

PARTICIPATION AGREEMENT

Project SPEED – Nurse-Driven LAI-CAB PrEP Implementation Study

This Participation Agreement (“Agreement”) is entered into on the date of the last signatory noted below (hereinafter “Effective Date”), by and between:

Kansas City CARE Clinic d/b/a KC CARE Health Center

3515 Broadway Blvd

Kansas City, MO 64111

(“KC CARE” or “Lead Institution”)

and

City of Columbia, Missouri

Public Health and Human Services Department

P.O. Box 6015

Columbia, MO 65205-6015

(“LPHD” or “Participating Site”).

KC CARE and LPHD may be referred to individually as a “Party” and collectively as the “Parties.”

1. PURPOSE

The purpose of this Agreement is to define the roles, responsibilities, and obligations of the Parties in connection with participation in Project SPEED (Streamlined Protocol for Early

Engagement and Delivery of HIV Prevention with Long-acting Injectable Cabotegravir), a Phase IV, investigator-sponsored implementation science study evaluating a nurse-driven PrEP delivery model in Missouri Local Public Health Departments (“Study”).

2. STUDY OVERSIGHT

2.1 Principal Investigators

The Study is led by:

- Blair Thedinger, MD, AAHIVS (KC CARE)
- Dima Dandachi, MD, MPH, FIDSA (Health Expeditions LLC)

2.2 Regulatory Oversight

The Study will be conducted in accordance with:

- The approved Study Protocol (Version 1.1 or subsequent IRB-approved versions)
- Applicable federal and state laws and regulations
- Good Clinical Practice (GCP), where applicable
- Institutional Review Board (“IRB”) requirements

3. TERM

This Agreement shall commence on the Effective Date and remain in effect for the duration of the Study, anticipated to be up to 24 months, unless terminated earlier in accordance with Section 14.

4. RESPONSIBILITIES OF KC CARE

KC CARE agrees to:

4.1 Serve as the Lead Institution and coordinating center for Project SPEED.

4.2 Provide:

- Study protocol, training materials, workflows, and implementation guidance
- RN training and education related to PrEP delivery and LAI-CAB administration
- Standing order templates and collaborative practice frameworks
- Data collection tools, surveys, and implementation instruments
- Ongoing technical assistance and facilitation

4.3 Coordinate:

- Specialty pharmacy partnerships
- Stakeholder engagement meetings
- Data analysis and reporting

4.4 Ensure:

- IRB approval is obtained and maintained
- Adverse event reporting pathways are clearly communicated
- Study monitoring and data integrity oversight

5. RESPONSIBILITIES OF LPHD

LPHD agrees to:

5.1 Study Participation

- Participate in Project SPEED as assigned through cluster randomization (intervention or current practice arm)
- Implement study procedures consistent with the Study Protocol

5.2 Staffing and Clinical Operations

- Designate sufficient staff (including at least one Registered Nurse) to carry out study-related activities

- Ensure participating staff complete required study training
- Integrate the study protocol into clinic workflows, as applicable

5.3 Clinical Activities (Intervention Sites Only)

- If randomized to the SPEED intervention arm, LPHD agrees to:
 - Allow trained RNs to assess PrEP eligibility under protocol
 - Medication procurement processes (benefits verification, shipping logistics)
 - Administer LAI-CAB injections per protocol and prescribing information
 - Perform required testing (HIV, STI, hepatitis, labs) per protocol
 - Provide vaccinations per ACIP guidelines when clinically indicated

5.4 Data Collection and Documentation

- Accurately document study-related activities in medical records
- Complete required study forms, surveys, and reports
- Allow secure transmission of de-identified data to KC CARE

5.5 Compliance

- Conduct all activities in compliance with applicable laws, regulations, and IRB requirements
- Promptly report adverse events, protocol deviations, or compliance concerns to KC CARE

6. FINANCIAL SUPPORT AND BUDGET

6.1 KC CARE shall provide financial support to LPHD in accordance with the Site-Specific Budget, attached as Addendum A.

6.2 Funds may be used only for allowable study-related costs, including:

- Personnel time
- Supplies

- Administrative support
- Participant engagement activities

6.3 LPHD agrees to maintain adequate documentation of expenses and provide financial reports upon request.

7. NO COST TO PARTICIPANTS

LPHD shall not charge participants any additional fees for participation in the Study beyond standard clinical care charges.

8. CONFIDENTIALITY AND DATA SECURITY

8.1 Each Party shall protect confidential and proprietary information, including Protected Health Information (PHI), in accordance with HIPAA and applicable state laws.

8.2 Only de-identified or IRB-approved limited datasets shall be shared with KC CARE unless otherwise authorized.

9. DATA OWNERSHIP AND PUBLICATIONS

9.1 Study data shall be jointly used for research and public health purposes.

9.2 KC CARE shall lead data analysis and dissemination efforts.

9.3 LPHD staff may be acknowledged or included as collaborators on publications consistent with contribution and authorship standards.

10. INTELLECTUAL PROPERTY

No new intellectual property is anticipated. Any materials developed specifically for Project SPEED may be used by LPHD for public health purposes following study completion.

11. INDEMNIFICATION

Each Party shall be responsible for the acts and omissions of its own employees and agents to the extent permitted by Missouri law. 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.

12. INSURANCE

Each Party represents that it maintains appropriate insurance or self-insurance coverage consistent with its obligations under this Agreement.

13. INDEPENDENT CONTRACTORS

The Parties are independent contractors. Nothing in this Agreement creates an employment, partnership, or joint venture relationship.

14. TERMINATION

14.1 Either Party may terminate this Agreement with 30 days written notice.

14.2 KC CARE may terminate immediately for:

- Failure to comply with the protocol
- Loss of IRB approval
- Material breach of this Agreement

15. GOVERNING LAW

This Agreement shall be governed by the laws of the State of Missouri.

16. 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.

17. ENTIRE AGREEMENT

This Agreement, including Addendum A (Budget), constitutes the entire agreement between the Parties and may be amended only in writing signed by both Parties.

18. SIGNATURES

Kansas City CARE Clinic

Signature: DocuSigned by: Leslie Hardin
AA13EBC08B874CB

Name: Leslie Hardin

Title: Chief Operating Officer

Date: 2/20/2026

City of Columbia, Missouri

DK Signature: _____

Name: De'Carlton Seewood

Title: City Manager

Date: _____

ATTEST:

By: _____

Sheela Amin, City Clerk

APPROVED AS TO FORM:

By: _____

Nancy Thompson, City Counselor/bt