federal agency with cognizance for indirect cost rate negotiation. However, as indicated in OMB Circular A-87, certain governmental organizations other than Indian tribal governments are not required to submit their indirect cost rate proposals to the Federal government, but must retain the documentation related to their indirect cost requests for audit purposes. Further, awarding offices will not require a recipient to establish an indirect cost rate if the organization's total operations consist of a single grant-supported project or if the organization appropriately and consistently treats all costs as direct costs to projects and accounts for them as such. In the latter case, the GMO must be satisfied that the organization's accounting system can adequately identify and support all costs as direct costs to the project or program. This includes being able to identify and segregate costs on the basis of a process that assigns costs commensurate with the benefits provided to individual projects or programs.

If an organization is advised by the GMO of the need to establish a rate, the GMO will refer the organization to the appropriate office. Indirect cost proposals must be prepared in accordance with the applicable cost principles and guidance provided by the cognizant office or agency. Further information concerning the establishment of indirect cost rates and the reimbursement of indirect costs may be obtained from DCA or DFAS.

Even if an organization has an established indirect cost rate, under training grants (including education grants and career awards) to all types of entities other than State, local, or Indian tribal governmental agencies, OPDIVs reimburse indirect costs at a fixed rate. Therefore, when requesting indirect costs, these applicants should budget indirect costs at a rate of 8 percent of modified total direct costs, exclusive of tuition and fees, expenditures for equipment, and subawards and contracts in excess of $25,000. Training grant applications from State, local, or Indian tribal governmental agencies may request full indirect cost reimbursement. State universities and hospitals are not considered governmental agencies for this purpose.

Matching or Cost Sharing

If the funding opportunity announcement specifies that matching or cost sharing is required, it also will specify the following:

- Whether the inclusion of matching or cost sharing in the application is an eligibility requirement or is an evaluation criterion
- The nature of the requirement, e.g., whether it is a fixed percentage or the OPDIV cannot fund more than a specified percentage of costs
- Required documentation, such as letters of commitment.

The terms "matching" and "cost sharing" are often used interchangeably. However, "matching" usually refers to a statutorily specified percentage, whether specified as a fixed or minimum percentage of non-Federal participation in allowable program or project costs that must be contributed by a recipient in order to be eligible for Federal funding or a not-to-exceed percentage of Federal participation. "Cost sharing" refers to any situation in which the recipient shares in the costs of a project other than as statutorily required matching. This includes situations in which contributions are voluntarily proposed by an applicant and accepted by the OPDIV by inclusion in the approved budget as shown in the NoA.

Unless restricted by statute or regulation, matching or cost sharing may be provided as direct and/or indirect costs, consistent with the recipient's accounting system—and its usual method of charging for similar items—and any restrictions or limitations in the applicable cost principles. Recipient contributions may be derived from any non-Federal source; from Federal sources if received as fees, payments, or reimbursements for the provision of a specific service, such as patient care reimbursements received under Medicare or Medicaid; or from other program income, if authorized by the OPDIV (see Part II). Otherwise, unless there is specific statutory authority, Federal funds may not be used to match HHS grant funds.

The source and amount of costs and/or the value of third-party in-kind contributions proposed by the applicant to meet a matching or cost-sharing requirement must be identified in the application budget. The determination of allowability of costs for

matching or cost-sharing purposes is based on the same requirements, including the cost principles, that apply to use of Federal funds. Also, the classification of a contributed cost as either direct or indirect must be consistent with the classification of other costs incurred by the recipient for the same purpose in like circumstances. Guidance on the valuation of in-kind contributions is found in 45 CFR 74.23, 45 CFR 92.24, and Part II of this policy statement.

Research Patient Care Costs

HHS provides funds for research patient care costs under grants to hospitals to cover the costs of routine services for inpatients or ancillary services for inpatient or outpatient subjects/volunteers involved in research studies. In order to receive reimbursement for research patient care costs, any hospital that, as a direct recipient of OPDIV funds, expects to incur more than $100,000 in patient care costs in any single budget period on a single OPDIV grant must either have in place, or take steps to negotiate, a research patient care rate agreement with the cognizant DCA office. Detailed information on research patient care costs is included in Part II.

Third-Party Reimbursement

Under health services delivery programs, OPDIV funding may serve as seed money to allow recipients to develop necessary capabilities and the ability to obtain funding from non-Federal sources or may be conditioned on recipients maximizing their funding from other sources, with Federal funding for the difference between those amounts and their costs of operation. In addition to any required narrative discussion of applicant plans to seek third-party reimbursement for delivery of health services and establishment of fee schedules to charge beneficiaries according to their ability to pay, the applicant may be required to show in the application budget the amounts expected to be collected from third-party payors (program income). More detailed discussion of program income is included in Part II.

Submitting an Application

Many OPDIV programs accept applications electronically through Grants.gov APPLY. Grants.gov provides a secure and reliable government-wide single portal for applying for Federal grants electronically, simplifying the grant application process and reducing paperwork. For OPDIV programs allowing submission of applications through Grants.gov, the OPDIV will post an application package at Grants.gov APPLY that includes the funding opportunity announcement, the required forms, and submission instructions. However, even if an OPDIV accepts applications electronically, an applicant may choose to submit its application in hard copy. Funding opportunity announcements also will indicate the date and time by which a competing application must be submitted in order to be considered as part of that competition, the address to which the application must be submitted (which may be a contractor), and, if hard copy, the number of copies. Generally, OPDIVs will require submission of an original and two copies of an application.

All applications must include a DUNS number, which is obtained from Dun & Bradstreet (D&B) at 1-866-705-5711 or at http://ccr.dnb.com/ccr/pages/CCRSearch.jsp. To determine if an organization already has a DUNS number or to obtain a DUNS number, the organization should contact D&B. There is no charge to obtain a DUNS number.

Before using Grants.gov APPLY, an applicant organization must register with Central Contractor Registration (http://www.ccr.gov/) and the credential provider. Central Contractor Registration can be accomplished online or by telephone (1-888-227-2423). The DUNS number is required before initiating registration with Central Contractor Registration. Specific details about Central Contractor Registration and credential provider registration associated with the use of Grants.gov are available at http://www.grants.gov/GetStartedRegister?type=organization. Organizations are not required to register with Central Contractor Registration if they submit applications by any means other than through Grants.gov, e.g., in hard copy.

For funding opportunity announcements with common deadline dates for application submission, to be considered timely, an application must be sent on or before the deadline date. The established receipt or deadline date may be waived only in extenuating circumstances such as extreme weather (e.g., floods or hurricanes), widespread disruptions of mail service, or disruptions of electronic or other services.

The deadline is the same for applications submitted electronically. For applications submitted through Grants.gov, the OPDIV will determine whether an application was submitted before the deadline based on the time it is received and clocked in at the Grants.gov portal. Applications may be sent through the United States Postal Service or delivered by a courier delivery service. Some OPDIVs will not accept applications hand-carried by individuals. For hard-copy applications, if sent on time to the address specified in the funding opportunity announcement (with documented proof of mailing) but received after the deadline, an application can be accepted for review only if it is received in time for orderly processing. If the receipt date falls on a weekend or a Federal holiday, the deadline date is extended to the next business day. If an application is sent to any address other than that specified in the funding opportunity announcement, it may result in a delay in processing or the application not being reviewed.

Executive Order 12372 and Public Health System Reporting Requirements

Certain HHS program/activities are subject to the requirements of EO 12372, as amended, "Intergovernmental Review of Federal Programs," and the HHS implementation at 45 CFR part 100, and to other intergovernmental cooperation provisions. These requirements allow State and local governments to provide input on applications submitted (or to be submitted) for funding consideration. If EO 12372 might apply to a program or applicants or applications under the program, the following information will be included in the funding opportunity announcement:

- Even if a program is covered by EO 12372, not all States participate in this process. To determine whether it must comply with a State process under EO 12372, an applicant should check the information maintained by OMB at its Web site (http://www.whitehouse.gov/omb/grants/spoc.html). If the State does not participate, no SPOC contact will be listed. Applications from federally recognized Indian tribal governments are not subject to EO 12372 requirements, even under covered programs.

- Before an award decision, the OPDIV must allow adequate time—60 days from the established deadline date for receipt of applications for a new or other competing application, or 30 days from the established deadline date

for receipt of the application for a non-competing continuation application—for completion (or expiration) of the State process.

The primary purpose of the Public Health System Reporting requirements is to provide State and/or local health agencies with information on proposed in-State grant activity by certain applicants applying for funding under health care delivery programs. When applicable, the applicant must prepare and submit a Public Health System Impact Statement. Applicants are required to submit the following information to the head of the appropriate State and local health agencies in the areas to be impacted no later than the application receipt due date:

- A copy of the application face page
- A summary of the project, not to exceed one page, which describes the population to be served and the services to be provided, and describes the coordination planned with the appropriate State and local health agencies (the application abstract may be substituted for the one-page Public Health System Impact Statement).

Although these requirements are specific to health care delivery programs, they are related to the EO 12372 requirements. The linkage occurs when a State and/or local health official wants to review an application, in whole or in part, submitted under these programs. In that case, the official must contact the SPOC for a copy of the application.

Use of Application Information

Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, if the application contains information that the applicant organization considers to be trade secrets, information that is commercial or financial, or information that is privileged or confidential, the pages containing that information should be identified as specified in the funding opportunity announcement or application instructions.

When non-Federal reviewers are used, the funding opportunity announcement or application instructions will specify that applicants have the option of omitting specific salary rates or amounts for individuals specified in the application budget and, if required by the OPDIV, Social Security numbers for individuals. For hard-copy applications, this can be accomplished by including the information in the original, but omitting it from the application copies. The copies may include summary salary information. For electronic applications, the information must be supplied to the OPDIV as part of the submission. The funding opportunity announcement will specify if the applicant should indicate, in the application or in a separate form, whether it wants to use that option. If the detailed information is an integral part of the application, the OPDIV will ensure that the information is not shared with reviewers.

The OPDIV will protect the information contained in an application from unauthorized disclosure, consistent with the need for objective review of the application and the requirements of the Freedom of Information Act and the Privacy Act. However, if a grant is awarded as a result of or in connection with an application, the Federal government has the right to use or disclose the information to the extent authorized by law. Post-award considerations concerning release of information and access to research data are addressed in Part II of this policy statement.

Freedom of Information Act

The Freedom of Information Act, 5 U.S.C. 552, provides individuals with a right to access certain records in the possession of the Federal government. The government may withhold information pursuant to the exemptions and exclusions contained in the act. The exact language of the exemptions can be found in the act. Additional guidance on the exemptions and how they apply to certain documents can be found in the HHS regulations implementing the FOIA (45 CFR part 5). (Also see the HHS Web site http://www.hhs.gov/foia/.)

OPDIVs generally do not release trade secrets and commercial, financial, and otherwise intrinsically valuable items of information that are obtained from a person or organization and are privileged or confidential; information that, if released, would adversely affect the competitive position of the person or organization; and patent or other valuable commercial rights of the person or organization.

OPDIVs generally will withhold the following types of records or information related to an application in response to a FOIA request:

- Pending competing grant applications
- Unfunded new and competing continuations and competing supplemental applications
- Evaluative portions of site visit reports and objective review summary statements, including scores.

If, after reviewing a FOIA request, an OPDIV has reason to believe that information in its records could reasonably be considered releasable, the appropriate OPDIV Freedom of Information office will notify the applicant (recipient), through the PI, before the information is released. The PI/PD will be given an opportunity to identify potentially patentable or commercially valuable information that the PI/PD believes should not be disclosed. After OPDIV consideration of the response, the PI/PD and applicant (recipient) will be informed if the OPDIV does not agree with the PI's/PD's position. If a document contains both disclosable and nondisclosable information, the nondisclosable information will be deleted and the balance of the document will be disclosed. This restriction does not limit the Federal government's right to use the information if it is obtained without restriction from another source.

The HHS regulations implementing FOIA provide that only designated Freedom of Information officers may deny requests for information. Requests for information, the release of which is believed to be exempt under FOIA, are referred to the OPDIV Freedom of Information officer along with written documentation of the rationale for nondisclosure. If the Freedom of Information officer determines that the requested information is exempt from release under FOIA, the requester may appeal that determination to the Deputy Assistant Secretary for Public Affairs (Media), HHS. Additional information on the FOIA process is available at OPDIV Web sites.

Post-award considerations concerning release of information and access to research data are addressed in Part II of this policy statement.

Privacy Act

The Privacy Act of 1974, 5 U.S.C. 552a, and its implementing regulations (45 CFR part 5b) provide certain safeguards for information about individuals maintained in a system of records (i.e., information may be retrieved by the individual's name or other identifying information). These safeguards include the rights of individuals to determine what information about them is maintained in Federal agencies' files (hard copy or electronic) and how it is used; to have access to such records; and to correct, amend, or request deletion of information in their records that is inaccurate, irrelevant, or outdated.

Records maintained by OPDIVs with respect to grant applications, grant awards, and the administration of grants may be subject to the provisions of the Privacy Act. For example, OPDIVs that maintain or access any such records by name of an individual, such as by the name of the PI/PD, are subject to the Privacy Act.

Parties other than PIs/PDs may request the release of Privacy Act records. Such requests are processed in the same manner as FOIA requests. For example, information requested by co-investigators in grant applications is released to them only when required under FOIA because they have no right of access under the Privacy Act. When releasing information about an individual to a party other than that individual, OPDIVs will balance the individual's right to privacy with the public's right to know as provided by the FOIA.

Records maintained by non-Federal parties ordinarily are not subject to the requirements of 45 CFR part 5b.

Objective Review of Applications

Applications under discretionary grant programs, whether received in response to a funding opportunity announcement, solicited from a single source, or received as unsolicited requests for funding, are subject to objective review. Objective review is an advisory review of discretionary grant applications conducted by a minimum of three unbiased reviewers with expertise in the programmatic area for which applications are submitted.

The review is intended to provide advice to the individuals responsible for making award decisions. Objective review is essential to ensuring selection of applications that best meet the needs of the program consistent with published evaluation criteria and providing assurance to the public that the evaluation process is impartial and fair.

Peer review is a form of objective review required by statute. It is an assessment of scientific or technical merit of applications by individuals with knowledge and expertise equivalent (peer) to that of the individuals whose applications of support they are reviewing. The statute may specify the types of reviewers or composition of review groups and include other requirements related to the approval of applications, e.g., review by a National Advisory Council or equivalent body that performs a second level of review for programmatic considerations that augments the results of the peer review process.

Application review criteria must be published as part of the funding opportunity announcement. Typical review criteria may include the approach to the proposed

project or program, whether to meet a health need or carry out an investigator-initiated research project; the potential of the program or project to contribute to meeting the objectives or purpose of the supporting program; the method used to evaluate project or program results; resources of the applicant organization, e.g., facilities, and the capabilities of its staff, including the PI/PD; and reasonableness and appropriateness of the budget. Reviewers also will review proposed involvement of human subjects and vertebrate animals, as applicable, and assess compliance with specified public policy requirements, e.g., inclusion of women and minorities in research. IRB approval may be required before objective review of a new or competing continuation application unless the OPDIV has implemented just-in-time procedures.

Applications received in response to the same funding opportunity announcement generally are scored individually and then ranked with other applications reviewed by the same review group in their order of relative programmatic, technical, or scientific merit. The highest ranked applications are those that receive priority consideration for award within available funding. Authorized program officials ("approving officials") make final award decisions from among those applications receiving a favorable objective review and, where applicable, National Advisory Council recommendation. OPDIV approving officials also may apply other factors, e.g., geographical distribution, as specified in the funding opportunity announcement. The decision to fund an application will be communicated to the applicant by issuance of a NoA. The decision not to fund an application will be communicated by letter. Depending on OPDIV procedures, the letter may include a summary of the review ("summary statement") and may be sent to the PI/PD and/or to the person who signed the application as the official authorized to obligate the applicant. A copy of a letter transmitting a summary statement also will be provided to the individual named as the PI/PD for the project covered by the application if that individual is not the individual that signed the application.

If an application has received a favorable objective review but is not expected to be funded in the current cycle due to funding constraints, the application may be held for one or more additional cycles and compete with other applications submitted for that subsequent cycle as long as the subsequent cycle(s) requirements remain unchanged from those under which the application was originally submitted. If an application is unsuccessful, under programs that have annual review cycles or multiple reviews within a year, the applicant may submit a revised application for review in a future review cycle. Some OPDIVs limit the number of times an application may be revised and resubmitted (see Part IV for any OPDIV limitations).

Disposition of Applications

All incomplete applications, ineligible, or otherwise non-compliant applications, and applications determined to be non-responsive to funding opportunity announcement requirements will not be reviewed. An applicant may withdraw an application from consideration at any time before an award is issued.

An applicant whose application receives a favorable review will be notified of additional information that it may be required to submit or other actions it or the OPDIV may or must take. The process leading to an award, including the business management review performed by the GMO, is described in the next section, "Business Management Reviews and Other Pre-Award Activities."

An unsuccessful applicant will be advised by letter (sent to the individual signing the application on behalf of the organization) that its application will not be held for further consideration or be funded. The decision not to award a grant, or to award a grant at a particular funding level, is discretionary and is not subject to appeal to any OPDIV or HHS official or board.

Business Management Reviews and Other Pre-Award Activities

Applications receiving a favorable objective review that an OPDIV is considering for funding are reviewed for other considerations. These include, as applicable, cost analysis of the project/program budget, assessment of the applicant's management systems, ensuring continued applicant eligibility, and compliance with any public policy requirements, including those requiring just-in-time submissions. The applicant may be asked to submit additional information (such as an updated budget or "other support" information or verification of IACUC review) or to undertake certain activities (such as negotiation of an indirect cost rate) in anticipation of an award. However, even at this point in the process, such requests do not guarantee that an award will be made. Following review of all applicable information, the OPDIV approving and business management officials will determine whether an award can be made, if special conditions are required, and what level of funding is appropriate.

Although these reviews and determinations occur before an awarding office makes a new or competing extension award, recipients must continue to comply with eligibility and public policy requirements and maintain adequate management systems throughout the period of support.

Assurances of Compliance

Civil Rights

Before an awarding office may make an award to a domestic organization, the authorized organizational representative must assure, by means of the signature on the application, that the organization has on file with OCR an Assurance of Compliance with the statutes enforced by OCR. The assurance, Form HHS 690, is filed for the organization and is not required for each application. If the application has been recommended for funding and the applicant organization does not have an Assurance of Compliance on file with OCR, it will receive, from the awarding office, the required form and instructions for completion and submission.

Domestic organizations that receive funding from recipients as subrecipients or contractors under grants rather than directly from HHS also are required to file an HHS 690. The recipient is responsible for determining whether those organizations have the required assurance on file and, if not, ensuring that it is filed with OCR.

Human Subjects and Animal Welfare

Under just-in-time procedures, following objective review, applicant organizations should proceed with IRB review for those applications that have not yet received IRB approval and which the OPDIV has indicated may be in a fundable range.

If, at the time of award, a recipient does not have an applicable assurance approved by OHRP and certification of IRB review and approval, the awarding office will place a restriction on the award so that no human subjects research can be conducted or

supported until the assurance and certification of IRB review and approval have been obtained and accepted.

The *PHS Policy on Humane Care and Use of Laboratory Animals* (the PHS Policy) requires applicants proposing to use vertebrate animals in HHS-supported activities to file a written Animal Welfare Assurance with OLAW. An awarding office will not make an award for research involving live vertebrate animals unless the applicant organization and all performance sites are operating in accordance with an approved Animal Welfare Assurance and provide verification that the IACUC has reviewed and approved those sections of the application that involve use of vertebrate animals, in accordance with the requirements of the PHS policy. If an application is selected for award and the verification of IACUC review has not been submitted, the awarding office will contact the organization with instructions for negotiating an assurance or submitting the IACUC verification.

Cost Analysis

The GMO will ensure that a cost analysis is performed on any application that requires a detailed budget. Cost analysis involves obtaining cost breakdowns, validating cost data, evaluating specific elements of cost, and examining data to determine the necessity for, and the reasonableness and allowability of, the costs included in the application budget. The extent of cost analysis depends on the complexity of the project, prior experience with the applicant, and other factors. Information on the applicable cost principles and on allowable and unallowable costs is provided in Part II.

Assessment of Financial and Other Management Systems

In addition to considering the specific information provided in the application, the GMO determines the adequacy of the applicant's financial and business management systems, including property management and procurement systems, that will support the expenditure of and accountability for grant funds if an award is made. Applicants/recipients are expected to have systems, policies, and procedures in place by which they manage grant funds and grant-supported activities. They may use their existing systems for this purpose as long as organizational policies are consistently applied regardless of the source of funds and systems meet the standards and requirements set forth in 45 CFR part 74 or 92, as applicable (see "Financial Management").

If an applicant has no prior experience with Federal grants or cost-reimbursement contracts, the GMO may review the applicant's financial management and other management systems before award, or within a reasonable time after award, to determine their adequacy and acceptability. For an applicant with prior OPDIV or other Federal cost-reimbursement awards, the GMO may review recent audit reports and other available information to determine whether the applicant's management systems meet the established standards. The GMO will advise the applicant if additional information is required. On the basis of the review results, the GMO will determine the need for any corrective action and may impose special conditions on the award. The OPDIV also will oversee the recipient's systems as part of its routine post-award monitoring.

The Notice of Award

The NoA is the legal document issued to the receiving organization that indicates an award has been made and that funds may be requested from the designated HHS payment system or office. A NoA, showing the amount of Federal funds authorized for obligation and any future-year commitments, is issued for each budget period in the approved project period (see "Project Period and Budget Period" below). Until an awarding office has issued a NoA for the initial budget period, any costs incurred by the applicant for the project are incurred at its own risk. A revised NoA may be issued during a budget period to effect an action resulting in a change in the period or amount of support or other change in the terms and conditions of award. An awarding office generally will not issue a revised NoA to reflect a recipient's post-award rebudgeting.

The NoA sets forth pertinent information about the grant, including, but not limited to, the following:

- Grant identification number ("grant number")
- Statutory authority for the award and any applicable program regulations
- Name of recipient organization
- Name of the PI/PD
- Approved project period and budget period start and end dates
- Amount of Federal funds authorized for obligation by the recipient
- Amount of matching or cost sharing (if applicable)
- Amount of anticipated future-year commitments (if applicable)
- Names of the cognizant OPDIV/awarding office, PO, GMO, and GMS
- Applicable terms and conditions of award, either by reference or inclusion.
- The HHS-assigned EIN (based on the IRS EIN), which must be used to request payment.

A recipient indicates acceptance of an award and its associated terms and conditions by drawing or requesting funds from the designated HHS payment system or office. For cooperative agreement awards, an awarding office may require the recipient to formally accept the award by signing and returning the NoA or separate document. When signature is required, the authorized organizational representative must be the signatory of the NoA. If a recipient cannot accept the award, including the legal obligation to perform in accordance with award terms and conditions, the organization should notify the GMO immediately upon receipt of the NoA. If resolution cannot be reached, the GMO will void the grant. The OPDIV's determination of applicable terms and conditions of award or a GMO's denial of a request to change the terms and conditions is discretionary and not subject to appeal. Once the award is accepted by the recipient, the contents of the NoA are

binding on the recipient unless and until modified by a revised NoA signed by the GMO.

Project Period and Budget Period

For most grants, HHS uses the project period system of funding. Under this system, projects are programmatically approved for support in their entirety, but are funded in annual increments called budget periods. The total project period consists of the initial competitive segment, any additional competitive segments authorized by approval of a competing continuation application, and any non-competing extensions. A competitive segment generally will be no longer than 5 years (exclusive of non-competing extensions). A single award covering the entire period of support generally is used if the project is solely for construction (or major A&R of real property) or if the total planned period of support will be less than 18 months.

The length of the project period (whether for one or more than one competitive segment) is determined by the OPDIV on the basis of the following:

- Any statutory, regulatory, or administrative requirements
- The length of time requested by the applicant
- Any limitation on the length of the project period recommended by the objective or reviewers
- The OPDIV's programmatic determination of the frequency of objective review necessary for managing the project, program, or activity
- The OPDIV's funding principles as specified in the funding opportunity announcement.

Most NoAs document approval of a project period that extends beyond the budget period for which funds are provided, indicating the OPDIV's intention to provide continued financial support. The amounts shown for subsequent years represent projections of future funding levels based on the information available at the time of the initial award. Such projected levels of future support are contingent on satisfactory progress, the availability of funds, and the continued best interests of the Federal government. They are not guarantees that the project or program will be funded or will be funded at those levels, and they create no legal obligation to provide funding beyond the ending date of the current budget period as shown in the NoA.

Recipients are required to submit a non-competing continuation application or annual progress report as a prerequisite to approval and funding of each subsequent budget period (non-competing continuation award) within an approved project period. A decision to fund the next budget period will be formalized by the issuance of a NoA indicating the new budget period and the amount of new funding. Part II explains this process in greater detail.

Budget periods usually are 12 months long; however, shorter or longer budget periods may be established for programmatic or administrative reasons. The NoA will show the total approved budget for the applicable budget period, including direct costs and, if applicable, indirect costs as well as any required matching or cost

sharing. SBIR and STTR awards also may include a fee; however, no other HHS awards may include profit or fee.

The initial and each subsequent NoA that provides funding sets forth the amount awarded under that action, amounts previously awarded for that budget period, and, after the initial budget period, any authorized carryover (see Part II). The amount awarded also is shown generally with a categorical (line item) budget breakdown. The recipient has certain rebudgeting flexibility within the overall amount awarded as specified in Part II. However, the total amount awarded (direct and indirect costs and fee, where applicable) is the OPDIV's maximum financial obligation to the recipient under that award; in other words, it is the ceiling on the amount payable to the recipient under that award. Once an award is made, the OPDIV is not obligated to make any supplemental or other award or to provide additional funding for indirect costs or other purposes.

If an applicant/recipient waives reimbursement of the full indirect costs to which it is otherwise entitled based on its negotiated rate, the awarding office will either not award indirect costs or will award only partial indirect costs, as appropriate. In general, regardless of the type of recipient, the negotiated indirect cost rate(s) in effect at the beginning of the competitive segment will be used to determine the amount budgeted for indirect costs for each year of the competitive segment. If the rate agreement does not extend to the end of the project period, the last rate in effect will be used to establish the total cost commitment for any remaining future years.

Under limited circumstances, the GMO may award indirect costs where none were previously awarded or may increase the amount previously awarded. If an award does not include an amount for indirect costs because the applicant or recipient has not established a rate or did not submit a timely rate proposal and the recipient subsequently establishes a rate, the GMO may amend the award to provide an appropriate amount for indirect costs if the amendment can be made using funds from the same Federal fiscal year in which the award was made. However, the amount will be limited to the indirect costs applicable to the period after the effective date of the rate agreement. This provision does not affect local governmental agencies that are not required to submit their indirect cost proposals to the Federal government. They may charge indirect costs to grants based on the rate computations they prepare and keep on file for subsequent Federal review.

Other Terms and Conditions

In addition to, or in lieu of, the standard terms and conditions of award specified in the HHS GPS, the OPDIV may use terms and conditions for program-specific or award-specific reasons. For example, if, on the basis of a recipient's application or other available information, the GMO finds—at the time of award or at any time subsequent to award—that the recipient's management systems and practices are not adequate to ensure the appropriate stewardship of grant funds or to achieve the objectives of the award, the GMO may impose special, more restrictive terms and conditions on the award in accordance with 42 CFR 52.9 and 45 CFR 74.14 or 92.12. For example, an OPDIV could require a recipient to obtain prior approval for expenditures that ordinarily do not require such approval or to provide more frequent reports. In addition to closer monitoring, the OPDIV may assist the recipient with taking any necessary corrective action.

Payment

HHS grant payments may be made by one of several advance payment methods, including SMARTLINK II/ACH, CASHLINE/ACH, or cash request, or by cash request on a reimbursement basis, as specified in the NoA and as described in this section. Payments under grants generally are made as advance payments. Except as indicated in this section, grant payments are made by the PMS, operated by HHS's DPM, in accordance with Department of the Treasury and OMB requirements, as implemented by 45 CFR 74.22 and 92.21. These requirements are intended to minimize the time elapsing between the transfer of funds from the Federal government and disbursement by a recipient. Therefore, although the grant may be financed by advance payments, the intent is that recipients draw funds as needed.

Federal funds advanced to the recipient should be fully disbursed (checks written, signed, and issued to the payees) by the close of business the next work day after receipt of the funds. The potential for excessive Federal cash on hand exists each time a recipient does not disburse Federal funds timely. The recipient is responsible for determining when the Federal funds have been deposited into its bank account for each drawdown, ensuring that the funds are fully disbursed by the close of business the next work day after they are received, and immediately returning undisbursed Federal cash on hand to PMS. An OPDIV may use reimbursement as the method of payment, in lieu of advance payment, if cash management requirements are not met. Advances made by recipients to subrecipients and contractors under grants must conform to substantially the same standards of timing and amount that govern advances to the recipient.

Operational guidance for recipients is contained in the *DHHS Manual for Recipients Financed under the Payment Management System* (available through the HHS Web site at http://www.dpm.psc.gov/doc/hhsrecmanual.pdf). Inquiries regarding payments should be directed to DPM at the address shown in Part III.

OPDIVs make payments under awards to foreign or international organizations, if those organizations do not have a U.S. bank account, and awards to agencies of the Federal government.

SMARTLINK II/ACH

The SMARTLINK II/ACH method of advance payment makes direct deposit of funds to a recipient's bank account and requires recipients to have Internet access to submit a request for funds to PMS. SMARTLINK II/ACH provides funds the day following the request with direct deposit using the ACH process of the Federal Reserve Bank (Richmond, Virginia).

CASHLINE/ACH

The CASHLINE/ACH method of advance payment provides for direct deposit of funds to the recipient's bank account using a touch-tone telephone to dial directly to a "voice-response" computer located at PMS. CASHLINE/ACH makes funds available the day following the request with direct deposit using the Federal Reserve Bank's ACH process.

Cash Request

Recipients not eligible for an unrestricted advance of funds by SMARTLINK II/ACH or CASHLINE/ACH must submit a cash request as specified in the NoA. Cash requests usually are submitted monthly using SF 270, Request for Advance or Reimbursement. The cash request may be on either an advance or reimbursement basis, as specified by the awarding office. Cash requests are used when a recipient's cash management must be closely monitored (for example, recipients whose financial management systems do not meet the standards specified in 45 CFR 74.21 or 92.20) or under programs where reimbursement financing is appropriate. A recipient also may be converted from an unrestricted advance payment method to a cash request basis if, during post-award administration, the GMO determines that the recipient is not complying with the cash management requirements or other requirements of the award, including the submission of complete and timely reports.

If the cash request is for an advance payment, the recipient may request funds monthly on the basis of expected disbursements during the succeeding month and the amount of Federal funds already on hand. A request for reimbursement may be submitted more often, if authorized. For timely receipt of cash, a recipient must submit the request through the awarding office early enough for it to be forwarded to PMS at least 2 weeks before the cash is needed. PMS makes payment electronically through the ACH process upon receipt of the approved payment request from the awarding office.

Post-Award Administration

The recipient, as the direct and primary recipient of HHS grant funds, is responsible for managing the day-to-day operations of grant-supported activities and is accountable to the OPDIV for the performance of the project, program, or activity; the appropriate expenditure of grant funds by all parties; and all other obligations of the recipient. Recipients may use their established controls and policies, as long as they are consistent with award requirements. HHS seeks to foster within recipient organizations an organizational culture that is committed to compliance with Federal and HHS grant regulations, policies, and procedures. Actions to achieve this result should include a clear delineation of the roles and responsibilities of the organization's staff, both programmatic and administrative; written policies and procedures; training; management controls and other internal controls; performance assessment; administrative simplifications; and information sharing.

In addition, to fulfill their role in regard to the stewardship of Federal funds, OPDIVs monitor their awards to identify potential problems and areas where technical assistance might be necessary. This active monitoring is accomplished through review of recipient-generated reports, including audit reports, and correspondence; site visits; and other information available to the OPDIV. The names and telephone numbers of the individuals responsible for monitoring the programmatic and business management aspects of a project or activity will be provided to the recipient at the time of award.

Monitoring will continue for as long as the OPDIV retains a financial interest in the project, program, or activity as a result of property accountability, audit, and other requirements that may continue for a period of time after the grant is

administratively closed out and the OPDIV is no longer providing active grant support.

Post-award requirements are addressed in detail in Part II.

Part II: Terms and Conditions of Award

Overview of Terms and Conditions of Award

General, Program-Specific, and Award-Specific Terms and Conditions

The terms and conditions of award include general administrative and public policy requirements that apply to all recipients or certain classes of awards or activities; program-specific-requirements; and, as necessary, award-specific requirements. This part of the HHS GPS serves as the general administrative and public policy terms and conditions of HHS discretionary grant and cooperative agreement awards, as referenced in NoAs. It addresses the applicability of those terms and conditions based on the type of award, recipient, or grant-supported activity.

The HHS GPS is consistent with the requirements of 45 CFR parts 74 and 92, only some of which are repeated or highlighted here, and is not intended to be all-inclusive. All awards or a specified subset of awards also may be subject to additional requirements, such as those included in appropriations acts and Executive orders. Notice of requirements not specified in the HHS GPS generally will be provided in the NoA, but such notice is not required for the award to be subject to the requirements of pertinent statutes and regulations.

In addition to all of the applicable administrative requirements of 45 CFR part 74 or 92, as appropriate for the type of recipient, and other general terms and conditions, each award also is subject to the requirements of the authorizing program legislation and program regulations, if any. These requirements will be specified or incorporated by reference in the NoA. An individual award also may contain award-specific terms and conditions included in full text. For example, the GMO may include terms and conditions necessary to address concerns about a recipient's management systems. For cooperative agreement awards, the NoA will specifically address the substantial programmatic involvement of Federal staff and any other special terms (e.g., ownership of data and research results, and use of equipment) appropriate for the cooperative agreement.

Effect and Order of Precedence

Any waivers of or deviations from these terms and conditions must be requested and approved in writing by the GMO. OPDIV determination of applicable terms and conditions of award or a GMO's denial of a request to change the terms and conditions is discretionary and not subject to appeal.

A recipient indicates acceptance of an award and its associated terms and conditions by requesting and accepting funds from PMS or the designated HHS payment office for that award. If a recipient cannot accept an award, including the legal obligation to perform in accordance with its provisions, it should notify the GMO immediately upon receipt of the NoA. If resolution cannot be reached, the GMO will void the grant. Once an award is accepted by a recipient, the contents of the NoA are binding on the recipient and the OPDIV unless and until modified by a revised NoA signed by the GMO.

If there is a perceived conflict between or among statutory and regulatory requirements, the terms and conditions in this part of the HHS GPS, Part IV of the HHS GPS and award-specific terms and conditions, or if the recipient has questions concerning award terms and conditions, the recipient should request written clarification from the GMO. This may be done at any time; however, if the inclusion of the term or condition would cause the organization not to accept the award or to be unable to comply, the question should be raised before award acceptance. In the case of a conflict, statutes and regulations take precedence over requirements or restatements of statutory or regulatory requirements in the HHS GPS, and OPDIV or award-specific requirements take precedence over Part II of the HHS GPS.

Flow-Down of Requirements under Subawards and Contracts under Grants

The terms and conditions in the HHS GPS apply directly to the recipient of HHS funds. The recipient is accountable for the performance of the project, program, or activity; the appropriate expenditure of funds under the award by all parties; and all other obligations of the recipient, as cited in the NoA. In general, the requirements that apply to the recipient, including public policy requirements, also apply to subrecipients and contractors under grants, unless an exception is specified.

Public Policy Requirements

This section addresses public policy requirements applicable to some or all HHS applications and/or awards. These requirements are in addition to the pre-award requirements specified in Part I or supplement the coverage in Part I by indicating how a requirement applies following award. The term "public policy" indicates that the requirement is based on social, economic, or other objectives or considerations that may be attached to the expenditure of Federal funds by recipients, subrecipients (including consortium participants), or contractors under grants, in general, or may relate to the expenditure of Federal funds for specified activities, e.g., research. In addition to cross-cutting requirements based in statutes, regulations, or Executive orders that some or all Federal agencies must apply to their grant programs, HHS recipients also are subject to requirements that apply to the use of grant funds as contained in HHS annual appropriations acts. Some of those requirements are included here because they have been included in the appropriations acts for several years without change, but those requirements may be changed or other requirements may be added in the future.

As indicated in Part I, by signing the application, the authorized organizational official certifies that the organization will comply with applicable public policies. Once a grant is awarded, the recipient is responsible for establishing and maintaining the necessary processes to monitor its compliance and that of its employees and, as appropriate, subrecipients and contractors under the grant with these requirements; taking appropriate action to meet the stated objectives; and informing the OPDIV of any problems or concerns. If a grant is awarded on the basis of false or misrepresented information, or if a recipient does not comply with these public policy requirements, the OPDIV or other cognizant office may take any necessary and appropriate action with respect to the recipient or the award.

Exhibit 3, which includes public policy requirements cited in Part I and in this section, contains information to help the applicant/recipient determine what public policy

requirements and objectives apply to its activities. The exhibit indicates, by exception, whether a requirement applies to less than all OPDIVs meeting the threshold requirement; for example, if a requirement applies to research awards, it applies to all OPDIVs awarding research grants unless otherwise specified. The table indicates—by "Y" for Yes or "NA" for Not Applicable—whether a given public policy requirement normally would apply to the recipient and under what conditions and whether it is required to be flowed down under subawards or contracts under grants for routine goods and services. However, even if the exhibit indicates that a requirement is not applicable, that public policy requirement potentially could be applicable in a specific situation, for example, if a contract under a grant involves research activity. Therefore, this exhibit should be used as general guidance only. The applicant/recipient should consult the funding opportunity announcement and the NoA (if applicable) as well as the statute, regulations, or other cited policies or documents for complete information and should contact the GMO if there is any question concerning the applicability of a particular public policy requirement or objective.

Exhibit 3. Public Policy Requirements

Requirement	Applicability	Recipient	Subrecipient (including consortium participant)	Contractor under grant (routine goods/services)
Acknowledgment of Federal Funding	All types of awards	Y	Y	NA
Activities Abroad	All types of awards	Y	Y	Y
Age Discrimination Act of 1975	All applications from and awards to domestic entities	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)
Animal Welfare	Applications and awards for activities involving warm-blooded animals	Y	Y	Y
Certificates of Confidentiality	Research awards (includes research training in each case specified as "research")	Y	Y	Y
Civil Rights Act of 1964 (Title VI)	All applications from and awards to domestic entities	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)
Clean Air and Clean Water Act	Construction grants	Y	Y	Y
Confidentiality of Patient/Client Records	All research awards and awards to substance abuse programs	Y	Y	Y

Exhibit 3. Public Policy Requirements

Requirement	Applicability	Recipient	Subrecipient (including consortium participant)	Contractor under grant (routine goods/services)
Controlled Substances	All types of awards	Y	Y	Y
Drug-Free Workplace	All covered applications and awards	Y	NA	NA
Education Amendments of 1972 (Title IX)	All applications from and awards to domestic entities	Y (NA to foreign and international organizations	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)
Elimination of Architectural Barriers to the Handicapped	All awards involving construction or major alteration and renovation	Y	Y	Y
Financial Conflict of Interest	All applications and awards for research except those for Phase I of the SBIR/STTR program and awards to Federal institutions/PHS OPDIVs[a]	Y (NA to Phase I of the SBIR/STTR programs and to Federal institutions)	Y	NA
Flood Insurance	Construction awards	Y	NA	NA
Hatch Act	Awards to State or local governments	Y	Y	NA
Health Insurance Portability and Accountability Act (HIPAA)	All awards to covered entities	Y (if a covered entity)	Y (if a covered entity)	Y (if a covered entity)
Historic Properties/ Archaeological Sites	All awards that include major or minor A&R, construction, or any work that will result in physical changes to real property	Y	Y	Y
Human Embryonic Stem Cell Research	Research awards	Y	Y	Y
Human Subjects	Research applications and awards	Y	Y	Y

Exhibit 3. Public Policy Requirements

Requirement	Applicability	Recipient	Subrecipient (including consortium participant)	Contractor under grant (routine goods/services)
Investigational New Drug Applications/ Investigational Device Exceptions	Research awards	Y	Y	Y
Limited English Proficiency	All types of awards	Y	Y	NA
National Environmental Policy Act (including Public Disclosure)	Applications and awards for construction and major alteration and renovation	Y	Y	NA
Pro-Children Act	All awards performed in facilities where children are served	Y	Y	Y
Protection of Research Subjects' Identity	All research awards/PHS OPDIVs	Y	Y	Y
Protection of Wetlands	Construction awards	Y	Y	Y
Public Health Security and Bioterrorism Preparedness and Response Act	All types of awards	Y	Y	Y
Recombinant DNA Molecules and Human Gene Transfer Research	Applications and awards for research	Y	Y	Y
Rehabilitation Act of 1973 (Section 504)	All applications from and awards to domestic organizations	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)
Research Misconduct	Applications and awards for research and research training/PHS OPDIVs	Y	N	NA
Research on Human Fetal Tissue	Research awards	Y	Y	Y
Research on Transplantation of Fetal Tissue	Research awards	Y	Y	Y

Exhibit 3. Public Policy Requirements

Requirement	Applicability	Recipient	Subrecipient (including consortium participant)	Contractor under grant (routine goods/services)
Resource Conservation and Recovery Act	All awards to States or agency of a political subdivision of a State (which for this purpose includes State and local institutions of higher education or hospitals)	Y	Y	Y
Restriction on Abortions	All types of awards	Y	Y	Y
Restriction on Distribution of Sterile Needles	All types of awards	Y	Y	Y
Safe Drinking Water Act	Construction awards	Y	Y	Y
Seat Belt Use	All types of awards	Y	NA	NA
Smoke-Free Workplace	All awards	Y	NA	NA
Standards of Conduct	All types of awards	Y	NA	NA
Uniform Relocation Assistance and Real Property Acquisition Policies Act	All awards	Y	Y	NA
U.S. Flag Air Carriers	All types of awards	Y	Y	Y
USA PATRIOT Act	All types of awards	Y	Y	Y

[a] PHS OPDIVs awarding research grants include AHRQ, CDC, FDA, HRSA, OPHS, and NIH.

Standards of Conduct for Recipient Employees

HHS requires recipients to establish safeguards to prevent employees, consultants, members of governing bodies, and others who may be involved in grant-supported activities from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others, such as those with whom they have family, business, or other ties. These safeguards must be reflected in written standards of conduct. Except as provided below, HHS does not require a recipient to establish separate standards of conduct if it maintains such standards for its non-grant-supported activities, as long as those standards are consistent with State and local laws and cover, at a minimum, expected conduct in regard to financial interests, gifts, gratuities and favors, nepotism, and such other areas for governmental organizations as political participation and bribery.

The standards also must do the following:

- Address the conditions under which outside activities, relationships, or financial interests are proper or improper.
- Provide for advance notification of outside activities, relationships, or financial interests to a responsible organizational official.
- Include a process for notification and review by the responsible official of potential or actual violations of the standards.
- Specify the nature of penalties that the recipient may impose. These penalties would be in addition to any penalties that HHS or a cognizant Federal agency may impose for infractions that also violate the terms and conditions of award.

Recipients are not required to submit its general standards of conduct to HHS for review or approval. However, a copy must be made available to each of the recipient's officers; each employee and consultant working on the grant-supported program, project, or activity; each member of the governing board, if applicable; and, upon request, the OPDIV. The recipient is responsible for enforcing its standards of conduct, taking appropriate action on individual infractions, and, in the case of financial conflict of interest, informing the GMO if the infraction is related to a research award (see "Other Research-Related Requirements—Financial Conflict of Interest" for the specific regulatory requirements that apply to financial conflict of interest under research grants).

If a suspension or separation action is taken by a recipient against a PI/PD or other key personnel, the recipient must request prior approval of the proposed replacement.

Hatch Act

The Hatch Act restricts political activity of executive branch employees of the federal government and District of Columbia government employees (5 U.S.C. 7321–7328) and State or local officers or employees (5 U.S.C. 1501–1528). "State or local officer or employee" means an individual employed by a State or local agency whose principal employment is in connection with an activity that is financed in whole or in part by loans or grants made by the United States or a Federal agency. (Certain State educational or research institutions are excluded from this definition.)

Age Discrimination Act of 1975

The Age Discrimination Act of 1975, 42 U.S.C. 6101 *et seq.*, prohibits discrimination on the basis of age in any program or activity receiving Federal financial assistance. The HHS implementing regulations are codified at 45 CFR part 91.

Civil Rights Act of 1964

Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d *et seq.*, provides that no person in the United States will, on the grounds of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. The HHS implementing regulations are codified at 45 CFR part 80.

Education Amendments of 1972

Title IX of the Education Amendments of 1972, 20 U.S.C. 1681, 1682, 1683, 1685, and 1686, provides that no person in the United States will, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any educational program or activity receiving Federal financial assistance. The HHS implementing regulations are codified at 45 CFR part 86.

Rehabilitation Act of 1973

Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 794, as amended, provides that no otherwise qualified handicapped individual in the United States will, solely by reason of the handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. These requirements pertain to the provision of benefits or services as well as to employment. The HHS implementing regulations are codified at 45 CFR parts 84 and 85.

Biological Agents and Toxins

USA PATRIOT Act

The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act (USA PATRIOT Act) amends 18 U.S.C. 175–175c. Among other things, it prescribes criminal penalties for possession of any biological agent, toxin, or delivery system of a type or in a quantity that is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose. The act also establishes restrictions on access to specified materials. "Restricted persons," as defined by the act, may not possess, ship, transport, or receive any biological agent or toxin that is listed as a select agent (see "Public Health Security and Bioterrorism Preparedness and Response Act" in this subsection).

Public Health Security and Bioterrorism Preparedness and Response Act

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 42 U.S.C. 201 Note, is designed to provide protection against misuse of select agents and toxins, whether inadvertent or the result of terrorist acts against the U.S. homeland, or other criminal acts (see 42 U.S.C. 262a). The act was implemented, in part, through regulations published by CDC at 42 CFR part 73, Select Agents and Toxins. Copies of these regulations are available from the Import Permit Program and the Select Agent Program, respectively, CDC, 1600 Clifton Road, MS E-79, Atlanta, GA 30333; telephone: 404-498-2255. These regulations also are available at http://www.cdc.gov/od/ohs/biosfty/shipregs.htm.

Research involving select agents and recombinant DNA molecules also is subject to the *NIH Guidelines for Research Involving DNA Molecules* (see "Guidelines for Research Involving DNA Molecules and Human Gene Transfer Research" in this section).

Human Subjects

HHS regulations for the protection of human subjects, in 45 CFR part 46, implement Section 491(a) of the PHS Act, 42 U.S.C. 289(a), and provide a systematic means, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by HHS.

The Federal regulations require that each institution, domestic or foreign, engaged in human subjects research provide OHRP with a satisfactory assurance of compliance with the regulations, unless the research is exempt under 45 CFR 46.101(b). An institution becomes engaged in human subjects research when its employees or agents (1) intervene or interact with living individuals for research purposes, or (2) obtain individually identifiable private information for research purposes (45 CFR 46.102(f)). For purposes of 45 CFR part 46, research means a systematic investigation, including research, development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

The HHS regulations specify that departments and agencies cannot conduct or support research covered by this policy unless the institution has an assurance approved by OHRP, and only if the institution has certified to the OPDIV that the research has been reviewed and approved by the IRB provided for in the assurance and will be subject to continuing review by the IRB. Under no condition will research covered by Section 46.03 of the regulations be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB (45 CFR 46.103(b) and (f)).

The regulations specify additional protections for research involving human fetuses, pregnant women, and neonates (Subpart B); prisoners (Subpart C); and children (Subpart D). The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR part 46.

Office for Human Research Protections' and Recipient Responsibilities

Assurances and Other OHRP Responsibilities

On behalf of the Secretary, HHS, OHRP negotiates assurances covering all of an institution's federally supported research activities involving human subjects.[11] Applicants proposing to involve human subjects in nonexempt research must file (or have previously filed) a written assurance (FWA) with OHRP setting forth the commitment of the institution to establish appropriate policies and procedures for the protection of human subjects. For institutions proposing nonexempt research involving human subjects and not currently holding an approved assurance, OHRP will negotiate an FWA.

Each legally separate entity must file its own FWA even if the institution does not operate its own IRB and designates another IRB (registered with OHRP and agreeing to the designation) for that purpose. Affiliated institutions or organizations that will serve as additional performance sites for the grant-supported research also must file an FWA.

OHRP also has responsibility for oversight of recipient compliance with the HHS human subjects regulations. In carrying out this responsibility, OHRP evaluates all written substantive allegations or indications of non-compliance with the HHS regulations it receives from any source. All compliance oversight evaluations are based on the HHS regulations and the institution's assurance of compliance. Any corrective actions imposed as a result of compliance oversight evaluations are intended to remedy identified non-compliance and prevent recurrence. Because each case is different, OHRP tailors corrective actions to foster the best interests of human research subjects and, to the extent possible, of the institution, research community, and HHS. Most compliance oversight evaluations and resultant corrective actions are resolved at the OHRP level. However, OHRP may recommend actions to be taken by other HHS officials.

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[11] As of February 28, 2001, OHRP no longer accepts applications for Multiple Project Assurances (MPAs) or Single Project Assurances (SPAs) limited to HHS-supported research, to special categories of research, or to individual research projects. All MPAs have been superseded. Current SPAs will remain in effect through the expiration of their respective grant (or contract) award and any non-competing continuation award.

Detailed information about FWA preparation and negotiation and about OHRP activities related to oversight and compliance, as well as copies of the human subjects regulations, may be obtained from OHRP at the address shown in Part III or from its home page at http://www.hhs.gov/ohrp. OHRP also has produced a publication, available through GPO,[12] and an instructional videotape, the OHRP Assurance Training Module, which is available on the OHRP Web site.

Institutional Review Board Certification and Other Recipient Responsibilities

The recipient bears ultimate responsibility for protecting human subjects under the award, including human subjects at all sites, and for ensuring that an assurance approved by OHRP and certification of IRB review and approval have been obtained before human subjects research can be conducted at each collaborating site. HHS will not award a grant for nonexempt research in which human subjects are involved unless the applicant/recipient provides a certification to the OPDIV that the research has been approved by an appropriate IRB, consistent with 45 CFR part 46, within 12 months before the budget period start date.

It also is the recipient's responsibility to comply with prior-approval requirements related to the addition of sites not included in the approved application. The list of organizations with approved assurances is available at the OHRP Web site (http://www.hhs.gov/ohrp). Recipients may not draw funds from the payment system, request funds from the paying office, or make obligations against Federal funds for research involving human subjects at any site engaged in nonexempt research for any period not covered by both an OHRP-approved assurance and IRB approval consistent with 45 CFR part 46. Costs associated with IRB review of human research protocols are not allowable as direct charges under grants unless such costs are not covered by the organization's indirect cost rate.

Regardless of when the IRB review occurs (before objective review or just-in-time as specified in Part I or before award of a non-competing continuation award), the IRB should ensure that the research described in the application is consistent with any corresponding protocols reviewed and approved by the IRB. As specified in 45 CFR 46.111, the IRB review must include a determination that, for research covered by the regulations, the following conditions are met:

- The procedures to be used will minimize risks to subjects.
- Risks to subjects are reasonable in relation to expected benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result.
- Selection of subjects is equitable.
- Informed consent is sought from each prospective subject or the subject's legally authorized representative and is appropriately documented in accordance with, and to the extent required by, the regulation.

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[12] *Protecting Human Research Subjects: Institutional Review Board Guidebook*, 1993, Stock No. 017-040-00525-3, may be ordered from the Superintendent of Documents, telephone: 202-512-1800. This guidebook is also available from OHRP's website (http://www.hhs.gov/ohrp/irb/irb_guidebook.htm).

- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects, the protection of privacy, and the confidentiality of data.

- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, people with acute or severe physical or mental illness, or people who are economically or educationally disadvantaged, appropriate additional safeguards are included in the study to protect the rights and welfare of these subjects.

Protection of Research Subjects' Identities

HHS expects recipients and others involved in grant-supported research to take appropriate actions to protect the confidentiality of information about and the privacy of individuals participating in the research. Investigators, IRBs, and other appropriate entities should ensure that policies and procedures are in place to protect identifying information and must oversee compliance with those policies and procedures.

Animal Welfare

As specified in Part I of the HHS GPS, the *PHS Policy on Humane Care and Use of Laboratory Animals* requires applicants proposing to use vertebrate animals in HHS-supported activities to file a written Animal Welfare Assurance with OLAW. The PHS policy defines "animal" as "any live, vertebrate animal used or intended for use in research, research training, experimentation, biological testing, or related purposes." The PHS policy implements and supplements the *U.S. Government Principles for Utilization and Care of Vertebrate Animals used in Testing, Research, and Training*. The PHS policy also requires the applicant to establish appropriate policies and procedures for the humane care and use of animals, based on the *Guide for the Care and Use of Laboratory Animals*, and to comply with the Animal Welfare Act, as amended, 7 U.S.C. 2131 *et seq.*, and its implementing regulations. This includes appointing an IACUC with specified responsibilities. The PHS policy does not affect applicable State or local laws or regulations that impose more stringent standards for the care and use of laboratory animals.

Verification of the IACUC review of proposed research involving animals may be filed at any time before award unless required earlier by the OPDIV. Regardless of when the review occurs, the IACUC should ensure that the research described in the application is consistent with any corresponding protocols reviewed and approved by the IACUC. When organizations collaborate and multiple recognized IACUCs may be involved, only one of those IACUCs is required to review the research project or evaluate a program facility. In such cases, organizations must define their respective responsibilities to ensure compliance with the policy. If both organizations have full Animal Welfare Assurances, they may exercise discretion in determining which IACUC will review the research protocol and under which organization's program the research will be performed. An applicant/recipient without an animal care and use program or IACUC may enter into an inter-organizational agreement to use the IACUC of an organization with an assurance. Assured organizations also have the option, with OLAW approval, to amend their Animal Welfare Assurances to cover performance sites without such assurances. Foreign organizations proposing activities involving vertebrate animals are required to comply with the PHS policy or

provide evidence that acceptable standards for the humane care and use of animals will be met.

Information about preparing and submitting Animal Welfare Assurances and copies of the PHS policy and other relevant materials are available from OLAW (see Part III for contact information).

Other Research-Related Requirements

Research Misconduct

The recipient is responsible for the actions of its employees and other research collaborators, including third parties, involved in the project. The recipient will inquire into and, if necessary, investigate and resolve promptly and fairly all instances of alleged or apparent research misconduct. 42 CFR part 93, "Public Health Service Policies on Research Misconduct," [13] specifies recipient responsibilities for dealing with and reporting possible research misconduct. The regulation is available from ORI on its home page (http://www.ori.dhhs.gov) and in hard copy at the address shown in Part III.

The recipient must carry out its responsibilities with extra care if a research misconduct inquiry has been initiated as specified in 42 CFR 93.307 or if the recipient or ORI has made a finding of research misconduct. The recipient must report promptly to ORI any incident of alleged or apparent research misconduct that it judges as warranting investigation and must advise ORI of any decision to initiate an investigation. The recipient also must notify ORI if it intends to close a case at the inquiry or investigation stage based on an admission of responsibility, settlement, or for any other reason. The regulations also require that the recipient submit an annual report.

If a misconduct investigation has been initiated, the recipient must take any necessary steps, in addition to its normal and ongoing responsibilities under the grant, to protect the scientific integrity of the project, protect human subjects and animals, provide reports to ORI, and ensure the proper expenditure of funds and continuation of the project during the investigation, if appropriate. ORI staff members are available to help recipients with investigating and reporting on research misconduct, and POs are available to provide technical assistance and to work with recipients to protect funded projects from the adverse effects of research misconduct.

If the recipient finds research misconduct by anyone working on an HHS grant-supported project, whether at its organization or at a third-party organization, the recipient must assess the effect of that finding on the ability to continue that project, as originally approved, and must promptly request OPDIV prior approval of any intended change of PI or other key personnel (see "Prior Approval Requirements—OPDIV Prior Approval"). In addition, the awarding office may impose sanctions, such as withdrawal of approval of the PI/PD or other key personnel, disallowance of costs associated with the invalid or unreliable research, withholding a non-competing

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[13] For this purpose and financial conflict of interest in the next subsection, PHS includes the following OPDIVs with research programs: NIH, CDC, FDA, HRSA, OPHS, and AHRQ.

continuation award, suspension or termination, in whole or in part, of the current award, or debarment.

If research misconduct has affected data validity or reliability, ORI or the OPDIV may require the recipient and its employee/collaborator authors to submit a correction or retraction of the data to a journal, publish the corrected data, or both. If the recipient does not comply with this requirement, the OPDIV may invoke its rights, under 45 CFR part 74 or 92, to access the data (including copyrightable material developed under the award), have the data reviewed, and submit the correction.

The recipient must promptly report issues involving potential civil or criminal fraud, such as false claims or misappropriation of Federal funds, to the HHS OIG (see Part III).

Financial Conflict of Interest

Recipients and investigators must comply with the requirements of 42 CFR part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought." That subpart promotes objectivity in research by establishing standards to ensure that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will not be biased by any conflicting financial interest of an investigator. These requirements do not apply to Phase I of the SBIR/STTR programs.

Under those requirements the organization must do the following:

- Have a written and enforced administrative process to identify and manage, reduce, or eliminate conflicting financial interests with respect to research projects for which PHS funding is sought
- Before spending any PHS funds awarded under a new award, inform the GMO of the existence of any conflicting financial interests it identified of the type covered by 42 CFR 50.605 and assure that the interest been managed, reduced, or eliminated in accordance with the regulations
- Continue to make similar reports on subsequently identified conflicts within 60 days of identifying them
- Make additional information available to the OPDIV, upon request, as to how it handled conflicting interests in accordance with the regulations.

As described in the regulations, examples of how financial conflicts of interest might be addressed include the following:

- Public disclosure of significant financial interests
- Monitoring of research by independent reviewers
- Modification of the research plan
- Disqualification from participation in all or a portion of the research funded by PHS
- Divestiture of significant financial interests

- Severance of relationships that create actual or potential conflicts.

Recipients also must ensure that subawards in the form of consortium agreements address whether the consortium participant's employees will be subject to the financial conflict of interest requirements of the consortium participant or to those of the recipient.

Some IRBs also consider investigator financial conflict of interest in their deliberations, although they are not required to do so. If an IRB considers the impact of potential financial (or other) conflicts of interest on the research and the protection of human subjects, it should refer to the organization's policies and procedures for identifying and monitoring conflicts of interest.

Following are some strategies used by IRBs:

- Make IRB members aware of the organization's conflict of interest policies and procedures
- Include a statement in the informed consent form that all investigators comply with the organizational guidelines
- Ask investigators to complete a short questionnaire about whether they—or any person responsible for the design, conduct, or reporting of research—have an economic interest in or act as an officer or a director of any outside entity whose financial interest could reasonably appear to be affected by the research
- Instruct IRB members during their orientation on how to identify and respond to a perceived financial, academic, or other conflict of interest.

Suggestions for recipients to consider when implementing the requirements of this regulation are available in an NIH publication, *Financial Conflict of Interest–Objectivity in Research: Institutional Policy Review*, available on the NIH Web site at http://grants.nih.gov/grants/policy/coi/nih_review.htm.

Recombinant DNA and Human Gene Transfer Research

The *NIH Guidelines for Research Involving Recombinant DNA Molecules* (NIH Guidelines) (April 2002 or latest revision) apply to (1) all research projects that involve recombinant DNA and are conducted at or sponsored by an organization that receives support for recombinant DNA research, or (2) research projects involving testing in humans of materials containing recombinant DNA developed with HHS funds, if the organization that developed the materials sponsors or participates in those projects. The NIH guidelines are available at http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html. As defined by the NIH guidelines, recombinant DNA molecules are either (1) molecules that are constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell or (2) molecules that result from the replication of those described in (1).

The NIH guidelines apply to both basic and clinical research studies. Recombinant DNA research involving select agents also is subject to pertinent CDC and USDA

regulations.[14] Specific guidance for the conduct of human gene transfer studies appears in Appendix M of the NIH guidelines. Failure to comply with these requirements may result in suspension or termination of an award for recombinant DNA research at the organization, or a requirement for OPDIV prior approval of any or all recombinant DNA projects at the organization. The recipient should carefully review the NIH guidelines in their entirety to ensure compliance with all of the requirements for projects involving recombinant DNA techniques.

Human Embryonic Stem Cell Research and Cloning

HHS funds may not be used to support human embryo research under any extramural award instrument. HHS funds may not be used for the creation of a human embryo for research purposes or for research in which a human embryo is destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses *in utero* under 45 CFR 46.204 and 46.207 and Subsection 498(b) of the PHS Act 42 U.S.C. 289g(b). The term "human embryo" includes any organism not protected as a human subject under 45 CFR part 46, as of the date of enactment of the governing appropriations act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

In addition to the statutory restrictions on human fetal research under Subsection 498((b) of the PHS Act, HHS is prohibited, by a March 4, 1997, Presidential memorandum, from using Federal funds for cloning human beings.

Research on Human Fetal Tissue

Human fetal tissue is defined as tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion or stillbirth. This definition does not include established human fetal cell lines. Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable State and local laws and with the following guidance.

The scientific and ethical challenges associated with research utilizing human fetal tissue make it imperative that researchers and their organizations be fully aware of and in compliance with the Federal requirements, particularly Section 498B of the PHS Act, 42 U.S.C. 289g-2. The statute specifically prohibits any person from knowingly acquiring, receiving, or transferring any human fetal tissue for valuable consideration. The term "valuable consideration" is a concept similar to profit and does not include reasonable payment for costs associated with the collection, processing, preservation, storage, quality control, or transportation of these tissues. Violation of this statute carries criminal penalties that apply to both those that supply and those that acquire human fetal tissue.

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[14] See 42 CFR part 73, *Select Agents and Toxins;* and 7 CFR part 331 and 9 CFR part 121, *Possession, Use, and Transfer of Biological Agents and Toxins.*

Sections 498A and 498B of the PHS Act, 42 U.S.C. 289g-1 and 289g-2, contain additional legal requirements for research on the transplantation of human fetal tissue for therapeutic purposes conducted or supported by PHS. Under Section 498A, the recipient must adhere to the following provisions:

- The woman who donates the fetal tissue must sign a statement declaring that the donation is being made
  - ➤ for therapeutic transplantation research,
  - ➤ without any restriction regarding the identity of individuals who may receive the transplantation, and
  - ➤ without the donor knowing the identity of the individual receiving the transplantation.
- The attending physician must sign a statement that he/she has
  - ➤ obtained the tissue in accordance with the donor's signed statement and
  - ➤ fully disclosed to the donor his or her intent, if any, to use the tissue in research and any known medical risks to the donor or risks to her privacy associated with the donation that are in addition to risks associated with the woman's medical care.

  In the case of tissue obtained pursuant to an induced abortion, the physician's statement also must state that he/she
  - ➤ obtained the woman's consent for the abortion before requesting or obtaining consent for the tissue to be used;
  - ➤ did not alter the timing, method, or procedures used to terminate the pregnancy solely for the purpose of obtaining the tissue for research; and
  - ➤ performed the abortion in accordance with applicable State and local laws.
- The PI must sign a statement certifying that he/she is aware that the tissue is human fetal tissue obtained in a spontaneous or induced abortion, or pursuant to a stillbirth, and that the tissue was donated for research purposes. The PI also must certify that this information has been shared with others who have responsibilities regarding the research and, before eliciting informed consent from the transplantation recipient, will obtain written acknowledgment that the patient is aware of the aforementioned information.
- The PI must certify in writing that he/she has had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy.

The recipient must certify that the physician's statement, the PI's statement, and the acknowledgment of the transplantation recipient must be available for audit by the HHS Secretary or designee.

Information for organizations conducting research on human fetal tissue, including information on the governing Federal statutes, Sections 498A and 498B of the PHS

Act, 42 U.S.C. 289g-1 and 298g-2, is available on the NIH Web site at http://grants.nih.gov/grants/guide/notice-files/not93-235.html.

Transplantation of Human Fetal Tissue

If research on the transplantation of human fetal tissue is conducted under the grant-supported project, the recipient must make available for audit by the HHS Secretary or designee, the physician statements and informed consents required by Subsections 498A(b)(2) and (c) of the PHS Act, 42 U.S.C. 289g-1(b)(2) and (c) or must ensure HHS access to those records, if maintained by an entity other than the recipient. This requirement is in addition to the requirements concerning human subjects in research.

In addition, FDA issued a letter on November 30, 2000, indicating that it has jurisdiction over fetal cells and tissues intended for use in humans. FDA requests that investigators contact it to determine whether any planned or ongoing clinical research would require submission of an IND application. Additional information and FDA contact information is available at http://www.fda.gov/cber/ltr/fetal113000.htm.

Certificates of Confidentiality

Section 301(d) of the PHS Act, 42 U.S.C. 241, provides that the Secretary may authorize people engaged in biomedical, behavioral, clinical, or other research activities to protect the privacy of research subjects by withholding the names and other identifying characteristics of those subjects from individuals not engaged in the research. Individuals that have authorization may not be compelled to disclose subjects' identities in any Federal, State, or local civil, criminal, administrative, legislative or other proceeding. CoCs may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. By protecting researchers from being compelled to disclose information that would identify research subjects, CoCs contribute to achieving research objectives and promote participation in studies by helping to ensure confidentiality and privacy to participants. Information on CoCs is available on the NIH Web site at the CoC Kiosk at http://grants.nih.gov/grants/policy/coc/index.htm. Requests for CoCs should be submitted to the GMO, and, subject to OPDIV review and approval, a certificate may be issued pursuant to Section 301(d).

Investigational New Drug Applications/Investigational Device Exceptions

To be eligible for funding, all clinical research involving INDs, drugs approved for a different indication, or experimental combinations of drugs must meet FDA IND regulations, FDA human subjects' protection requirements, and HHS human subjects' requirements. As provided in the FDA regulations, an IND or IDE also may apply to biologics or devices. The FDA regulations are published in 21 CFR parts 50 and 312.

The official sponsor of the IND/IDE, whether a Federal agency, a recipient, or a third party, is legally responsible for meeting the FDA requirements. If the IND/IDE sponsor is a third party, such as a pharmaceutical company or research organization under contract to a recipient or to a pharmaceutical company, the legal responsibility for monitoring the clinical trial and reporting to FDA rests with the sponsor rather than the recipient. This generally will be the case for larger, multi-site clinical trials. If the recipient is the IND/IDE holder, commonly referred to as an "investigator-

initiated IND/IDE," the recipient or the investigator serves as the sponsor and assumes the legal responsibility. In any case, the recipient is ultimately responsible for ensuring compliance with the requirements for protection of human subjects, including compliance with FDA's requirements.

Following the filing of an IND, FDA has a 30-day period in which to review it. FDA may allow the IND to proceed or may defer approval of the IND until changes it deems acceptable are made. FDA also may order a clinical trial to be suspended or terminated, at any time, based on information it receives about that clinical trial.

When HHS funds all, or part of, a clinical study involving an IND or an IDE, the OPDIV must be aware of any significant communications with FDA concerning the study. The recipient must report certain types of FDA communications to the OPDIV within 72 hours of receiving a copy of or upon being informed of the FDA communication (through the PI or another person acting on behalf of the recipient), whichever occurs first. This notification requirement applies to any of the following communications from FDA with the sponsor of the IND or IDE:

- Warning letters (whether sent to the recipient or to the commercial sponsor)
- Notice of Initiation of Disqualification Proceedings and Notice of Opportunity to Explain
- Notice of Opportunity for Hearing
- Notice of Disqualification
- Consent agreements
- Clinical hold letters that pertain to breaches of good manufacturing practices, good clinical practices, or other major issue requiring significant changes in the protocol.

The notification should be made in writing, but also may be done by telephone if a written notice would delay the notification. It should include a statement of the action taken or contemplated and the assistance needed to resolve the situation. These requirements apply to the recipient even if the recipient or the funded PI is the sponsor. Failure to comply with this requirement may result in HHS imposing a corrective and/or enforcement action. FDA communications are considered grant-related records for purposes of retention and access.

Controlled Substances

Grantees are prohibited from knowingly using appropriated funds to support activities that promote the legalization of any drug or other substance included in Schedule I of the schedule of controlled substances established by section 202 of the Controlled Substances Act, 21 U.S.C. 812. This limitation does not apply if the recipient notifies the GMO that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage.

If controlled substances are proposed to be administered as part of a research protocol or if research is to be conducted on the drugs themselves,

applicants/recipients must ensure that the DEA requirements, including registration, inspection, and certification, as applicable, are met. Regional DEA offices can supply forms and information concerning the type of registration required for a particular substance for research use. The main registration office in Washington, DC, may be reached at 800-882-9539. Information also is available from the National Institute on Drug Abuse at 301-443-6300.

Construction-Related Requirements

In addition to those requirements specified in "Requirements Related to Construction, Modernization, and Other Designated Activities," the following public policy requirements apply to grants that involve construction or A&R.

Flood Insurance

The Flood Disaster Protection Act of 1973, as amended, 42 U.S.C. 4001 *et seq.*, provides that no Federal financial assistance to acquire, modernize, or construct property may be provided in identified flood-prone communities in the United States, unless the community participates in the National Flood Insurance Program and flood insurance is purchased within 1 year of the identification. The flood insurance purchase requirement applies to both public and private applicants for HHS support. Lists of flood-prone areas that are eligible for flood insurance are published in the *Federal Register* by FEMA.

Architectural Barriers

The Architectural Barriers Act of 1968, 42 U.S.C. 4151 *et seq.*, as amended, the Federal Property Management Regulations (see 41 CFR 102-76), and the Uniform Federal Accessibility Standards issued by GSA (see 36 CFR 1191, Appendixes C and D) set forth requirements to make facilities accessible to, and usable by, the physically handicapped and include minimum design standards. All new facilities designed or constructed with HHS grant support must comply with these requirements. These minimum standards must be included in the specifications for any HHS-funded new construction unless the recipient proposes to substitute standards that meet or exceed these standards. Where HHS assistance is provided for alteration or renovation (including modernization and expansion) of existing facilities, the altered facility (or part of the facility) must comply, including use of the minimum standards in the specifications. The recipient is responsible for conducting inspections to ensure compliance with these standards by any contractor performing construction services under the grant.

Clean Air and Clean Water Act

42 U.S.C. 7606 and EO 11738 provide for the protection and enhancement of the quality of the nation's air resources to promote public health and welfare and for restoring and maintaining the chemical, physical, and biological integrity of the nation's waters.

Safe Drinking Water Act

42 U.S.C. 300h-3 provides for the protection of underground sources of drinking water that have an aquifer, which is the sole source of drinking water. Specifically,

no grant may be entered into for any project that the EPA Administrator determines may contaminate such aquifer.

Health, Safety, and Related Requirements

Restriction on Funding Abortions

HHS funds may not be spent for an abortion.

Restriction on Distribution of Sterile Needles/Needle Exchange

Funds appropriated for HHS may not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

Standards for Privacy of Individually Identifiable Health Information

The "Standards for Privacy of Individually Identifiable Health Information" (the Privacy Rule) implement the Health Insurance Portability and Accountability Act (HIPAA) of 1996, 42 U.S.C. 1320d *et seq.*, which governs the protection of individually identifiable health information. The Privacy Rule is administered and enforced by HHS's OCR and is codified at 45 CFR parts 160 and 164. Not all HHS recipients are subject to the Privacy Rule. The Privacy Rule applies only to "covered entities," as defined by the rule, which include health plans and most health-care providers.

The OCR Web site (http://www.hhs.gov/ocr/hipaa) provides information on the Privacy Rule, including the complete text of the regulation and a set of decision tools for determining whether a particular entity is subject to the rule. An educational booklet, *Protecting Health Information in Research: Understanding the HIPAA Privacy Rule*, is available through OCR's Web site and at http://privacyruleandresearch.nih.gov/. That Web site also includes other educational materials approved by OCR and the HHS Office of the General Counsel.

Confidentiality of Patient/Client Records

Section 543 of the PHS Act, 42 U.S.C. 290dd-2, requires that records of substance abuse patients be kept confidential except under specified circumstances and purposes. The covered records are those that include the identity, diagnosis, prognosis, or treatment of any patient maintained in connection with any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research that is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States. This requirement is implemented in 42 CFR part 2.

Drug-Free Workplace

The Drug-Free Workplace Act of 1988, 42 U.S.C. 701 *et seq.*, requires that all organizations receiving grants from any Federal agency agree to maintain a drug-free workplace. The recipient must notify the awarding office if an employee of the recipient is convicted of violating a criminal drug statute. Failure to comply with these requirements may be cause for debarment. HHS implementing regulations are

set forth in 45 CFR part 82, "Governmentwide Requirements for Drug-Free Workplace (Financial Assistance)."

Pro-Children Act

The Pro-Children Act of 1994, 20 U.S.C. 7183, imposes restrictions on smoking in facilities where federally funded children's services are provided. HHS grants are subject to these requirements only if they meet the Act's specified coverage. The Act specifies that smoking is prohibited in any indoor facility (owned, leased, or contracted for) used for the routine or regular provision of kindergarten, elementary, or secondary education or library services to children under the age of 18. In addition, smoking is prohibited in any indoor facility or portion of a facility (owned, leased, or contracted for) used for the routine or regular provision of federally funded health care, day care, or early childhood development, including Head Start services to children under the age of 18. The statutory prohibition also applies if such facilities are constructed, operated, or maintained with Federal funds. The statute does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, portions of facilities used for inpatient drug or alcohol treatment, or facilities where WIC coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to $1,000 per violation and/or the imposition of an administrative compliance order on the responsible entity. Any questions concerning the applicability of these provisions to an HHS grant should be directed to the GMO.

Smoke-Free Workplace

HHS strongly encourages recipients to provide smoke-free workplaces and to promote the nonuse of tobacco products. HHS defines the term "workplace" to mean office space (including private offices and other workspace), conference or meeting rooms, corridors, stairways, lobbies, rest rooms, cafeterias, and other public spaces.

Health and Safety

Recipients are responsible for meeting Federal, State, and local health and safety standards and for establishing and implementing necessary measures to minimize their employees' risk of injury or illness in activities related to HHS grants. In addition to applicable Federal, State, and local laws and regulations, the following regulations must be followed when developing and implementing health and safety operating procedures and practices for both personnel and facilities:

- 29 CFR 1910.1030, Bloodborne pathogens; 29 CFR 1910.1450, Occupational exposure to hazardous chemicals in laboratories; and other applicable occupational health and safety standards issued by the Occupational Health and Safety Administration and included in 29 CFR part 1910. These regulations are available at http://www.osha.gov/comp-links.html.

- Nuclear Regulatory Commission Standards and Regulations, pursuant to the Energy Reorganization Act of 1974 (42 U.S.C. 5801 *et seq.*). Copies may be obtained from the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Recipients are not required to submit documented assurance of their compliance with or implementation of these requirements. However, if requested by the OPDIV,

recipients should be able to provide evidence that applicable Federal, State, and local health and safety standards have been considered and have been put into practice.

Acknowledgment of Federal Funding

As required by HHS appropriations acts, all HHS recipients must acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid invitations, and other documents describing projects or programs funded in whole or in part with Federal funds. Recipients are required to state (1) the percentage and dollar amounts of the total program or project costs financed with Federal funds and (2) the percentage and dollar amount of the total costs financed by nongovernmental sources.

Activities Abroad

HHS recipients must ensure that project activities carried on outside the United States are coordinated as necessary with appropriate government authorities and that appropriate licenses, permits, or approvals are obtained.

Limited English Proficiency

Recipients of Federal financial assistance must take reasonable steps to ensure that people with limited English proficiency have meaningful access to health and social services and that there is effective communication between the service provider and individuals with limited English proficiency. To clarify existing legal requirements, HHS published "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons." This guidance, which is available at http://www.hhs.gov/ocr/lep/revisedlep.html, provides a description of the factors that recipients should consider in determining and fulfilling their responsibilities to individuals with limited English proficiency under Title VI of the Civil Rights Act of 1964.

Resource Conservation and Recovery Act

Under RCRA (42 U.S.C. 6901 *et seq.*), any State agency or agency of a political subdivision of a State using appropriated Federal funds must comply with 42 U.S.C. 6962. This includes State and local institutions of higher education or hospitals that receive direct HHS awards. Section 6962 requires that preference be given in procurement programs to the purchase of specific products containing recycled materials identified in guidelines developed by EPA (40 CFR parts 247–254).

Seat Belts

Pursuant to EO 13043 (April 16, 1997), Increasing the Use of Seat Belts in the United States, HHS recipients are encouraged to adopt and enforce on-the-job seat belt policies and programs for their employees when operating vehicles, whether organizationally owned or rented or personally owned.

Cost Considerations

General

This section addresses the general principles underlying the allowability of costs, differentiates direct costs from indirect costs, and highlights a number of specific costs and categories of cost. It is not intended to be all-inclusive and should be used as a supplement to the applicable cost principles.

The Cost Principles

Cost principles establish general standards for the allowability of costs, provide detailed guidance on the cost accounting treatment of costs as direct or indirect costs, and set forth allowability principles for selected items of cost. Applicability of a particular set of cost principles depends on the type of organization making the expenditure. For example, a non-profit organization receiving a subaward from a State recipient would be subject to the cost principles for non-profit organizations, while the State would be subject to the cost principles for States, local governments, and Indian tribal governments.

The cost principles are set forth in the following documents and are incorporated by reference in 45 CFR 74.27 and 92.22:

- OMB Circular A-21—Cost Principles for Educational Institutions (2 CFR part 220)
- OMB Circular A-87—Cost Principles for State, Local, and Indian Tribal Governments[15] (2 CFR part 225)
- OMB Circular A-122—Cost Principles for Non-Profit Institutions[16] (2 CFR part 230)
- 45 CFR part 74, Appendix E—Principles for Determining Costs Applicable to Research and Development under Grants and Contracts with Hospitals
- 48 CFR subpart 31.2 (Federal Acquisition Regulation)—Contract Cost Principles and Procedures—Contracts with Commercial Organizations

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[15] Additional information on cost allocation plans and indirect cost rates is found in HHS's *A Guide for State, Local and Indian Tribal Governments: Cost Principles and Procedures for Developing Cost Allocation Plans and Indirect Cost Rates for Agreements with the Federal Government - Implementation Guide for Office of Management and Budget Circular A-87 (ASMB C-10),* which is available on the Internet at http://www.hhs.gov/grantsnet/state, *and Review Guide for State and Local Governments State/Local-Wide Central Service Cost Allocation Plans and Indirect Cost Rates*, which is available at http://rates.psc.gov/.

[16] Non-profit organizations that are specifically listed in Attachment C to OMB Circular A-122 are subject to the Federal cost principles applicable to commercial organizations (48 CFR subpart 31.2) rather than to the cost principles for non-profit organizations.

Recipients can use their own accounting systems, policies, and procedures to implement the cost principle requirements as long as the standards prescribed in 45 CFR 74.21 or 92.20 for financial management systems are met (see "Financial Management").

The cost principles address four tests in determining the allowability of costs. The tests are as follows:

- *Reasonableness (including necessity).* A cost is reasonable if, in its nature or amount, it does not exceed that which would be incurred by a prudent person under the circumstances prevailing at the time the decision was made to incur the cost. The cost principles elaborate on this concept and address considerations such as whether the cost is of a type generally necessary for the organization's operations or the grant's performance, whether the recipient complied with its established organizational policies in incurring the cost or charge, and whether the individuals responsible for the expenditure acted with due prudence in carrying out their responsibilities to the Federal government and the public at large as well as to the organization.

- *Allocability.* A cost is allocable to a specific grant, function, department, or other component, known as a cost objective, if the goods or services involved are chargeable or assignable to that cost objective in accordance with the relative benefits received or other equitable relationship. A cost is allocable to a grant if it is incurred solely in order to advance work under the grant; it benefits both the grant and other work of the organization, including other grant-supported projects or programs; or it is necessary to the overall operation of the organization and is deemed to be assignable, at least in part, to the grant.

- *Consistency.* Recipients must be consistent in assigning costs to cost objectives. They must be treated consistently for all work of the organization under similar circumstances, regardless of the source of funding, so as to avoid duplicate charges.

- *Conformance.* This test of allowability—conformance with limitations and exclusions contained in the terms and conditions of award, including those in the cost principles—may vary by the type of activity, the type of recipient, and other characteristics of individual awards. "Allowable Costs and Activities" below provides information common to most HHS grants and, where appropriate, specifies some of the distinctions if there is a different treatment based on the type of grant or recipient.

These four tests apply regardless of whether the particular category of costs is one specified in the cost principles or one governed by other terms and conditions of an award. These tests also apply regardless of treatment as a direct cost or an indirect cost. The fact that a proposed cost is awarded as requested by an applicant does not indicate a determination of allowability.

Direct Costs and Indirect Costs

Direct costs are costs that can be identified specifically with a particular award, project or program, service, or other organizational activity or that can be directly assigned to such an activity with a high degree of accuracy. Direct costs include, but

are not limited to, salaries, travel, equipment, and supplies directly benefiting the grant-supported project or program. Indirect costs (also known as "facilities and administrative costs") are costs incurred for common or joint objectives that cannot be identified specifically with a particular project, program, or organizational activity. Facilities operation and maintenance costs, depreciation, and administrative expenses are examples of costs that usually are treated as indirect costs. The organization is responsible for presenting costs consistently and must not include costs associated with its indirect rate as direct costs.

Reimbursement of Indirect Costs

HHS considers activities conducted by recipients that result in indirect charges a necessary and appropriate part of HHS grants. OPDIVs reimburse their share of those costs either as a fixed amount or through use of a rate. The amount may be specified in statute, regulations, or policy or be determined based on a rate negotiated by DCA, DFAS in the Office of Acquisition Management and Policy, NIH (responsible for negotiating indirect cost rates for for-profit entities receiving awards from HHS), or other cognizant Federal agency and reflected in a formal rate agreement. For certain governmental organizations, amounts claimed are based on documentation retained by the governmental organization. State and local governmental organizations also may be eligible for reimbursement of costs associated with provision of central services as provided in OMB Circular A-87.[17] If an applicant is advised by the GMO of the need to establish a rate prior to issuance of a NoA, the GMO will indicate the responsible office to be contacted.

If reimbursement of indirect costs is allowable under an award, HHS will not reimburse those costs unless the recipient has established an indirect cost rate covering the applicable activities and period of time unless indirect costs are reimbursed at a fixed rate (e.g., HHS indirect cost reimbursement for training grants to other than governmental recipients) or the applicant is not required to submit a proposal to the Federal government as specified in OMB Circular A-87. The awarding office uses the applicable indirect cost rate covering the award budget period (or part thereof) in calculating the amount to be shown or to be included on the NoA. If, on the basis of statute, regulation, or policy, allowable indirect cost reimbursement is restricted to an amount less than full indirect cost reimbursement, the difference between those two amounts may be used to satisfy a recipient's matching or cost-sharing requirement (see "Matching or Cost Sharing").

Indirect cost proposals must be prepared in accordance with the applicable cost principles and guidance provided by the cognizant office or agency. Further information concerning the establishment of indirect cost rates and the reimbursement of indirect costs may be obtained from DCA or DFAS (see Part III). DCA should be consulted to determine the need to submit a Disclosure Statement (DS-2) pursuant to the requirements of OMB Circular A-21.

If the GMO determines that a recipient does not have a currently effective indirect cost rate, the award may not include an amount for indirect costs unless the organization has never established an indirect cost rate (usually a new recipient) and

[17] OMB Circular A-87 also addresses public assistance cost allocation plans; however, the types of programs eligible for such costs are not covered by this HHS GPS.

intends to establish one. In such cases, the award shall include a provisional amount equaling one-half of the amount of indirect costs requested by the applicant, up to a maximum of 10 percent of direct salaries and wages (exclusive of fringe benefits). If the recipient fails to provide a timely proposal, indirect costs paid in anticipation of establishment of a rate will be disallowed.

There are several other limited circumstances under which the GMO may award indirect costs if none were previously awarded or may increase the amount previously awarded. If an award does not include an amount for indirect costs because the recipient did not submit a timely indirect cost proposal and the recipient subsequently establishes a rate, the GMO may amend the award to provide an appropriate amount for indirect costs if the amendment can be made using funds from the same Federal fiscal year in which the award was made. However, the amount will be limited to the indirect costs applicable to the period after the effective date of the rate agreement. This provision does not affect those local governmental agencies that are not required to submit their indirect cost proposals to the Federal government. They may charge indirect costs to HHS grants based on the rate computations they prepare and keep on file for subsequent Federal review.

Rebudgeting within the direct cost category may affect the amount of eligible indirect cost reimbursement, depending on the direct cost base on which indirect costs are calculated (for example, salaries and wages). The recipient is expected to accommodate such changes within the ceiling amount of the award. If permissible direct cost rebudgeting or unobligated balances of Federal funds result in the need for a lesser amount of indirect costs than awarded or a higher permanent rate results in a need for additional indirect costs beyond those awarded, recipients may rebudget between direct and indirect costs (in either direction) to accommodate such an increase or decrease without OPDIV prior approval unless it would constitute a change in the scope of the project (see "Prior-Approval Requirements—OPDIV Prior Approval").

Generally, award amounts will not be adjusted based on a negotiated indirect cost rate different from that used at the time of the award (whether competitive segment or budget period).

If funds are available, a GMO may, but is not obligated to, amend an award to provide additional funds for indirect costs, but only under the following circumstances:

- An error was made in computing the award. This includes situations in which a higher rate than the rate used in the grant award is negotiated and the date of the rate agreement for the higher rate is on or before 1 calendar month prior to the beginning date of the grant budget period.

- The awarding office restores funds previously recaptured as part of a recipient's unobligated balance.

- The recipient is eligible for additional indirect costs associated with additional direct costs awarded, e.g., a supplemental award.

For all recipients other than those subject to OMB Circular A-21, the negotiated rate in effect at the beginning of each budget period will be used as the basis for determining indirect costs for that budget period. For recipients subject to OMB

Circular A-21, the rate in effect at the beginning of a competitive segment will be used to determine indirect cost funding levels for the entire segment. If the rate agreement in effect at the outset of the competitive segment does not cover the entire competitive segment, then the rate in effect for the last year of the negotiated agreement will be used to determine indirect cost funding for the duration of the competitive segment. For all recipients, if the rate in effect at the beginning of the competitive segment or budget period, as applicable, was provisional and is superseded by a permanent rate, whether higher or lower, the latter rate will be used to determine indirect cost reimbursement. The award will not be adjusted downward, based on a lower permanent indirect cost rate than a provisional rate used in calculating the award, unless the indirect cost proposal that served as the basis for the negotiation included unallowable costs. The OPDIV also is not required to provide any additional funding to accommodate this situation but may do so if an error was made in computing the award as indicated above.

The recipient is responsible for establishing indirect cost rates for its subrecipients if those subrecipients do not have a current, applicable rate negotiated by a cognizant Federal agency.

Applicable Credits

The term "applicable credits" refers to those receipt or negative expenditure types of transactions that operate to offset or reduce direct or indirect cost items. Typical examples are purchase discounts, rebates or allowances, recoveries or indemnities on losses, and adjustments for overpayments or erroneous charges. Additional information concerning applicable credits is included in the cost principles.

Applicable credits to direct charges made to HHS grants must be treated as an adjustment on the recipient's FSR, whether those credits accrue during or after the period of grant support. The awarding office will notify the recipient of any additional actions that may be necessary.

Allowable Costs and Activities

The governing cost principles address selected items of cost, some of which are mentioned in this subsection for emphasis. This subsection is not intended to be all-inclusive. The cost principles should be consulted for the complete explanation of the allowability or unallowability of costs they address. The allowability of costs under individual OPDIV awards also may be governed by requirements specified in the program legislation, regulations, or the specific terms and conditions of the award, which will take precedence over the general discussion provided here (see "Overview of Terms and Conditions of Award—Effect and Order of Precedence"). Recipients that have questions concerning the allowability of costs should contact the GMO.

If a cost is allowable, it is allocable as either a direct cost or an indirect cost, depending on the recipient's accounting system. For some costs addressed in this subsection, the text specifies whether the cost is usually a direct cost or an indirect cost.

Unless otherwise indicated in the NoA, an award based on an application that includes specific information concerning any direct costs or activities that require OPDIV prior approval constitutes the prior approval for those costs or activities. The recipient is not required to obtain any additional approval for those costs/activities. If

a cost or activity requiring OPDIV prior approval is not included or fully described in the approved application, the recipient must obtain post-award prior approval as described in "Prior Approval Requirements—OPDIV Prior-Approval").

Subrecipients and contractors under grants are subject to the requirements of the cost principles otherwise applicable to their type of organization and to any requirements placed on them by the recipient to be able to comply with the terms and conditions of the award.

The cost principles do not address profit or fee. HHS policy allows the payment of fee on SBIR/STTR grants, but HHS will not provide profit or fee to any other type of recipient under any other grant program. A fee may not be paid by a recipient to a subrecipient/consortium participant, including a for-profit organization. However, a fee (profit) may be paid to a contractor providing routine goods or services under a grant in accordance with normal commercial practice.

Exhibit 4 describes selected cost items.

Exhibit 4. Selected Items of Cost

Item	Description
Advertising	Allowable only for recruitment of staff or trainees, procurement of goods and services, disposal of scrap or surplus materials, and other specific purpose necessary to meet the requirements of the grant-supported activity.
Alcoholic Beverages	Unallowable as an entertainment expense. Allowable if within the scope of an approved project.
Alteration and Renovation	A&R costs are allowable unless the program legislation, implementing regulations, or other terms and conditions of the award specifically exclude such activity. See "Prior Approval Requirements—OPDIV Prior-Approval" for A&R costs requiring GMO prior approval. A&R costs that do not exceed the prior approval thresholds specified in that section (or in Part IV, as applicable) generally are considered "minor A&R" and those exceeding that amount generally are considered "major A&R." Major A&R is allowable only if the authorizing statute specifically permits that type of activity, whether characterized as modernization, remodeling, or A&R (see "Construction" in this exhibit). A&R must be consistent with the following criteria and documentation requirements: ◆ The building has a useful life consistent with program purposes and is architecturally and structurally suitable for conversion to the type of space required. ◆ The A&R is essential to the purpose of the grant-supported project or program. ◆ The space involved will be occupied by the project or program. ◆ The space is suitable for human occupancy before A&R work is started except where the purpose of the A&R is to make the space suitable for some purpose other than human occupancy, such as storage. ◆ For minor A&R, if the space is rented, evidence is provided that the terms of the lease are compatible with the A&R proposed and cover the duration of the project period. ◆ If the A&R will affect a site listed in (or eligible for inclusion in) the National Register of Historic Places, the requirements specified in "Preservation of Cultural and Historic Resources" have been followed. Routine maintenance and repair of the organization's physical plant or its equipment, which is allowable and is ordinarily treated as an indirect cost, is not considered A&R. Work necessary to obtain an initial occupancy permit for the intended use is not an allowable A&R cost. Certain allowable costs of installing equipment, such as the temporary removal and replacement of wall sections and door frames to place equipment in its permanent location, or the costs of connecting utility lines, replacing finishes and furnishings, and installing any accessory devices required for the equipment's proper and safe utilization, may be considered either equipment costs or A&R costs, depending on the recipient's accounting system. A&R costs are not allowable under grants in support of scientific meetings (conference grants).
Animals	Allowable for the acquisition, care, and use of animals for use in research and research-related activities, contingent upon compliance with the applicable requirements of the *PHS Policy on Humane Care and Use of Laboratory Animals*. If the recipient operates an animal resource facility, charges for use of the facility should be determined in accordance with the *Cost Analysis and Rate Setting Manual for Animal Resource Facilities* (May 2000), available from NIH's National Center for Research Resources (NCRR) (http://www.ncrr.nih.gov/newspub/CARS.pdf) or from NCRR's Office of Science Policy and Public Liaison (e-mail: info@ncrr.nih.gov).

Exhibit 4. Selected Items of Cost

Item	Description
Audiovisual Activities	Allowable for the production of an audiovisual. "Audiovisual" means any product containing visual imagery, sound, or both, such as motion pictures, films, videotapes, live or recorded radio or television programs or public service announcements, slide shows, filmstrips, audio recordings, multimedia presentations, or exhibits where visual imagery, sound, or both are an integral part. "Production" refers to the steps and techniques used to create a finished audiovisual product, including, but not limited to, design, layout, scriptwriting, filming or taping, fabrication, sound recording, and editing. A recipient with in-house production capability must determine whether it would be more efficient and economical to use that capability or to contract for the production of an audiovisual. If an audiovisual intended for members of the general public (i.e., people who are not researchers, health professions, or service delivery personnel or who are not directly involved in project activities as employees, trainees, or participants, such as clients, volunteers or patients) is produced under an HHS grant-supported project or program, the recipient must submit two prints or tapes of the finished product along with its annual or final progress report. The costs of such prints or tapes are allowable costs. Audiovisuals produced under a grant-supported project or program must bear an acknowledgment and disclaimer, such as the following: The production of this [type of audiovisual (motion picture, television program, etc.)] was supported by Grant [number of grant] from [name of OPDIV]. Its contents are solely the responsibility of [name of recipient] and do not necessarily represent the official views of [name of OPDIV].
Audit Costs	Allowable (as specified in Section 230 of OMB Circular A-133). The charges may be treated as a direct cost when the audit's scope is limited to a single HHS grant-supported project or program, as specified in 45 CFR 74.26(d), or when it includes more than one project but the costs can be specifically identified with, and allocated to, each project on a proportional basis, and this practice is followed consistently by the recipient. Otherwise, charges for audits should be treated as indirect costs. In addition, a pass-through entity may charge an HHS award for the cost of a limited scope audit to monitor a subrecipient provided the subrecipient is not required to have a single audit and the other conditions of Section 230(b) (2) of OMB Circular A-133 are met.
Bad Debts	Unallowable.
Bid and Proposal Costs	Allowable as an indirect cost. See 45 CFR 74.27(b)(1) for policy for non-profit organizations covered by OMB Circular A-122.
Bonding	Allowable. See 45 CFR 74.21, 74.48(c) and 92.36 for policies and requirements concerning bonding.
Books and Journals	Allowable. If an organization has a library, books and journals generally should be provided as part of normal library services and treated as indirect costs.
Capital expenditures for land or buildings	See "Land or Building Acquisition" in this exhibit.
Child-Care Costs	Allowable if within the scope of an approved project or program or as incidental costs of a project or program if incurred to enable individuals to participate as subjects in research projects or to receive health services. Such costs also may be allowable as a fringe benefit for individuals working on a grant-supported project (see "Fringe Benefits" in this exhibit).
Communica-tions	Allowable. Such costs include local and long-distance telephone calls, telegrams, express mail, postage, messenger, and electronic or computer transmittal services and usually are treated as indirect costs.
Compliance with Historic Preservation Requirements	Allowable. May include hiring special consultants to research and document the historic value of proposed performance sites and costs associated with preparation and presentation of required materials to inform the public and others.

Exhibit 4. Selected Items of Cost

Item	Description
Construction/ Modernization	Allowable only when program legislation specifically authorizes new construction, modernization, or other activities considered major A&R, and the OPDIV specifically authorizes such costs in the NoA. When authorized, construction activities may include construction of a new facility or projects in an existing building that are considered to be construction, such as relocation of exterior walls, roofs, and floors; attachment of fire escapes; or completion of unfinished shell space to make it suitable for human occupancy.
Consultant Services	Allowable. A consultant is an individual retained to provide professional advice or services for a fee but usually not as an employee of the requiring organization. The term "consultant" also includes a firm that provides paid professional advice or services. Recipients must have written policies governing their use of consultants that are consistently applied regardless of the source of support. Such policies should include the conditions for paying consulting fees. The general circumstances of allowability of these costs, which may include fees and travel and subsistence costs, are addressed in the applicable cost principles under "professional services costs." In unusual situations, a person may be both a consultant and an employee of the same party, receiving compensation for some services as a consultant and for other work as a salaried employee as long as those separate services are not related to the same project and are not charged to the same project. For example, consulting fees that are paid by an educational institution to a salaried faculty member as extra compensation above that individual's base salary are allowable, provided the consultation is across departmental lines or involves a separate or remote operation and the work performed by the consultant is in addition to his or her regular departmental workload. For employee consulting costs to be allowable under grant-supported projects (including subawards or contracts under the grant), recipients, subrecipients, and contractors must establish written guidelines permitting such payments regardless of the source of funding and indicating the conditions under which the payment of consulting fees to employees is proper. Unless subject to OMB Circular A-21, the recipient, subrecipient, or contractor also must document that it would be inappropriate or infeasible to compensate the individual for those services through payment of additional salary. Under no circumstances can an individual be paid as a consultant and an employee under the same HHS grant. Authorization for consulting fees paid to individuals serving as both employees and consultants of the same party must be provided in writing, on a case-by-case basis, by the head of the recipient, subrecipient, or contractor organization incurring the costs, or his/her designee. If the designee is personally involved in the project, the authorization may be given only by the head of the organization. This authorization must include a determination that the required conditions are present and that there is no apparent or actual conflict of interest. Recipients, subrecipients, and contractors under grants are encouraged to obtain written reports from consultants unless such a report is not feasible given the nature of the consultation or would not be useful. Documentation maintained by the receiving organization should include the name of the consulting firm or individual consultant; the nature of the services rendered and their relevance to the grant-supported activities, if not otherwise apparent from the nature of the services; the period of service; the basis for calculating the fee paid (e.g., rate per day or hour worked or rate per unit of service rendered); and the amount paid. This information may be included in the consultant's invoice, in the report, or in another document.

Exhibit 4. Selected Items of Cost

Item	Description
Consumer/ Provider Board Participation	Allowable in accordance with applicable program regulations. When not specifically authorized by program regulations, only the following costs are allowable with OPDIV prior approval: ◆ Reasonable and actual out-of-pocket costs incurred solely as a result of attending a scheduled meeting, including transportation, meals, babysitting fees, and lost wages. ◆ The reasonable costs of necessary meals furnished by the recipient to consumer or provider participants during scheduled meetings if not reimbursed to participants as per diem or otherwise. Where programmatic regulations permit such payments but establish a maximum annual income for eligibility for reimbursement of consumer/provider board members for wages lost by reason of their participation in board activities, the determination of eligibility will be made on the basis of gross rather than net income. Members of consumer/provider boards are not considered employees or consultants of the recipient. Therefore, they may not be compensated for their services other than as above, nor are they eligible for associated fringe benefits. Although not eligible for individual insurance coverage, board members may be covered by an organizational insurance policy while acting in their official capacities as board members.
Contingency Funds	Contributions set aside for events whose occurrence cannot be foretold with certainty as to time, intensity, or assurance of their happening are unallowable under nonconstruction grants. Contingency funds do not include pension funds, self-insurance funds, and normal accruals for severance and post-retirement health costs (also see "Reserve Funds" in this exhibit). Construction grants may include a contingency fund in initial construction contract cost estimates to provide for unanticipated charges. These funds will be limited to 5 percent of construction and equipment costs before bids or proposals are received and must be reduced to 2 percent after a construction contract has been awarded.
Customs and Import Duties	Allowable under grants to domestic organizations when performance will take place entirely within the United States, its possessions, or its territories, or when foreign involvement in the project is incidental to the overall grant-supported project. Charges may include consular fees, customs surtaxes, value-added taxes, and other related charges. (Also see "Requirements for Specific Types of Recipients" of this part for the allowability of these costs.)
Depreciation or Use Allowances	Allowable. Such costs usually are treated as indirect costs. Depreciation or use charges on equipment or buildings acquired under a federally supported project are not allowable.
Donor Costs	Allowable for payment to volunteers or research subjects who contribute blood, urine samples, and other body fluids or tissues that are specifically project related.
Drugs	Allowable if within the scope of an approved project. Project funds may not be used to purchase drugs classified by FDA as "ineffective" or "possibly effective" except in approved clinical research projects or in cases where there is no alternative other than therapy with "possibly effective" drugs. Recipient acquisition practices for drugs used in outpatient treatment must meet Federal requirements regarding cost-effectiveness and reasonableness as found in 42 CFR part 40, Subpart E, and OMB Circulars A-122 and A-87.
Dues or Membership Fees	Allowable as an indirect cost for organizational membership in business, professional, or technical organizations or societies. Payment of dues or membership fees for an individual's membership in a professional or technical organization is allowable as a fringe benefit or an employee development cost, if paid according to an established organizational policy consistently applied regardless of the source of funds.
Entertainment Costs	Unallowable. This includes the cost of amusements, social activities, and related incidental costs.

Exhibit 4. Selected Items of Cost

Item	Description
Equipment	Allowable for purchase of new, used, or replacement equipment as a direct cost or as part of indirect costs, depending on the intended use of the equipment. OPDIV prior approval may be required as specified in "Prior-Approval Requirements." Funds provided under a conference grant may not be used to purchase equipment. For policies governing the classification, use, management, and disposition of equipment, see "Property Management." For policies governing the allowability of costs for rental of equipment, see "Rental or Lease of Facilities and Equipment" in this exhibit.
Federal (U.S. Government) Employees	Only four types of costs—consultant fees, outpatient or subject costs, salary or fringe benefits, and travel costs—can be charged to HHS grants on behalf of Federal employees, and only under the conditions specified. Recipients should advise any Federal employees with whom these types of arrangements may be made to consult with their employing agency concerning their ability to meet the required conditions. Regardless of whether costs will be charged to the grant, special requirements apply when a Federal employee will be involved in an HHS grant-supported activity in any capacity other than as an employee working on a grant to a Federal institution, an outpatient, or a study subject. The requirements of that section do not apply to individuals that are classified as special government employees because of service on advisory groups or as a result of a formal consulting arrangement with a Federal agency. (See the HHS Standards of Conduct at 45 CFR part 73, Subpart J for additional guidance.) See "Requirements for Specific Types of Recipients—Grants to Federal Institutions and Allowable Costs and Payments to (or on Behalf of) Federal Employees under Grants" for the allowability of payments made to, or on behalf of, Federal employees under HHS grants.
Fines and Penalties	Unallowable except when resulting from violations of, or failure of the organization to comply with, Federal, State, or local laws and regulations and incurred as a result of compliance with specific provisions of an award, or when such payments are authorized in advance in writing by the GMO.
Fringe Benefits	Allowable as part of overall employee compensation in proportion to the amount of time or effort an employee devotes to the grant-supported project or program, provided such costs are incurred under formally established and consistently applied policies of the organization (see "Salaries and Wages" in this exhibit). Tuition or tuition remission for regular employees is allowable as a fringe benefit. For organizations subject to OMB Circular A-21, tuition benefits for family members other than the employee are unallowable. For policies applicable to tuition remission for students working on grant-supported research projects, see "Salaries and Wages" in this exhibit.
Fundraising Costs	Unallowable.
Hazardous Waste Disposal	Allowable. Usually treated as an indirect cost.
Honoraria	Unallowable when the primary intent is to confer distinction on, or to symbolize respect, esteem, or admiration for, the recipient of the honorarium. A payment for services rendered, such as a speaker's fee under a conference grant, is allowable.
Hospitalization	See "Research Patient Care" in this exhibit.
Incentive Costs	Incentive payments to volunteers or patients participating in a grant-supported project or program are allowable. Incentive payments to individuals to motivate them to take advantage of grant-supported health care or other services are allowable if within the scope of an approved project. See "Salaries and Wages" in this exhibit for incentive payments to employees.
Indemnification	Allowable to the extent expressly provided in the award for indemnification against liabilities to third parties and any other loss or damage not compensated by insurance or otherwise. The Federal government is obligated to indemnify the institution only to the extent expressly provided for in the NoA.

Exhibit 4. Selected Items of Cost

Item	Description
Independent Research and Development Costs	Unallowable, including their proportionate share of indirect costs.
Insurance	Allowable. Insurance usually is treated as an indirect cost. In certain situations, however, where special insurance is required as a condition of the grant because of risks peculiar to the project, e.g., provision of health services, the premium may be charged as a direct cost if doing so is consistent with organizational policy. If so, the insurance should be treated as a direct cost and assigned to individual grants based on the manner in which the insurer allocates the risk to the population covered by the insurance. Medical liability (malpractice) insurance is an allowable cost of research programs at educational institutions only if the research involves human subjects. The cost of insuring equipment, whether purchased with grant funds or furnished as federally owned property, normally should be included in indirect costs but may be allowable as a direct cost if this manner of charging is the normal organizational policy.
Interest	Allowable as an indirect cost for certain assets as specified in the applicable cost principles. Unallowable for hospitals.
Invention, Patent, or Licensing Costs	Unallowable as a direct cost unless specifically authorized in the NoA. May be allowable as indirect costs provided they are authorized under applicable cost principles and are included in the negotiation of indirect cost rates. Such costs include licensing or option fees, attorney's fees for preparing or submitting patent applications, and fees paid to the U.S. Patent and Trademark Office for patent application, patent maintenance, or recordation of patent-related information.
Land or Building Acquisition	Not allowable unless acquisition or construction is specifically authorized by program legislation and provided for in the NoA. Under those programs that have authority to permit recipients to acquire facilities, considerations such as the type of program being supported and the Federal interest in purchased property will be taken into account by the awarding office in determining whether property should be leased or purchased. For real property acquired with grant support, the cost of title insurance may be charged to the grant in proportion to the Federal share of the acquisition cost. Filing fees incurred with the recordation in appropriate official records of the applicable jurisdiction of the Federal interest in the real property also may be charged to the grant. Use allowance or depreciation on buildings that were not acquired under a Federal project are allowable, usually as an indirect cost.
Leave	Allowable for employees as a fringe benefit (see "Fringe Benefits" in this exhibit). See program guidance or Part IV for policy on leave for fellows and trainees.
Legal Services	Allowable. Generally treated as an indirect cost but, subject to the limitations described in the applicable cost principles, may be treated as a direct cost for legal services provided by individuals who are not employees of the recipient. Before a recipient incurs legal costs that are extraordinary or unusual, the recipient should make an advance agreement regarding the appropriateness and reasonableness of such costs with the GMO. Legal costs incurred in defending or prosecuting claims, whether equitable or monetary, including administrative grant appeals, are unallowable charges, except as provided in the applicable cost principles.
Library Services	General library support is not allowable as a direct cost but may be included in a recipient's indirect cost pool. These services are allowable as a direct cost when specifically required for the conduct of the project and when identifiable as an integral part of the grant-supported activity (e.g., in those programs designed to develop and support such services).
Lobbying	Generally unallowable, including costs of lobbying activities to influence the introduction, enactment, or modification of legislation by the U.S. Congress or a State legislature. Under certain circumstances, as provided in the applicable cost principles, costs associated with activities that might otherwise be considered "lobbying" that are directly related to the performance of a grant may be allowable. The recipient should obtain an advance understanding with the GMO if it intends to engage in these activities.

Exhibit 4. Selected Items of Cost

Item	Description
Meals	Generally unallowable except for the following: ◆ Subjects and patients under study ◆ Where specifically approved as part of the project or program activity, e.g., in programs providing children's services ◆ When an organization customarily provides meals to employees working beyond the normal workday, as a part of a formal compensation arrangement ◆ As part of a per diem or subsistence allowance provided in conjunction with allowable travel ◆ Under a conference grant, when meals are a necessary and integral part of a conference, provided that meal costs are not duplicated in participants' per diem or subsistence allowances. Guest meals are not allowable. (See "Consumer/Provider Board Participation" in this exhibit regarding the allowability of the cost of meals for consumer and provider board participants in grant-supported activities.)
Moving	See "Recruitment Costs," "Relocation Costs," and "Transportation of Property" in this exhibit.
NEPA Analysis	Costs associated with evaluation of the environmental effects of a proposed activity and producing the Environmental Impact Statement (EIS) are allowable.
Overtime	See "Salaries and Wages" in this exhibit.
Pension Plan Costs	Allowable. For institutions of higher education and non-profit organizations, the following applies: ◆ Such costs must be incurred according to the established policies of the organization consistently applied regardless of the source of funds. ◆ The organization's policies must meet the test of reasonableness. ◆ The methods of cost allocation must be equitable for all activities. ◆ The amount assigned to each fiscal year must be determined in accordance with generally accepted accounting principles. ◆ The cost assigned to a given fiscal year must be paid or funded for all plan participants within 6 months after the end of that fiscal year. State, local, or Indian tribal governments or hospitals may use the "pay-as-you-go" cost method (i.e., when pension benefits are paid by the recipient directly to, or on behalf of, retired employees or their beneficiaries) in lieu of the method described above. Under this method, the benefits may be charged in the recipient's fiscal year in which the payments are made to, or on behalf of, retired employees or their beneficiaries, provided that the recipient follows a consistent policy of treating such payments as expenses in the year of payment. See the applicable cost principles for additional information on the allowability of costs associated with pension plans.

Exhibit 4. Selected Items of Cost

Item	Description
Pre-Award (Pre-Agreement) Costs	Allowable. Where authorized by the OPDIV as an expanded authority (see Part IV of the HHS GPS), a recipient may, at its own risk and without OPDIV prior approval, incur obligations and expenditures to cover costs up to (and including) 90 days before the beginning date of the initial budget period of a new or competing continuation award if such costs ◆ are necessary to conduct the project or program, and ◆ would be allowable under the grant, if awarded. However, even if authorized as an expanded authority, if a specific expenditure would otherwise require prior approval, the cost or activity must meet the same tests of allowability as if incurred after award. If not authorized as part of expanded authorities, the applicant/recipient must seek OPDIV prior approval before incurring pre-award costs. OPDIV prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new or competing continuation award. Recipients may incur pre-award costs before the beginning date of a non-competing continuation award without regard to the time parameters stated above and without prior approval. The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on the OPDIV either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. Recipients are expected to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the recipient's ability to accomplish the project or program objectives in the approved time frame or in any way adversely affect the conduct of the project or program.
Public Relations Costs	Allowable only for costs specifically required by the award or for costs of communicating with the public and the press about specific activities or accomplishments under the grant-supported activity or other appropriate matters of public concern. Such costs may be treated as direct costs but should be treated as indirect costs if they benefit more than one sponsored agreement or if they benefit the grant and other work of the organization.
Publications	Allowable. Page charges for publication in professional journals are allowable if the published paper reports work supported by the grant and the charges are levied impartially on all papers published by the journal, whether or not by government-sponsored authors. The costs of reprints and publishing in other media, such as books, monographs, and pamphlets, also are allowable. Publications and journal articles produced under an HHS grant-supported activity must bear an acknowledgment and disclaimer, as appropriate, as provided in "Intellectual Property—Publications."
Recruitment Costs	Allowable subject to the conditions and restrictions contained in the applicable cost principles. These costs may include help-wanted advertising costs, costs of travel by applicants for interviews for prospective employment, and travel costs of employees while engaged in recruiting personnel. Grant funds may not be used for a prospective trainee's travel costs to or from the recipient organization for the purpose of recruitment. However, other costs incurred in connection with recruitment under training programs, such as advertising, may be allocated to a grant-supported project according to the provisions of the applicable cost principles (also see "Travel" and "Relocation Costs" in this exhibit).
Registration Fees	Allowable for attendance at conferences, symposiums, or seminars if necessary to accomplish project or program objectives.

Exhibit 4. Selected Items of Cost

Item	Description
Relocation Costs	Allowable—in other than change of grantee organization situations—when such costs are incurred incidental to a permanent change of duty assignment (for an indefinite period or for a stated period of no less than 12 months) for an existing employee working on a grant-supported project, or when a new employee is recruited for work on the project, provided that the move is for the recipient's benefit rather than the individual's and that payment is made according to established organizational policies consistently applied regardless of the source of funds. Relocation costs may include the cost of transporting the employee and his or her family, dependents, and household goods to the new location and certain expenses associated with the sale of the former home. If relocation costs have been incurred in connection with the recruitment of a new employee, whether as a direct cost or an indirect cost, and the employee resigns for reasons within his or her control within 12 months after hire, the recipient must credit the grant account for the full cost of the relocation charged to the grant. When there is a change in the grantee organization, the personal relocation expenses of the PI/PD and others moving to the new recipient are not allowable charges.
Rental or Lease of Facilities and Equipment	Allowable subject to the limitations below. Rental costs are allowable to the extent that the rates are reasonable at the time of the decision to lease in light of such factors as rental costs of comparable property, if any; market conditions in the area; the type, life expectancy, condition, and value of the property leased; and available alternatives. Because of the complexity involved in determining the allowable amount under certain types of leases, recipients are encouraged to consult the GMO before entering into leases that will result in direct charges to an award. In general, the rental costs for facilities and equipment applicable to each budget period should be charged to that period. However, see "Property Management" for an exception to this general rule. Rental costs under leases that create a material equity in the leased property, as defined in the applicable cost principles, are allowable only up to the amount that would be allowed had the recipient purchased the property on the date the lease agreement was executed. This would include depreciation or use allowances, maintenance, taxes, and insurance, but would exclude unallowable costs. When a recipient transfers property to a third party through sale, lease, or otherwise and then leases the property back from that third party, the lease costs that may be charged to an HHS grant generally may not exceed the amount that would be allowed if the recipient continued to own the property. Rental costs under "less-than-arms-length" leases are allowable only up to the amount that would be allowed under the applicable cost principles had title to the property been vested in the recipient. A less-than-arms-length lease is one in which one party to the lease agreement is able to control or substantially influence the actions of the other. Such leases include, but are not limited to, those between divisions of an organization; between organizations under common control through common officers, directors, or members; and between an organization and its directors, trustees, officers, or key employees (or the families of these individuals), directly or through corporations, trusts, or similar arrangements in which they hold a controlling interest.
Research Patient Care	The costs of routine and ancillary services provided by hospitals to individuals, including patients and volunteers, participating in research programs are allowable if included in the NoA or approved as a post-award change as specified in "Prior-Approval Requirements—OPDIV Prior Approval." "Routine services" include the regular room services, minor medical and surgical supplies, and the use of equipment and facilities for which a separate charge is not customarily made. "Ancillary services" are those special services for which charges customarily are made in addition to routine services, e.g., x-ray, operating room, laboratory, pharmacy, blood bank, and pathology. See "Research Patient Care Costs" for policy concerning reimbursement of these costs. The following otherwise allowable costs are not classified as research patient care costs: items of personal expense reimbursement, such as patient travel; consulting physician fees; and any other direct payments to individuals, including inpatients, outpatients, subjects, volunteers, and donors.
Reserve Funds	Contributions to a reserve fund for self-insurance are allowable as specified in the governing cost principles (also see "Contingency Funds" in this exhibit).

Exhibit 4. Selected Items of Cost

Item	Description
Sabbatical Leave Costs	Sabbatical leave costs may be included in a fringe benefit rate or in the organization's indirect cost rate. Costs of leave of absence by employees for performance of graduate work or sabbatical study, travel, or research are allowable as a direct charge provided the organization has a uniform policy on sabbatical leave for people engaged in research and the salary is proportional to the service rendered. Where sabbatical leave is included in fringe benefits for which a cost is determined for assessment as a direct charge, the aggregate amount of such assessments applicable to all work of the organization during the base period must be reasonable in relation to the organization's actual practice under its sabbatical leave policy. Sabbatical leave paid by an individual's employer, in combination with other compensation (e.g., partial salary from an HHS grant), may not exceed 100 percent of that individual's regular salary from his or her organization.
Salaries and Wages	Allowable. Compensation for personal services covers all amounts, including fringe benefits, paid currently or accrued by the organization for employee services rendered to the grant-supported project or program. Compensation costs are allowable to the extent that they are reasonable, conform to the established policy of the organization consistently applied regardless of the source of funds, and reflect no more than the percentage of time actually devoted to the OPDIV-funded project or program. Where restricted by language in the HHS appropriations act, OPDIVs will not reimburse recipients for the direct salaries of individuals at a rate in excess of the level specified. Direct salary is exclusive of fringe benefits and indirect costs. If there is a salary limitation, it does not apply to consultant payments or to contracts for routine goods and services, but it does apply to subrecipients (including consortium participants). Specific considerations are addressed below.
Payroll Distribution	Salary and wage amounts charged to grant-supported projects or programs for personal services must be based on an adequate payroll distribution system that documents such distribution in accordance with generally accepted practices of like organizations. Standards for payroll distribution systems are contained in the applicable cost principles (other than those for for-profit organizations). Briefly summarized, acceptable systems are as follows: *Hospitals* ◆ Monthly after-the-fact reports of the distribution of time or effort for professional staff members. ◆ Time and attendance and payroll distribution records for non-professional employees. *Non-profit organizations* ◆ Monthly after-the-fact reports, including a signed certification, by the employee, or by a responsible supervisory official having first-hand knowledge of the work performed, that the distribution of activity represents a reasonable estimate of the actual work performed by the employee during the period covered by the report. Each report must account for the total activity required to fulfill the employee's obligations to the organization as well as the total activity for which he or she is compensated. ◆ For non-professional employees, additional supporting reports, indicating the total number of hours worked each day, must be maintained in conformance with DoL regulations implementing the Fair Labor Standards Act (29 CFR part 516). ◆ The distribution of salaries and wages must be supported by personnel activity reports as described above, except when a substitute system has been approved, in writing, by the Federal cognizant agency designated under OMB Circular A-122. *State, local, and Indian tribal governments* ◆ Time and attendance or equivalent records for all employees. ◆ Time distribution records for employees whose compensation is chargeable to more than one grant or other cost objective.

Exhibit 4. Selected Items of Cost

Item	Description
	Educational institutions ◆ A plan confirmation system for professorial and other professional staff members that is based on budgeted, planned, or assigned work activity and that is updated to reflect any significant changes in work distribution. This system must be incorporated into the organization's official records and must identify activity applicable to each sponsored agreement and to each category needed to identify indirect costs and the functions to which they are allocable. At least annually, the employee, PI/PD, or responsible officials will verify, by suitable means, that the work was performed and that the salaries and wages charged to sponsored agreements, whether as direct charges or in other categories of cost, are reasonable in relation to the work performed. ◆ A system, supported by after-the-fact activity reports, that reflects the distribution of covered employees' activity allocable to each grant and includes identification and recording of significant changes in work activity when initial charges were based on estimates. The system also must specify each category of activity needed to identify indirect costs and the functions to which they are allocable. For professorial and other professional staff members, the activity reports will be prepared each academic term, but at least every 6 months. For other employees, unless the OPDIV agrees to alternate arrangements, the reports will be prepared at least monthly and will coincide with one or more pay periods. ◆ A multiple confirmation records system, for professorial and other professional staff members, that is supported by records certifying costs separately for direct costs and indirect costs, with reports prepared each academic term, but at least every 6 months, that confirm the activities as allocable to direct or indirect costs. ◆ By mutual agreement, any other method meeting the criteria specified in Section J.10 of OMB Circular A-21. *For-profit organizations* HHS requires for-profit organizations to conform with industry standards to support salary and wage charges to HHS grants. Therefore, unless an alternate system is approved by the GMO, the recipient must maintain a time-and-effort reporting system for both professional and other-than-professional staff reflecting daily after-the-fact reporting of hours expended on individual projects or indirect activities. The system must record both hours worked and hours absent. This information must be certified by an authorized organizational representative no less frequently than every pay period.
Overtime Premiums	Premiums for overtime generally are allowable; however, such payments are not allowable for faculty members at institutions of higher education. If overtime premiums are allowable, the categories or classifications of employees eligible to receive overtime premiums should be determined according to the formal policies of the organization consistently applied regardless of the source of funds.
Bonuses/ Incentive Payments	Allowable for employees as part of a total compensation package, provided such payments are reasonable and are made according to a formal policy of the recipient that is consistently applied regardless of the source of funds.
Payments for Dual Appointments	For investigators with university and clinical practice plan appointments, compensation from both sources may be considered the base salary if the following criteria are met: ◆ Clinical practice compensation must be guaranteed by the university. ◆ Clinical practice effort must be shown on the university appointment form and must be paid through the university. ◆ Clinical practice effort must be included and accounted for on the university's effort report.

Exhibit 4. Selected Items of Cost

Item	Description
Compensation of Students	Tuition remission and other forms of compensation paid as, or in lieu of, wages to students (including fellows and trainees) under research grants are allowable, provided the following conditions are met: ◆ The individual is performing activities necessary to the grant. ◆ Tuition remission and other forms of compensation are consistently provided, in accordance with established institutional policy, to students performing similar activities conducted in non-sponsored as well as in sponsored activities. ◆ During the academic period, the student is enrolled in an advanced degree program at a recipient or affiliated institution and the activities of the student in relation to the federally sponsored research project are related to the degree program. ◆ The tuition or other payments are reasonable compensation for the work performed and are conditioned explicitly upon the performance of necessary work. ◆ It is the institution's practice to similarly compensate students in non-sponsored as well as sponsored activities. Charges for tuition remission and other forms of compensation paid to students as, or in lieu of, salaries and wages are subject to the reporting requirements in Section J.10 of OMB Circular A-21, or an equivalent method for documenting the individual's effort on the research project. Tuition remission may be charged on an average rate basis. Payments made for educational assistance (e.g., scholarships, fellowships, and student aid costs) are allowable only when the purpose of the grant is to provide training to selected participants and the charge is approved by the OPDIV. These costs are unallowable charges to research grant funds even when they would appear to benefit the research project.
Service Charges	Allowable. The costs to a user of organizational services and central facilities owned by the recipient, such as central laboratory and computer services, are allowable and must be based on organizational fee schedules consistently applied regardless of the source of funds.
Severance Pay	Allowable only to the extent that such payments are required by law, are included in an employer-employee agreement, are part of an established policy effectively constituting an implied agreement on the part of the organization, or meet the circumstances of the particular employment. The amount of severance pay to be provided should be determined according to established organizational policy consistently applied regardless of the source of funds and should be reasonable, taking into consideration the practice of similar types of organizations and the extent of the organization's dependence on Federal funds. The applicable cost principles should be consulted regarding the different treatment of severance pay in regular and mass termination situations.
Stipends	Allowable as cost-of-living allowances for trainees and fellows if permitted by a program's statute authorizing or implementing regulations. The specific amounts may be established by policy. Generally, these payments are made according to a pre-established schedule based on the individual's experience and level of training. (See "Traineeships, Fellowships, and Similar Awards Made to Organizations on Behalf of Individuals—Allowable Costs.") A stipend is not a fee-for-service payment and is not subject to the cost accounting requirements of the cost principles. Stipends are not allowable under research grants even when they appear to benefit the research project.
Subawards/ Contracts under Grants	Allowable to carry out a portion of the programmatic effort or for the acquisition of routine goods or services under the grant. Such arrangements may be in the form of consortium agreements or commercial contracts and may require OPDIV approval (see "Prior-Approval Requirements").
Supplies	Allowable.
Taxes	Allowable. Such costs include taxes that an organization is required to pay as they relate to employment, services, travel, rental, or purchasing for a project. Recipients must avail themselves of any tax exemptions for which activities supported by Federal funds may qualify. State sales and use taxes for materials and equipment are allowable only when the State does not grant a refund or exemption on such taxes.

Exhibit 4. Selected Items of Cost

Item	Description
Termination or Suspension Costs	Unallowable except as follows. If a grant is terminated or suspended, the recipient may not incur new obligations after the effective date of the termination or suspension and must cancel as many outstanding obligations as possible. The awarding office will allow full credit to the recipient for the Federal share of otherwise allowable costs if the obligations were properly incurred before suspension or termination—and not in anticipation of it—and, in the case of termination, are not cancelable. The GMO may authorize other costs in, or subsequent to, the notice of termination or suspension. See 45 CFR 74.62(c) and 92.43.
Toys and Nursery Items	Allowable for the purchase of items such as toys and games to allow patients to participate in research protocols or, if age appropriate, in programs or projects serving children.
Trailers and Modular Units	Allowable only if considered equipment as provided below. A "trailer" is defined as a portable vehicle built on a chassis that is designed to be hauled from one site to another by a separate means of propulsion and that serves, wherever parked, as a dwelling or place of business. A "modular unit" is a prefabricated portable unit designed to be moved to a site and assembled on a foundation to serve as a dwelling or a place of business. The determination of whether costs to acquire trailers or modular units are allowable charges to HHS grant-supported projects depends on whether such units are classified as real property or equipment. The classification will depend on whether the recipient's intended use of the property is permanent or temporary. A trailer or modular unit is considered real property when the unit and its installation are designed or planned to be installed permanently at a given location so as to seem fixed to the land as a permanent structure or appurtenance thereto. Units classified as real property may not be charged to an HHS grant-supported project unless authorizing legislation permits construction or acquisition of real property and the specific purchase is approved by the OPDIV. A trailer or modular unit is considered equipment when the unit and its installation are designed or planned to be used at any given location for a limited time only. Units classified as equipment may be charged to HHS grant-supported projects only if the terms and conditions of the award do not prohibit the purchase of equipment and OPDIV prior approval is obtained, as appropriate. A trailer or modular unit properly classified as real property or as equipment at the time of acquisition retains that classification for the life of the item, thereby determining the appropriate accountability requirements under 45 CFR 74.32 or 74.34 or 92.31 or 92.32, as applicable.
Trainee Costs	Allowable if permitted by statute, regulation, or program policy, as defined in the authorizing document, and included in the NoA.
Transportation of Property	Allowable for freight, express, cartage, postage, and other transportation services relating to goods either purchased, in process, or delivered, including instances when equipment or other property is moved from one recipient to another. In a change-of-grantee situation, the cost of transportation may be charged to the grant at either the original or the new organization, depending on the circumstances and the availability of funds in the appropriate active grant account.
Travel	Allowable as a direct cost where such travel will provide direct benefit to the project or program.
Employees	Consistent with the organization's established travel policy, costs for employees working on the grant-supported project or program may include associated per diem or subsistence allowances and other travel-related expenses, such as mileage allowances if travel is by personal automobile. Domestic travel is travel performed within the recipient's own country. For U.S. and Canadian recipients, it includes travel within and between any of the 50 States of the United States and its possessions and territories and also travel between the United States and Canada and within Canada.

Exhibit 4. Selected Items of Cost

Item	Description
	Foreign travel is defined as any travel outside of Canada and the United States and its territories and possessions. However, for an organization located outside Canada and the United States and its territories and possessions, foreign travel means travel outside that country. In all cases, travel costs are limited to those allowed by formal organizational policy; in the case of air travel, the lowest reasonable commercial airfares must be used. For-profit recipients' allowable travel costs may not exceed those established by the FTR, issued by GSA, including the maximum per diem and subsistence rates prescribed in those regulations. This information is available at http://www.gsa.gov. If a recipient organization has no formal travel policy, those regulations will be used to determine the amount that may be charged for travel costs. Recipients are strongly encouraged to take advantage of discount fares for airline travel through advance purchase of tickets if travel schedules can be planned in advance (such as for national meetings and other scheduled events). Recipients must comply with the requirement that U.S. flag air carriers be used by domestic recipients to the maximum extent possible when commercial air transportation is the means of travel between the United States and a foreign country or between foreign countries. This requirement must not be influenced by factors of cost, convenience, or personal travel preference. The cost of travel under a ticket issued by a U.S. flag air carrier that leases space on a foreign air carrier under a code-sharing agreement is allowable if the purchase is in accordance with GSA regulations on U.S. flag air carriers and code shares (see http://www.gsa.gov/gsa/cm_attachments/GSA_DOCUMENT/110304_FTR_R2QA53_0Z5RDZ-i34K-pR.pdf). (A code-sharing agreement is an arrangement between a U.S. flag carrier and a foreign air carrier in which the U.S. flag carrier provides passenger service on the foreign air carrier's regularly scheduled commercial flights.)
Patients or Service Beneficiaries	If patient care, including research patient care, or other direct health or social services are approved activities of the grant-supported project or program, the costs of transporting individuals participating in the program or project to the site where services are being provided, including costs of public transportation, are allowable. The purchase of motor vehicles for this purpose also may be allowable.

Cost Transfers

Cost transfers by recipients between grants, whether as a means to compensate for cost overruns or for other reasons, generally are unallowable; however, cost transfers by recipients (or subrecipients or cost-type contractors) may sometimes be necessary to correct bookkeeping or clerical errors. Recipients (and subrecipients and contractors) should have systems in place to detect such errors within a reasonable time frame. Untimely discovery of errors could be an indication of poor internal controls.

Permissible cost transfers should be made promptly after the error occurs but no later than 90 days following occurrence unless a longer period is approved in advance by the GMO. The transfer must be supported by documentation, pursuant to 45 CFR 74.53 or 92.42, that fully explains how the error occurred and a certification of the correctness of the new charge by a responsible official of the recipient, subrecipient, or contractor. An explanation merely stating that the transfer was made "to correct error" or "to transfer to correct project" is not sufficient. This information need not be submitted to the GMO but is subject to audit. If the transfer affects a previously submitted FSR, a revised FSR must be submitted.

Frequent errors in recording costs may indicate the need for accounting system improvements, enhanced internal controls, or both. If such errors occur,

organizations are encouraged to evaluate the need for improvements and to make whatever improvements are deemed necessary to prevent reoccurrence. An awarding office also may require a recipient to take corrective action by imposing additional terms and conditions on an award.

Cost Overruns and Rate of Expenditure

Transfers of costs from one project to another or from one competitive segment to the next solely to cover cost overruns are not allowable. The GMO monitors expenditure rates under individual awards during each budget period and within the overall project period. Although HHS allows its recipients certain flexibilities with respect to rebudgeting, HHS expects the rate and types of expenditures to be consistent with the approved project/program and budget and may question or restrict expenditures that appear inconsistent with these expectations. In addition, recipients are expected to monitor their fund drawdowns and amounts reported on financial reports (e.g., PMS 272) to ensure that they do not exceed the amount authorized on the NoA.

The GMO may review recipient cash drawdowns to determine whether they indicate any pattern of accelerated or delayed expenditures. Expenditure patterns are of particular concern because they may indicate a deficiency in the recipient's financial management system or internal controls. Accelerated or delayed expenditures may result in an inability to complete the approved project or program within the approved budget and period of performance. In these situations, the GMO may seek additional information from the recipient and may make any necessary and appropriate adjustments.

Allocation of Costs

When salaries or other activities are supported by two or more sources, issues arise as to how the direct costs should be allocated among the sources of support. In general, a cost that benefits two or more projects or activities in proportions that can be determined without undue effort or cost should be allocated to the projects on the basis of the proportional benefit.

A cost that benefits two or more projects or activities in proportions that cannot be determined because of the interrelationship of the work involved may be allocated or transferred to the benefiting projects on any reasonable basis as long as the costs charged are allowable, allocable, and reasonable under the applicable cost principles and the recipient's financial management system includes adequate internal controls. Costs may be assigned entirely to one project, with written prior approval from the GMO, under the following conditions only:

- The projects are scientifically and technically related.
- The projects are under the direction of the same PI/PD.
- The projects have been funded by the same OPDIV or OPDIV component.
- There is no change in the scope of the individual grants involved.
- The relating of costs will not be detrimental to the conduct of work approved under each individual award.

- The relatedness will not be used to circumvent the terms and conditions of an individual award.

Services Provided by Affiliated Organizations

A number of universities and other organizations have established closely affiliated, but separately incorporated, organizations to facilitate the administration of research and other programs supported by Federal funds. Such legally independent entities are often referred to as "foundations," although this term does not necessarily appear in the name of the organization. Typically, the parent organization provides considerable support services, in the form of administration, facilities, equipment, accounting, and other services, to its foundation, and the latter, acting in its own right as a recipient, includes the cost of these services in its indirect cost proposal.

Costs incurred by an affiliated, but separate, legal entity in support of a recipient foundation (foundation) are allowable for reimbursement under HHS grants only if at least one of the following conditions is met:

- The foundation is charged for, and is legally obligated to pay for, the services provided by the parent organization.

- The affiliated organization is subject to State or local law that prescribes how Federal reimbursement for the costs of the parent organization's services will be expended and requires that a State or local official acting in his or her official capacity approves such expenditures.

- There is a valid written agreement between the affiliated organizations whereby the parent organization agrees that the foundation may retain Federal reimbursement of parent organization costs. The parent organization may either direct how the funds will be used or permit the foundation that discretion.

If none of the above conditions is met, the costs of the services provided by the parent organization to the foundation are not allowable for reimbursement under an HHS grant. However, the services may be acceptable for cost-sharing (matching) purposes.

Matching or Cost Sharing

All required matching or cost sharing, whether required by statute or regulation, will be shown as part of the total approved budget in the NoA and becomes an award requirement enforceable through the NoA. The costs that the recipient incurs in fulfilling its matching or cost-sharing requirement are subject to the same requirements, including the cost principles, that are applicable to the use of Federal funds, including prior approval requirements and other rules for allowability described in 45 CFR 74.23 and 45 CFR 92.24. Third-party in-kind contributions must meet the requirements specified 45 CFR 74.23 and 45 CFR 92.24.

If a recipient does not meet the specified level of matching or cost sharing as reflected in the NoA, an OPDIV may take one or more of the following actions:

- Make a downward adjustment in the Federal award amount

- Take an enforcement action affecting the current or future awards to that recipient (see "Enforcement Actions")

- If the amount in the NoA exceeds the statutory (or implementing regulatory requirement) for matching, where justified, reduce the matching to no less than the statutory or regulatory requirement

- If the amount in the NoA exceeds a regulatory cost-sharing requirement, where justified and authorized by the regulation, reduce the cost sharing to no less than the regulatory requirement.

If a recipient provides matching or cost sharing that exceeds that required by the NoA, the excess amount is not subject to the requirements of 45 CFR part 74 or 92 unless the amount is used to offset otherwise unallowable matching or cost-sharing amounts.

When satisfying a matching or cost-sharing requirement by not claiming the full indirect cost reimbursement to which the recipient is otherwise entitled, the recipient should reduce its charge to the grant to reflect the amount claimed. The amount of the reduction qualifies as matching or cost sharing. The recipient should include an explanation in the "Remarks" section of the Financial Status Report (see "Reporting—Financial Reporting").

Valuation of Donated Goods and Services

Donated Supplies, Equipment, Space, or Land

Donated supplies may include such items as expendable property, office supplies (unless treated as an indirect cost), laboratory supplies, or workshop and classroom supplies. The value assigned to donated supplies must be reasonable and cannot exceed the fair market value of the supplies at the time of donation.

The value of donated equipment cannot exceed the fair market value of equipment of the same age and condition at the time of donation. The value of loaned equipment cannot exceed its fair rental value. If any part of the donated property was acquired with Federal funds, only the non-Federal share of the property may be counted as matching or cost sharing.

If a third party donates equipment, buildings, or land and title passes to a recipient or subrecipient, the treatment of the donated property depends upon the purpose of the grant or subgrant as follows:

- If the purpose of the grant or subgrant is to assist the recipient with the acquisition of property, the market value of that property at the time of donation may be counted as matching.

- If the purpose of the grant or subgrant is other than to assist with the acquisition of property, the following applies:

  - With GMO approval, the market value at the time of donation of the donated equipment or buildings and the fair rental rate of the donated land may be counted as matching or cost sharing. In the case of a subgrant, the terms of the grant award may require that the approval be

obtained both from the GMO and from the recipient. In either case, approval may be given only if purchase of the equipment or rental of the land would be allowable as a direct cost.

- If any part of the donated property was acquired with Federal funds, only the non-Federal share of the property may be counted as matching or cost sharing.

- Unless GMO approval is obtained, no amount may be counted for donated land and only depreciation or use allowances may be counted for donated equipment and buildings. The depreciation or use allowances for such property are not treated as third party in-kind contributions. Instead, they are treated as costs incurred by the recipient or subrecipient. The allowances are computed and allocated (usually as indirect costs) in accordance with the cost principles in the same way as depreciation or use allowances for purchased equipment and buildings. The amount of depreciation or use allowances for donated equipment and buildings is based on the property's market value at the time it was donated.

- If a recipient or subrecipient donates real property for a construction or facilities acquisition project, the current market value of that property may be counted as matching or cost sharing. If any part of the donated property was acquired with Federal funds, only the non-Federal share of the property may be counted as matching or cost sharing.

The value of donated space cannot exceed the fair rental value of comparable space as established by an independent appraisal of comparable space and facilities in a privately-owned building in the same locality.

The awarding office may require that the market value of land or buildings or the fair rental rate of land or of space in a building be established by an independent property appraiser or by a GSA representative and certified by a responsible official of the recipient, subrecipient, or contractor.

Volunteer Services

Rates for donated services used to satisfy a matching or cost-sharing requirement must be consistent with those paid for similar work in the organization. In those instances in which the required skills are not found in the recipient's organization, rates must be consistent with those paid for similar work in the labor market in which the recipient would compete for the kind of services involved. When an employer other than the recipient furnishes the services of an employee, the services must be valued at the employee's regular rate of pay. Only the amount representing an amount consistent with the function performed are allowable, e.g., if a doctor serves as a receptionist, only the amount that would be allowable for a receptionist is allowable as a contribution to the grant. Fringe benefits consistent with those that would be paid by the employing organization that are reasonable, allowable, and allocable may be included in the valuation.

Using Program Income to Meet a Matching or Cost-Sharing Requirement

Costs financed by program income may not count toward satisfying a matching or cost-sharing requirement unless they are expressly permitted by the NoA (see "Financial Management—Program Income").

Documentation

The basis for determining the valuation of personal services, materials, equipment, buildings, and land must be verifiable from the records of the recipient, subrecipient, or contractor under the grant. Volunteer services, to the extent feasible, should be supported by the same level of documentation used by the recipient for its own employees, including time and attendance records.

Prior-Approval Requirements

HHS anticipates that the recipient may need to modify its award budget or other aspects of its approved application during performance to accomplish the award's programmatic objectives. In general, recipients are allowed a certain degree of latitude to rebudget within and between budget categories to meet unanticipated needs and to make other types of post-award changes. In some cases, OPDIV prior written approval may be required. When OPDIV prior approval is required, the requirement applies whether the costs/activities are proposed in the application or in a separate request following award. If an application includes general language about a cost or activity that requires OPDIV prior approval, approval of the application does not necessarily mean that the prior-approval requirement has been satisfied. The recipient is still required to obtain any applicable OPDIV prior approval when specific details are known.

This section addresses the post-award prior-approval requirements related to making certain direct cost budget modifications or undertaking specified activities. Other post-award changes may be made without OPDIV prior approval as long as they are within the limits established by HHS (see "Expanded Authorities" in this section) or may be subject to different procedures as specified in other parts of the HHS GPS (e.g., as specified in "Property Management—Nonexempt Property," the OPDIV must approve any proposal to convey, transfer, assign, mortgage, lease, or in any other manner encumber the property while the recipient remains accountable to the OPDIV for the use of the property). Also, prior approval of costs considered indirect costs is governed by the procedures of the cognizant agency rather than those of the OPDIV.

The post-award changes that are considered changes to budgets or program plans and require OPDIV approval and the changes that may be made under the recipient's authority are outlined below. If OPDIV approval is required, it must be requested of, and obtained from, the GMO in advance of the change or obligation of funds as specified in "Requesting OPDIV Prior Approval" in this section.

OPDIV Prior Approval

OPDIV prior-approval requirements are summarized in Exhibit 5, which is provided for guidance only. For the post-award prior-approval requirements specified in the exhibit, approval is required whether or not the change has a budgetary impact

except as indicated (e.g., if provided as an expanded authority). The circumstances under which prior approval is required also are summarized in the exhibit. Supplementary policy or procedural information related to certain of these categories follows the exhibit. Recipients also should see Part IV of this HHS GPS for OPDIV-specific prior-approval requirements that apply to specific types of grants and types of recipients. Any questions about the need for prior approval for an activity or cost under a specific OPDIV award should be directed to the GMO.

Exhibit 5. Summary of Actions Requiring OPDIV Prior Approval

OPDIV prior approval is required for	Under the following circumstances
A&R	Rebudgeting into A&R costs in a single budget period that would exceed the lesser of $150,000 (or amount specified by the OPDIV in Part IV of the HHS GPS) or 25 percent of the total approved budget (direct and indirect costs) for a budget period (also see "Allowable Costs and Activities"). Any single A&R project exceeding $150,000 (or amount specified by the OPDIV in Part IV of the HHS GPS). Aggregate costs that would exceed the lesser of $150,000 (or amount specified by the OPDIV in Part IV of the HHS GPS) or 25 percent of the total costs reasonably expected to be awarded by the awarding office for a project period (or competitive segment under programs that entertain competing continuation applications).
Carryover of unobligated balances	If not provided as an expanded authority. Also see "Carryover of Unobligated Balances" below for potential OPDIV actions if provided as an expanded authority.
Change of grantee organization	All instances. Recipients must notify the awarding office of other changes in organizational status. See "Change of Grantee Organization" below.
Change in scope	All instances. See "Change in Scope" below for a discussion of the post-award changes that may indicate a change in scope: transfer of substantive programmatic work to a third party; significant rebudgeting; incurrence of research patient care costs; purchase of a unit of general- or special-purpose equipment exceeding $25,000.
Changes in status of PI, PD, or other key personnel named in the NoA	For PIs/PDs, replacement; absence for any continuous period of 3 months or more; reduction of time devoted to project by 25 percent or more from level in approved application. For other key personnel, substitution for named personnel. See "Change in Status, including Absence, of PI/PD and Other Key Personnel" below.
Construction, land, or building acquisition	All instances when purchase proposed; any proposal to convey, transfer, assign, mortgage, lease, or in any other manner encumber real property acquired with OPDIV grant funds.
Cost principles prior-approval requirements	All instances unless provided as an expanded authority (not available for construction, land, or building acquisition or indemnification of third parties).
Deviation from award terms and conditions	All instances. Includes undertaking any activities disapproved or restricted as a condition of the award.

Exhibit 5. Summary of Actions Requiring OPDIV Prior Approval

OPDIV prior approval is required for	Under the following circumstances
Foreign component added to a grant to a domestic organization	All instances.
Indemnification of third parties	All instances.
Need for additional OPDIV funding	All instances whether or not additional time is needed, including extension of a final budget period of a project period with additional funds. See "Need for Additional OPDIV Funding" below.
No-cost extension	All instances unless authority to approve a one-time extension of up to 12 months without a change in scope is provided as an expanded authority. See "Need for Additional Time to Complete Project- or Program-Related Activities ('No-Cost Extension')" below.
Pre-award costs	All instances before the effective date of the initial budget period of a new or competing continuation award unless the authority to approve pre-award costs up to (and including) 90 days before the beginning date is provided as an expanded authority. In either case, the costs are incurred at the applicant's/recipient's own risk.
Research patient care costs	For States, local governments, and tribal governments, all instances. For institutions of higher education, non-profit organizations, and commercial organizations, any instance in which such costs were not part of the approved budget shown in the NoA or a recipient wants to rebudget out of the approved research patient care category.
Retention of research grant funds when career award made	All instances.
Transfer of amounts for training allowances (stipends, tuition, and fees) to other budget categories	All instances unless provided as an expanded authority to States, local governments, or tribal governments. (The training allowance does not include trainee travel, which HHS does not consider to be a trainee cost, and other training-related expenses.)
Transfer of funds between construction and nonconstruction work	All instances.
Transfer of substantive programmatic work	All instances if the recipient is a governmental entity or, for recipients subject to 45 CFR part 74, the grant is a construction grant; otherwise considered an indicator of change in scope. See "Transfer of Substantive Programmatic Work" below.

Carryover of Unobligated Balances

Recipients should be aware of the difference between unliquidated obligations and unobligated balances. Unliquidated obligations are commitments of the recipient and are considered to be obligations and, therefore, should not be reported as unobligated balances.

To ensure the timely use of unobligated balances, recipients must use the "first-in/first-out" principle for recognizing and recording obligations and expenditures of those funds. Upon receipt of the annual FSR, the GMO will compare the total of any unobligated balance shown and the funds awarded for the current budget period with the OPDIV share of the approved budget for the current budget period. If the funds available exceed the OPDIV share of the approved budget for the current budget period, the GMO may select one of the following options:

- In response to a written request from the recipient, revise the current NoA to authorize the recipient to spend the excess funds for additional approved purposes (approval is intended to cover only prospective costs, not costs already incurred by the recipient)

- Offset the current award or a subsequent award by an amount representing some or all of the excess

- For awards subject to expanded authorities, restrict the recipient's authority to automatically carry over unobligated balances in the future, use the balance to reduce or offset OPDIV funding for a subsequent budget period, or use a combination of these actions.

Change of Grantee Organization

OPDIV prior approval is required for the transfer of the legal and administrative responsibility for a grant-supported project or program from one legal entity to another before the expiration of the approved project period (competitive segment for grants where there may a competing continuation for the same project). For other changes in organizational status, e.g., a name change, the recipient must notify the awarding office as specified in "Changes in Organizational Status."

A change of grantee organization may be accomplished under most OPDIV grants, including construction grants, if any of the following conditions are met and the OPDIV determines that the purpose and scope of the approved grant will not change and the transfer is consistent with Federal appropriations law requirements:

- The grant to be transferred has been terminated at the original organization in accordance with 45 CFR 74.61 or 92.43.

- A non-competing continuation award that is within an approved project period has been withheld for a reason other than project performance, e.g., the recipient's management of the grant or non-compliance with award terms and conditions.

- The original recipient has agreed to relinquish responsibility for an active project before the expiration of the approved project period. This includes any proposed change of grantee as a result of a PI on a research project

transferring from one organization to another organization. The project under the same PI may be supported at a new organization for a period up to the remainder of the previously approved project period in an amount not to exceed that previously recommended for direct costs (plus applicable indirect costs) for the remainder of the approved project period.

A request for a change of grantee organization (change of grantee) must be submitted to the GMO before the anticipated start date at the new organization and preferably several months in advance. Failure to provide timely notification may result in disapproval of the request or a delay in processing. As part of the request, the original organization must submit PHS 3734, "Official Statement Relinquishing Interests and Rights in a Public Health Service Research Grant," or equivalent form as specified by the OPDIV, and, if the request involves a research grant, a "Final Invention Statement and Certification." The request also must include an application from the proposed recipient organization. (The relinquishing organization must submit a final FSR to the awarding office no later than 90 days after the end of HHS support.)

The application from the proposed recipient should include the following, as applicable:

- Face page
- Budget pages (current and future years)
- Updated biographical sketches for the PI/PD and existing key personnel and biographical sketches for any proposed new key personnel
- Statement indicating whether the overall plans/aims or objectives have changed from the original submission, and, if so, how
- For research grants
  - Updated "other support" pages, if necessary
  - Resources page
  - Checklist page
  - Certification of IRB/IACUC approval, if applicable
- Detailed list of any equipment purchased with grant funds being transferred to the new organization (inclusion of this list in the transfer application from the new organization indicates its acceptance of title to that equipment).

The OPDIV may request additional information necessary to accomplish its review of the request. Acceptance of a relinquishing statement by the OPDIV does not guarantee approval of a transfer application for the continued funding of a project.

A change of grantee request normally will be permitted only when all of the permanent benefits attributable to the original grant can be transferred, including equipment purchased in whole or in part with grant funds. In reviewing a request to transfer a grant, an OPDIV will consider whether there is a continued need for the

grant-supported project or program and whether there will be any a change in scope of the previously approved project. A change of grantee may be made without objective review, provided the PI/PD plans no change in scope and the facilities and resources at the new organization will allow for successful performance of the project or program. If the change involves a change in scope, the request may not be processed as a change of grantee, will require objective review, and may be subject to a different process, e.g., treated as an exception to competition. A change of grantee that involves the transfer of a grant to or between foreign organizations or international organizations also may require special OPDIV approval, e.g., approval by an Advisory Council or Board. If these conditions or other programmatic or administrative requirements are not met, the OPDIV may require objective review or may disapprove the request and, if appropriate, terminate the award.

The OPDIV will accomplish a change of grantee organization by issuing a revised NoA to the original recipient reflecting the revised budget and project period end dates, deletion of any future-year support, and deobligation of remaining funds, if applicable. (A deobligation of funds will be based on the estimated grant expenditures through the relinquishment date, as determined from the relinquishing statement.) Concurrently, the new recipient will receive a NoA reflecting the balance reported on the relinquishing statement or, if the change of grantee organization occurs on the anniversary date of the project, the NoA to the new recipient will reflect the previously committed direct cost level plus applicable indirect costs. This amount is subject to change as a result of the closeout of the original grant and may be adjusted downward. If a change of grantee involves the transfer of equipment purchased with grant funds, the transfer may be accomplished as part of the original recipient's relinquishment of the grant or HHS may transfer title to equipment to the new organization using its right to transfer title (see "Property Management").

Change in Scope

In general, the PI/PD may make changes in the methodology, approach, or other aspects of the project/program objectives. However, the recipient must obtain prior approval from the GMO for a proposed change in scope. A change in scope occurs when the recipient proposes to change (or changes) the objectives, aims, or purposes identified in the approved application, such as shifting the research emphasis from one disease area to another, changing the service area, applying a new technology (e.g., changing assays from those approved to a different type of assay), changing the approved design under a construction grant, eliminating a primary care delivery site, or making budget changes that cause a project to change substantially from that which was approved. Also see the indicators specified below. The recipient must make the initial determination of whether a proposed change would be considered a change in scope and should consult with the GMO as necessary.

In addition to explicit changes in the objectives, aims, or purposes identified in the approved grant application, post-award changes that are clear indicators of a change in scope or that are likely to be considered a change in scope include, but are not limited to, the following:

- Any change from the approved use of animals or human subjects.
- Transfer of the performance of substantive programmatic work to a third party through a subaward, contract, or any other means, if the authority for

such activities is not included in the approved application. If the third party is a foreign component, this type of action always requires OPDIV prior approval.

- Significant rebudgeting, whether or not the particular expenditures require prior approval. Significant rebudgeting occurs when, under a grant with a Federal share exceeding $100,000, cumulative transfers among direct cost budget categories for the current budget period exceed 25 percent of the total approved budget (which includes direct and indirect costs, whether chargeable to Federal funds or required matching or cost sharing) for that budget period or $250,000, whichever is less.

- Incurrence of research patient care costs if costs in that category were not previously approved by the OPDIV or if a recipient wants to rebudget funds out of the research patient care category.

- Purchase of a unit of general-purpose or special-purpose equipment exceeding $25,000.

Change in Status, including Absence, of Principal Investigator/Project Director and Other Key Personnel

The recipient is required to notify the GMO in writing if the PI/PD or key personnel specifically named in the NoA will withdraw from the project entirely, be absent from the project during any continuous period of 3 months or more, or reduce time devoted to the project by 25 percent or more from the level that was approved at the time of award (for example, a proposed change from 40 percent effort to 30 percent or less effort). The OPDIV must approve any alternate arrangement proposed by the recipient, including any replacement of the PI/PD or key personnel named in the NoA.

The request for approval of a substitute PI/PD/key person should include a justification for the change, the biographical sketch of the individual proposed, other sources of support (if applicable), and any budget changes resulting from the proposed change. If the arrangements proposed by the recipient, including the qualifications of any proposed replacement, are not acceptable to the OPDIV, the grant may be suspended or terminated. If the recipient wants to terminate the project because it cannot make suitable alternate arrangements, it must notify the GMO, in writing, of its wish to terminate, and the GMO will forward closeout instructions.

The requirement to obtain OPDIV prior approval for a change in status pertains only to the PI/PD and those key personnel the OPDIV names in the NoA regardless of whether the applicant organization designates others as key personnel for its own purposes.

Need for Additional OPDIV Funding

A request for additional funding for a current budget period to meet increased costs that are within the scope of the approved application, but that were unforeseen when the new or competing continuation application (or progress report for non-competing continuation support) was submitted, is a non-competing supplemental application. Such requests must be submitted, in writing, directly to the GMO and are not

required to compete with other applications for funding. Other recipient-initiated requests for supplemental funding during a current budget period are considered to change the scope of the approved project or program and are required to compete for funding with other applications.

A request for a non-competing extension of the final budget period of a project period with a minimal amount of additional funds should be submitted to the GMO, in writing, at least 30 days before the project period is scheduled to expire. Such requests usually are for a period of up to 12 months, based on a need to provide continuity of project or program activities while a competing continuation application is being reviewed or to permit orderly phase-out of activities for which there will be no further HHS support. The request must specify the proposed revised ending date and must include justification for both the extension and the additional funds requested.

Need for Additional Time to Complete Project- or Program-Related Activities ("No-Cost Extension")

Unless provided as an expanded authority, OPDIV prior approval is required for any extension of up to 12 months. All extensions that would exceed 12 months, whether as part of an initial request or a subsequent request that would result in an aggregate period of that duration, require special justification. The OPDIV will not approve any extension request if the primary purpose of the proposed extension is to permit the use of unobligated balances of funds. All terms and conditions of the award apply during the extended period.

Significant Rebudgeting

The base used for determining significant rebudgeting excludes carryover balances but includes any amounts awarded as competing or non-competing supplements. For example, the significant rebudgeting threshold has been reached if, under a grant in which the Federal share for a budget period is $100,000, the total approved budget is $300,000 and cumulative changes within that budget period exceed $75,000. Once the significant rebudgeting threshold is reached, the recipient must request and receive OPDIV prior approval for the changes that cause the recipient to exceed the threshold.

The OPDIV will determine if there has been a change in scope and do one of the following:

- Modify the award, as appropriate, to reflect an approved change in scope
- Advise the recipient that the change is not approved and specify the consequences of having rebudgeted to that extent without prior approval
- Advise the recipient that each subsequent budget change in that budget period—regardless of type or dollar value—requires OPDIV prior approval.

The calculation generally begins anew with each subsequent budget period unless the OPDIV has concerns with the overall extent of the recipient's rebudgeting and, on the basis of a high-risk designation, uses an alternate condition in an award.

Transfer of Substantive Programmatic Work

The transfer of substantive programmatic work does not include contracting for routine goods or services used in or in support of a grant. Subgranting is allowable only if authorized by statute or regulation and specified in the NoA. Unless the program is intended as a pass-through program (i.e., one in which the recipient's role is to select subrecipients that are expected to provide the services that are the purpose of the grant, coordinate and oversee their activities, and provide the administrative support needed to meet OPDIV requirements), the recipient is expected to perform a substantive role in the project or program. In the case of a pass-through program, prior approval for the transfer of substantive programmatic work generally is not required. In all other cases, prior approval is required to ensure that the recipient is not acting as a conduit to another party (that may not be eligible to receive OPDIV funding directly) and remains eligible for the award.

When prior approval is required, the request must include the following information:

- A description of the activities or functions involved
- A justification for their performance by a third party
- A breakdown of and justification for the estimated costs, including the manner in which indirect costs, if any, will be reimbursed
- The method to be used to select the subaward and the type of contract/agreement expected to be awarded
- The kinds of entities to be solicited (if selection has already taken place, identification of the organization and the reasons for selection).

Requesting OPDIV Prior Approval

All requests for OPDIV prior approval other than a request for carryover of an unobligated balance must be made in writing (which includes submission by e-mail) to the GMO no later than 30 days before the proposed change. Requests for carryover of unobligated balances should be initiated once the actual unobligated balance is known (generally during the period allowed for preparation and submission of the FSR). Requests for carryover of unobligated balances must include only prospective costs and activities, i.e., ones that will be incurred or undertaken following OPDIV review and approval of the request. Prior-approval requests must be signed by both the PI/PD and the authorized organizational representative. Failure to make a timely request and obtain required OPDIV prior approval from the GMO may result in the disallowance of costs, termination of the award, or other enforcement action within the OPDIV's authority.

All requests must include the name of the recipient; the name of the initiating PI/PD; the PI/PD's telephone number, fax number, and e-mail address; and comparable identifying information for the authorized organization official. E-mail requests must be clearly identified as prior-approval requests, must reflect the complete grant number in the subject line, and should be sent by or through the authorized organizational representative to the GMO that signed the NoA. If the entire message of the request cannot be included in the body of the e-mail, the request should be submitted to the GMO in hard copy.

The OPDIV will review the request and the GMO will provide a response to the authorized organizational representative, with a copy to the PI/PD, indicating the final disposition of the request. Only responses provided by the GMO are to be considered valid. Recipients that proceed on the basis of actions by unauthorized officials do so at their own risk, and HHS is not bound by such responses.

Whenever a recipient contemplates rebudgeting or other post-award changes and is uncertain about the need for prior approval, the recipient is strongly encouraged to consult, in advance, with the GMO.

Under a subaward or contract under a grant, the prior-approval authority usually is the recipient. However, the recipient may not approve any action or cost that is inconsistent with the purpose or terms and conditions of the HHS grant. If an action by a subrecipient or contractor will result in a change in the project/program scope or budget requiring OPDIV approval, the recipient must obtain that approval from the OPDIV before giving its approval to the subrecipient or contractor.

Expanded Authorities

OPDIVs may waive certain direct cost-related and other prior-approval requirements and provide authority for the recipient to undertake these activities and expenditures without the need for OPDIV prior approval. These operating authorities are termed "expanded authorities." Exhibit 6 presents a summary of the expanded authorities that may be provided by an OPDIV. Procedures for implementing several of these authorities follow the exhibit. The recipient should consult Part IV for detailed applicability of expanded authorities to specific award instruments and types of recipients.

Certain grants or recipients are not eligible for expanded authorities, including those that require closer monitoring or technical assistance. In addition, one or more of these authorities may be overridden by a special term or condition of the award. The NoA will indicate the applicability of expanded authorities by reference to the HHS GPS and the OPDIV supplement in Part IV, or through specific terms and conditions of the award. Therefore, recipients must review the NoA to determine whether and to what extent they are permitted to use expanded authorities.

When using expanded authorities, recipients must ensure that they exercise proper stewardship over Federal funds and that costs charged to awards are allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds. HHS may disallow the costs if it determines, through audit or otherwise, that the costs do not meet the tests of allowability, including allocability, reasonableness, necessity, and consistency.

Several expanded authorities have specific deadlines for submission of reports or for timely notification to the awarding office. Recipients should be aware that a consistent pattern of failure to adhere to those deadlines for reporting or notification will be grounds for excluding that recipient from expanded authorities.

Exhibit 6. Summary of Expanded Authorities

May exercise as expanded authority	Except
Carryover of unobligated balances from one budget period to the next successive budget period	If the NoA indicates otherwise
Cost-related prior approvals for direct cost items, including research patient care costs and equipment	If the scope would change
Extension of final budget period of a project period without additional funds	If the recipient already has given itself one extension of up to 12 months
Pre-award costs up to (and including) 90 days before the beginning date of the initial budget period of a new or competing continuation award	If the NoA indicates otherwise
Transfer of performance of substantive programmatic work to a third party (by subaward or a contract under the grant)	If the transfer would be to a foreign component or it would result in a change in scope

Carryover of Unobligated Balances

Under expanded authorities, OPDIV prior approval is not required to carry forward an unobligated balance from one budget period to the subsequent budget period. However, if the GMO determines that some or all of the unobligated funds are not necessary to complete the project or perform the program activity, the GMO may restrict the recipient's authority to automatically carry over unobligated balances in the future, use the balance to reduce or offset OPDIV funding for a subsequent budget period, or use a combination of these actions. The GMO's decision about the disposition of the reported unobligated balance will be reflected in the NoA.

Extension of Final Budget Period of a Previously Approved Project Period

The recipient may extend the final budget period of a previously approved project period one time for a period of up to 12 months beyond the original expiration date shown in the NoA if

- no additional funds are required to be obligated by the awarding office; and
- the originally approved scope will not change; and
- any one of the following applies:
  - ➤ additional time beyond the established expiration date is required to ensure adequate completion of the originally approved project or program, or
  - ➤ continuity of grant support is required while a competing continuation application is under review, or
  - ➤ the extension is necessary to permit an orderly phase-out of a project or program that will not receive continued support.

The fact that funds remain at the expiration of the grant is not, in itself, sufficient justification for an extension without additional funds.

The recipient must notify the awarding office, in writing, of the extension 10 days before the expiration date of the project period. Upon notification, the awarding office will revise the project period ending date and provide an acknowledgment to the recipient. All terms and conditions of the award apply during the extended period and, by extending the final budget period of the project period, the recipient agrees to update all required certifications and assurances, including those pertaining to human subjects and animal welfare, in accordance with applicable regulations and policies. A recipient may not extend a project period previously extended by the awarding office. Any additional project period extension beyond the one-time extension of up to 12 months requires OPDIV prior approval.

Financial Management

Financial Management System

Recipients are required to meet the standards and requirements for financial management systems set forth or referenced in 45 CFR 74.21 or 92.20, as applicable. The adequacy of the financial management system is integral to the ability of the recipient to account for the expenditure of grant funds. These standards are intended to ensure that Federal funds are handled in a responsible manner that includes adequate internal controls, cash management consistent with Department of the Treasury requirements (see "HHS Grants Process—Payment").

States may expend and account for funds in accordance with State laws and procedures that apply to the expenditure of and the accounting for the State's own funds as long as those procedures are sufficient to permit preparation of required reports and tracing of expenditures to a level adequate to establish that award funds have not been used in violation of any applicable statutory restrictions or prohibitions.

All other types of recipients must use financial systems that enable the recipient to do the following:

- Provide accurate, current, and complete financial information about Federal awards and, for subawards, reasonable procedures for ensuring that subrecipients provide financial reports in sufficient time to allow preparation of OPDIV-required reports.

- Maintain records that adequately identify the sources of funds for federally assisted activities and the purposes for which the award was used, including authorizations, obligations, unobligated balances, assets, liabilities, outlays or expenditures, and any program income. Accounting records must be supported by source documentation such as canceled checks, paid bills, payrolls, and time and attendance records.

- Maintain effective control over and accountability for all cash, real and personal property, and other assets under the award; adequately safeguard those assets; and ensure that they are used only for authorized purposes.

- Compare actual expenditures or outlays with the approved budget for the award.

- Determine the allowability of costs in accordance with the applicable Federal cost principles, program regulations, and other requirements cited in the NoA. This includes the ability to readily identify unobligated balances, accelerated or delayed expenditures, and cost transfers.

- Minimize the time elapsing between any advance payment under this award and the disbursement of the funds for direct program costs and the proportionate share of any allowable indirect or facilities and administrative costs, and ensure that the timing and amount of any payments to subrecipients conform to this standard.

Recipients must notify the GMO when financial management problems are discovered. Deficiencies in a recipient's financial management system, whether reported by the recipient or identified by the OPDIV, may result in the imposition of special award conditions, use of the reimbursement payment method, or other increased monitoring by the awarding office.

Program Income

Accountability and Alternatives for Use

Program income is gross income—earned by a recipient, subrecipient, or a contractor under a grant—directly generated by the grant-supported activity or earned as a result of the award. Program income includes, but is not limited to, income from fees for services performed; charges for the use or rental of real property, equipment, or supplies acquired under the grant; the sale of commodities or items fabricated under an award; charges for research resources; and license fees and royalties on patents and copyrights.

The requirements for accountability for the various types of income under HHS grants are specified in this section. However, the NoA governs the disposition of royalties and other income earned from a copyrighted work, patents, patent applications, trademarks, or inventions. Generally such income is not subject to the requirements of this section.

Accountability refers to whether the OPDIV specifies how the income is to be used and whether the income needs to be reported to the OPDIV and for what length of time. Program income earned during the project period must be reported by the recipient as discussed in this section.

Each NoA will indicate the alternative for disposition of program income. For non-research grants, if no alternative is specified, the program income must be used under the deductive alternative. The default alternative for research grants (except for awards to commercial organizations under programs *other than* the Small Business Innovation Research and Small Business Technology Transfer programs) is the addition alternative as provided in 45 CFR 74.24(d). Regardless of the alternative applied, program income may be used only for allowable costs in accordance with the applicable cost principles and the terms and conditions of the award. Subawards and contracts under grants are subject to the terms of the subaward or contract with regard to any income generated, but the terms specified by the recipient must be consistent with the requirements of the NoA.

Program income earned during the period of grant support—other than income earned as a result of copyrights, patents, or inventions (see "Intellectual Property—Rights in Data") or as a result of the sale of real property, equipment, or supplies ("Property Management")—must be retained by the recipient and, as specified in the NoA, may be used in one or a combination of the ways indicated in Exhibit 7. Unless otherwise specified in the terms and conditions of the award, recipients are not accountable for program income earned after the period of grant support.

Exhibit 7. Use of Program Income Alternatives

Alternative	Use of program income
Additive	Added to funds committed to the project or program and used to further eligible project or program objectives
Deductive	Deducted from total allowable costs of the project or program to determine the net allowable costs on which the Federal share of costs will be based
Combination	Uses all program income up to (and including) $25,000 as specified under the additive alternative and any amount of program income exceeding $25,000 under the deductive alternative
Matching	Used to satisfy all or part of the non-Federal share of a project or program

Exhibit 8 summarizes the accountability requirements related to the timing of earning and use of program income.

Exhibit 8. Summary of Accountability Requirements for Program Income

If program income is earned...	and that income is ...	then the recipient is...
During the project period	Received and expended during the project period	Required to use program income as provided in the NoA
During the project period	Received and expended after the project period	Required to adjust the final FSR to reflect receipt and use of the income as directed by the GMO
During the project period	Received during the project period but expended after the project period because (1) earned during the final budget period of the project period or (2) with GMO approval	(1) Required to use income as provided in the NoA and adjust final FSR accordingly (if earned during the final budget period of the project period) or (2) use the income under addition alternative and report as specified by the GMO
After the project period	Received and expended after the project period	Not accountable for that program income unless specifically provided in the NoA

Reporting of Program Income

The amount of program income earned and the amount expended must be reported on the FSR (SF 269—Long Form). Any costs associated with the generation of the gross amount of program income that are not charged to the grant should be deducted from the gross program income earned, and the net program income should be the amount reported. Program income subject to the additive alternative must be reported on lines 10r and 10s, as appropriate, of the FSR; program income subject to the deductive alternative must be reported on lines 10c and 10q of the FSR; and program income subject to the matching alternative must be reported on lines 10g and 10q of the FSR.

Income earned from the sale of equipment must be reported on the FSR for the period in which the proceeds are received in accordance with the reporting requirements for the program income alternative specified. Amounts due the OPDIV for unused supplies must be reflected as a credit to the grant on line 10c of the FSR.

Reporting requirements for accountable income accrued after grant support ends will be specified in the NoA.

Interest Earned on Advances of Grant Funds

The Treasury and OMB policies also establish requirements for recipients to account for interest earned on advances of grant funds and provide for use of the reimbursement method if cash management requirements are not met. Except as provided in 45 CFR 74.22(k), any HHS recipient subject to the requirements of 45 CFR part 74 that receives advance payments must maintain those advances in an interest-bearing account.

Interest earned on advances of Federal funds must be handled as follows:

- *Nongovernmental recipients*. Any interest earned by nongovernmental recipients on advances of Federal funds under all Federal grant awards and subawards that, in the aggregate, exceeds $250 per year (based on the recipient's or subrecipient's fiscal year) must be remitted annually to PMS (as the government-wide agent for collection). Recipients with electronic funds transfer (EFT) capability should use an electronic medium to remit interest.

- *Governmental recipients other than States*. Except as provided in 45 CFR 92.21(i), any interest earned by local governments or Indian tribal governments on advances of Federal funds under all Federal grant awards and subawards that, in the aggregate, exceeds $100 per year (based on the recipient's or subrecipient's fiscal year) must be remitted promptly, and at least quarterly, to PMS.

- *State governments*. State governments operating under Treasury-State agreements are subject to the payment and receipt of interest as specified in their agreements. All other State recipients are expected to follow sound financial management practices that minimize the potential for excessive Federal cash on hand and to comply with the cash management requirements of 45 CFR 92.20 and 21.

Property Management

Generally, recipients may use their own property management policies and procedures for property purchased, constructed, or fabricated as a direct cost using HHS grant funds, provided they observe the requirements in 45 CFR 74.31 through 74.37 or 92.31 through 92.34, as applicable. State governments may use and manage equipment acquired under a grant in accordance with State laws and procedures as specified in 45 CFR 92.32. Unless otherwise indicated, the following requirements for use and management of equipment and supplies do not apply to State governments. See "Intellectual Property" for requirements related to that type of property.

These property management requirements do not apply to equipment for which only depreciation or use allowances are charged or to equipment acquired primarily for sale or rental rather than for use. When acquiring replacement equipment, the recipient may use the equipment to be replaced as a trade-in or may sell the equipment and use the proceeds to offset the costs of the replacement equipment subject to the approval of the OPDIV.

The dollar threshold for determining the applicability of several of the requirements in 45 CFR part 74 or 92 is based on the unit acquisition cost of an item of equipment. As defined in 45 CFR 74.2, the cost of an item of equipment includes necessary modifications and attachments that make it usable for the purpose for which it was acquired or fabricated. When such accessories or attachments are acquired separately and serve to replace, enhance, supplement, or otherwise modify the equipment's capacity and when they individually meet the definition of equipment, required OPDIV prior approval for equipment must be observed for each item (see "Prior-Approval Requirements"). However, the aggregate acquisition cost of a piece of equipment will be used to determine the applicable provisions of 45 CFR 74.34 or 92.32. Fixed equipment that is part of a construction grant also is subject to these requirements. If property is fabricated from individual component parts, each component must itself be classified as equipment if it meets the definition of equipment. In this case, the aggregate acquisition cost of the resulting piece of equipment will determine the appropriate accountability requirements in 45 CFR 74.34 or 92.32.

In general, title to equipment and supplies acquired by a recipient or subrecipient with HHS funds vests in the recipient or subrecipient upon acquisition, subject to the property management requirements of 45 CFR 74.31, 74.34, 74.35, and 74.37 or of 45 CFR 92.32 and 92.33.

Recipients (and subrecipients, as applicable) are required to be prudent in the acquisition of property under a grant-supported project. It is the recipient's responsibility to conduct a prior review of each proposed property acquisition to ensure that the property is needed and that the need cannot be met with property already in the possession of the organization. If prior approval is required for the acquisition, the recipient must ensure that appropriate approval is obtained in advance of the acquisition. The recipient also must follow appropriate procurement procedures in acquiring property as specified in "Procurement Management."

Recipients of HHS grants other than Federal institutions cannot be authorized to use Federal supply sources except that States may acquire hardware and software from

Federal Supply Schedules consistent with the terms and conditions of those schedules.

Recipients of HHS grants must not use equipment acquired with grant funds to provide services for a fee to compete unfairly with private companies that provide equivalent services, unless the NoA provides otherwise.

Exempt Property

Under the Federal Grant and Cooperative Agreement Act, 31 U.S.C. 6306, HHS may permit non-profit institutions of higher education and non-profit organizations whose primary purpose is the conduct of scientific research to obtain title to equipment and supplies acquired under grants for support of basic or applied scientific research without further obligation to the Federal government. However, an OPDIV has the right to require transfer of title to equipment with an acquisition cost of $5,000 or more to the Federal government or to an eligible third party named by the OPDIV under the conditions specified in 45 CFR 74.34(h). An OPDIV may exercise this right within 120 days of the completion or termination of an award or within 120 days of receipt of an inventory, as provided in 45 CFR 74.34(h)(2), whichever is later.

Nonexempt Property

All other equipment and supplies acquired under all other HHS grant-supported projects by any other type of non-State recipient are subject to the full range of acquisition, use, management, and disposition requirements of 45 CFR 74.34 and 74.35 or of 45 CFR 92.32 and 92.33. Property acquired or used under an HHS grant-supported project, including any federally owned property, also is subject to the requirements for internal control specified in 45 CFR 74.21 or 92.20. Pursuant to 45 CFR 74.37, for recipients subject to those regulations, equipment (and intangible property and debt instruments) acquired with, or improved with, HHS funds may not be encumbered without OPDIV approval.

Equipment Management System

The recipient's management system for equipment must meet the requirements of 45 CFR 74.34(f) or 92.32, which include the following:

- Records that adequately identify (according to the criteria specified in the regulations) items of equipment owned or held by the recipient and state the current location of each item
- A physical inventory of the equipment, at least once every 2 years, to verify that the items in the records exist and either are usable and needed or are surplus (a statistical sampling basis is acceptable)
- Control procedures and safeguards to prevent loss, damage, and theft
- Adequate maintenance procedures to keep the equipment in good condition
- Proper sales procedures when the recipient is authorized to sell the equipment.

For items of equipment having a unit acquisition cost of $5,000 or more, an OPDIV has the right to require transfer title to the equipment to the Federal government or to an eligible third party named by the OPDIV under the conditions specified in 45 CFR 74.34(h) and 92.32, respectively. This right applies to nonexempt property acquired by all types of recipients, including State governments and Federal institutions, under all types of grants under the stipulated conditions.

Sale of Equipment and Supplies

For equipment and supplies purchased under HHS grants for basic or applied research by non-profit institutions of higher education or non-profit organizations whose principal purpose is the conduct of scientific research, the recipient is exempt from any requirement to account for proceeds from their sale; however, OPDIVs have certain rights with respect to such property as specified in "Exempt Property" in this section.

All other types of grants and recipients are subject to the requirements in 45 CFR 74.34 or 92.32, if title to the equipment vests in the recipient rather than in the OPDIV. These requirements also apply to donated property used to meet a matching or cost-sharing requirement. If the grant-supported project or program for which equipment was acquired is still receiving OPDIV funding at the time of sale, the recipient must credit the OPDIV share of the proceeds to the grant and use that amount under the deductive alternative for program income. If the recipient is no longer receiving OPDIV grant support, the amount due should be paid in accordance with instructions from the OPDIV.

If there is a residual inventory of unused supplies exceeding $5,000 in aggregate fair market value upon termination or completion of the grant and if the supplies are not needed for other federally sponsored programs or projects, the recipient may either retain them for use on other than federally sponsored activities or sell them, but, in either case, the recipient must compensate the OPDIV for its share as a credit to the grant.

These grants and recipients also are subject to the requirements in 45 CFR 74.35 or 92.33 with respect to the use or sale of unused supplies. If the recipient retains the supplies for use on other than federally sponsored activities, an amount is due the OPDIV as if they were sold.

Revocable License

In some cases, federally owned tangible personal property may be made available to a recipient under a revocable license agreement. The revocable license agreement between the OPDIV and the recipient provides for recipient use of the property for the period of grant support under the following conditions:

- Title to the property remains with the Federal government.
- The OPDIV reserves the right to require the property to be returned to the Federal government should it be determined to be in the best interests of the Federal government to do so.
- The use to which the recipient puts the property does not permanently damage it for Federal government use.

- The property is controlled and maintained in accordance with the requirements of the NoA.

Debt Instruments

Under certain programs and when authorized in the NoA, recipients may be allowed or required to enter into financing arrangement with third parties. Under such circumstances, the NoA will address the OPDIV's role; provisions to be included in agreements with third parties; the recipient's role with respect to the third parties, including responsibilities and liabilities in the event of non- or late payment by a third party; and the recipient's accountability during and after the project period.

Real Property

Acquisition, Use, and Management

Real property may be acquired only when authorized by statute and when specifically provided for in the NoA. In addition, activities under individual grants that constitute major renovation of real property or purchase of a trailer or modular unit that will be used as real property may be charged to HHS grants only with specific statutory authority and GMO approval.

Real property constructed or acquired under an HHS grant is subject to the requirements of 45 CFR 74.30 through 74.32 and 74.37 or of 45 CFR 92.31, as applicable, regarding use, transfer of title, and disposition, unless alternate requirements are specified in the governing statute. For example, the governing statute for a construction grant program may contain usage and disposition requirements that are in addition to or different from the usage and disposition requirements of the governing regulations. To the extent statutory provisions differ from the requirements of 45 CFR part 74 or 92, including those described in this subsection, the statutory provisions, as reflected in the NoA, apply. In addition, statutory provisions or implementing program regulations may specify the duration of the recipient's accountability obligations (e.g., 20 years) or allow for waivers.

Real property constructed or renovated with HHS grant support may not be conveyed, transferred, assigned, mortgaged, leased, or in any other manner encumbered by the recipient, except as expressly authorized in writing by OPDIV. If the recipient defaults in any way on a mortgage, the recipient must immediately notify the GMO by telephone and in writing. If the mortgagor intends to foreclose, the recipient must notify the GMO in writing at least 30 days before the foreclosure action is initiated.

The mortgage agreement must specifically allow, in the case of default, that HHS or its designee may assume the role of mortgagor and continue to make payments. If HHS (or its designee) chooses not to assume the role of mortgagor in the case of default, the recipient must pay HHS an amount equal to the share of the sales proceeds otherwise due the recipient multiplied by the HHS share of the property. Any assignment of the property and mortgage responsibilities to any party other than HHS is subject to prior approval of the mortgagor.

Disposition

The recipient is accountable to the OPDIV for use of grant-supported real property as long as it owns the property or until it requests disposition instructions from the OPDIV. See Part IV to determine if an OPDIV has statutory or regulatory provisions that specify a different accountability period.

For disposition of property acquired on an amortized acquisition basis, the formulas in 45 CFR 74.32 and 92.31 do not apply in determining the Federal share. In cases of amortized acquisition, the Federal share will be determined by multiplying the amount of mortgage principal already repaid at the time of disposition by the average Federal participation (taken from the FSR) plus the increase in value over the purchase price multiplied by the average Federal participation plus the Federal participation in the down payment. The computation of the Federal share of real property acquired with long-term debt financing must be computed for each year of grant support in which Federal funds are used to meet all or a portion of the down payment, the principal on the mortgage, or both.

If a real estate transaction funded in whole or in part by HHS requires the use of a real estate appraisal (including, but not limited to, appraisals to determine the Federal share of real property and appraisals to determine required insurance levels), the appraisal must be performed by appraisers certified or licensed by the applicable State in accordance with the requirements established by Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended (P.L. 101-73).

Notice of Federal Interest

To protect the Federal interest in real property that has been constructed or has undergone major renovation with HHS grant funds, recipients must record an NFI in the appropriate official records of the jurisdiction in which the property is located. Recordation must occur when construction or renovation begins. Fees charged for recording or modifying the NFI may be charged to the grant. A copy of the NFI must be provided to the awarding office.

Insurance

Immediately upon completion of construction, a nongovernmental recipient must, at a minimum, provide the same type of insurance coverage as it maintains for other property it owns, consistent with the minimum coverage specified below. "Completion of construction" means either the point at which the builder turns the facility over to the recipient (e.g., the date of the final acceptance of the building) or the date of beneficial occupancy, whichever comes first.

If title to real property acquired with HHS grant funds vests in the recipient, the following minimum insurance coverage is required:

- *Title insurance policy that insures the fee interest in the real property for an amount not less than the full appraised value of the property.* When the Federal participation in the construction of real property covers only a portion of a building, title insurance should cover the total cost of the facility to prevent liens on the unsecured portion from having an adverse impact on the portion with a Federal interest. If the recipient already owns the land (for

example, land in the middle of a campus setting on which a building is being constructed), in lieu of a title insurance policy, the recipient may provide evidence satisfactory to the OPDIV, such as legal or title opinion, that it has good and merchantable title free of all mortgages or other foreclosable liens to all land, rights of way, and easements necessary for the project. In instances where a recipient is given land by the State, if the State recently acquired the land in a land swap transaction, the recipient should obtain title insurance. However, if the State has owned the land for a considerable period of time, title insurance would not be necessary; a copy of the State documents giving the land to the recipient would be sufficient. If the recipient must buy the land on which to build, a legal opinion would not be sufficient; title insurance must be obtained in order to protect the Federal interest in the building to be constructed.

- *Physical destruction insurance policy that insures the full appraised value of the facility from risk of partial and total physical destruction.* When the Federal participation in the construction or renovation of real property covers only a portion of a building, the insurance should cover the total cost of the facility, because any damage to the building could make the building unusable and could thus affect the Federal interest. The insurance policy is to be maintained for the duration of the Federal interest in the property. The cost of insurance coverage after the period of grant support must be borne by a source other than the grant that provided the funds for the construction or renovation. The grant account will not remain active for this purpose.

Governmental recipients may follow their own insurance requirements. Federally owned property provided to a recipient for use need not be insured by the recipient.

Within 5 days of completion or beneficial occupancy, the recipient must submit, to the GMO, a written statement signed by the authorized organizational representative assuring that the recipient has purchased the required insurance policies on the OPDIV-funded facility and will maintain the insurance coverage at the full appraised value of the facility throughout the period of Federal interest as specified in the NoA.

The OPDIV may waive one or both of the requirements above if the recipient shows that it is effectively self-insured against the risks involved. The term "effectively self-insured" means that the recipient has sufficient funds to pay for any damage to the facility, including total replacement if necessary, or to satisfy any liens placed against the facility. If a recipient claims self-insurance, it must provide the OPDIV an assurance that it has sufficient funds available to replace or repair the facility or to satisfy all liens. This certification should state the source of the funds, such as the organization's endowment or other special funds set aside specifically for this purpose.

Intellectual Property

It is HHS policy that the results and accomplishments of the activities that it funds should be made available to the public. PIs/PDs and recipient organizations are expected to make the results and accomplishments of their activities available to the research community and to the public at large. If the outcomes of the research result in inventions, the provisions of the Bayh-Dole Act of 1980, as implemented in 37 CFR part 401, apply.

As long as recipients comply with the provisions of the Bayh-Dole Act, as amended by the Technology Transfer Commercialization Act of 2000 (P.L. 106-404), and 37 CFR part 401, they have the right to retain title to any invention conceived or first actually reduced to practice using HHS grant funds. The principal objectives of these laws and the implementing regulation are to promote commercialization of federally funded inventions, while ensuring that inventions are used in a manner that promotes free competition and enterprise without unduly encumbering future research and discovery.

The regulation requires the recipient to develop and commercialize the technology or use patent and licensing processes to transfer grant-supported technology to industry for development. Alternatively, unpatented research products or resources may be made available through licensing to vendors or other investigators. Sharing of copyrightable outcomes of research may be in the form of journal articles or other publications.

The importance of each of these outcomes is reflected in the specific policies pertaining to rights in data, sharing of research data and unique research resources, and inventions and patents described in this section.

Rights in Data

In general, recipients own the rights in data resulting from a grant-supported project or program. However, the NoA may indicate alternative rights, e.g., under a cooperative agreement or based on specific programmatic considerations as stated in the applicable program announcement or solicitation. Except as otherwise provided in the NoA, any publications, data,[18] or other copyrightable works developed under an HHS grant may be copyrighted without OPDIV prior approval. Rights in data also extend to students, fellows, or trainees under awards whose primary purpose is educational, with the authors free to copyright works without OPDIV approval. In all cases, whether HHS funded all or part of the project or program resulting in the data, the Federal government must be given a royalty-free, nonexclusive, and irrevocable license for the Federal government to reproduce, publish, or otherwise use the material and to authorize others to do so for Federal purposes, e.g., to make it available in government-sponsored databases for use by other researchers. The specific scope of OPDIV rights with respect to a particular grant-supported effort will be addressed in the NoA. Data developed by a subrecipient also are subject to this policy.

Access to Research Data

HHS handles requests for the release of research data from certain types of recipients as FOIA requests (see 45 CFR 74.36). The term "research data" is defined as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings. It does not include preliminary analyses;

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[18] For this purpose, "data" means recorded information, regardless of the form or media on which it may be recorded, and includes writings, films, sound recordings, pictorial reproductions, drawings, designs or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other research data.

drafts of scientific papers; plans for future research; peer reviews; communications with colleagues; physical objects (e.g., laboratory samples, audio or video tapes); trade secrets; commercial information; materials necessary to be held confidential by a researcher until publications in a peer-reviewed journal; information that is protected under the law (e.g., intellectual property); personnel or medical files and similar files, the disclosure of which would constitute an unwarranted invasion of personal privacy; or information that could be used to identify a particular person in a research study.

As required by 45 CFR 74.36, recipients that are institutions of higher education, hospitals, or non-profit organizations must release research data first produced in a project supported in whole or in part with Federal funds that are cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., regulations and administrative orders). If the data are publicly available, HHS directs the requester to the public source. Otherwise, the OPDIV FOI coordinator handles the request, consulting with the affected recipient and the PI. This requirement also provides for assessment of a reasonable fee to cover grantee costs and (separately) the HHS costs of responding.

This requirement to release research data does not apply to commercial organizations or to research data produced by State or local governments. However, if a State or local governmental recipient contracts with an educational institution, hospital, or non-profit organization, and the contract results in covered research data, those data are subject to the disclosure requirement.

Publications

As a means of sharing knowledge, HHS encourages recipients to arrange for publication of the results and accomplishments of HHS-supported activities. OPDIV prior approval is not required for publishing the results of an activity under a grant. Recipients also may assert copyright in scientific and technical articles based on data produced under the grant and transfer it to the publisher or others where necessary to effect journal publication or inclusion in proceedings associated with professional activities. Any such transfer is subject to the royalty-free, non-exclusive and irrevocable license to the Federal government and any agreement should note explicitly that the assignment is subject to the government license.

Journal or other copyright practices are acceptable unless the copyright policy prevents the recipient from making copies for its own use (as provided in 45 CFR 74.36 and 92.34). The recipient should account for royalties and other income earned from a copyrighted work as specified by the OPDIV (see Part IV and the NoA).

For each publication that results from HHS grant-supported activities, recipients must include an acknowledgment of grant support using one of the following statements:

> "This publication was made possible by Grant Number _____ from _____."
>
> "The project described was supported by Grant Number _____ from _____."

Recipients also must include a disclaimer stating the following:

> "Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the [name of OPDIV, OPDIV component, or HHS]."

If the recipient plans to issue a press release concerning the outcome of HHS grant-supported activities, it should notify the OPDIV in advance to allow for coordination. One copy of each publication resulting from work performed under an HHS grant-supported project must accompany the annual or final progress report submitted to the OPDIV.

Patents and Inventions

The Bayh-Dole Act of 1980 (P.L. 96-517; 35 U.S.C. 200–212) and the related EO 12591 (April 10, 1987) provide incentives for the practical application of research or results of other activities supported through Federal funding agreements. To be able to retain rights and title to inventions made with Federal funds, so-called "subject" inventions, the recipient must comply with a series of regulations that ensure the timely transfer of the technology to the private sector, while protecting limited rights of the Federal government.

The regulations apply to any subject invention—defined as any invention either conceived or first actually reduced to practice in the performance of work under the Federal award—and to all types of recipients of Federal funding. This includes non-profit entities and small businesses or large businesses receiving funding through grants, cooperative agreements, or contracts as direct recipients of funds or as subrecipients or subcontractors under those awards.

HHS recipients may retain intellectual property rights to subject inventions provided they do the following:

- Report all subject inventions to the OPDIV
- Make efforts to commercialize the subject invention through patent or licensing
- Formally acknowledge the Federal government's support in all patents that arise from the subject invention
- Formally grant the Federal government a limited use license to the subject invention.

Subawards and contracts under an award also must reflect the objectives of the Bayh-Dole Act and the Technology Transfer Commercialization Act of 2000 to ensure that inventions made are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery.

Royalties and Licensing Fees from Copyrights, Inventions, and Patents

HHS recipients do not have to report program income resulting from royalties or licensing fees from sale of copyrighted material unless the NoA provides otherwise.

The NoA may include additional terms and conditions if commercialization of an invention is an anticipated outcome of a research project.

Pursuant to the regulations implementing the Bayh-Dole Act (37 CFR 401.14(h)), HHS requires reporting of income resulting from HHS-funded inventions and patents. Specifically, as part of the annual invention utilization report, recipients must report income generated by all subject inventions to which title has been elected, including inventions that have been patented and those that are licensed but not patented (see "Invention Reporting" in this section).

Invention Reporting

Exhibit 9 summarizes recipient responsibilities for invention reporting as specified in 37 CFR part 401. Recipients should refer to 37 CFR part 401 (available on the Interagency Edison site: https://s-edison.info.nih.gov/iEdison/) for a complete discussion of the regulations.

Exhibit 9. Extramural Invention Reporting Compliance Responsibilities

Action required	When action must be taken	Discussion	37 CFR part 401 reference
Employee Agreement to Disclose All Inventions			
The PI/PD (employee) must sign an agreement to abide by the terms of the Bayh-Dole Act and the HHS GPS as they relate to intellectual property rights.	At time of employment.	Recipients and subrecipients must have policies in place regarding ownership of intellectual property.	401.14(f)(2)
Invention Report and "Disclosure"			
The recipient must submit to the OPDIV a report of any subject invention. This includes a written description (the so-called "invention disclosure") of the invention.	Within 2 months of the inventor's initial report of the invention to the recipient.	There is no single format for disclosing the invention to the Federal government. The report must identify inventor(s), OPDIV grant number, and date of any public disclosure.	401.14(a)(2) 401.14(c)(1)
Rights to Subrecipient Inventions			
Subrecipients retain rights to any subject inventions they make.	Within 2 months of the inventor's initial report of the invention to the subrecipient. (The subrecipient has the same invention reporting obligations as the recipient.)	The recipient cannot require ownership of a subrecipient's subject inventions as a term of the agreement.	401.14(g)(1) 401.14(g)(2)
Election of Title to Invention			
The recipient must notify the OPDIV of its decision to retain or waive title to invention and patent rights.	Within 2 years of the initial reporting of the invention to the OPDIV.		401.14(b) 401.14(c)(2) 401.14(f)(1)

Exhibit 9. Extramural Invention Reporting Compliance Responsibilities

Action required	When action must be taken	Discussion	37 CFR part 401 reference
Confirmatory License			
For each invention, the recipient must provide a use license to the OPDIV for each invention.	Promptly after election of title to the invention.		401.14(f)(1)
Patent Application			
The recipient must inform the OPDIV of the filing of any non-provisional patent application. The patent application must include a Federal government support clause.	Within 1 year after election of title, unless there is an extension.	Initial patent application is defined as a non-provisional U.S. application. The patent application number and filing date must be provided.	401.14(c)(3) 401.2(n)
Assignment of Rights to Third Party			
If the recipient is a non-profit organization, it must seek OPDIV approval to assign invention or U.S. patent rights to any third party, including the inventor(s).	As needed.	Recipients that are for-profit entities (including small businesses) do not need to seek approval.	401.14(k)
Issued Patent			
The recipient must notify the OPDIV that a patent has been issued.	When the patent is issued.	The patent issue date, number, and evidence of Federal government support clause must be provided.	401.5(f)(2)
Extension of Time to Elect Title or File Patent			
The recipient may request an extension of up to 2 years for election of title, or 1 year for filing a patent application.	As needed.	Request for extension of time must be made. Such requests are preapproved.	401.14(c)(4)
Change in Patent Application Status			
The recipient must notify the OPDIV of changes in patent status.	At least 30 days before any pending patent office deadline.	This notification allows the OPDIV to consider continuing the patent action.	401.14(f)(3)
Invention Utilization Report			
The recipient must submit information about the status of commercialization of any invention for which title has been elected.	Annually.	This report gives an indication of whether the objectives of the law are being met. Specific reporting requirements can be found in *i*-Edison (https://s-edison.info.nih.gov/iEdison/).	401.14(h)

Exhibit 9. Extramural Invention Reporting Compliance Responsibilities

Action required	When action must be taken	Discussion	37 CFR part 401 reference
Annual Invention Statement			
The recipient must indicate any inventions made during the previous budget period on all grant awards.	Generally part of the competing application or non-competing grant progress reports.	For PHS OPDIVs, the information is requested as a checklist item on the PHS 398 application or through the SF 424 (R&R), as applicable, and on the non-competing grant progress report (PHS 2590).	PHS 398 and PHS 2590; SF 424 (R&R)
Final Invention Statement and Certification			
The recipient must submit to the GMO a summary of all inventions made during the entire term of each grant award.	Within 90 days after the project period (competitive segment) ends.	Required information is specified on the HHS 568 form. If no inventions occurred during the project period, a negative report must be submitted.	401.14(f)(5)

A recipient's failure to comply with any of these or other regulations cited in 37 CFR part 401 may result in the loss of patent rights or an enforcement action.

The Bayh-Dole Act includes provisions for the recipient to assign invention rights to third parties. Recipients that are non-profit organizations must request OPDIV approval for the assignment. If the assignment is approved and the rights are assigned to a third party, invention and patent reporting requirements apply to the third party. The recipient should review existing agreements with third parties and revise them, as appropriate, to ensure that they are consistent with the terms and conditions in the NoA and that the objectives of the Bayh-Dole Act are adequately represented in the assignment.

Any invention made using funds awarded for educational purposes, e.g., training grants or certain types of career development awards, is not considered a subject invention and therefore is not subject to invention reporting requirements (as provided in 45 CFR part 74 and 37 CFR 401.1(b)). The recipient should seek the advice of the GMO to verify whether any invention made under a career development award should be considered a subject invention.

All issues or questions regarding extramural technology transfer policy and reporting of inventions and their utilization should be referred to the GMO or other designated individual.

Sharing Research Tools

HHS believes that sharing of data and other research tools produced or developed by investigators under HHS grants, such as cell lines, certain types of animals (e.g., transgenic mice), and computer programs, is essential for expedited translation of research results into knowledge, products, and procedures to improve human health.

HHS endorses the sharing of final research data and research tools to serve these and other important scientific goals and expects and supports the timely release and sharing of final research data and research tools from HHS-supported studies for use by other researchers. "Timely release and sharing" is defined as no later than the acceptance for publication of the main findings from the final data set or after submission to the OPDIV. Restricting the availability of unique resources can impede the advancement of further research.

For any subaward, including a consortium agreement, that may result in research data or tools, the recipient must include a provision requiring third-party data or research tools to be made available to the recipient and, as appropriate, the OPDIV upon request, to allow for sharing.

HHS recognizes that data sharing may be complicated or limited, in some cases, by organizational policies, local IRB rules, and local, State and Federal laws and regulations, including the Privacy Rule. The rights and privacy of individuals who participate in HHS-sponsored research must be protected at all times. Thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects. Investigators also must exercise great care to ensure that resources involving human cells or tissues do not identify original donors or subjects, either directly or through identifiers such as codes linked to the donors or subjects.

To facilitate the availability of research tools developed with OPDIV funds, investigators may distribute the materials through their own laboratory or organization or submit them, if appropriate, to a repository. Investigators are expected to submit unique biological information, such as DNA sequences or crystallographic coordinates, to the appropriate data banks so that they can be made available to the broad scientific community. When distributing unique resources, investigators are to include pertinent information on the nature, quality, or characterization of the materials.

In addition to sharing data and research resources with the research community, upon request of the OPDIV, the recipient also must provide a copy of documents or a sample of any material developed under an HHS grant award. The recipient may charge a nominal fee to cover shipping costs for providing this material. Income earned from these charges must be treated as program income.

Organizations that believe they will be unable to comply with these requirements should promptly contact the GMO to discuss the circumstances, obtain information that might enable compliance, and reach an understanding in advance of an award.

Procurement Management

Recipients may acquire a variety of commercially available goods or services in connection with a grant-supported project or program. States may follow the same policies and procedures they use for procurements from non-Federal funds. All other recipients must follow the requirements in 45 CFR 74.40 through 74.48 or 92.36, as applicable, for the purchase of goods or services through contracts under grants. The requirements for third-party activities involving transfer of substantive programmatic work are addressed under "Subawards" in this section.

A contract under a grant must be a written agreement between the recipient and the third party. The contract must, as appropriate, state the activities to be performed; the time schedule; the policies and requirements that apply to the contractor, including those required by 45 CFR 74.48 or 92.36(i) and other terms and conditions of the grant (these may be incorporated by reference where feasible); the maximum amount of money for which the recipient may become liable to the third party under the agreement; and the cost principles to be used in determining allowable costs in the case of cost-type contracts. The contract must not affect the recipient's overall responsibility for the direction of the project or program and accountability to the Federal government. Therefore, the agreement must reserve sufficient rights and control to the recipient to enable it to fulfill its responsibilities.

When a recipient enters into a service-type contract in which the term is not concurrent with the budget period of the award, the recipient may charge the costs of the contract to the budget period in which the contract is executed even though some of the services will be performed in a succeeding period if the following conditions are met:

- The awarding office has been made aware of this situation either at the time of application or through post-award notification.
- The project has been recommended for a project period extending beyond the current year of support.
- The recipient has a legal commitment to continue the contract for its full term.

However, costs will be allowable only to the extent that they are for services provided during the period of OPDIV support. To limit liability if continued OPDIV funding is not forthcoming, it is recommended that recipients insert a clause in such contracts of $100,000 or less stipulating that payment beyond the end of the current budget period is contingent on continued Federal funding. The contract provisions prescribed by 45 CFR 74.48 and 92.36(i)(2) specify termination provisions for contracts in excess of $100,000.

In general, the rental costs for facilities and equipment applicable to each budget period should be charged to that period. Recipients are encouraged to consult the GMO before entering into leases that will result in direct charges to the grant project.

Approval Requirements

The procurement standards in 45 CFR 74.44 and 92.36(g) allow OPDIVs to require approval of specific procurement transactions under the following circumstances (and provide a mechanism for governmental recipients to be exempt from this type of review):

- A recipient's procurement procedures or operations do not comply with the procurement standards required by those regulations.

- The procurement is expected to exceed the "simplified acquisition threshold" (currently $100,000) (formerly the "small purchase threshold") established by the Federal Property and Administrative Services Act, as amended, and is to be awarded without competition, or only one bid or proposal is received in response to a solicitation.

- A procurement that will exceed the simplified acquisition threshold specifies a "brand name" product.

- A proposed award over the simplified acquisition threshold is to be awarded to other than the apparent low bidder under a sealed-bid procurement.

- A proposed contract modification changes the scope of a contract or increases the contract amount by more than the amount considered to be a simplified acquisition.

When OPDIV prior approval is required, the recipient must make available sufficient information to enable review. This may include, at OPDIV discretion, pre-solicitation technical specifications or documents, such as requests for proposals or invitations for bids, or independent cost estimates. Approval may be deferred pending submission of additional information by the recipient or may be conditioned on the receipt of additional information. Any resulting OPDIV approval does not constitute a legal endorsement of the business arrangement by the Federal government nor does such approval establish the OPDIV as a party to the contract or any of its provisions.

Requirements for Using Small Businesses, Minority-Owned Firms, and Women-Owned Businesses

Recipients must make positive efforts to use small businesses, minority-owned firms, and women-owned businesses as sources of goods and services whenever possible. Recipients are required to take the following steps to implement this policy:

- Place qualified small, minority-owned, and women-owned business enterprises on solicitation lists

- Ensure that small, minority-owned, and women-owned business enterprises are solicited whenever they are potential sources

- Consider contracting with consortia of small, minority-owned, or women-owned business enterprises when an intended contract is too large for any one such firm to handle on its own or, if economically feasible, divide larger requirements into smaller transactions for which such organizations might compete

- Make information on contracting opportunities available and establish delivery schedules that encourage participation by small, minority-owned, and women-owned business enterprises

- Use the services and assistance of the SBA and DoC's Minority Business Development Agency, as appropriate

- If subcontracts are to be let, require the prime contractor to take the affirmative steps listed above.

Subawards

This section includes the requirements for a grant involving subawards, including consortium agreements in which the recipient collaborates with one or more other organizations in carrying out the grant-supported activity. Subrecipients should be selected by the recipient using its established policies. HHS does not require that subawards comply with the procurement standards and requirements outlined above.

The recipient is accountable to the OPDIV for the performance of the project, the appropriate expenditure of grant funds by all parties, and all other obligations of the recipient, as specified in the HHS GPS. In general, the requirements that apply to the recipient, including the intellectual property and program income requirements of the award, also apply to subrecipients. The recipient is responsible for including the applicable requirements of the HHS GPS in its subaward agreements.

The recipient must enter into a formal written agreement with each subrecipient that addresses the arrangements for meeting the programmatic, administrative, financial, and reporting requirements of the grant, including those necessary to ensure compliance with all applicable Federal regulations and policies. At a minimum, the subaward agreement must include the following:

- Identification of the PI/PD and individuals responsible for the programmatic activity at the subrecipient organization along with their roles and responsibilities.

- Procedures for directing and monitoring the programmatic effort.

- Procedures to be followed in providing funding to the subrecipient, including dollar ceiling, method and schedule of payment, type of supporting documentation required, and procedures for review and approval of expenditures of grant funds.

- If different from those of the recipient, a determination of policies to be followed in such areas as travel reimbursement and salaries and fringe benefits (the policies of the subrecipient may be used as long as they meet HHS requirements).

- Incorporation of applicable public policy requirements and provisions indicating the intent of the subrecipient to comply, including submission of applicable assurances and certifications.

- For research subawards, inclusion of the following:

  - Statement specifying whether the financial conflict of interest requirements of the collaborating organization or those of the recipient apply.

  - Provision addressing ownership and disposition of data produced under the agreement.

  - Provision making the sharing of data and research tools and the inventions and patent policy applicable to the subrecipient and its employees in order to ensure that the rights of the parties to the

agreement are protected and that the recipient can fulfill its responsibilities to the OPDIV. This provision must include a requirement to report inventions to the recipient and specify that the recipient has the right to request and receive data from the subrecipient on demand.

- Provisions regarding property (other than intellectual property), program income, publications, reporting, record retention, and audit necessary for the recipient to fulfill its obligations to the OPDIV.

Changes in Organizational Status

Recipients must give HHS advance notice of the following types of changes in organizational status:

- *Merger*—legal action resulting in the unification of two or more legal entities. When such an action involves the transfer of HHS grants, the procedures for recognizing a successor-in-interest will apply. When the action does not involve the transfer of HHS grants, the procedures for recognizing a name change normally will apply.

- *Successor-in-interest*—process whereby the rights to and obligations under an HHS grant are acquired incidental to the transfer of all of the assets of the recipient or the transfer of that part of the assets involved in the performance of the grant. A successor-in-interest may result from legislative or other legal action, such as a merger or other corporate change.

- *Name change*—action whereby the name of an organization is changed without otherwise affecting the rights and obligations of that organization as a recipient.

If the change would be considered a change of grantee organization as described in "Prior-Approval Requirements—OPDIV Prior Approval," the recipient must obtain that approval rather than simply notifying the OPDIV of its intent.

Advance notification is required to ensure that the recipient still is able to meet its legal and administrative obligations to HHS and payments are not interrupted. Recipients are encouraged to contact the GMO of the lead OPDIV awarding office to explain the nature of the change in organizational status and receive guidance on whether it will be treated as a name change or successor-in-interest. The lead awarding office ordinarily will be the OPDIV with which the organization has the most HHS grants. If there is no advance consultation, HHS reserves the right to review the material provided, seek clarification or additional information, and make an independent determination.

A recipient's formal request for a change in organizational status should be submitted as soon as possible so that HHS can determine whether the organization will continue to meet the grant program's eligibility requirements and take the necessary action to reflect the change in advance of the change in status.

For a successor-in-interest, a letter signed by the authorized organizational representative of the current recipient (transferor) and the successor-in-interest (transferee) must be sent to the lead awarding office, following consultation with the GMO of that office. The letter must do the following:

- Stipulate that the transfer will be properly effected in accordance with applicable law.
- Indicate that the transferor relinquishes all rights and interests in all of the affected grants.
- Request that the HHS awarding office (offices) modify its (their) records to reflect the transferee as the recipient of record.
- State the effective date of the transfer.
- Provide the transferee's Entity Identification Number and DUNS number.
- Include verification of the transferee's compliance with applicable requirements (e.g., research misconduct).
- Include a list of all affected HHS grants (active and pending) with the following information for each:
  - Complete grant number.
  - Name of PI/PD.
  - Current budget period and project period.
  - Total direct costs (as originally recommended) plus applicable indirect costs for each remaining budget period. If the successor-in-interest will occur during a budget period rather than on the anniversary date, the transferor also must provide estimated levels of current-year direct and indirect costs remaining as of the effective date of the transfer. The estimate may be reported on the official statement relinquishing interests and rights in the grant (e.g., PHS 3734 is available at http://www.hhs.gov/forms/publicuse.html or an equivalent relinquishing statement) for each affected grant or may be itemized by grant number as an attachment to the letter.
- Include a complete application face page for each affected grant showing the transferee as the applicant organization. Each face page must be signed by both the PI/PD and the authorized organizational representative at the transferee organization.
- Include a copy of the current negotiated indirect cost rate agreement for the transferee.

In order to be recognized as the successor-in-interest, the "new" (transferee) organization must meet each grant program's eligibility requirements. Upon review and acceptance of this information, the awarding office will revise the NoA to show the transferee as the recipient of record.

For name changes, the recipient's written notification to the lead awarding office must include the effective date of the change. Revised face pages are not required for name changes because name changes are processed with the next award action (e.g., non-competing continuation award), and the organization will submit a face page with the information submitted as part of that action.

Federally Sponsored Surveys

Recipients may use HHS grant funds to collect information through surveys or questionnaires under the following conditions:

- When the collection of information is not a primary objective of the grant but is incidental to, or is an integral part of, a grant-supported activity.

- When the collection of information is a primary objective of the grant, but such information is not intended primarily for the use of the Federal government or a party designated by the Federal government. (Contracts are used for this purpose unless a grant is specifically required by legislation.)

When information is collected according to either of the two conditions above, recipients are prohibited from representing to their respondents that the information is being collected for, or in association with, the Federal government unless OPDIV approval has been obtained and, when required, OMB report clearance procedures as contained in OMB regulations implementing the PRA at 5 CFR part 1320, Controlling Paperwork Burdens on the Public, have been followed. (When OMB approval is required, the OPDIV, rather than the recipient, is responsible for obtaining the necessary clearance.)

OMB clearance is required whenever HHS sponsors the use of a reporting form or plan to collect identical kinds of information or data from 10 or more people. Information collection is considered to be sponsored by HHS when one or more of the following circumstances exist:

- The OPDIV authorizes the recipient of a grant to represent to respondents that the information is being collected for, or in association with, an OPDIV.

- The recipient of a grant uses the report form or plan to collect information that an OPDIV has requested for the planning, operation, or evaluation of its program.

- The terms and conditions of a grant award provide for OPDIV approval of the study design, questionnaire content, or data collection procedure.

- The terms and conditions of a grant award provide for either submission of the data for individual respondents or the preparation and submission of special requested tabulations to the OPDIV.

- Any information collection under a cooperative agreement.

HHS and OMB approval may also be required if the use of a report form or plan presents a relatively high risk of unwarranted invasion of privacy.

Collection of the following types of information is not subject to the clearance requirements under OMB regulations at 5 CFR part 1320:

- Health professions data as described in Section 708 of the PHS Act, as amended

- Tests or examinations given individuals for determining knowledge, abilities, or aptitudes of the person tested and the collection of information for identification or classification in connection with such tests

- Information from patients that is to be used exclusively for research on or direct treatment of a clinical disorder; for the interpretation of biological analyses of body fluids, tissues, or other specimens; or for identification or classification of such specimens (see 5 CFR part 1320 for additional exemptions from clearance requirements).

Monitoring

Recipients are responsible for managing the day-to-day operations of grant-supported activities using their established controls and policies, as long as they are consistent with HHS requirements. However, to fulfill their role in regard to the stewardship of Federal funds, OPDIVs monitor their grants to identify potential problems and areas where technical assistance might be necessary. This active monitoring is accomplished through review of reports and correspondence from the recipient, audit reports, site visits, and other information available to the OPDIV. The names and telephone numbers of the individuals responsible for monitoring the programmatic and business management aspects of a project or activity will be provided to the recipient as part of the NoA.

During post-award administration, the GMO monitors expenditures for conformance with cost policies. The GMO's monitoring includes, among other things, responding to prior-approval requests and reviewing financial reports, audit reports, and other periodic reports. The GMO also may use audit findings as the basis for final cost adjustments. The PO's monitoring includes review of progress reports, prior-approval requests, and other correspondence (written or telephonic), and site visits.

Monitoring of a project or activity will continue for as long as the OPDIV retains a financial interest in the project or activity as a result of property accountability, audit, and other requirements that may continue for a period of time after the grant is administratively closed out and the OPDIV is no longer providing active grant support.

Reporting

HHS requires that recipients periodically submit financial and progress reports. Other required reports may include annual invention utilization reports, research misconduct reports, property reports, lobbying disclosures (as required by 45 CFR 93.110(c)), audit reports, reports to the appropriate payment points (in accordance with instructions received from the payment office), and specialized programmatic reports.

Unless otherwise indicated in the NoA, the GMO is generally the receipt point for most required reports, including non-competing continuation applications, annual and final progress reports, FSRs, final invention statements and certifications, property reports, and lobbying disclosure statements. Generally, an original and two copies of progress reports must be submitted. Submission of these reports to individuals other than the GMO may result in delays in processing of the non-competing continuation award or the submission being considered delinquent. Also see Part IV of the HHS GPS.

Recipients are allowed a specified period of time in which to submit required financial and final progress reports (see 45 CFR 74.51, 74.52, 92.40, and 92.41 and the discussion in this subsection). Failure to submit complete, accurate, and timely reports may indicate the need for closer monitoring by HHS or may result in possible award delays or enforcement actions, including conversion to a reimbursement payment method or withholding a non-competing continuation award (also see "Overdue Reports" in this section).

Financial Reporting

Reports of expenditures are required as documentation of the financial status of grants according to the official accounting records of the recipient. Financial or expenditure reporting is accomplished using the FSR (SF 269 or SF 269A); the recipient must use the long form (SF 269) to report program income earned and used.

The FSR generally is required annually, unless otherwise indicated in the NoA. If an FSR is required annually and the award is operating under an authorized no-cost extension, an FSR must be submitted for each 12 months of activity, regardless of the overall length of the extended budget period. For example, if the budget period would have ended on July 31, 2006, but is extended to July 31, 2007, the recipient must submit two FSRs—one for the period August 1, 2005-July 31, 2006 and one for the period August 1, 2006-July 31, 2007. When required annually, the report must be submitted for each budget period no later than 90 days after the close of the budget period or applicable 12-month period.

If FSRs are required more frequently than annually, the NoA will specify both the frequency and due date. Some OPDIVs provide for electronic submission to the OPDIV. See Part IV for OPDIV-specific information concerning financial reporting, including the means of submission.

For some awards, in lieu of the annual FSR, the OPDIV will use the quarterly FCTR, submitted to PMS to monitor the financial aspects of grants. The GMO may review the report for patterns of cash expenditures, including accelerated or delayed drawdowns, and to assess whether performance or financial management problems exist. For these awards, an FSR generally is required only at the end of a competitive segment. It must be submitted within 90 days after the end of the competitive segment and must report on the cumulative support awarded for the entire segment. An FSR must be submitted at this time whether or not a competing continuation award is made. If no further award is made, this report will serve as the final FSR.

Before submitting FSRs, recipients must ensure that the information submitted is accurate, complete, and consistent with the recipient's accounting system. The authorized organizational representative's signature on the FSR certifies that the

information in the FSR is correct and complete and that all outlays and obligations are for the purposes set forth in grant documents, and represents a claim to the Federal government. Filing a false claim may result in the imposition of civil or criminal penalties (see "Fraud, Waste, and Abuse" in Part I of the HHS GPS).

In some cases, the recipient may have to revise or amend a previously submitted FSR. When the revision results in a balance due to the OPDIV, the recipient must submit a revised FSR whenever the overcharge is discovered, no matter how much time has lapsed since the original due date of the report. Revised expenditure reports representing additional expenditures by the recipient that were not reported to the OPDIV within the 90-day time frame may be submitted to the GMO with an explanation for the revision. The explanation also should indicate why the revision is necessary and describe what action is being taken by the recipient to preclude similar situations in the future. This should be done as promptly as possible, but not later than 1 year from the due date of the original report, i.e., 15 months following the end of the budget period. If an adjustment is to be made, the awarding office will advise the recipient of actions it will take to reflect the adjustment. The OPDIV will not accept any revised report received after that date and will return it to the recipient.

Progress Reporting

Progress reports generally are required annually as part of the non-competing continuation award process. However, the OPDIV may require these reports more frequently. Progress reports must be submitted to, and approved by, the OPDIV to non-competitively fund each additional budget period within a previously approved project period (competitive segment). When used in lieu of a non-competing continuation application, the progress report typically includes an updated budget in addition to other required information.

The form/format to be used and the information to be included in the progress report are specified in the NoA or in specific OPDIV guidance, e.g., non-competing continuation guidance. Some OPDIVs have implemented procedures for the electronic transmission of progress reports. See Part IV for OPDIV-specific information on electronic procedures for submitting progress reports.

Progress reports must be submitted directly to the awarding office. Late submission or receipt of an incomplete grant progress report will result in delaying the issuance and funding of the non-competing continuation award and may result in a reduced award amount.

The progress report for the final budget period of a competitive segment for which a competing continuation application is submitted will be part of that application; however, if an award is not made or the recipient does not submit an application for continued support, a final progress report is required.

The OPDIV will specify the requirements for progress reporting under construction grants or grants supporting both construction activities, including acquisition or modernization, and nonconstruction activities.

Other Reporting

Each competing continuation grant application and progress report (when used in lieu of a non-competing continuation application) must indicate whether or not any subject inventions were made during the preceding budget period. If inventions were made, the recipient must indicate whether they have been reported. The recipient also must submit an annual invention utilization report for all subject inventions to which title has been elected and inventions that have been licensed but not patented (research tools). The utilization report provides a way to evaluate the extent of commercialization of subject inventions, consistent with the objectives of the Bayh-Dole Act.

Bayh-Dole regulations allow recipients to report inventions electronically (37 CFR 401.16). Electronic reporting is available through an Internet-based system called Interagency Edison (https://s-edison.info.nih.gov/*i*-Edison/). Recipients should make all reasonable efforts to submit invention reports using *i*-Edison, where possible. The system supports confidential transmission of required information and provides a utility for generating reports and reminders of pending reporting deadlines. Further information about the system, including instructions for creating an account needed to submit reports electronically, is available on the *i*-Edison site.

Title to federally owned property remains vested in the Federal government. Annually, recipients must submit to the OPDIV an inventory listing federally owned property in the recipient's custody. Upon completion of the award or when the property is no longer needed, the recipient must report the property to the awarding office for further agency utilization. If the OPDIV has no further need for the property, it must be declared excess and reported to GSA, unless the OPDIV has statutory authority to dispose of the property by alternative methods (e.g., the authority provided by the Federal Technology Transfer Act, 15 U.S.C. 3710(I) to donate research equipment to educational and non-profit organizations in accordance with EO 12821, "Improving Mathematics and Science Education in Support of the National Education Goals"). The OPDIV will issue appropriate instructions to the recipient.

Overdue Reports

Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding a non-competing continuation award, or other enforcement actions, including withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in the imposition of special award provisions or cause other eligible projects or activities involving that recipient or the individual responsible for the delinquency to not be funded.

If at any time the recipient provides an acceptable explanation regarding the late submission of a report, the OPDIV may waive the reporting requirement or set a new due date. However, once a report becomes overdue, such action will be taken by the OPDIV only if the reasons for the recipient's inability to submit the report on time are legitimately beyond its control or if the purposes for which the report is to be used can be accomplished through other means. Failure to meet a new date may result in the OPDIV taking action as described above.

Submission of a required report does not necessarily fulfill the recipient's obligation. Such reports must also meet the content requirements in regulations or other grant terms. Where reports need to be revised in order to be accepted, the recipient must provide a revised report by the due date indicated or immediate fund cutoff or other enforcement actions may be taken with regard to the delinquency.

Record Retention and Access

Recipients generally must retain financial and programmatic records, supporting documents, statistical records, and all other records that are required by the terms of a grant, or may reasonably be considered pertinent to a grant, for a period of 3 years from the date the annual FSR is submitted. For awards where the FSR is submitted at the end of the competitive segment, the 3-year retention period will be calculated from the date the FSR for the entire competitive segment is submitted. Those recipients must retain the records pertinent to the entire competitive segment for 3 years from the date the FSR is submitted. See 45 CFR 74.53 and 92.42 for exceptions and qualifications to the 3-year retention requirement (e.g., if any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period, the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken). Those sections also specify the retention period for other types of grant-related records, including indirect cost proposals and property records. See 45 CFR 74.48 and 92.36 for record retention and access requirements for contracts under grants.

Audit Requirements

An audit is a systematic review or appraisal made to determine whether internal accounting and other control systems provide reasonable assurance of the following:

- Financial operations are properly conducted.
- Financial reports are timely, fair, and accurate.
- The entity has complied with applicable laws, regulations, and terms and conditions of award.
- Resources are managed and used economically and efficiently.
- Desired results and objectives are being achieved effectively.

Recipients (other than Federal institutions) and subrecipients are subject to the audit requirements of OMB Circular A-133, as implemented by 45 CFR 74.26 and 92.26, or the audit requirements stated in 45 CFR 74.26(d) and in the HHS GPS (for types of organizations to which OMB Circular A-133 does not directly apply). In general, OMB Circular A-133 requires a State government, local government, or non-profit organization (including institutions of higher education) that expends $500,000 or more per year under Federal grants, cooperative agreements, and/or procurement contracts to have an annual audit by a public accountant or a Federal, State, or local governmental audit organization. The audit must meet the standards specified in generally accepted government auditing standards (GAGAS).

A for-profit organization is required to have a non-Federal audit if, during its fiscal year, it expended a total of $500,000 or more under one or more HHS awards (as a direct recipient and/or as a subrecipient). Title 45, part 74.26(d) of the CFR incorporates the thresholds and deadlines of OMB Circular A-133 but provides for-profit organizations two options regarding the type of audit that will satisfy the audit requirements. The recipient either may have (1) a financial-related audit (as defined in, and in accordance with, the Government Auditing Standards [commonly known as the "Yellow Book"], (GPO stock 020-000-00-265-4) of all the HHS awards, or (2) an audit that meets the requirements of OMB Circular A-133. Foreign recipients are subject to the same audit requirements as for-profit organizations specified in 45 CFR 74.26(d).

When a recipient procures audit services, the procurement must comply with the procurement standards of 45 CFR part 74 or 92, as applicable, including obtaining competition and making positive efforts to use small, minority-owned, and women-owned business enterprises. Recipients should ensure that comprehensive solicitations made available to interested firms include all audit requirements and specify the criteria to be used for selection of the firm. Recipients' written agreements with auditors must specify the rights and responsibilities of each party.

OMB Circular A-133 explains in detail the scope, frequency, and other aspects of the audit. Some highlights of this circular are as follows:

- Covered organizations expending $500,000 or more per year in Federal awards are required to have an audit made in accordance with the circular. However, if the awards are under one program, the organization can have either a single organization-wide audit or a program-specific audit of the single program, subject to the provisions of Section 235 of the circular. OPDIV research awards may not be considered a single program for this purpose. Covered organizations expending less than $500,000 in any year are exempt from these audit requirements in that year but must have their records available for review by the OPDIV.

- The data collection form and copies of the reporting package must be submitted to the FAC at the following address:

  Federal Audit Clearinghouse
  Bureau of the Census
  1201 E. 10th Street
  Jeffersonville, IN 47132

- The reporting package must contain the following:

  - Financial statements and Schedule of Expenditures of Federal Awards

  - Independent auditor's report, including an opinion on the financial statements and the Schedule of Expenditures of Federal Awards, a report on compliance and internal control over financial reporting, and a report on compliance with requirements applicable to each major program and on internal control over such compliance requirements

  - A schedule of findings and questioned costs

- If applicable, a summary of prior audit findings and a corrective action plan.

- An audit under OMB Circular A-133 is in lieu of a financial audit of individual Federal awards. However, Federal agencies may request additional audits necessary to carry out their responsibilities under Federal laws or regulations. Any additional audits will build upon work performed by the independent auditor.

If the schedule of findings and questioned costs discloses an audit finding related to an HHS award or if the schedule of prior audit findings reports the status of any audit finding relating to an HHS award, the FAC will provide copies of the audit report to NEARC, OIG, HHS. NEARC will, in turn, distribute them within HHS for further action, as necessary.

Recipients must follow a systematic method for ensuring timely and appropriate resolution of audit findings and recommendations, whether discovered as a result of a Federal audit or a recipient-initiated audit. Recipients usually are allowed 30 days from the date of request to respond to the responsible audit resolution official (Action Official) concerning audit findings. Failure to submit timely responses may result in cost disallowance or other actions by HHS or the OPDIV. At the completion of the audit resolution process, the recipient will be notified of the Action Official's final decision. The recipient may appeal this decision if the adverse determination is of a type covered by the OPDIV or HHS grant appeals procedures (see "Grant Appeals Procedures"). Refunds owed to the Federal government as a result of audit disallowances must be made in accordance with instructions issued by the Action Official.

It is imperative that recipients submit required OMB Circular A-133 audits within the time limits specified in the circular. If recipients are delinquent in complying with the provisions of the circular, HHS or the OPDIV will impose sanctions that may result in the loss of Federal funds. No audit costs will be allowed either as indirect costs or direct costs to Federal awards if the required audits have not been completed or have not been conducted in accordance with the provisions of OMB Circular A-133.

Enforcement Actions

A recipient's failure to comply with the terms and conditions of award, including confirmed instances of research misconduct, may cause an OPDIV to take one or more enforcement actions, depending on the severity and duration of the non-compliance. The OPDIV will undertake any such action in accordance with applicable statutes, regulations, and policies. The OPDIV generally will afford the recipient an opportunity to correct the deficiencies before taking enforcement action unless public health or welfare concerns require immediate action. However, even if a recipient is taking corrective action, the OPDIV may take proactive steps to protect the Federal government's interests, including placing special conditions on awards or precluding the recipient from obtaining future awards for a specified period, or may take action designed to prevent future non-compliance, such as closer monitoring. If the OPDIV takes an enforcement action as a result of research misconduct or will more closely monitor an award through the use of special conditions, the OPDIV will share this information with other HHS components.

Modification of the Terms and Conditions of Award

During grant performance, the GMO may include special conditions in the award to require correction of identified financial or administrative deficiencies. When the special conditions are imposed, the GMO will notify the recipient of the nature of the conditions, the reason why they are being imposed, the type of corrective action needed, the time allowed for completing corrective actions, and the method for requesting reconsideration of the conditions. (See 45 CFR 74.14 or 92.12.)

The OPDIV also may withdraw approval of the PI/PD or other key personnel if there is a reasonable basis to conclude that they are no longer qualified or competent to perform. In that case, the OPDIV may request that the recipient designate a new PI/PD or other key personnel.

The decision to modify the terms of an award—by imposing special conditions, by withdrawing approval of the PI/PD or other key personnel, or otherwise—is discretionary on the part of the OPDIV.

Withholding a Non-Competing Continuation Award

An OPDIV may decide not to make a non-competing continuation award within the current competitive segment for one or more of the following reasons:

- Adequate Federal funds are not available to support the project.
- A recipient failed to show satisfactory progress in achieving the objectives of the project.
- A recipient failed to meet the terms and conditions of a previous award.
- For whatever reason, continued funding would not be in the best interests of the Federal government.

If a non-competing continuation award is denied (withheld) because the recipient failed to comply with the terms and conditions of a previous award, the recipient may appeal that determination.

Depending on the nature of the deficiency, an OPDIV also may temporarily withhold payment or convert the grant from an advance payment method to a reimbursement method.

Suspension or Termination

If a recipient has failed to materially comply with the terms and conditions of award, the OPDIV may suspend the grant, pending corrective action, or may terminate the grant for cause. The regulatory procedures that pertain to suspension and termination are specified in 45 CFR 74.61 and 74.62 and in 45 CFR 92.43.

The OPDIV generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before making a termination decision. The OPDIV may decide to terminate the grant if the recipient does not take appropriate corrective action during the period of suspension.

The OPDIV may terminate—without first suspending—the grant if the deficiency is so serious as to warrant immediate termination or if public health or welfare concerns require immediate action. Termination for cause may be appealed under the OPDIV and HHS grant appeals procedures.

A grant also may be terminated, partially or totally, by the recipient or by the OPDIV with the consent of the recipient. If the recipient decides to terminate a portion of a grant, the OPDIV may determine that the remaining portion of the grant will not accomplish the purposes for which the grant was originally awarded. In any such case, the recipient will be advised of the possibility of termination of the entire grant and will be allowed to withdraw its termination request. If the recipient does not withdraw its request for partial termination, the OPDIV may initiate procedures to terminate the entire grant for cause.

See "Selected Items of Cost" for the allowability of termination costs. Allowability of these costs does not vary whether a grant is terminated for cause by the OPDIV, terminated at the request of the recipient, or terminated by mutual agreement.

Other options available to an OPDIV include suspension or debarment under 45 CFR part 76. Suspension under 45 CFR part 76 (see Eligibility—Suspension and Debarment" in Part I) is a distinct action from "suspension" described above in conjunction with termination.

Closeout

The OPDIV will close out a grant as soon as possible after expiration if the grant will not be extended or after termination, as provided in 45 CFR 74.71 through 74.73 and in 45 CFR 92.50. Closeout includes ensuring timely submission of all required reports and adjustments for amounts due the recipient or the OPDIV. Closeout of a grant does not automatically cancel any requirements for property accountability, record retention, or financial accountability. Following closeout, the recipient remains obligated to return funds due as a result of later refunds, corrections, or other transactions, and the Federal government may recover amounts based on the results of an audit covering any part of the period of grant support.

Unless the GMO grants an extension, recipients must submit a final FSR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant support. Failure to submit timely and accurate final reports may affect future funding to the organization or awards with the same PI/PD.

Final Financial Status Report

A final FSR is required for

- any grant that is terminated,
- any grant that is transferred to a new recipient, or
- any award at the end of the project period (or if comprised of multiple competitive segments, at the end of each competitive segment).

The final FSR must cover the entire project period (competitive segment) or as much of the project period (competitive segment) as has been funded before termination or transfer. Final FSRs must have no unliquidated obligations and must indicate the exact balance of unobligated funds. Unobligated funds must be returned to the OPDIV or must be reflected by an appropriate accounting adjustment in accordance with instructions from the GMO or from the payment office. For those organizations receiving their funds through PMS, final reports, as specified by PMS, must be submitted to that office. It is the recipient's responsibility to reconcile reports submitted to PMS and to the OPDIV. Reconciliation consists of ensuring that disbursements equal obligations and drawdowns or making any adjustments as necessary, e.g., for an overpayment. Withdrawal of the unobligated balance following expiration or termination of a grant is not considered an adverse action and is not subject to appeal.

When the submission of a revised final FSR results in additional claims by the recipient, the OPDIV will consider the approval of such claims subject to the following minimum criteria:

- The recipient must indicate why the revision is necessary and explain and implement internal controls that will preclude similar occurrences in the future.
- The charge must represent otherwise allowable costs under the provisions of the grant.
- There must be an unobligated balance for the budget period sufficient to cover the claim.
- The funds must still be available for use.
- The OPDIV must receive the revised FSR within 12 months of its original due date.

Final Progress Report

A final progress report is required for any grant that is terminated and at the end of the project period. The final progress report should follow specific OPDIV instructions and be submitted to the GMO, but minimally will include a summary of progress toward the achievement of the originally stated aims, a list of significant results (positive or negative), and a list of publications. If the recipient submits a competing continuation application, the final progress report requirement will be met by the information included in that application.

Final Invention Statement and Certification

For research grants, the recipient must submit a Final Invention Statement and Certification (HHS 568), whether or not the funded activity results in any subject inventions. The HHS 568 must list all inventions that were conceived or first actually reduced to practice during the course of work under the grant, and it must be signed by the PI/PD and an authorized organizational representative. The completed form to be submitted to the GMO should cover the period from the original effective date of support through the date of expiration or termination of the award. If there were no inventions, the form should indicate "None." Copies of the HHS 568 are available on the *i*-Edison Web site at https://s-edison.info.nih.gov/iEdison/.

Debt Collection

An OPDIV may administratively recover funds paid to a recipient in excess of the amount to which the recipient is finally determined to be entitled under the terms and conditions of the award, including misspent funds or unallowable costs incurred. If the recipient does not pay back the funds in accordance with the demand by the OPDIV, which specifies the period of time for repayment, the OPDIV may collect the debt by

- making an administrative offset against payments that would be due under other grant awards,
- withholding advance payments that would otherwise be due, or
- taking any other action permitted by statute.

Several Federal statutes governing debt collection and the Federal Claims Collection Standards (31 CFR parts 900-904) require the OPDIV to collect debts due to the Federal government and, except where prohibited by law, to charge interest on all delinquent debts owed to the OPDIV by recipients (also see HHS claims collection regulations at 45 CFR part 30). Debts may result from cost disallowances, recovery of funds, unobligated balances, or other circumstances.

Unless otherwise specified in law, regulation, or the terms and conditions of the award, debts are considered delinquent 30 days after notification to the recipient of the indebtedness. The interest on delinquent debts will be computed from the original notification date to the recipient of the indebtedness. The interest rate applied will be the current value of funds rate or the private consumer rate of interest fixed by Treasury, whichever is higher. A higher rate may be charged if necessary to protect the interests of the Federal government.

Penalties and administrative collection costs also will be charged in accordance with the act and the implementing HHS regulations, as follows:

- A penalty charge of 6 percent a year will be assessed on debts that are more than 90 days overdue. Penalty charges will accrue from the date the debt became overdue until the indebtedness is paid.
- Delinquent debtors will be assessed charges to cover the Federal government's administrative costs of collecting overdue debts. From time to

time, HHS will publish a notice in the *Federal Register* setting forth the amounts to be assessed for administrative collection costs.

If a recipient appeals an adverse monetary determination under 45 CFR part 16 or specific OPDIV appeal procedures, collection will be suspended pending a final decision on the appeal. If the determination is sustained (either fully or partially), interest will be charged beginning with the date of the original notification to the recipient of the indebtedness.

Appeals

HHS permits recipients to appeal to the DAB certain post-award adverse administrative decisions made by HHS officials (see 45 CFR part 16). In addition, some OPDIVs have implemented OPDIV-specific appeal procedures (see Part IV). In general, a recipient may appeal the following OPDIV actions:

- Termination, in whole or in part, of a grant for failure of the recipient to carry out its approved project in accordance with the applicable law and the terms and conditions of award or for failure of the recipient otherwise to comply with any law, regulation, assurance, term, or condition applicable to the grant

- Determination that an expenditure not allowable under the grant has been charged to the grant or that the recipient has otherwise failed to discharge its obligation to account for grant funds

- Denial (withholding) of a non-competing continuation award for failure to comply with the terms of a previous award

- Determination that a grant is void (i.e., a decision that an award is invalid because it was not authorized by statute or regulation or because it was fraudulently obtained).

The formal notification of an adverse determination will contain a statement of the recipient's appeal rights. As the first level in appealing an adverse determination, the recipient must submit a request for review to the HHS or OPDIV official specified in the notification, detailing the nature of the disagreement with the adverse determination and providing supporting documents in accordance with the procedures contained in the notification. A recipient may not submit an appeal directly to the DAB where OPDIV appeal procedures are in place. In those instances, the DAB will review only those appeals that have been reviewed and acted on by the OPDIV.

In addition to the adverse determinations indicated, the DAB is the single level of appeal for disputes related to the establishment of indirect cost rates, research patient care rates, and certain other cost allocations used in determining amounts to be reimbursed under HHS grants (e.g., cost allocation plans negotiated with State or local governments and computer, fringe benefit, and other special rates).

HHS encourages its OPDIVs and recipients to try to resolve disputes by using alternative dispute resolution (ADR) techniques. ADR often is effective in reducing the cost, delay, and contentiousness involved in appeals and other traditional ways of handling disputes. ADR techniques include mediation, neutral evaluation, and other consensual methods. Information about ADR is available from the HHS Dispute Resolution Specialist at the Departmental Appeals Board, U.S. Department of Health and Human Services, Washington, DC 20201.

Requirements for Specific Types of Grants

Conference Grants

This section addresses requirements for grants that support domestic and international conferences, which may be supported by grants or cooperative agreements. If no specific or alternative requirement for conference grants is stated below or elsewhere in this HHS GPS, the requirements applicable to all other types of grants apply. Questions concerning conference grants or the allowability of conference activity under other types of OPDIV grants should be directed to the GMO.

Definitions

Definitions of key terms are as follows:

- Scientific meeting (conference)—a gathering, symposium, seminar, workshop, or any other organized, formal event where people assemble to coordinate, exchange, and disseminate information or to explore or clarify a defined subject, problem, or area of knowledge.

- International conference—a meeting so designated by its sponsor or one to which open invitations are issued on an equal basis to potential participants in two or more countries other than the United States or Canada. The meeting may be held in any country, including the United States.

- Domestic conference—a meeting held in the United States or Canada primarily for U.S. or U.S.-Canadian participation (even if foreign speakers are invited).

Representation

Appropriate representation of women, individuals who are members of racial/ethnic minority groups, people with disabilities, and other individuals who have been traditionally underrepresented must be included in all aspects of planning, organization, and implementation of OPDIV-sponsored or -supported meetings. "Appropriate representation" is based on the availability of individuals from these groups known to be working in a particular field of endeavor. If appropriate representation is not apparent, the OPDIV will not make an award until the applicant has submitted acceptable documentation of its compliance.

Funding

Awards in support of a single conference will be made for a project period commensurate with the time involved in planning and conducting the conference and post-conference follow-up, usually 1 year. A conference grant made to a permanently sponsoring organization for conferences held annually or biennially on a recurring topic may be awarded for up to a total of 5 years and will be funded annually, based on the availability of funds. Continued funding beyond the first year will be contingent on a report of satisfactory progress. A change in conference focus is considered a change in scope and requires OPDIV prior approval.

Acknowledgment of Support and Disclaimer

Conference grant materials, including promotional materials, the agenda, and any Internet sites that advertise the conference, must acknowledge that HHS provided support for the conference, whether in whole or in part. That acknowledgment must be accompanied by a disclaimer indicating that information provided or views expressed at the conference, whether orally or in writing, or in any documents resulting from the conference, do not necessarily reflect the official views of the OPDIV providing the support or imply endorsement by the Federal government.

Use of the following language fulfills this requirement:

> "Funding for this conference was made possible [*in part, if applicable*] by [*insert grant or cooperative agreement number*] from [*insert name of OPDIV*]. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government."

Use of HHS and OPDIV Logos

Generally, the NoA will indicate the conditions for use of the HHS or OPDIV logo in conference materials. If not specified in the NoA, a recipient must obtain prior approval to use an HHS or OPDIV logo. Unauthorized use of the HHS or OPDIV name or logo may result in imposition of civil monetary penalties (as provided in 42 CFR part 1003).

Allowable and Unallowable Costs

Grant funds may be awarded to provide general support of domestic or international conferences held in the United States or Canada. Grant funds may not be used to provide general support for international conferences held outside the United States or Canada. Grant funds may be awarded to support only specific aspects of an international conference held outside the United States or Canada. An example of a specific aspect would be a selected symposium, panel, or workshop.

This section highlights allowable and unallowable costs under conference grants. No costs other than those specified in Exhibit 10 as allowable, including any qualifications on their allowability, are permitted under conference grants. Exhibit 11 addresses areas for which applicants/recipients frequently seek clarification about allowability.

Exhibit 10. Allowable Costs under Conference Grants

Grant funds may be used for	Under the following circumstances
Conference services	Necessary recording of proceedings, simultaneous translation, and subsequent transcriptions.
Consultant services	Consultant fees, including travel and supporting costs (per diem or, where applicable, subsistence).
Equipment rental	Rental of necessary equipment.
Federal employees	See "Requirements for Specific Types of Recipients–Grants to Federal Institutions and Payments to (or on Behalf of) Federal Employees under Grants."
Meals	When certain meals are an integral and necessary part of a conference (i.e., a working meal where business is transacted), grant funds may be used for such meals, as qualified under "Travel" in this exhibit.
Publication costs	When grant funds are awarded to pay for either the entire or partial cost of publication of proceedings or a book or pamphlet, costs of special plates, charts, diagrams, printing, distribution, mailing, postage, and general handling, unless otherwise specified in the NoA.
Registration fees	Registration fees paid by the recipient to other organizations on behalf of attendees, provided such fees cover only those allowable costs properly chargeable to the grant.
Salaries	In accordance with the policy of the recipient, all or part of the salaries of professional personnel, clerical assistants, editorial assistants, and other non-professional staff in proportion to the time or effort directly related to the conference.
Speakers' fees	Speakers' fees for services rendered.
Supplies	Purchase of supplies for the conference if the supplies are received and used during the project period.

Exhibit 10. Allowable Costs under Conference Grants

Grant funds may be used for	Under the following circumstances
Travel	Travel of staff, speakers, participants, and attendees, if identified in the application and approved at the time of award. Travel expenses for employees of the recipient are governed by the recipient's travel policies, consistently applied regardless of the source of funds. Any U.S. foreign travel restrictions that are in effect at the time of the award will be followed, such as ◆ limitations or restrictions on countries to which travel will be supported or budgetary or ◆ other limitations on availability of funds for foreign travel. Proposed per diem or subsistence allowances must be reasonable and limited to the days of attendance at the conference plus the actual travel time to reach the conference location by the most direct route. Local mileage costs only may be paid for local participants. Where meals and/or lodgings are furnished without charge or at a nominal cost (e.g., as part of the registration fee), the proposed per diem or subsistence allowance must take this into consideration. Transportation costs for attendees and participants at the conference may not exceed coach class fares. In all cases, U.S. flag carriers will be used where possible.

Exhibit 11. Selected Unallowable Costs under Conference Grants

Item	Description
A&R	Not allowable under any circumstances.
Entertainment and personal expenses	Costs of amusement, diversion, social activities, ceremonials, and related incidental costs, such as bar charges, tips, personal telephone calls, and laundry charges of participants or guests, are unallowable. However, meals may be allowable as provided under "Meals" in Exhibit 10.
Equipment purchase	Not allowable under any circumstances.
Honoraria	Honoraria or other payments given for the purpose of conferring distinction or to symbolize respect, esteem, or admiration may not be paid from grant funds.
Indirect costs	Not allowable under any circumstances.
Local participants' expenses	With the exception of local mileage as indicated under "Travel" in Exhibit 10, grant funds may not be used to pay per diem or expenses for local participants in the conference.
Membership dues	Not allowable under any circumstances.
Research patient care	Not allowable under any circumstances.

Intellectual Property: Publications, Copyright, and Public Disclosure

If a recipient publishes material developed in whole or in part with HHS funds, the material may be distributed free of charge. If the recipient charges for the material, the sales proceeds are considered program income and must be accounted for as specified in the NoA and reported on the FSR.

Unless otherwise provided in the terms and conditions of the award, the recipient is free to arrange for copyright of any publication resulting from an OPDIV-supported conference. However, any such copyrighted publication is subject to a nonexclusive, irrevocable, royalty-free license to the Federal government to reproduce, translate, publish, and dispose of the material and to authorize others to use the work for government purposes. Copyright does not extend to any materials prepared by Federal employees as part of their official duties.

The recipient should notify conference participants that any presentation or discussion constitutes public disclosure of information. Once information is disclosed publicly, it may adversely impact the degree to which any intellectual property rights could be protected.

Reporting and Record Retention

Recipients are responsible for submitting the following reports to the OPDIV upon completion or termination of a grant in support of a conference.

Progress/Final Report

For single conferences, a final report of the conference must be submitted in accordance with OPDIV instructions to the awarding office within 90 days after the end of the project period.

With the approval of the OPDIV, copies of proceedings or publications resulting from a conference may be substituted for the final report, provided they contain the information specified for inclusion in the final report.

Financial Status Report

An FSR is required from the recipient within 90 days after the end of the project period. Records of expenditures and any program income generated must be maintained in accordance with the provisions of 45 CFR 74.53 or 92.42.

Construction and Modernization of Facilities

This section applies to the following OPDIV grant-supported activities:

- Construction of new facilities, which includes the installation of fixed equipment, but excludes the cost of land and off-site improvements

- Modernization of existing facilities, which includes alteration, renovation, remodeling, improvement, expansion, or repair; provision of equipment necessary to make the building suitable for use by a particular program; and the modernization, or completion, of shell space. This may be under a grant for this purpose or as A&R under another type of grant.

To provide support for construction or modernization that is considered "major", an OPDIV must have specific statutory authority allowing construction or modernization. Even if an OPDIV has this authority, a recipient may not incur costs for construction or modernization unless the OPDIV specifically authorizes such costs.

In addition, an applicant/recipient may propose to undertake an A&R project under a non-construction grant. HHS characterizes A&R projects as "minor" or "major," depending on the type of activity proposed and the cost of the project and the threshold set by the HHS GPS or the OPDIV (see "Cost Considerations—Allowable Costs and Activities," "Prior-Approval Requirements—OPDIV Prior Approval," and Part IV). An OPDIV may support a major A&R project only if it has specific statutory authority allowing modernization. Generally, an A&R project that is under the OPDIV threshold is treated as minor A&R; however, depending on the activity proposed, it may be considered modernization (which cannot be supported unless the OPDIV has the required statutory authority). The requirements that apply to minor A&R projects are addressed in "Allowable Costs and Activities."

Except where indicated, the requirements in this section apply to HHS grant-supported construction or modernization (hereafter, "construction") in lieu of the requirements stated elsewhere in Part II of the HHS GPS for construction or modernization. Other activities under the award would be subject to those other policies. However, there may be areas of overlap, e.g., a rebudgeting action that causes a minor A&R project to become a major A&R project.

Funding

Construction grants usually involve a single award, covering more than 1 year, made on the basis of an application for the entire construction project. Incremental funding (budget periods) within a project period normally is not used for construction grants.

Allowable and Unallowable Costs and Activities

Exhibits 12 and 13 indicate types of costs and activities generally allowable and unallowable under HHS construction grants. The allowability and unallowability of costs and activities apply to the use of Federal funds and funds expended by the grantee to satisfy cost sharing or matching requirements (see "Matching or Cost Sharing"). The lists are not all-inclusive. Program guidelines and other terms and conditions of the award should be consulted for the specific costs allowable under a particular program or grant.

Exhibit 12. Allowable Costs and Activities under Construction Grants

Item	Description
Acquisition and installation of fixed equipment	Allowable.
Architectural and engineering services	Allowable.
Bid advertising	Allowable.
Bid guarantees and performance and payment bonds	Bid guarantees and performance and payment bonds are allowable as provided in 45 CFR 74.48 or 92.36(h).
Contingency fund	Applicants for construction grants may include a project contingency amount with the initial cost estimates for construction contracts to provide for unanticipated charges. This amount will be limited to 5 percent of construction costs before bids are received and must be reduced to 2 percent after a construction contract has been awarded.

Exhibit 12. Allowable Costs and Activities under Construction Grants

Item	Description
Filing fees for recording the NFI	Allowable.
Force account	If the grantee's own construction and maintenance staffs are used in carrying out modernization activities (i.e., force account), the associated costs are allowable provided the grantee can document that a force account is less expensive than if the project were competitively bid and can substantiate all costs with appropriate receipts for the purchase of materials and certified pay records for the labor involved. This requires OPDIV prior approval.
Compliance with the National Historic Preservation Act	Allowable. May include hiring special consultants to research and document the historic value of proposed performance sites and costs associated with preparation and presentation of required materials to inform the public and others.
Incentive costs for contractors	Allowable consistent with contract type as specified in the solicitation of bids or proposals and in the contract. Incentive costs must be reasonable and appropriately documented, e.g., that conditions to earn the incentive were met. In addition to an incentive fee provision, incentive-type contracts may also contain a penalty provision. Other types of bonus payments are not allowable.
Inspection fees	Allowable.
Insurance	Costs of title insurance, physical-destruction insurance, and liability insurance are generally allowable. Physical destruction and liability insurance are usually treated as F&A costs but may be treated as direct costs in accordance with the established policy of the recipient, consistently applied regardless of the source of funds. Title insurance, if required, may be charged to the grant in proportion to the amount of OPDIV participation in the property (see "Real Property —Insurance ").
Legal fees	Legal fees related to obtaining a legal opinion regarding title to a site are allowable.
Pre-award costs	Costs incurred before award for architect's fees and consultant's fees necessary to the planning and design of the project are allowable if the project is subsequently approved and funded.
Project management	Allowable.
Relocation expenses	Allowable.
Sidewalks necessary for use of facility	Allowable.
Site clearance.	Site clearance costs are allowable as long as they are reflected in the bid.
Site survey and soil investigation	Allowable.
NEPA analysis	Costs associated with evaluation of the environmental effects of proposed construction activity and producing the Environmental Impact Statement (EIS) are allowable.

Exhibit 12. Allowable Costs and Activities under Construction Grants

Item	Description
Threat-risk assessment.	Costs incurred for a site-specific or project-specific assessment of security risk by a qualified professional are allowable. The threat-risk assessment identifies and quantifies potential threats, both internal and external to the building, its contents, the personnel working in it, and the general public. The analysis also includes a thorough examination and evaluation of the physical aspects of the proposed facility, along with operational issues.

Exhibit 13. Unallowable Costs and Activities under Construction Grants

Bonus payments other than earned incentive payments to contractors under formal incentive arrangements are unallowable.
Construction of shell space designed for completion at a future date.
Consultant fees not related to actual construction.
Damage judgment suits.
Equipment purchased through a conditional sales contract.
Indirect/F&A costs.
Fund-raising expenses.
Land acquisition.
Legal services not related to site acquisition.
Movable equipment.
Off-site improvements such as parking lots are not allowable.

Prior-Approval Requirements

Recipients must obtain OPDIV prior approval for the following types of recipient-initiated project or budget changes:

- A revision that would result in a change in scope of the project, including proposed modifications that would materially alter the costs of the project, space utilization, or financial layout, resulting in changes in the previously approved procurement method or contract. Modifications that would materially alter the costs include significant rebudgeting actions, whether or not the particular expenditure requires prior approval and increase in the amount of Federal funds needed to complete the project.
- Any other applicable change as specified in "Prior-Approval Requirements."
- Change in the use of the facility (see "Use of Facility and Disposition" in this section).

The request for approval must include sufficient information to allow the OPDIV to review the circumstances and need for the proposed change. After receipt of OPDIV prior approval, the recipient may make or authorize the approved modifications of

the construction contract. Other less substantive modifications to construction contracts may be made without OPDIV prior approval. However, copies of all change orders to construction contracts must be retained as grant-related records (see "Record Retention and Access").

Procurement Requirements

Construction activity usually is carried out through one or more contracts under the grant. Therefore, the circumstances of the procurement are critical to the successful completion of the grant-supported project. All construction work must be procured by the methods described in 45 CFR 74.40 through 74.48 or in 92.36, as applicable.

Equal Employment Opportunity, Labor Standards, and Other Contract Requirements

Equal employment opportunity and labor standards requirements for federally assisted construction and modernization must be specified in the information provided to potential bidders/offerors on construction contracts under HHS grants and must be included in the resulting contract documents (see 45 CFR part 74, Appendix A, and 45 CFR 92.36(i)). The Davis-Bacon Act or the Copeland "Anti-Kickback" Act apply only if specifically required by the program's authorizing statute. The NoA will indicate if they apply.

Equal Employment Opportunity Requirements

Construction contracts (and subcontracts) awarded under HHS grants are subject to the requirements of EO 11246 (September 24, 1965), as amended, as implemented in 41 CFR part 60-1 by OFCCP, DoL. The recipient is required to include the "Equal Opportunity Clause" at 41 CFR 60-1.4(b) in any construction contract under the grant. The contractor must be directed to include this clause in any applicable subcontracts.

In addition, recipients and construction contractors under HHS grants are required to comply with the solicitation and contract requirements for affirmative action specified in 41 CFR part 60-4 for contracts in specified geographical areas that will exceed $10,000. These requirements are specified in EO 11246 ("Notice of Requirement for Affirmative Action to Ensure Equal Employment Opportunity") and EO 11246 ("Standard Federal Equal Employment Opportunity Construction Contract Specifications").

The OFCCP regulations also require that the recipient notify the applicable OFCCP regional, area, or field office when it expects to award a construction contract that will exceed $10,000.

Further information about these requirements and the full text of these regulations are available at http://www.dol.gov/esa/ofcp_org.htm

Labor Standards Requirements

Preservation of Open Competition and Government Neutrality toward Government Contractors' Labor Relations on Federal and Federally Funded Construction Projects. Pursuant to EO 13202, as amended by EO 13208 (April 6, 2001), executive agencies issuing grants, providing Federal assistance, or entering into cooperative agreements

for construction projects (including major and minor A&R) must ensure that bid specifications, project agreements, or other controlling documents for construction services contracts awarded by recipients of grants, cooperative agreements, or other financial assistance do *not* do the following:

- Require or prohibit bidders, offerors, contractors, or subcontractors to enter into or adhere to agreements with one or more labor organizations, on the same or other related construction projects. It does not prohibit contractors or subcontractors from voluntarily entering into such agreements.

- Otherwise discriminate against bidders, offerors, contractors, or subcontractors for becoming, refusing to become, or remaining signatories, or otherwise adhering to agreements with one or more labor organizations, on the same or other related construction projects.

Non-segregated Facilities. Pursuant to 41 CFR 60-1.8, for any contract for construction services that will exceed $10,000, the grantee must require each prospective contractor to submit a certification that the contractor

- does not, and will not, maintain any facilities it provides for its employees in a segregated manner;

- does not or will not permit its employees to perform their services at any location, under the contractor's control, where segregated facilities are maintained; and

- will obtain a similar certification before awarding any covered subcontract.

Contract Work Hours and Safety Standards. Contractors and subcontractors providing construction services under HHS grants with contracts or subcontracts exceeding $100,000 are subject to the requirements of the Contract Work Hours and Safety Standards Act, 40 U.S.C. 3701–3708, concerning the payment of overtime and the maintenance of healthful and safe working conditions if the statute authorizing the grant provides wage standards for the project to be funded by the grant.

Under this act, wages paid any laborer or mechanic employed by the contractor or subcontractor must be computed on the basis of a standard workweek of 40 hours. For all work in excess of the standard workweek, mechanics and laborers must be compensated at a rate not less than one-and-a-half times the basic rate of pay. If this requirement is violated, the contractor or subcontractor is liable to the employee for the unpaid wages and may be liable to the Federal government for liquidated damages. The OPDIV or the recipient may withhold otherwise payable funds to satisfy any such liability. The statute also specifies penalties for intentional violation of these requirements.

Further, pursuant to standards issued by the Secretary of Labor, a contractor or subcontractor under an HHS grant (with contracts or subcontracts exceeding $100,000) must not require any laborer or mechanic employed in the performance of the contract to work in surroundings or under working conditions that are unsanitary, hazardous, or dangerous to an individual's health or safety. Violation of these requirements may be cause for debarment from future Federal contracts or financial assistance.

Other Requirements

Liquidated Damages. Invitations for bids must stipulate a time for completion of the project, expressed either in calendar days or as a fixed date, for each prime contract to be awarded under the project. At the option of the grantee, a liquidated damages provision may be included in the contract, allowing for assessment of damages when the contractor has not completed the construction or modernization by the date specified in the contract. Liquidated damages must be real and justified and must be approved by the OPDIV before solicitation. Where damages are assessed, any amounts paid belong to the recipient.

Disposition of Unclaimed Wages. During or after the period of performance of an HHS-assisted contract for construction services, if it is discovered that an employee is entitled to wages but cannot be located for the purposes of payment (or for some reason refuses to accept payment), the grantee may eventually have to repay the Federal government.

The recipient should notify the GMO that an escrow account has been established in the affected employee's name and should maintain the account for 2 years (or longer if required by State or local law) following the completion of the contract. Upon the expiration of this period, any amounts still unclaimed will be disbursed by refunding to the OPDIV either the entire amount, if the construction or modernization project was
100 percent funded by the OPDIV, or an amount representing the percentage of OPDIV participation in the project. If the project was funded by more than one HHS program at differing rates, the refund should be based on an average percentage calculated by weighting each program's rate of participation by the dollar amount of that program's contribution.

If the contractor has made a reasonable effort to locate the employee by having mail forwarded and contacting the employee's union, the recipient need not repeat such attempts. If there is reason to believe that the contractor's efforts to locate employees that are due wages were not thorough, the recipient should attempt to locate the employees. Doing so will reduce the likelihood of future claims against the recipient. If any wages held in escrow are paid to an employee or an employee's legal representative while the account is maintained, a complete report must be made to the GMO when the account is closed.

Use of Facility and Disposition

HHS awards for construction or modernization generally require that a facility be used for the programmatic purpose of the award as long as needed for that purpose (see the NoA or Part IV). During that time, the recipient must use the facility for the originally authorized purpose unless it obtains prior approval from the OPDIV to use the facility for an alternate purpose. If, during the required usage period, the facility is no longer used for the original intended purpose, the OPDIV may, for recipients covered by 45 CFR part 74, provide prior approval for alternate use as specified in 45 CFR 74.32; direct the recipient to sell the property or allow it to retain title and recover the OPDIV share; or direct that title be transferred to a third party named by the OPDIV (see "Property Management—Real Property").

The usage obligation may also be transferred to facilities of substantially comparable or greater monetary value or utility to carry out the original purpose for which the

grant was awarded. In this event, the remaining usage obligation must be released from the original facility constructed with grant funds and transferred to the new facility. The recipient remains subject to all other requirements imposed by the NoA or successor document (if the change occurs following the period of grant support). The OPDIV will monitor compliance with these requirements through periodic facility use certifications or reports, site visits, and other appropriate means for the duration of the required usage period. After the required usage period, the organization has no further accountability to the OPDIV concerning the use of the property or any sales proceeds.

If, during the required usage period, the facility is no longer used for the original intended purpose and the OPDIV did not provide prior approval for an alternate use, the recipient must comply with disposition requirements. The OPDIV may recover its share of the construction or modernization costs. For disposition of property acquired on an amortized acquisition basis, the formulas in 45 CFR 74.32 and 92.31 do not apply in determining the Federal share. In cases of amortized acquisition, the Federal share will be determined by multiplying the amount of mortgage principal already repaid at the time of disposition by the average Federal participation (taken from the FSR) plus the increase in value over the purchase price multiplied by the average Federal participation plus the Federal participation in the down payment. The computation of the Federal share of real property acquired with long-term debt financing must be computed for each year of grant support in which Federal funds are used to meet all or a portion of the down payment, principal on the mortgage, or both.

Traineeship, Fellowship, and Similar Awards Made to Organizations on Behalf of Individuals

Applicants/recipients should consult the funding opportunity announcement and any program guidance or guidelines for application instructions; eligibility requirements, including citizenship and sponsorship requirements; and other program-specific requirements related to required forms, allowable costs, and reporting requirements. Detailed requirements for the Kirschstein-National Research Service Awards program are found at http://grants1.nih.gov/training/extramural.htm. Some of the administrative requirements that pertain to fellowships under that program are described below. See Part IV for other programs.

Initiation of Support

The OPDIV will notify the individual of the intention to make an award and confirm the plans for the start of fellowship support. The fellowship award notice allows the individual to begin the fellowship immediately on or after the issue date, but permits up to 6 months for the individual to make final arrangements, such as the completion of degree requirements, final coordination with the sponsor, and, if necessary, a move to the sponsoring institution. The fellow must start the period of training under the award by the latest activation date as shown on the award notice, i.e., 6 months from the award issue date. The activation period may be extended in unusual circumstances. Written requests for extensions should be submitted by the fellow and must be countersigned by the sponsor and the authorized organizational representative.

An activation notice must be submitted to the awarding office as of the day the fellow begins training. A payback agreement may also be required to be completed and submitted (see Part IV or the program guidelines). A stipend may not be paid until the forms are submitted and the fellow begins training. If necessary for payroll purposes, the activation notice and payback agreement may be submitted up to 30 days before the start date. However, any change in the planned activation start date must be reported immediately to the sponsoring institution's business office and to the OPDIV. If an award is conditioned upon completion of degree requirements, the fellow must submit, with the activation notice, proof of completion by the degree-granting institution.

Fellowship support generally is approved for consecutive years of training. The initial award usually is for 12 months. Subsequent periods of approved fellowship training are consecutive with the first year of support and are usually in 12-month increments (budget periods). Awards for less than 12 months will be prorated accordingly. If a fellow decides not to activate the award, or to terminate early, he or she should notify the recipient organization's business office, the sponsor, and the OPDIV immediately, in writing. The OPDIV will make any necessary adjustments in the stipend and other costs, including the institutional allowance.

Payment

Payment is as follows:

- *Domestic organizations*. Non-Federal sponsoring organizations receive an award for the stipend, institutional allowance, and tuition and fees (when applicable). The organization directly pays the fellow and disburses all other awarded costs.

- *Federal laboratories.* Fellows training at Federal laboratories are paid stipends directly by the OPDIV. Reimbursement to the fellow for appropriate expenditures from the institutional allowance also is paid by the OPDIV.

- *Foreign organizations.* Fellows training at foreign sites receive stipends directly from the OPDIV. However, the institutional allowance is awarded to and disbursed by the sponsoring organization.

Allowable Costs

Exhibit 14 lists and describes allowable costs of fellowships.

Exhibit 14. Allowable Costs of Fellowships

Item	Description

Exhibit 14. Allowable Costs of Fellowships

Item	Description
Stipend	A stipend is provided as a subsistence allowance for fellows to help defray living expenses during the training experience. It is not provided as a condition of employment with either the Federal government or the sponsoring organization. Stipends must be paid in accordance with stipend levels established by the OPDIV, which are based on a 12-month full-time training appointment. In the event of early termination, the stipend will be prorated according to the amount of time spent in training, and the OPDIV will issue a revised NoA. No departure from the standard stipend provided by the OPDIV under the fellowship may be negotiated by the sponsoring institution with the fellow. Stipend levels are updated nearly every year. When increases are approved, they are published and posted on the OPDIV Web site. The awarding office will adjust fellowship awards on their anniversary dates to include the currently applicable stipend amount.
Institutional allowance	An institutional allowance is generally provided to help support the costs of training. The specific levels of allowance for support, including those for individuals training at Federal laboratories, for-profit organizations, or foreign organizations, are published by the OPDIV and posted on its Web site. Costs for tuition and fees, where appropriate, will be awarded independent of the institutional allowance. The institutional allowance is a fixed amount. Expenditures under institutional allowances are not subject to OPDIV prior-approval requirements, and the institution is not required to account for these expenditures on an actual cost basis. Except for fellows at Federal training sites, consistent with OPDIV policy governing the type of expenditures appropriate for the institutional allowance, the sponsoring organization authorizes the expenditure of the institutional allowance on behalf of the fellow according to the organization's policy. The organization is entitled to expend up to the full institutional allowance upon official activation of the award. However, if an individual fellow is not in a training status for more than 6 months of the award year, only one-half of that year's institutional allowance may be charged to the grant. The NoA will be revised and the balance must be refunded to the OPDIV. The type of sponsoring institution dictates what costs may be charged to this category and how the funds are to be administered.
Non-Federal public and private non-profit organizations (domestic and foreign)	The allowance is intended to defray expenses for the individual fellow such as supplies, equipment, travel to meetings, and health insurance and to otherwise offset, insofar as possible, appropriate administrative costs of training. Funds are paid directly to and administered by the sponsoring organization.
Federal laboratories	The allowance is intended to cover the costs of meeting travel, health insurance, and books. Funds are administered by the OPDIV.

Exhibit 14. Allowable Costs of Fellowships

Item	Description
For-profit institutions	The allowance is intended to cover the costs of meeting travel, health insurance, and books. Funds are paid directly to the sponsoring organization for disbursement to the fellow.
	The following are guidelines for the use of the institutional allowance: ◆ *Travel.* Payment for travel to meetings is appropriate when it is necessary for the individual's training and when the costs are incurred within the period of grant-supported training. For fellows at Federal laboratories, reimbursement of travel costs must be in accordance with current Federal travel regulations. Funds may not be expended to cover the costs of travel between the fellow's place of residence and the domestic training organization, except that the sponsoring organization may authorize the cost of a one-way travel allowance in an individual case of extreme hardship. ◆ *Extraordinary costs.* Additional funds may be requested by the organization when the training of a fellow involves extraordinary costs for travel to field sites remote from the sponsoring organization or accommodations for fellows who are disabled, as defined by the Americans with Disabilities Act. The funds requested for extraordinary costs must be reasonable in relationship to the total dollars awarded under a fellowship and must be directly related to the approved training activity. Such additional funds will be provided only in exceptional circumstances that are fully justified and explained by the organization. ◆ *Health insurance.* A fellow's health insurance is an allowable cost only if applied consistently to all people in a similar training status regardless of the source of support. Family health insurance is an allowable cost for fellows who have families and are eligible for family health insurance coverage at the sponsoring organization. Self-only health insurance is an allowable cost for fellows without families. Health insurance can include coverage for costs such as vision and/or dental care if consistent with organizational policy.
Tuition and fees	Costs associated with tuition and fees are allowable only if they are required for specific courses in support of the training. The recipient should consult the OPDIV guidelines or Part IV for specific guidance on the reimbursement of tuition and fees.
Travel to foreign training sites	For fellows at foreign training sites, in addition to the institutional allowance, awards may include a single economy or coach round-trip travel fare. No allowance is provided for dependents. U.S. flag air carriers must be used to the maximum extent possible when commercial air transportation is the means of travel between the United States and a foreign country or between foreign countries. This requirement will not be influenced by factors of cost, convenience, or personal travel preference.
Employee benefits	Since fellowships are not provided as a condition of employment with either the Federal government or the sponsoring organization, recipients may not seek funds, or charge fellowship awards, for costs that normally would be associated with employee benefits (for example, FICA, workers compensation, and unemployment insurance).

Supplementation of Stipends, Compensation, and Other Income

Stipend Supplementation

Fellows receive stipends to defray living expenses. Stipends may be supplemented by an organization from non-Federal funds provided this supplementation does not require any additional obligation from the fellow. An organization can determine the amount of stipend supplementation, if any, it will provide according to its own formally established policies governing stipend support. These policies must be consistently applied to all individuals in a similar status regardless of the source of funds. Federal funds may not be used for stipend supplementation unless specifically authorized under the terms of the program from which funds are derived. Under no circumstances may OPDIV funds be used for supplementation. An individual may use Federal educational loan funds or VA benefits when permitted by those programs as described in this section.

Compensation

Fellows may seek part-time employment incidental to their training program to offset further their expenses. Funds characterized as compensation may be paid to fellows only when there is an employer-employee relationship, the payments are for services rendered, and the situation otherwise meets the conditions for compensation of students as detailed in "Selected Items of Cost." In addition, compensation must be in accordance with organizational policies applied consistently to both federally and non-federally supported activities and must be supported by acceptable accounting records that reflect the employer-employee relationship agreement. Under these conditions, the funds provided as compensation (salary, fringe benefits, and/or tuition remission) for services rendered, such as teaching or laboratory assistance, are not considered stipend supplementation; they are allowable charges to Federal grants, including HHS grants. However, the OPDIV expects that compensation from HHS grants will be for limited part-time employment apart from the normal training activities. Compensation may not be paid from a grant that supports the same activity that is part of the fellow's planned training experience as approved in the fellowship application. Under no circumstances may the conditions of stipend supplementation or the services provided for compensation interfere with, detract from, or prolong the fellow's approved training program. Fellowship sponsors must approve all instances of employment on HHS grants to verify that the circumstances will not detract from or prolong the approved training program.

Concurrent Benefits

A fellowship under the Kirschstein-National Research Service Awards may not be held concurrently with another federally sponsored fellowship or similar Federal award that provides a stipend or otherwise duplicates provisions of the fellowship award.

Educational Loans or GI Bill

An individual may accept concurrent educational remuneration from the VA (GI Bill) and Federal educational loan funds. Such funds are not considered supplementation or compensation.

Taxability of Stipends

Section 117 of the Internal Revenue Code applies to the tax treatment of scholarships and fellowships. Degree candidates may exclude from gross income (for tax purposes) any amount used for course tuition and related expenses such as fees, books, supplies, and equipment required for courses of instruction at a qualified educational organization. Non-degree candidates are required to report as gross income any monies paid on their behalf for stipends or any course tuition and fees required for attendance. The taxability of stipends in no way alters the relationship between fellows and sponsoring organizations. Stipends are not considered salaries. In addition, recipients of fellowships are not considered to be in an employee-employer relationship with the OPDIV or the sponsoring organization solely as a result of the fellowship award. The interpretation and implementation of the tax laws are the domain of the IRS and the courts. HHS takes no position on what the status may be for a particular taxpayer, and it does not have the authority to dispense tax advice. Individuals should consult their local IRS office about the applicability of the law to their situation and for information on their tax obligations.

Form 1099

Although stipends are not considered salaries, this income is still subject to Federal and, sometimes, State income tax. Such income may be reported by the sponsoring organization on IRS Form 1099, Statement of Miscellaneous Income. Normally, the business office of the sponsoring organization will be responsible for annually preparing and issuing IRS Form 1099 for fellows paid through the organization (fellows at domestic non-Federal organizations). Sponsoring organizations are not required to issue a Form 1099, but it is a useful form of documentation of income received and a reminder to the fellow that some tax liability may exist. Fellows are reminded that, even if the sponsoring organization does not issue a Form 1099, they still are required to report stipends as income. The OPDIV will issue a Form 1099 for each fellow training at a Federal or foreign laboratory and receiving a stipend check from the U.S. Treasury.

Reporting Requirements

The submission of the forms described in this section is critical to establishing and paying stipends and other costs and determining payback service, if applicable. All of these forms generally are available in PDF-fillable and RTF formats at the OPDIV Web site or http://grants.nih.gov/grants/forms.htm. The awarding office may provide copies of applicable forms with—or reference the Web site in—the NoA.

Activation Notice

Immediately upon the initiation of training, the individual must complete and sign a fellowship activation notice (e.g., PHS 416-5), obtain the signature of the authorized organizational representative, and forward the notice along with a payback agreement (where required) to the awarding office. For fellows paid directly by the OPDIV, the activation notice is required at the start of each award year. The form should not be submitted before the fellow actually begins training. Stipend checks are issued when both the activation notice and the payback agreement (where required) are received by the awarding office. For fellows whose stipend is paid through the organization, the activation notice is required for the initial year only. The activation notice may be submitted up to 30 days before the individual begins training if necessary for payroll purposes. However, the organization must not release any funds until the individual has started training. Furthermore, if the

individual does not begin training on the day indicated, the organization must notify the awarding office immediately. Competing continuation awards must be activated on the day following the end of the last budget period of the previous award.

Payback Agreement

A payback agreement (e.g., PHS 6031), where required, must be signed by each person who is to receive a fellowship. Recipients should consult the OPDIV program guidelines or Part IV for guidance regarding the submission of a payback agreement.

Termination Notice

The termination notice (e.g., PHS 416-7) (along with the activation notice and the award notice) is the basis for validating the total period of fellowship support and establishing the amount of payback obligation, if any. A reminder of this reporting requirement may be sent to the fellow by the awarding office before the scheduled termination date. For early terminations, the completed form will be required immediately upon receipt of notification from the fellow or an authorized organizational representative. The lack of timely and accurate information on this form could adversely affect the payback process.

Progress Reports

Progress reports must be submitted for non-competing continuation support. Progress report forms and instructions generally are available from the OPDIV Web site or at http://grants.nih.gov/grants/forms.htm. Report form pages are available in PDF-fillable and RTF formats. Inadequate or incomplete progress reports may be returned to the fellow for revision and may result in a delay of continued support. A final progress report is required as part of the termination notice.

Financial Status Report

An annual or final FSR is not required on fellowship awards.

Changes in the Project/Activity

Fellowship awards are made for training at a specific organization under the guidance of a particular sponsor. OPDIV approval is required for a transfer of the award to another organization, a change in sponsor, or a project/activity change. As part of the approval process, if a fellow sponsored by a domestic non-Federal organization requests a transfer to another domestic non-Federal organization before the end of the current award year, the initial organization may be requested to continue to pay the stipend until the end of the current year. Disposition of the institutional allowance is negotiable between the two sponsoring organizations. No activation notice is required from the new sponsoring organization.

Transfers involving Federal or foreign sponsoring organizations require unique administrative procedures and approvals. Because each transfer varies depending on individual circumstances, the sponsoring organization should contact the awarding office for specific guidance.

Any proposed change in the individual's specified area of training must be reviewed and approved in writing by the OPDIV to ensure that the training continues to fall within the area of the original reviewed application. When the sponsor is going to be absent for more than 3 months, an interim sponsor must be named by the organization and approved in writing by the OPDIV.

Consecutive Support

If a fellow switches from one grant mechanism to another (e.g., from an institutional research training grant to a fellowship or from one OPDIV or OPDIV component to another), the requirement for payback service incurred is deferred until the total period of support is completed. All fellowship applications are reviewed to determine if previous fellowship support has been provided.

Termination

An OPDIV may terminate a fellowship before its normal expiration date if it determines that the recipient has materially failed to comply with the terms and conditions of the award or to carry out the purpose for which it was made. If an award is terminated for cause, the OPDIV will notify the fellow in writing of the determination, the reasons for the determination, the effective date, and the right to appeal the decision.

The OPDIV also may terminate an award at the request of the sponsoring organization or the recipient. The awarding office must be notified immediately if a sponsoring organization wants to terminate an individual fellow or the fellow decides to terminate training before the scheduled expiration date. If a fellowship is terminated early, the stipend must be prorated according to the amount of time spent in training, and the award notice will be revised. The balance of any institutional allowance (at least one-half) must be refunded if the training has been for 6 months or less.

Copyright

Except as otherwise provided in the conditions of the award, when a publication or similar copyrightable material is developed from work supported by HHS, the author is free to arrange for copyright without approval of the OPDIV. Such copyrighted materials are subject to a royalty-free, nonexclusive, and irrevocable license to the Federal government to reproduce them, translate them, publish them, and use and dispose of them, and to authorize others to do so for Federal government purposes.

Inventions and Patents

Fellowships funded primarily for educational purposes are not subject to invention reporting requirements nor does the OPDIV have any rights to inventions under those awards (as specified in 37 CFR 401.1(b)). Kirschstein-National Research Service Award fellows training at HHS represent an exception to this policy. Those fellows are subject to the provisions of EO 10096 and the OPDIV determines the disposition of rights to any invention conceived or actually reduced to practice during the period of the fellowship.

Disposition of Professional Fees

Fees resulting from clinical practice, professional consultation, or other comparable activities performed pursuant to the purpose of the award must be assigned to the sponsoring organization for disposition in accordance with established organizational policy. The term "professional fees" does not apply to honoraria, fees for scholarly writing, delivery of occasional outside lectures, or service in an advisory capacity to public or private non-profit organizations, which, if permitted by organizational policy, may be retained by the fellow.

Requirements for Specific Types of Recipients

Grants to Foreign Organizations, International Organizations, and Domestic Grants with Foreign Components and Subawards to Foreign Organizations

Most of the policies contained in this HHS GPS apply to grants made to foreign organizations and international organizations (hereafter "foreign grants"), including the requirements of 45 CFR part 74 or 45 CFR part 92, as applicable to the type of foreign organization, and the cost principles incorporated by reference in those regulations. If an applicant/recipient would be unable to comply with these requirements, the authorized organizational representative should contact the GMO. Specific exceptions and modifications of the HHS GPS requirements for foreign grants, and highlights of other policies, are set forth in this section. This section also includes policies that apply to domestic grants with a foreign component.

Public Policy Requirements

All public policy requirements included in "Public Policy Requirements" in Part I apply to foreign grants, with the following exceptions:

- *Civil rights.* None of the civil rights requirements specified in "Public Policy Requirements" apply to foreign grants.

- *Debarment and suspension.* Applicants and recipients that are foreign governments or governmental entities, public international organizations, or foreign-government-owned or -controlled (in whole or in part) entities are not subject to the debarment or suspension certification requirement or to debarment or suspension under 45 CFR part 76. All other foreign organizations and international organizations are subject to these requirements.

- *Drug-free workplace.* Foreign applicants and recipients may be exempted from the drug-free workplace requirements of 45 CFR part 83 based on a documented finding by the OPDIV that application of those requirements is inconsistent with U.S. international obligations or the laws and regulations of a foreign government.

- *Environmental requirements.* Receipt of a grant does not make a foreign applicant/recipient subject to environmental requirements that would not otherwise apply to it.

Funding and Payment

The application budget, requests for funds, and financial reports must be stated in U.S. dollars using the currency rate in effect at the time of submission. Once an award is made, the OPDIV may adjust for currency exchange fluctuations as part of the non-competing continuation award process. This may result in an upward or downward adjustment from the total approved budget for that budget period based on the net change from the prior year's award.

Awards to foreign organizations and international organizations generally are paid by the OPDIV's servicing finance office rather than through PMS unless the recipient is serviced by a U.S. owned- or -based bank. All payments will be in U.S. dollars at the rate of exchange current at the time of payment. Foreign recipients are strongly encouraged to use U.S. banks to ensure that payments arrive on time.

Payments are made by U.S. Treasury check. If paid by the OPDIV, grants normally will be paid on a predetermined quarterly advance basis, usually in four equal installments, unless the total amount of the award is $25,000 or less. If the amount advanced to an organization based on the predetermined quarterly advance is insufficient to meet the grant's cash requirements, the recipient must make a written request to the GMO for any additional funds needed. If payments are made by PMS, they are made on the same basis as for domestic grants (see "HHS Grants Process—Payment").

Allowable Costs

The costs that are generally allowable under grants to domestic organizations also are allowable under foreign grants, with the following exceptions:

- *A&R.* Major A&R costs are unallowable under foreign grants and domestic grants with foreign components. Minor A&R costs are allowable (see "Cost Considerations—Allowable Costs and Activities" and "Prior-Approval Requirements").

- *Audit costs.* Costs of financial-related audits are allowable (see "Audit" in this section).

- *Customs and import duties.* These costs, which include consular fees, customs surtax, value-added taxes, and other related charges, are unallowable under foreign grants and domestic grants with foreign components.

- *Indirect costs.* With the exception of the American University of Beirut, which is not considered a foreign organization, and the World Health Organization, indirect costs will not be reimbursed.

- *Research patient care costs.* Research patient care costs are allowable only in exceptional circumstances as determined by the OPDIV.

Prior-Approval Requirements

Foreign grants generally are included in expanded authorities.

A change in the performance site within a foreign country or performance in a country other than that specified in the approved application requires OPDIV prior approval. The transfer of work by a domestic recipient to a foreign component also requires OPDIV prior approval.

A change of grantee organization that involves the transfer of a grant to or between foreign organizations or international organizations requires OPDIV approval and, where applicable, the associated National Advisory Council or Board. OPDIV approval also is required for the transfer of a grant from a foreign organization to a domestic organization.

Audit

Foreign recipients are subject to the same audit requirements as for-profit organizations (specified in 45 CFR 74.26(d)).

Subawards

Subawards to foreign entities that are considered financial assistance arrangements (rather than acquisition of goods or services) require special oversight by recipients. The recipient must do the following:

- Ensure that appropriate OPDIV approval is obtained for a foreign subaward; i.e., that the OPDIV approves of the intent to subaward (subgrant) as defined in 45 CFR 74.2 and 45 CFR 92.3 (see "Prior Approval Requirements—OPDIV Prior Approval"). The recipient does not have to obtain GMO approval of the selected subrecipient or the agreement between the recipient and subrecipient.

- Determine whether the subaward recipient is subject to OMB Circular A-133 audit requirements (generally the case only if the subaward recipient has direct awards from HHS because HHS has adopted A-133 as the standard audit requirement for foreign recipients).

- Determine appropriate means of oversight, including review of reports, or on-site reviews, or alternatives to an A-133 audit if one will not be available during the period of the subaward, as part of seeking OPDIV approval, and indicate how it will monitor foreign subawards.

- Provide adequate evidence during its own A-133 audit and in reports to the OPDIV that it is meeting its subrecipient monitoring responsibilities.

Grants to Federal Institutions and Allowable Costs and Payments to (or on Behalf of) Federal Employees under Grants

Most of the policies contained in this HHS GPS apply to grants made to Federal institutions. If an applicant/recipient would be unable to comply with these requirements, the authorized Federal official should contact the GMO. Specific exceptions and modifications of the HHS GPS requirements for Federal recipients, and highlights of other policies, are set forth in this section.

Eligibility

Federal institutions are eligible to receive certain types of grants from PHS OPDIVs. This includes, but is not necessarily limited to, grants for research, training, and demonstration projects. Federal institutions must meet the eligibility requirements of the grant program from which support is sought. However, in no case may an awarding office issue a grant award to any component of its own OPDIV.

Although the performance site may be at a level lower than the agency or department, when an award is made to an eligible Federal institution, the Federal agency or department will be the designated recipient and must assume responsibility for the project. Federal institutions must also ensure that their own authorizing legislation will allow them to receive a PHS grant and be able to comply with the award terms and conditions.

A document certifying both the assumption of responsibility and authority to receive a grant must be submitted at the time of each new and competing continuation application. The certification must be signed by the head of the responsible Federal department or independent agency or a designee who reports directly to the department or agency head. (In the case of the Department of Defense, the Departments of the Army, Navy, and Air Force are considered the Federal department and their Secretaries as the responsible Department head.)

The certification requirement does not apply to VA hospitals, Bureau of Prisons (Department of Justice) hospitals, IHS hospitals, or other PHS OPDIVs applying for grants. Generally an award to a PHS OPDIV other than to an IHS hospital will be considered only if a project cannot be supported within the mission of the applicant OPDIV or organizational segment, the activity cannot be performed elsewhere, its non-pursuit would have an adverse or potentially important impact on the OPDIV mission, and a grant is determined to be the appropriate means of carrying out the activity.

Payment

Grants to DoD normally will be paid by U.S. Treasury check after submission of the appropriate interagency form. Payments to all other Federal departments and agencies generally will be accomplished by transfers of funds between appropriations.

Allowable Costs under Grants to Federal Institutions

Allowable costs under grants to Federal institutions will be determined by the established policies of the institution, consistently applied to both its own activities and to grant-supported activities, and by the requirements shown in Exhibit 15. In the absence of a governing organizational policy, the cost principles for State, local, and Indian tribal governments (OMB Circular A-87) will apply.

Exhibit 15. Allowable Costs under Grants to Federal Institutions

These costs are allowable only as specified	If
Indirect costs	Indirect costs will not be provided to Federal institutions.
Institutional allowances under fellowships	Institutional allowances may be requested by Federal institutions sponsoring a predoctoral or postdoctoral fellow.
Federal (U.S. Government) employees	No salary or fringe benefit payments may be made from HHS grant funds to support career, career-conditional, or other Federal employees (civilian or uniformed services) with permanent appointments provided for under existing position ceilings of a Federal institution receiving a grant. While the level of effort required for the project must be allowed by the recipient as part of the individuals' official duties, salary costs associated with an individual participating in an official capacity as a Federal employee under a grant to that Federal institution are not allowable costs under an HHS grant. See "Payments to (or on behalf of) Federal Employees under Grants" for the conditions under which salary and fringe benefits may be paid for Federal employees working on a grant-supported project when the recipient is a non-Federal organization or a Federal institution other than the one that employs the individual. Project-related travel costs of such employees are allowable as long as they consistent with the FTR. See Exhibit 16 in this section.
Payments to temporary employees	Payments to individuals specifically hired to assist in the performance of the grant are allowable.

Equipment Accountability

HHS will consider all nonexpendable personal property acquired under a grant awarded to a Federal institution as federally owned, subject to 45 CFR 92.32. Upon completion of the award, or when the property is no longer needed, the recipient must request disposition instructions from the OPDIV.

Procurement Requirements

Procurement under grants to Federal institutions is governed by the FAR and the recipient agency's FAR supplement.

Intellectual Property

Inventions resulting from grants supporting the activities of Federal employees under grants to Federal institutions must be reported simultaneously to the OPDIV and to the employing agency under the terms of EO 10096, as amended, and are subject to the licensing requirements of 37 CFR part 401. (See https://s-edison.info.nih.gov/iEdison/ for reporting requirements.) In cases where the VA is involved with the invention but is not the recipient, and the recipient chooses not to elect title or pursue practical application of an invention, the recipient must note VA's involvement on its notice to the OPDIV and provide a courtesy copy of the OPDIV notification to the appropriate VA office. The OPDIV will notify the recipient and the VA whether the OPDIV has an interest in taking title and/or continuing the pursuit of practical application of the invention.

Reporting Requirements

Federal institutions must submit annual FSRs and progress reports.

Allowable Costs and Payments to (or on Behalf of) Federal Employees under Grants

Exhibit 16 lists and describes allowable costs and payments to Federal employees under grants.

Exhibit 16. Allowable Costs and Payments to (or on Behalf of) Federal Employees under Grants

Item	Description
General	Only four types of costs—consultant fees, outpatient or subject costs, salary or fringe benefits (when the employee is not an employee of a recipient Federal institution or is a part-time VA employee as described in this exhibit), and travel costs—can be charged to OPDIV grants on behalf of Federal employees, whether by a recipient or subrecipient, and under the conditions specified only. Applicants/recipients should advise any Federal employees with whom these types of arrangements may be made to consult with their employing agency concerning their ability to meet the required conditions. The applicant/recipient must submit, as part of the grant application or subsequent request, any letters or documentation specified below, and that documentation must be deemed acceptable by the GMO before the Federal employee may be involved in a project. These limitations do not apply to individuals that are classified as special government employees because of service on advisory groups or as a result of a formal consulting arrangement with a Federal agency. (See the HHS Standards of Conduct at 45 CFR part 73, Subpart J for additional guidance.)
Consultant fees	These costs are allowable only for medical personnel of the Uniformed Services of the United States (excluding PHS Commissioned Officers) and when all of the following conditions are present: ◆ The employees are providing the kind and extent of medical services approved in the grant award. ◆ Adequate numbers of qualified civilian personnel are not available to provide these services, and eligible Federal medical personnel are hired only in addition to those qualified civilian medical personnel, if any, who are available. The applicant/recipient organization provides prior written authorization from the proposed consultant's commanding officer that he or she is authorized to work on the grant-supported activity during non-duty hours or while on authorized leave, and can be paid for his or her efforts.
Outpatient or subject costs	These costs are allowable when the employee is an outpatient or subject under study in connection with grant-supported activities.

Exhibit 16. Allowable Costs and Payments to (or on Behalf of) Federal Employees under Grants

Item	Description
Salary or fringe benefits	Salary payments may be made from OPDIV grant funds to career, career-conditional, or other Federal employees (civilian or uniformed services) with permanent appointments provided under existing position ceilings of a Federal institution only if prior approval is obtained from an authorized official of the employee's agency and the employee is one of the following: ◆ A PHS Commissioned Officer or a civil service employee carrying out duties for which specific statutory authorization exists permitting direct Federal assistance in lieu of cash under the grant, or where the government is reimbursed for services rendered subject to restrictions applicable to such personnel, including the applicable Federal standards of conduct (for HHS, 45 CFR part 73). ◆ A PHS Commissioned Officer on LWOP if the ▪ recipient has obtained written prior approval from the OPDIV; ▪ total amount of salary paid from OPDIV grant funds is proportional to the time devoted to the project and does not exceed the total annual amount of pay and allowances the individual would have received if not in LWOP status; and ▪ parties concerned have made a prior determination that there is no possibility of dual compensation and there is no actual or apparent conflict of interest or other violation of the applicable standards of conduct.
	◆ A civil service employee participating in a grant to a non-Federal organization and all of the following conditions are met: ▪ The individual is participating as part of an approved IPA assignment in a role other than as PI/PD. IPA assignments generally do not exceed 2 years and may not exceed 4 years of continuous duration (5 U.S.C. 3372). Based on this statutory time restriction, the involvement of the civil service employee should be limited in scope. Therefore, the proposed PI/PD for an HHS grant may not be participating through an IPA. On a case-by-case basis, the OPDIV may determine that certain other key personnel on the project are sufficiently critical to its long-term success that participation through an IPA is not appropriate.
	▪ Before making any payment from HHS grant funds to such an employee, the recipient must certify that the employee is on an IPA assignment and must provide adequate documentation, as determined by OPDIV, of the IPA assignment and information about its nature and duration. ▪ The level of effort required for the project must be allowed by the employing agency as part of the individual's official duties. Salary payments from OPDIV grant funds must be proportional to the time an individual devotes to the grant-supported project. The total salary support may not exceed the normal level of compensation from Federal salary if the individual were not participating in the grant. ▪ The parties concerned have made a prior determination that there is no possibility of dual compensation and there is no actual or apparent conflict of interest or other violation of the applicable standards of conduct.

Exhibit 16. Allowable Costs and Payments to (or on Behalf of) Federal Employees under Grants

Item	Description
Salaries under research grants to VANPCs	In accordance with the established policies and salary structure of the VANPC, if the PI is a part-time VA employee, grant funds may be used to pay the differential between the individual's VA part-time salary and the salary level for a full-time VANPC commitment in proportion to the level of effort devoted to the project. Therefore, if the PI has a part-time appointment with the VANPC, an appropriate portion of the individual's salary that would otherwise be supported by the non-profit VANPC may be charged to the grant. An HHS grant may not be the source of funding for an increase in an investigator's salary regardless of the type of entity with which the investigator holds an appointment (e.g., university, VA, or VANPC).
Travel costs	These costs are allowable if the employee is ◆ performing allowable reimbursable services as specified under "Salary or Fringe Benefits" above, or ◆ attending an OPDIV grant-supported conference ▪ during non-duty hours, ▪ while in a preexisting LWOP status or one that continues beyond the conference, or ▪ while on detail to a State or local government, educational institution, or other non-profit organization. Such payments must be made in accordance with established organizational policy, consistently applied regardless of the source of funds, and the parties concerned must take reasonable steps to ensure that there is no actual or apparent conflict of interest.

Grants to For-Profit Organizations

General

For-profit organizations generally are subject to the same requirements specified in the HHS GPS for non-profit organizations, including those relating to personal property title and management. However, some of the terms and conditions for grants to for-profit (commercial) organizations vary from the standard terms and conditions included in the HHS GPS. In addition, the terms and conditions of the SBIR and STTR programs vary from those otherwise applicable to for-profit organizations. This section addresses separately the policies applicable to for-profit organizations generally and those that apply to SBIR and STTR awards specifically. It also highlights several policies that apply equally to for-profit and non-profit recipients. If an exception is not stated below or in the NoA, the public policy requirements cited in the "Public Policy Requirements" section of this HHS GPS, including the requirements for the protection of human subjects and animal welfare, apply.

Allowable Costs and Payment of Fee

No cost principles are specifically applicable to grants to for-profit organizations. Therefore, the cost principles for commercial organizations set forth in the FAR (48 CFR Subpart 31.2) generally are used to determine allowable costs under HHS grants to for-profit organizations. As provided in those costs principles, allowable travel costs may not exceed those established by the FTR (available at http://www.gsa.gov). In addition, as provided in 45 CFR 74.27(a), HHS does not

allow for-profit organizations to be reimbursed for IR&D (self-sponsored) costs. The cost principles in 45 CFR part 74, Appendix E, are used to determine allowable costs under HHS grants to proprietary hospitals.

Except for grants awarded under the SBIR/STTR programs, no profit or fee will be provided to a for-profit organization, whether as a recipient or subrecipient. A profit or fee under a grant is not a cost, but is an amount in excess of actual allowable direct and indirect costs. In accordance with normal commercial practice, a profit/fee may be paid to a contractor under an HHS grant providing routine goods or services to the recipient.

Intellectual Property

Intellectual property requirements set forth in 37 CFR part 401 apply to for-profit organizations, whether small businesses or large businesses. However, invention reporting requirements for for-profit organizations differ somewhat from those for non-profit organizations. When the recipient is a for-profit organization, assignment of invention rights to a third party does not require OPDIV approval. To the extent authorized by 35 U.S.C. 205 (the Patent Act, as amended), the Federal government will not make public any information disclosing a Federal government-supported invention.

Audit

The requirements for non-Federal audits of for-profit organizations are specified in 45 CFR 74.26(d). A for-profit organization is required to have a non-Federal audit if, during its fiscal year, it expended a total of $500,000 or more under one or more HHS awards (as a direct recipient and/or as a subrecipient). Title 45, part 74.26(d), of the CFR incorporates the thresholds and deadlines of OMB Circular A-133 but provides for-profit organizations two options regarding the type of audit that will satisfy the audit requirements:

- A financial-related audit, as defined in, and in accordance with, the Government Auditing Standards, of all its HHS awards. The standards, commonly known as the "Yellow Book" (GPO stock 020-000-00-265-4), are available at http://www.gao.gov/govaud/ybk01.htm. The Government Auditing Standards audits must be completed and submitted within 30 days after receipt of the auditor's report or 9 months after the end of the audit period (i.e., the end of the organization's fiscal year), whichever is earlier.

- An audit that meets the requirements of OMB Circular A-133. OMB Circular A-133 is available at http://www.whitehouse.gov/omb/circulars/a133/a133.html.

Within 30 days after receipt of the auditor's report(s), or 9 months after the end of the audit period, i.e., the end of the organization's fiscal year, whichever is earlier, the audit must be submitted to the following office:

National External Audit Review Center
HHS Office of Audit Services
323 West 8th Street
Lucas Place
Room 514
Kansas City, MO 64105.

For-profit organizations expending less than $500,000 a year are not required to have an annual audit for that year but must make their grant-related records available to the OPDIV or other designated officials for review or audit.

Small Business Innovation Research and Small Business Technology Transfer Programs

Certain OPDIVs are required by statute to reserve a portion of its annual extramural budget for projects under the SBIR and STTR programs. These programs primarily are intended to encourage private-sector commercialization of technology and to increase small business participation in federally funded R&D.

Both the SBIR and STTR programs consist of the following three phases; however, individual projects may not be eligible for all three phases:

- *Phase I.* The objective of this phase is to establish the technical merit and feasibility of proposed research or R&D efforts and to determine the quality of performance of the applicant (small business concern or SBC) before providing further Federal support in Phase II.

- *Phase II.* The objective of this phase is to continue the research or R&D efforts initiated in Phase I. Funding will be based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II application. Only Phase I recipients are eligible to receive Phase II funding. Unless submitted as a Fast-Track application (see below), Phase II applications may be submitted only after the Phase I award is made. OPDIVs expect non Fast-Track Phase II applications to be submitted within the first six receipt dates following expiration of the Phase I budget period, i.e., normally 2 years beyond the expiration date of the Phase I award.

- *Phase III.* The objective of this phase, where appropriate, is for the SBC to pursue, with non-Federal funds, the commercialization of the results of the research or R&D funded in Phases I and II.

There are two major differences between the SBIR and STTR programs:

- The STTR program requires that the SBC formally partner with a single, non-profit research institution in the collaborative conduct of a project that has potential for commercialization. To be eligible for an STTR award, at least 40 percent of the research must be performed by the SBC and at least 30 percent of the research must be performed by a domestic non-profit research institution through a formal, cooperative arrangement. Such organizations

include universities, non-profit hospitals, and other non-profit research organizations as well as Federally Funded Research and Development Centers. (The same requirement applies to Phase I and to Phase II.) STTR grants are awarded to the SBC, which will receive all of the funding for the project and disperse the appropriate funding to the research institution. The SBIR program does not have this requirement; therefore, the SBC may conduct the entire SBIR project without outside collaboration.

- The SBIR program requires that the primary employment of the PI (greater than 50 percent of the individual's time) be with the SBC at the time of award and during the conduct of the project. The STTR program does not have this requirement, i.e., the PI may have his or her primary employment with an organization other than the SBC, including the collaborating research institution. However, there must be an official relationship between the PI and the SBC. As an eligibility criterion, the PI also is required to devote at least 10 percent of his or her time to the STTR project.

The Fast-Track application process expedites award decisions and funding of SBIR and STTR Phase II applications for scientifically meritorious projects that have a high potential for commercialization. The Fast-Track process allows Phase I and Phase II grant applications to be submitted and reviewed together. Typically, Fast-Track applications will receive a single rating. An OPDIV determines whether to allow SBCs to use the Fast-Track review option. Therefore, before submitting applications for Fast-Track review, applicants are strongly encouraged to consult with OPDIV program staff. SBIR/STTR Phase I and Phase II applications submitted concurrently without prior consultation with the OPDIV may be redirected for review under the OPDIV's normal review procedures. For additional information on the submission of Fast-Track applications, see the OPDIV's SBIR/STTR program solicitations.

Qualification as a Small Business Concern

Each organization receiving a grant under the SBIR/STTR programs must qualify as a U.S.-owned SBC—an entity that, at the time of the Phase I and Phase II awards, meets all of the following criteria:

- The entity is organized for profit and has a place of business located in the United States, operates primarily within the United States, or makes a significant contribution to the U.S. economy through payment of taxes or use of American products, materials, or labor.

- It is in the legal form of an individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust, or cooperative. If the entity is a joint venture, there can be no more than 49 percent participation by foreign business entities.

- As provided by the express terms of 13 CFR 121.702(a), it is at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States. In the case of a joint venture, each party to the venture must be 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States. Under these regulations, corporations or artificial entities cannot quality as individuals who are U.S. citizens. Further, indirect

ownership of the entity by a U.S. citizen does not satisfy the requirements of 13 CFR 121.702(a).

- *Example 1.* An entity applying for an SBIR/STTR grant is 100 percent owned by Company A. Company A is 100 percent owned by U.S. citizens. The entity is not eligible for support under the SBIR/STTR program because it is not 51 percent directly owned and controlled by citizens of, or permanent resident aliens in, the United States.

- *Example 2.* An entity applying for an SBIR/STTR grant is 51 percent owned by U.S. citizens of and permanent resident aliens in the United States and 49 percent owned by a corporation. The entity is eligible for support under the SBIR/STTR program, assuming it meets the other eligibility criteria (e.g., size), because 51 percent of the ownership rests directly with U.S. citizens and permanent resident aliens of the United States.

- The entity, including its affiliates, cannot have more than 500 employees. In accordance with 13 CFR 121.103, affiliation exists when, either directly or indirectly, (1) one concern controls or has the power to control the other, or (2) a third party or parties controls or has the power to control both. One of the circumstances that would lead to a finding that an organization is controlling or has the power to control another organization involves sharing common office space, employees, and/or other facilities (e.g., laboratory space). The research and analytical work performed by the recipient under an SBIR/STTR award is to be conducted in research space occupied by, available to, and under the control of, the recipient. However, when required by the project activity, access to special facilities or equipment in another organization is permitted, as in cases where the SBIR recipient has entered into a consortium arrangement with another organization for a specific, limited portion of the research project. See 13 CFR 121.3-2(a) and 13 CFR 121.3-2(t) for additional information concerning this criterion.

All appropriate factors will be considered in determining whether an entity qualifies for an SBIR/STTR award, including common ownership, common management, and contractual relationships.

Place of Performance

For both Phase I and Phase II SBIR/STTR awards, the research or R&D project activity must be performed in its entirety in the United States. (The United States is defined as the 50 States, the territories and possessions of the United States, the Commonwealth of Puerto Rico, the Federated States of Micronesia, the Republic of Palau, the Republic of the Marshall Islands, and the District of Columbia.)

In those rare instances where the study design requires use of a foreign site (e.g., to conduct testing of specific patient populations), the investigator must thoroughly justify in the application the need for use of a foreign site. Similarly, in those rare instances where it may be necessary to purchase materials from other countries, investigators must thoroughly justify the request. The OPDIV will consider these instances on a case-by-case basis, and they should be discussed with cognizant OPDIV staff before submitting an application. Whether the request is approved or disapproved, it will be explicitly addressed in the NoA if an award is made. Whenever

possible, work outside the United States, which is necessary to the completion of the project, should be supported by funding other than SBIR/STTR grants.

Minimum Level of Effort

Generally, under SBIR Phase I awards, a minimum of two-thirds or 67 percent of the research or analytical effort must be carried out by the SBC. In addition, payments, in the aggregate, to consultants, consortium participants and contractors for portions of the scientific/technical effort generally may not exceed 33 percent of the total requested amount.

Generally, under SBIR Phase II awards, a minimum of one-half or 50 percent of the research or analytical effort must be carried out by the SBC. In addition, payments, in the aggregate, to consultants, consortium participants, and contractors for portions of the scientific/technical effort generally may not exceed 50 percent of the total requested amount.

For STTR awards (both Phase I and Phase II), at least 40 percent of the work is to be performed by the SBC and at least 30 percent of the work is to be performed by the single, non-profit research institution. The basis for determining the percentage of work to be performed by each of the cooperating parties is the total of direct and F&A costs attributable to each party, unless otherwise described and justified in the "Contractual Arrangements" portion of the "Research Plan" section of the grant application.

Public Policy Requirements

The requirements concerning disclosure of financial conflicts of interest (see "Public Policy Requirements—Other Research-Related Requirements—Financial Conflict of Interest") do not apply to applications or awards under Phase I of the SBIR/STTR programs.

Allowable Costs and Fee

Profit or Fee. A reasonable profit or fee may be paid to an SBC receiving an award under Phase I or Phase II of the SBIR and STTR programs. The profit or fee is not considered a "cost" for purposes of determining allowable use, program income accountability, or audit thresholds. The profit or fee may be used by the SBC for any purpose, including additional effort under the SBIR/STTR award. It is intended to provide a reasonable profit consistent with normal profit margins for for-profit organizations for R&D work. Fee amounts may not exceed 8 percent of total costs (direct plus indirect) exclusive of fee, unless there is compelling justification and the request is approved by the OPDIV. Regardless, total costs and fee must be accommodated within the statutory limitations on the size of awards under the SBIR/STTR programs (see Part IV for allowable fee percentage). The profit or fee should be drawn from PMS in increments proportional to the drawdown of funds for direct and indirect costs. The profit or fee applies solely to the SBC receiving the SBIR/STTR award and not to any other participant; however, in accordance with normal commercial practice, the SBC may pay a profit or fee to a contractor providing routine goods or services to the SBC under the grant.

For multi-year awards, i.e., those where the approved project period will exceed 1 year, the overall fee negotiated will be divided into the number of years in the

project period and the resulting amount added to each budget period as a "fixed fee." The fee paid is not subject to the cost principle tests of allowability and it will not be adjusted downward based on actual allowable costs incurred. However, in the event of a termination or the withholding a non-competing continuation award for failure to make satisfactory progress, non-compliance with the terms and conditions of a previous award or absence of an appropriation, the recipient is not entitled to any fee amount in excess of the negotiated percentage applied to the period for which grant support has been provided.

Indirect Costs.

- *Phase I.* If the applicant SBC has a currently effective indirect cost rate with a Federal agency, that rate should be used when calculating proposed indirect costs for an application. (However, the rate must be adjusted for IR&D expenses, which are not allowable under HHS awards.) If the applicant SBC does not have a currently effective negotiated indirect cost rate with a Federal agency, the applicant should propose estimated indirect costs at a rate not to exceed 40 percent of the total direct costs. However, SBCs are reminded that only actual indirect costs are to be charged to projects. (If awarded at a rate of 40 percent or less, the rate used to charge actual indirect costs to projects cannot exceed the awarded rate unless the SBC negotiates an indirect cost rate with a Federal agency.) OPDIVs will not negotiate indirect cost rates for Phase I awards.

- *Phase II.* If the applicant SBC has a currently effective negotiated indirect cost rate with a Federal agency, that rate should be used when calculating proposed indirect costs for an application. (However, the rate must be adjusted for IR&D expenses, which are not allowable under HHS awards.) If the applicant SBC does not have a currently effective negotiated indirect cost rate with a Federal agency, the applicant should propose an estimated indirect cost rate in the application. If the requested indirect cost rate is 25 percent of total direct costs or less, no further justification is required at the time of award, and indirect costs will be awarded at the requested rate. However, SBCs are reminded that only actual indirect costs may be charged to projects. If awarded at a rate of 25 percent or less of total direct costs, the rate used to charge actual indirect costs to projects cannot exceed the awarded rate unless the SBC negotiates an indirect cost rate with DFAS. DFAS—the office authorized to negotiate indirect cost rates with SBCs receiving HHS SBIR/STTR awards—will negotiate indirect cost rates for SBCs receiving Phase II awards that requested a rate greater than 25 percent of total direct costs.

  Upon request, the applicant SBC should provide DFAS with an indirect cost proposal and supporting financial data for its most recently completed fiscal year. If financial data are not available for the most recently completed fiscal year, the applicant should submit a proposal showing estimated rates with supporting documentation. Further information about DFAS is available at its Web site or by telephone (see Part III of the HHS GPS).

Market Research

HHS will not support market research, including studies of the literature that lead to a new or expanded statement of work, under the grant. For purposes of the

SBIR/STTR programs, "market research" is the systematic gathering, editing, recording, computing, and analyzing of data about problems relating to the sale and distribution of the subject of the proposed research. It includes various types of research, such as the size of potential markets and potential sales volume, the identification of consumers most apt to purchase the products, and the advertising media most likely to stimulate their purchases. However, "market research" does not include activities under a research plan or protocol that include a survey of the public as part of the objectives of the project to determine the impact of the subject of the research on the behavior of individuals.

Intellectual Property

Rights to data, including software developed under the terms of any funding agreement resulting from an HHS award, must remain with the recipient except that any such copyrighted material is subject to a royalty-free, nonexclusive and irrevocable license to the Federal government to reproduce, publish, or otherwise use the material, and to authorize others to do so for Federal purposes. In addition, under the SBIR/STTR programs, in contrast to awards to for-profit organizations under other support mechanisms, such data must not be released outside the Federal government without the recipient's permission for a period of 4 years from completion of the project under which the data were generated.

The STTR program requires that the small business recipient and the single, non-profit research institution execute an agreement allocating between the parties intellectual property rights and rights, if any, to carry out follow-on research, development, or commercialization of the subject research. (A model agreement, "Allocation of Rights in Intellectual Property and Rights to Carry Out Follow-On Research, Development, or Commercialization," is available at the NIH Web site at http://grants.nih.gov/grants/funding/sbir.htm.) By signing the face page of the grant application, the SBC's AOO certifies that the agreement with the research institution will be effective at the time the grant award is made. A copy of the agreement must be furnished upon request to the awarding office.

SBIR/STTR recipients are covered by 37 CFR part 401 with respect to inventions and patents.

Data Sharing. Applicants for SBIR Phase II funding of $500,000 or more of direct costs in any single year must comply with the HHS policy on data sharing consistent with the Small Business Act. If the final data would not be amenable to sharing, e.g., proprietary data, the SBC should explain that in the application. In addition, as indicated under "Intellectual Property" in this subsection, whether or not the award meets the threshold for data sharing, the OPDIV will not release data outside the Federal government without the recipient's permission for a period of 4 years from completion of the project under which the data were generated. The entire policy may be found at http://grants.nih.gov/grants/policy/data_sharing/index.htm.

Part III: Points of Contact

Exhibit 17 lists pertinent offices and officials, along with their addresses and telephone numbers.

Exhibit 17. Points of Contact

Office or Official	Address and telephone numbers
Office of the Inspector General (OIG) http://www.oig.hhs.gov	Department of Health and Human Services OIG Hotline Attn: HOTLINE 330 Independence Avenue, SW Washington, DC 20201 800-HHS-TIPS (1-800-447-8477) e-mail: HHSTips@org.hhs.gov
	For questions concerning A-133 audit requirements: National External Audit Resources Office of Audit Services 323 West 8th Street Lucas Place, Room 514 Kansas City, MO 64105 800-374-6714 (voice) 816-374-6727 (fax) http://harvester.census.gov/sac
Office for Human Research Protections (OHRP) http://www.hhs.gov/ohrp	The Tower Building 1101 Wootton Parkway, Suite 200 Rockville, MD 20852 866-447-4777 (toll free) 240-453-6900 (local) e-mail: ohrp@osophs.dhhs.gov
Office of Laboratory Animal Welfare (OLAW) http://grants.nih.gov/grants/olaw/olaw.htm	6705 Rockledge Drive Rockledge I, Suite 360, MSC-7982 Bethesda, MD 20892-7982 301-496-7163 e-mail: olaw@od.nih.gov (for general questions, copies of documents, or compliance issues) assurance.olaw@od.nih.gov (for questions or information about assurances)
Office of Research Integrity (ORI) http://ori.dhhs.gov	The Tower Building 1101 Wootton Parkway, Suite 750 Rockville, MD 20852 240-453-8200 e-mail: askORI@osophs.dhhs.gov

Exhibit 17. Points of Contact

Office or Official	Address and telephone numbers
Departmental Appeals Board (DAB) http://www.hhs.gov/dab/	Department of Health and Human Services Departmental Appeals Board, MS 6132 Alternative Dispute Resolution and Civil Remedies Divisions 330 Independence Avenue, SW Room G-644 Washington, DC 20201 Note: DAB does not receive courier deliveries at this address. 202-565-0200 (Chair and Appellate and ADR Divisions) 202-565-9462 (Civil Remedies Division) e-mail: DAB@hhs.gov
Office for Civil Rights (OCR) http://www.hhs.gov/ocr	Office of Program Operations 200 Independence Avenue, SW Room 509 F Washington, DC 20201 800-368-1019 e-mail: OCRMail@hhs.gov
Program Support Center Financial Management Service Division of Payment Management (DPM) http://www.dpm.psc.gov http://www.dpm.psc.gov/Contact.aspx (Find Account Representative	P.O. Box 6021 Rockville, MD 20852 301-443-9193 301-443-3586 (fax) e-mail: info@psc.dhhs.gov
Division of Cost Allocation (DCA) http://rates.psc.gov/	
Mid-Atlantic Field Office (Services Alabama, Delaware, District of Columbia, Florida, Georgia, Kentucky, Maryland, Mississippi, North Carolina, Pennsylvania, South Carolina, Tennessee, Virginia and West Virginia)	330 Independence Avenue, SW Cohen Building, Room 10-67 Washington, DC 20201 202-401-2808
Northeastern Field Office (Services Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, Vermont, Puerto Rico, the Virgin Islands, Canada and Europe)	26 Federal Plaza Room 41-122 New York, NY 10278 212-264-2069
Central States Field Office (Services Arkansas, Illinois, Indiana, Iowa, Kansas, Louisiana, Michigan, Minnesota, Missouri, Nebraska, New Mexico, Ohio, Oklahoma, Texas and Wisconsin)	1301 Young Street Room 702 Dallas, TX 75202 214-767-3261
Western Field Office (Services Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming, Australia, and Asia)	50 United Nations Plaza Room 347 San Francisco, CA 94102 415-437-7820

Exhibit 17. Points of Contact

Office or Official	Address and telephone numbers
Office of Acquisition Management and Policy (OAMP) Division of Financial Advisory Services (DFAS) http://oamp.od.nih.gov/dfas/dfas.asp	6100 Executive Boulevard, Room 6B05 MSC-7540 Bethesda, MD 20892-7540 301-496-4401 301-402-0177

Appendix A: Abbreviations

Following are abbreviations of terms used throughout this document. They are included in a single location as an aid to the reader.

A&R	alteration and renovation
ACH	Automated Clearinghouse
AHRQ	Agency for Healthcare Research and Quality
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CoC	certificate of confidentiality
DAB	Departmental Appeals Board
DCA	Division of Cost Allocation, HHS
DEA	Drug Enforcement Administration
DFAS	Division of Financial Advisory Services, NIH
DoC	Department of Commerce
DoD	Department of Defense
DoL	Department of Labor
DPM	Division of Payment Management, HHS
EIN	Entity Identification Number
EO	Executive Order
F&A	facilities and administrative (costs)
FAC	Federal Audit Clearinghouse
FAR	Federal Acquisition Regulation
FCTR	Federal Cash Transactions Report (SF 272)
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
FOIA	Freedom of Information Act
FSR	Financial Status Report (SF 269 or 269A)
FTR	Federal Travel Regulation
FWA	Federal-Wide Assurance
GMO	Grants Management Officer
GMS	Grants Management Specialist
GPO	Government Printing Office
GSA	General Services Administration
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
IACUC	Institutional Animal Care and Use Committee
IDE	investigational device exception
IHS	Indian Health Service
IND	Investigational new drug

IPA	Intergovernmental Personnel Act
IR&D	independent research and development
IRB	Institutional Review Board
IRS	Internal Revenue Service
LOI	Letter of intent
LWOP	leave without pay
NEARC	National External Audit Review Center, OIG
NEPA	National Environmental Policy Act
NFI	Notice of Federal Interest
NIH	National Institutes of Health
NoA	Notice of Award (Notice of Grant Award)
OCR	Office for Civil Rights, HHS
OFCCP	Office of Federal Contract Compliance Programs, DoL
OG	Office of Grants
OHRP	Office for Human Research Protections
OIG	Office of the Inspector General
OLAW	Office of Laboratory Animal Welfare, NIH
OMB	Office of Management and Budget
ONR	Office of Naval Research
OPDIV	Operating Division
OPHS	Office of Public Health and Science
ORI	Office of Research Integrity
PA	program announcement
PD	Program Director/Project Director
PHS	Public Health Service
PI	Principal Investigator
P.L.	Public Law
PMS	Payment Management System
PO	Project Officer/Program Official
PRA	Paperwork Reduction Act
RA	Review Administrator
R&D	research and development
RFA	Request For Applications
SAMHSA	Substance Abuse and Mental Health Services Administration
SBA	Small Business Administration
SBC	small business concern
SBIR	Small Business Innovation Research Program
SF	Standard Form
SPOC	State Single Point of Contact
STTR	Small Business Technology Transfer Program
U.S.C.	United States Code

USDA	United States Department of Agriculture
VA	Department of Veterans Affairs
VANPC	VA-Affiliated Non-Profit Research Corporation

Appendix B: Glossary

This glossary defines terms commonly used in the HHS GPS. These definitions are included for purposes of clarity in this document and are not intended to replace controlling definitions found in applicable statutes and regulations. The policy associated with these definitions is found in Part II of the HHS GPS, unless otherwise indicated.

accrual basis	An accounting method in which revenues and expenses are identified with specific periods of time, such as a month or year, and are recorded when they are earned or incurred without regard to the date of receipt or payment of cash; distinguished from cash basis.
acquisition cost	The net invoice price of property or supplies, including the cost of modifications, attachments, accessories, or auxiliary apparatus necessary to make the property usable for the purpose for which it was acquired. Other charges, such as the cost of installation, transportation, taxes, duty, and protective in-transit insurance, are included or excluded from the unit acquisition cost in accordance with the recipient's regular accounting practices. The term does not include costs for rental of property or alteration and rental of real property.
administrative requirements	The general practices that are common to the administration of grants, such as financial accountability, reporting, equipment management, and retention of records.
advance payment	A payment made to a recipient upon its request either before cash disbursements are made by the recipient or through the use of predetermined payment schedules. Most HHS advance payments are made by the Payment Management System (PMS), the HHS centralized grant payment system.
allocable cost	A cost that is allocable to a particular cost objective (i.e., a specific function, grant project, service, department, or other activity) in accordance with the relative benefits received. A cost is allocable to a Federal award where it is treated consistently with other costs incurred for the same purpose in like circumstances and (1) is incurred specifically for the award, (2) benefits both the award and other work and can be distributed in reasonable proportion to the benefits received, or (3) is necessary for the overall operation of the organization.
allowable cost	A cost incurred by a recipient that is (1) reasonable for the performance of the award; (2) allocable; (3) in conformance with any limitations or exclusions set forth in the Federal cost principles applicable to the organization incurring the cost or in the NoA as to the type or amount of cost; (4) consistent with regulations, policies, and procedures of the recipient that are applied uniformly to both federally supported and other activities of the organization; (5) accorded consistent treatment as a direct or indirect cost; (6) determined in accordance with generally accepted accounting principles; and (7) not included as a cost in any other federally supported award (unless specifically authorized by statute).

alteration and renovation	Work that changes the interior arrangements or other physical characteristics of an existing facility or installed equipment so that it can be used more effectively for its currently designated purpose or adapted to an alternative use to meet a programmatic requirement. Alteration and renovation may include work referred to as improvements, conversion, rehabilitation, remodeling, or modernization, but is distinguished from construction and large-scale permanent improvements.
alternative dispute resolution	A process in which mediation or other techniques are used to avoid or resolve disputes. Alternative dispute resolution is intended to reduce cost, delay, and contentiousness in the resolution process as well as to prevent disputes from escalating to levels requiring more formal or judicial resolution.
applicable credit	Those receipts that offset or reduce direct or indirect costs. Typical examples of such transactions include purchase discounts, rebates, or allowances; recoveries or indemnities on losses; insurance refunds; and adjustments of overpayments or erroneous charges.
application	A request for financial support of a project, program, or activity submitted on specified forms and in accordance with OPDIV instructions. (See "Types of Applications and Letters of Intent" in Part I for an explanation of the types of applications.)
approved budget	The financial expenditure plan for a grant-supported project, program, or activity, including revisions approved by the OPDIV and permissible revisions made by the recipient. The approved budget consists of Federal (grant) funds and, if required by the terms and conditions of the award, non-Federal participation in the form of matching or cost sharing. Expenditures under an approved budget that consists of both Federal and non-Federal shares are deemed to be borne by the recipient in the same proportion as the percentage of Federal/non-Federal participation in the overall budget.
assurance	A written statement by an applicant, normally included with the application, indicating that it will abide by a particular requirement if a grant is awarded. (See Part I.)
audit resolution	The process of resolving audit findings, including those related to management and systems deficiencies and monetary findings (i.e., questioned costs).
award	The document that provides OPDIV funds to a recipient to carry out an approved program or project (based on an approved application or progress report). The term, when used as a noun, is sometimes used interchangeably with "grant."
awarding office	The OPDIV organizational component responsible for the business management and non-programmatic aspects of the award and administration of grants. When referring to the focal point for recipient-initiated prior approval requests or actions by an awarding office that may require changes in the terms and conditions of award, reference will be to the GMO.
budget periods	The intervals of time (usually 12 months each) into which a project period is divided for budgetary and funding purposes. Funding of individual budget periods sometimes is referred to as "incremental funding."
carryover	Unobligated Federal funds remaining at the end of any budget period that may be carried forward to another budget period to cover allowable costs of that budget period (whether as an offset or additional authorization). Obligated but unliquidated funds are not considered carryover.

cash basis	An accounting method in which revenue and expenses are recorded on the books of account when received and paid, respectively, without regard to the period in which they are earned or incurred; distinguished from accrual basis.
cash contribution	The recipient's cash outlay, including the outlay of money contributed to the recipient by third parties.
change of grantee	A process in which the legal and administrative responsibility for a grant-supported project, program, or activity is transferred from one legal entity to another before the end of the project period. This action also may be termed "transfer of a grant."
clinical trial	A biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Clinical trials of an experimental drug, treatment, device, or intervention may proceed through four phases: Phase I—testing in a small group of people (e.g., 20 to 80) to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects). Phase II—study in a larger group of people (several hundred) to determine efficacy and further evaluate safety. Phase III—study to (1) determine efficacy in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions, (2) monitor adverse effects, and (3) collect information to allow safe use. Phase IV—studies done after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.
closeout	The process by which an OPDIV determines whether all applicable administrative actions and all work required under the award have been completed by the recipient and the awarding office.
cognizant agency	The Federal agency that, on behalf of all Federal agencies, is responsible for reviewing, negotiating, and approving cost allocation plans, indirect cost rate and similar rates; monitoring non-Federal audit reports; conducting Federal audits as necessary; and resolving cross-cutting audit findings. The cognizant agency under applicable cost principles and under OMB Circular A-133 may be different for a given recipient.
competition	A process in which applications undergo an objective review; the applications are evaluated against established review criteria and scored and rated accordingly.
competitive segment	The initial project period recommended for support (up to 5 years) or each extension of a project period resulting from a competing continuation award.
completion date	The date on which all work under an award is completed or the date in the NoA (as amended) on which Federal sponsorship ends (i.e., the end of a project period).

consortium agreement	A formal agreement whereby a project is carried out by a recipient and one or more other organizations that are separate legal entities. Under the agreement, the recipient must perform a substantive role in the conduct of the planned project or program activity and not merely serve as a conduit of funds to another party or parties. Consortium agreements are considered subawards for purposes of this policy statement.
contract under a grant	A written agreement between a recipient and a third party to acquire commercial goods or services.
construction	A project to support the initial building or major A&R (i.e., large-scale modernization or permanent improvement) of a facility.
consultant	An individual who provides professional advice or services for a fee, but normally not as an employee of the engaging party. The term "consultant" also includes a firm that provides paid professional advice or services.
cooperative agreement	A financial assistance support mechanism used when there will be substantial Federal programmatic involvement. Substantial involvement means that OPDIV program staff will collaborate or participate in project or program activities as specified in the NoA.
copyright	A form of protection provided by the laws of the United States (Title 17, U.S. Code) to the authors of "original works of authorship," including literary, dramatic, musical, artistic, and certain other intellectual works, including computer programs. This protection is available to both published and unpublished works.
cost analysis	The breakdown and verification of cost data proposed in an application budget, including evaluating specific elements of costs and examining them to determine the necessity, reasonableness, and allocability of the costs and their allowability pursuant to the applicable Federal cost principles and other governing requirements.
cost sharing	See "matching or cost sharing."
Departmental Appeals Board	The administrative board responsible for resolving certain disputes arising under HHS assistance programs. The DAB provides an impartial adjudicatory hearing process for appealing certain final written decisions by GMOs. The DAB's jurisdiction is specified in 45 CFR part 16, "Procedures for HHS Grant Appeals Board."
direct assistance	A financial assistance support mechanism, which must be specifically authorized by statute, whereby goods or services are provided to recipients in lieu of cash. Direct assistance generally involves the assignment of Federal personnel or the provision of equipment or supplies such as vaccines. This type of financial assistance also is described as "non-monetary assistance."
direct costs	Costs that can be identified specifically with a particular sponsored project, an instructional activity, or any other institutional activity, or that can be directly assigned to such activities relatively easily with a high degree of accuracy.
domestic organization	A public (including a State or other governmental agency) or private non-profit or for-profit organization that is located in the United States or its territories, is subject to U.S. laws, and assumes legal and financial accountability for funds awarded and for the performance of the grant-supported activities.

Entity Identification Number	A three-part coding scheme of 12 characters used in PMS to identify organizations and individuals. The first character identifies the recipient as an organization or an individual. The next 9 characters are the Internal Revenue Service tax number identification (TIN) for organizations or the social security number (SSN) for individuals. The last 2 characters are a suffix to provide distinction between organizational entities that are assigned a single EIN and those that have more than one EIN. The entities could be subsidiaries, divisions, branches, subdivisions, or other organizational groupings of a major organizational entity.
equipment	An article of tangible nonexpendable personal property that has a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit or the capitalization threshold established by the recipient, whichever is less.
excess property	The property under the control of any OPDIV that, as determined by the head of the OPDIV or designee, is no longer required for its needs or the discharge of its responsibilities.
exempt property	Tangible personal property acquired, in whole or part, with Federal funds, where the OPDIV has statutory authority to vest title in the recipient without further obligation to the Federal government.
expanded authorities	Operating authorities provided to recipients that waive the requirement for OPDIV prior approval for specified actions.
expenditure report	For non-construction grants, generally the FSR; and for construction grants, the Outlay Report and Request for Reimbursement for Construction Programs.
expiration date	The date signifying the end of the current budget period, as indicated in the NoA, after which the recipient does not have authority to obligate grant funds.
facilities and administrative costs	See "indirect costs."
Federal cash transactions report	A standard form, PMS 272, used to obtain disbursement information and to monitor cash advanced to recipients.
Federal funds authorized	The total amount of Federal funds obligated by the OPDIV for use by the recipient. This amount may include any authorized carryover of unobligated funds from one of the two preceding budget periods.
Federal institution	A Cabinet-level department or independent agency of the executive branch of the Federal government or any component organization of such a department or agency.
Federal share	The amount, generally expressed as a percentage of total project costs, of financial, property, and other direct assistance provided by the OPDIV, as specified in the NoA.
federally recognized Indian tribal government	The governing body of an Indian tribe, band, nation, or other organized group or community, including any Native village as defined in Section 3 of the Alaska Native Claims Settlement Act of 1971 (43 U.S.C. 1601 et seq.), that is certified by the Secretary of the Interior as eligible for the special programs and services provided through the Bureau of Indian Affairs and the Indian Health Service.
fee	An amount, in addition to actual, allowable costs, paid to an organization providing goods or services consistent with normal commercial practice. This payment also is referred to as "profit."
financial assistance	Transfer of money, property in lieu of money, or other direct assistance to an eligible recipient to support or stimulate a public purpose authorized by statute.

Financial Status Report	A standard Federal form, SF 269 (long form) or SF 269A (short form), that shows the status of funds in non-construction programs and is used to monitor the financial progress of awards. The forms require information on total outlays (Federal and recipient shares) and unobligated balances of Federal funds. The long form is used for grants that involve program income.
flow-down or flow-through provisions	The rules governing whether, and how, grant terms apply to subawards or contracts under grants.
foreign component	The performance of any significant element or segment of a project outside of the United States, either by the recipient or by a researcher or other individual employed by a foreign organization, whether or not grant funds are expended.
foreign organization	An organization located in a country other than the United States and its territories that is subject to the laws of that country, regardless of the citizenship of the proposed PI/PD.
for-profit organization	An organization, institution, corporation, or other legal entity that is organized or operated for the profit or financial benefit of its shareholders or other owners. Such organizations also are referred to as "commercial organizations."
full-time appointment	The number of days per week and/or months per year representing full-time effort at the applicant/recipient organization, as specified in organizational policy. The organization's policy must be applied consistently, regardless of the source of support.
funding opportunity announcement	An OPDIV's formally issued announcement of the availability of Federal funding through one of its financial assistance programs. The announcement invites applications and provides such information as eligibility and evaluation criteria, funding preferences/priorities, how to obtain application kits, and the submission deadline (see Part I).
grant	A financial assistance support mechanism providing money, property or other direct assistance in lieu of money, or both, to an eligible entity to carry out an approved project or activity in support of a public purpose and not the direct benefit of the government. A grant is used whenever the OPDIV anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities.
grant-supported project or activity	Those activities specified or described in an application or in a subsequent submission that are approved by an OPDIV for funding, regardless of whether Federal funding constitutes all or only a portion of the financial support necessary to carry them out.
high risk	The term used to describe a recipient who is at risk of financial failure or failure to perform based on a history of poor performance or poor business practices, financial instability, or inadequate management systems.
human subject	A living individual about whom an investigator obtains data through intervention or interaction with the individual or obtains identifiable private information. Regulations governing the use of human subjects extend to use of human organs, tissues, and body fluids from identifiable individuals as human subjects and to graphic, written, or recorded information derived from such individuals.
indirect costs	Costs that are incurred by a recipient for common or joint objectives and cannot be identified specifically with a particular project or program. These costs also are known as "facilities and administrative costs."

institutional review board	An administrative body whose purpose is to protect the rights and welfare of human subjects recruited to participate in research activities conducted under the auspices of the organization with which it is affiliated. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction.
intangible property	This term means property that ordinarily does not have physical existence. It includes, but is not limited to, copyrights for which assignments of rights are acquired under awards; patents and other intellectual property for which ownership is acquired under awards; loans, notes, and other debt instruments (even if considered tangible for other purposes); lease agreements; and stock and other instruments of property ownership. The term excludes copyrights, patents, and other intellectual property that are generated or developed, rather than acquired, under awards.
international organization	An organization that identifies itself as international or intergovernmental and has membership from, and represents the interests of, more than one country, without regard to whether the headquarters of the organization and location of the activity are inside or outside of the United States.
invention	Any discovery that is or may be patentable or otherwise protectable. The term "subject invention" means any invention of an awardee conceived or first actually reduced to practice in the performance of work under a funding agreement, i.e., contract, grant, or cooperative agreement.
key personnel	The PI/PD and other individuals who contribute to the programmatic development or execution of a project or program in a substantive, measurable way, whether or not they receive salaries or compensation under the grant.
local government	A county, municipality, city, town, township, local public authority (including any public and Indian housing agency), school district, special district, intra-State district, council of governments (whether or not incorporated under State law), any other regional or interstate government entity (such as regional planning agencies), or any agency or instrumentality of a local government. The term does not include institutions of higher education and hospitals.
matching or cost sharing	The value of third-party in-kind contributions and the portion of the costs of a federally assisted project or program not borne by the Federal government. Costs used to satisfy matching or cost-sharing requirements are subject to the same policies governing allowability as other costs under the approved budget.
misconduct in science	See "research misconduct."
monitoring	A process in which a grant's programmatic performance and business management performance are assessed by reviewing information gathered from various required reports, audits, site visits, and other sources.
non-competing extension	A limited period of time beyond the end of the project period, authorized by an OPDIV or a recipient under an expanded authority, needed to complete project activities.
non-Federal share	The portion of allowable project costs not borne by the Federal government.
objective review	An advisory review of discretionary grant applications conducted by unbiased reviewers with expertise in the programmatic area for which applications are submitted.
obligations	The amounts of orders placed, contracts and subawards, goods and services received, and similar transactions by a recipient during a budget period that will require payment during the same or a future budget period.

outlays or expenditures	The charges made to the federally sponsored project or program. They may be reported on a cash or accrual basis.
patent	A property right awarded by the Federal government whereby the government grants the right to exclude others from making, using, or selling the invention for a period of years.
peer review	A form of objective review, generally required by statute, in which the assessment of scientific or technical merit of applications is carried out by individuals with knowledge and expertise equivalent (peer) to that of the individuals whose applications for support they are reviewing.
pre-award costs	Costs incurred prior to the beginning date of the project period, in anticipation of an award and at the applicant's own risk, for otherwise allowable costs.
prior approval	Written consent or issuance of an award by the OPDIV GMO in response to a written request from the recipient to incur a specific direct cost or take other action that requires such approval (as specified in Part II of the HHS GPS). If the costs or other actions are specifically identified in an application, approval of the application, and issuance of an award based thereon, constitutes such authorization. Prior approval for components of indirect costs must be obtained from the cognizant agency or as specified in the applicable cost principles.
profit	See "fee."
program income	Gross income earned by a recipient that is directly generated by the grant-supported project, program, or activity or earned as a result of the award.
progress report	Periodic, usually annual, reports submitted by the recipient and used by the OPDIV to assess progress and, except for the final progress report, to determine whether to provide funding for the budget period subsequent to that covered by the report.
project or program costs	The total allowable costs incurred by a recipient (and the value of in-kind contributions made by third parties) in accomplishing the objectives of the award during the project period.
project period	The total time for which support of a project has been programmatically approved. The total project period comprises the initial competitive segment, any subsequent competitive segments resulting from a competing continuation award, and any non-competing extensions.
real property	Land, including land improvements, structures, and appurtenances, but not movable machinery and equipment.
reasonable cost	A cost whose nature or amount does not exceed that which would be incurred by a prudent person under the circumstances prevailing when the decision was made to incur the cost.
recipient	The organization or individual that receives a grant or cooperative agreement award from an OPDIV and is responsible and accountable for the use of the funds provided and for the performance of the grant-supported project or activity. The recipient is the entire legal entity even if a particular component is designated in the NoA. The term includes "grantee."
reimbursement	A payment made to a recipient upon its request after it makes cash disbursements. Most reimbursement payments are processed through the Payment Management System (PMS), the Department's centralized grants payment system.

research	A systematic, intensive study intended to increase knowledge or understanding of the subject studied, a systematic study specifically directed toward applying new knowledge to meet a recognized need, or a systematic application of knowledge to the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements. Also termed "research and development."
research misconduct	Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. The term does not include honest error or differences of opinion.
research patient care	Routine and ancillary services provided by hospitals to patients participating in research programs. The costs of these services are normally assigned to individual research projects through the development and application of research patient care rates or amounts (collectively referred to as "rates").
significant rebudgeting	A threshold that is reached when expenditures in a single direct cost budget category deviate (increase or decrease) from the approved budget amount for that budget category for that budget period by a specified amount, usually more than 25 percent of the total costs awarded. Significant rebudgeting is one indicator of change in scope.
small business concern	A business that is independently owned and operated and not dominant in its field of operation; has its principal place of business in the United States and is organized for profit; is at least 51 percent owned or, in the case of a publicly owned business, at least 51 percent of its voting stock is owned by U.S. citizens or lawfully admitted permanent resident aliens; has, including its affiliates, not more than 500 employees; and meets other regulatory requirements established by the SBA at 13 CFR 121.
State government	The government of any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any U.S. territory or possession, or any agency or instrumentality of a State exclusive of local governments. State institutions of higher education and State hospitals are not considered State governments for purposes of the HHS general administrative requirements for grants and the HHS GPS.
stipend	A payment made to an individual under a fellowship or training grant in accordance with established levels to provide for the individual's living expenses during the period of training. A stipend is not considered compensation for the services expected of an employee.
subaward	Financial assistance in the form of money or property in lieu of money provided under an award by a recipient to an eligible subrecipient (or by an eligible subrecipient to a lower-tier subrecipient). The term includes financial assistance when provided by any legal agreement, even if the agreement is called a contract, but does not include either procurement of goods or services or, for purposes of this policy statement, any form of assistance other than grants and cooperative agreements. The term includes consortium agreements.
subrecipient	An entity that receives a subaward from a recipient or another subrecipient under an award of financial assistance and is accountable to the recipient or other subrecipient for the use of the Federal funds provided by the subaward.

substantive programmatic work	The primary project activities for which grant support is provided.
supplies	Personal property other than equipment, intangible property, and debt instruments. The category of "supplies" includes items that could be considered equipment, but do not meet the threshold definition.
suspension	Temporary withdrawal of a recipient's authority to obligate grant funds, pending either corrective action by the recipient, as specified by the OPDIV, or a decision by the OPDIV to terminate the award. This meaning of the term "suspension" differs from that used in conjunction with the debarment and suspension process.
tangible property	Equipment, supplies, and any other property other than that defined as intangible property. It also does not include copyrights, patents, and other intellectual property that is generated or developed (rather than acquired) under an award.
termination	Permanent withdrawal by the OPDIV of a recipient's authority to obligate previously awarded grant funds before that authority would otherwise expire, including the voluntary relinquishment of that authority by the recipient.
terms and conditions of award	All legal requirements imposed on a grant by the OPDIV, whether based on statute, regulation, policy, or other document referenced in the NoA, or specified by the NoA itself. In addition to general terms and conditions, the NoA may include other conditions that are considered necessary to attain the award's objectives, facilitate post-award administration, conserve grant funds, or otherwise protect the Federal government's interests.
third-party in-kind contributions	The value of non-cash contributions directly benefiting a grant-supported project or program that is provided by non-Federal third parties to the recipient, the subrecipient, or a cost-type contractor under the grant or subgrant without charge. In-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and goods and services directly benefiting and specifically identifiable to the project or program.
total project or program costs	The total allowable costs (both direct and indirect) incurred by the recipient to carry out a grant-supported project or activity. Total project or program costs include costs charged to the award and costs borne by the recipient to satisfy a matching or cost-sharing requirement.
unallowable cost	A cost specified by law or regulation, Federal cost principles, or term and condition of award that may not be reimbursed under a grant or cooperative agreement
unliquidated obligations	The amount of obligations incurred by the recipient that has not been paid (for financial reports prepared on a cash basis) or the amount of obligations incurred by the recipient for which an outlay has not been recorded (for reports prepared on an accrual basis).
unobligated balance	The portion of the funds authorized by the Federal agency that has not been obligated by the recipient.
vertebrate animal	Any live animal having a backbone or spinal column used or intended for use in research, research training, experimentation, biological testing, or related purposes.
withholding of payment	An action taken by an OPDIV, after appropriate administrative procedures have been followed, that restricts a recipient's ability to access its grant funds until the recipient takes corrective action required by the OPDIV.

withholding of support	A decision by an OPDIV not to make a non-competing continuation award within a previously approved project period.
woman-owned business	A business that is, at least, 51 percent owned, controlled, and operated by a woman or women.

Index

Page references containing an *n* refer to footnotes.
Pages references preceded by B refer to definitions

A

B

C

D

E

F

G

H

I

J

K

L

M

N

O

P

R

S

T

U

V

W

Exhibit F

Project Scope and Approved Subrecipient Budget

Disparate population of focus: The disparate population of focus will be white males. These individuals carry the bulk of the burden of disease in Boone County. In 2021, Whites accounted for 91% of the drug overdose fatalities in the central region of Missouri. Over that same period and region, males accounted for 65% of overdose fatalities 3 . Reaching this population with services and outreach will be key to reducing the overall burden of drug overdose fatalities in our community. The data sources for this project will include DHSS databases and primary data collected by the Community Paramedics and MU Hospital system.

Objectives and Activities

Objective 1. Provide resources to support the purchase and distribution of naloxone by first responders and submit a plan for education and distribution to the City within the first 5 months of the federal award.

Activity 1.1 Secure mechanism to purchase naloxone for first responders.

Activity 1.2 Develop a Naloxone Education and Distribution Plan for submission to the City within the first 5 months of the award.

Objective 2. Train first responders on carrying and administering naloxone, and safety measures around fentanyl and other drugs associated with overdoses

Activity 2.1 Train first responders in Boone County on the administration of naloxone, laws protecting those who administer naloxone, and circumstances leading to disparity in unequal administration of naloxone.

Activity 2.2 Provide education about fentanyl and other drugs with potential overdose risk. First responders will receive information on safe handling of drugs based on best practice evidence.

Objective 3. Create county-wide policies and provide resources for other community entities to establish policies for the implementation of evidence-based trauma-informed care practices, and mechanisms for referral to appropriate treatment for follow-up services to those at risk for overdose

Activity 3.1.1 Develop policies for adequate training of community paramedicine professionals for comprehensive community care including evidence-based trauma-informed care.

Activity 3.1.2 Create a county-wide community paramedic program to provide more comprehensive services to those who most need it. Community paramedicine professionals will respond to patients at risk for overdose and their loved ones. Community paramedics will be dispatched to the scene of the incident along with first responders. They will provide medical attention, if needed, and stay on scene with the patient and their families to provide them with education and resources for next steps. This model allows the 9-1-1-dispatched first responders to return to emergency service as quickly as the patient is stable. This also prevents unnecessary and costly emergency transport to the hospital potentially far away from home.

Activity 3.2 When the county-wide community paramedic program is implemented, develop mechanisms of treatment referral for persons at risk for drug overdose.

Objective 4. Expand the established advisory committee.
Activity 4.1 A representative from the community paramedic program will attend Boone County Overdose Response Coalition (BCORC)I meetings.

Objective 5. Hire staff that represent the population of the community. Positions funded by this agreement include the following: 3.0 FTE Community Paramedics; 1.0 Paramedic Evaluator
Activity 5.1 Hire staff that represent the diverse population of the community.

Objective 6. Translate tools and resources available to recipients of services
Activity 6.1 Information and education resources developed through this program will be translated for the most accessible use of the materials.

Objective 7. Develop strategies to provide, increase, or enhance access to services for people of all racial/ethnic/marginalized groups in the community
Activity 7.1.1 Ensure that all persons receive care appropriate for them, including referral services like OUD/SUD treatment programs, behavioral health, and other public health services.
Activity 7.1.2 Develop and maintain a common referral system so all people are able to have access to care and services.
Activity 7.1.3 Refer patients to the PHHS DIVERT program for additional services and follow-up as needed.

Objective 8. Create conflict and grievance resolutions processes that are culturally and linguistically appropriate
Activity 8.1 Working with the expanded BCORC, there will be development of a grievance resolution process for those who need it. The process will be culturally and linguistically appropriate.

Data Collection
Collect required data from participants including data necessary to report to SAMHSA. Including, but not limited to:

- Number of individuals provided naloxone
- Number of individuals who encountered a Community Paramedic due to an overdose response
- Number of referrals made to resources and programs
- Number of individuals served at 200% or more of the poverty level
- Number of individuals served by race and gender
- Number of Community Outreach or Educational Events supported by a Community Paramedic or other Community Paramedic Program Staff, including specific events intended to reach White males
- Number of Community Paramedics
- Number of people trained in administering Naloxone

- Number of partners engaged to provide services, after a Community Paramedic's encounter

Performance Indicators

- By September 29, 2024, administer Naloxone in response to an EMS call to 73 White males. This activity will be monitored and updated quarterly as data is collected, it is expected more will be served than this initial amount.
- By September 29th, 2024, distribute 180 boxes of Naloxone through community outreach and individual education, with at least 25% having the intent to be provided to White populations. This activity will be monitored and potentially updated quarterly as data is collected, it is expected more will be served than this initial amount.
- By September 29th, 2024, make 25 referrals to EPICC and other social services or mental health resources for White males. The number of referrals is expected to increase in subsequent grant years as the program is more accepted among partners and patients. This activity will be updated annually.
- By September 29th, 2025, participate in 24 outreach and education community events with 6 held in White population areas. Community Paramedic program staff will participate in 12 outreach and education community events annually for the remainder of the grant period.
- By September 29th, 2025, train 600 individuals in the administration of naloxone, with efforts to reach White male individuals. Community Paramedic program staff and PHHS staff will train individuals in the administration of naloxone to 400 individuals annually for the remainder of the grant period.

Reporting Requirements

-Collect and report certain data so that SAMHSA can meet its obligations under the Government Performance and Results (GPRA) Modernization Act of 2010.
-Report performance data quarterly on the fiscal quarter to the City. These GPRA data are collected and reported by the City using SAMHSA's Performance Accountability and Reporting System (SPARS). Reports need to be completed 7 days prior to the SPARS due dates below to allow the City time for final review and submission.

City will be required to submit these data quarterly:

- Submit data on activities from October 1 through December 31 by January 31
- Submit data on activities from January 1 through March 30 by April 30
- Submit data on activities from April 1 through June 30 by July 31
- Submit data on activities from July 1 through September 30 by October 31

*The approved Quarter 4 report must be uploaded into eRA Commons by December 28, 2024. This requirement extends to all years of the grant program.

Programmatic Progress Report
By 4/1/2024 and 12/1/2024 provide the City

- Progress achieved in the project, including qualitative and quantitative data (GPRA) to demonstrate programmatic progress and updates on required activities, successes, challenges, and changes or adjustments that have been made to the project;
- Progress addressing quality care of underserved populations related to the Disparity Impact Statement (DIS);
  Barriers encountered, including challenges serving populations of focus;
- Efforts to overcome these barriers;
- Evaluation activities for tracking DIS efforts.

By 04/30/2024 & 12/28/2024, the City will submit a progress report to SAMSHA on project performance at the midpoint of Year -01 within 30 days of the end of the second quarter and annually within 90 days of the end of each 12-month budget period (two reports will be required in Year 1 and one report will be required at the completion of each year thereafter).

A final performance report must be submitted to the City within 60 days after the end of the project period. The final performance report must be cumulative and report on all activities during the entire project period.

Provide any information necessary for the City to complete required SAMHSA reports throughout the contract period.

Other requirements
Maintain confidential records.

If necessary, comply with the Protection of Human Subjects Regulations (45 CFR 46), which requires Institutional Review Board (IRB) approval.

Budget

Personnel	$340,268
Fringe	$102,081
Travel/mileage	$12,000
Total	$454,349

Exhibit G

Subrecipient Name	The Curators of the University of Missouri
Subrecipient Unique Entity Identifier:	SZPJL5ZRCLF4
Federal Award Identification Number (FAIN):	H79TI086392
Federal Award Date of Award to the Recipient by the Federal Agency:	08/07/2023
Subaward Period of Performance Start Date:	Effective Date
Subaward Period of Performance End Date:	September 29, 2024
Amount of Federal Funds Obligated by this Action by the Pass-Through Entity to the Subrecipient:	$454,349
Total Amount of Federal Funds Obligated to the Subrecipient by the Pass-Through Entity Including the Current Obligation:	$454,349
Total Amount of the Federal Award Committed to the Subrecipient by the Pass-Through Entity:	$454,349
Federal Award Project Description:	Boone County Paramedic Program
Name of Federal Awarding Agency:	Department of Health and Human Services
Name of Pass-Through Entity:	City of Columbia, Missouri
Contact Information for City of Columbia Authorizing Official:	Andrew Wyatt Andrew.wyatt@como.gov
Contact Information for City Project Manager:	Michelle Shikles Michelle.shikles@como.gov
Assistance Listing Number and Name:	93.243 Substance Abuse and Mental Health Services_Projects of Regional and National Significance
Identification of Whether Subaward is R&D:	Not R&D
Subrecipient Indirect Costs:	See Exhibit F– Budget Section