PROJECT REQUEST

Project Stage

Choose one by selecting a checkbox:

☒ **New:** Fill out entire form, even if a protocol is attached (approval is for work by CDC/NCHHSTP employees).

☐ **Continuation:** For projects expected to continue beyond NCHHSTP approved date; include brief description of changes and attach clean and marked copies of approved determination (approval is for continued work by CDC/NCHHSTP employees).

☐ **Amendment:** Include brief description of changes and attach clean and marked copies of approved determination (approval is for continued work by CDC/NCHHSTP employees).

Project Information:

Project Title: Project PrIDE [PS15-1506: Health Department Demonstration Projects to Reduce HIV Infections and Improve Engagement in HIV Medical Care among Men Who Have Sex with Men (MSM) and Transgender Persons]

NCHHSTP Project Number: PS15-1506

Project Location/Country(ies): Division of HIV/AIDS Prevention/Prevention Research Branch

CDC Project Officer or CDC Co-Leads: Cynthia Prather and Mary Neumann

Division: Division of HIV/AIDS Prevention

Telephone: 404-639-5234 / 404-639-1928

Project Dates:
Start 9/30/2015
End 9/29/2018

Laboratory Branch Submission:
If applicable, select the checkbox: ☐

Project Categories

Select the corresponding checkbox to choose the category and subcategory.

☐ I. **Activity is not human subject research.** The primary intent of the project is public health practice or a disease control activity.

- ☐ A. Epidemic or endemic disease control activity; collected data directly relate to disease control. If this project is an Epi-AID; provide the Epi-AID number and documentation of the request for assistance, per division policy. Epi-AID no.
- ☐ B. Routine disease surveillance activity; data will be used for disease control program or policy purposes.
- ☐ C. Program evaluation activity; data will be used primarily for that purpose.
- ☐ D. Postmarketing surveillance of effectiveness or adverse effects of a new regimen, drug, vaccine, or

device.

☐ E. Laboratory proficiency testing.

☒ II. Activity is not human subjects research. The primary intent is public health program activities.

☒ A. Public health program activity (e.g., service delivery; health education programs; social marketing campaigns; program monitoring; electronic database construction or support; development of patient registries; needs assessments; and demonstration projects to assess organizational needs, management, and human resource requirements for implementation).

☐ B. Activity is purely administrative (e.g., purchase orders or contracts for services or equipment).

☐ III. Activity is research but does NOT involve identifiable human subjects.

☐ A. Activity is research involving collection or analysis of data about health facilities or other organizations or units (i.e., not individual persons.)

☐ B. Activity is research involving data or specimens from deceased persons.

☐ C. Activity is research using unlinked or anonymous data or specimens: ALL (1–4) below are required:

☐ 1. No one has contact with human subjects in this project; and

☐ 2. Data or specimens are or were collected for another purpose; and

☐ 3. No extra data or specimens are or were collected for this project; and

☐ 4. Identifying information was (one of the following boxes must be checked)

☐ a. not obtained;

☐ b. removed before this submission, or before CDC receipt, so that data cannot be linked or re-linked with identifiable human subjects; or

☐ c. protected through an agreement (i.e., CDC investigators and the holder of the key linking the data to identifiable human subjects enter into an agreement prohibiting the release of the key to the investigators under any circumstances. A copy of the agreement must be attached.)

☐ IV. Activity is research involving human subjects, but CDC involvement does not constitute "engagement in human subject research." Select only one option by checking the box: A indicates the project has current funding; B or C indicates no current funding is applicable.

☐ A. This project is funded under a grant, cooperative agreement, or contract award mechanism. ALL of the following 3 elements are required:

☐ 1. CDC staff will not intervene or interact with living individuals for research purposes.

☐ 2. CDC staff will not obtain individually identifiable private information.

☐ 3. Supported institution(s) must have a Federalwide Assurance (FWA), and the project must be

reviewed and approved by a registered IRB or an institutional office linked to the supported institution's FWA.*

Supported institution of primary investigator or co-investigators/entity name:* Click to add your answer. The space will expand as you type.

Supported institution/entity FWA Number:* Click to add your FWA number.

FWA expiration date:* Click to add FWA expiration date.

Expiration date of IRB approval:* Click to add IRB expiration date.

***Attach copy of IRB approval letter(s) supporting project review and approval.**

☐ **B.** CDC staff provide technical support that does not involve possession or analysis of data or interaction with participants from whom data are being collected (no current CDC funding).

☐ **C.** CDC staff are involved only in manuscript writing for a project that has closed. For the project, CDC staff did not interact with participants and were not involved with data collection (no current CDC funding).

Project Description

Participating project staff must complete all 18 elements of this section.

This is a required description from CDC employees or staff for review and approval of a project plan or proposal (or for changes) for projects conducted by CDC or in which CDC is involved. All 18 elements are required to standardize the review and approval process across NCHHSTP, document that all 18 elements have been addressed, expedite review and approval by the NCHHSTP ADS or ADLS office, and minimize CDC/OD/ADS office audit requests for additional information. A protocol may be attached to this form, but it does not eliminate the requirement to complete all 18 elements.

PROJECT TITLE: Project PrIDE

Instructions: Use the following boxes to complete the 18 items. Each box will expand as you type, and you are not limited in the length of your answers. Formatting features and symbols also may be used.

1. CDC Principal Investigator(s) or Project Directors and branch/division/office affiliations:

2. CDC Project Officer(s) and each person's role and responsibilities and affiliations:

Cynthia Prather, (NCHHSTP/DHAP/PRB), PrIDE Lead Project Officer and Mary Neumann, (NCHHSTP/DHAP/PRB), PrIDE Co-Lead Project Officer: Lead project team and coordinate technical and fiscal oversight for the entire project

3. Other CDC project members, branches, divisions, and other participating institutions, partners, and staff:

PRB: Stephen Flores, Cari Courtenay-Quirk, Deb Gelaude, Yamir Salabarria-Pena, Pilgrim Spikes, Damian Denson, Daryl Higa, Linda Koenig

PEB: Tamika Hoyte, Shubha Rao, Sam Dooley, Aba Essuon

PPB: Dwayne Banks, Donato Clarke, George Hill, Laura Kearns, Stacey Muckleroy, Audrey Moffitt, Kevin Ramos, Shuenae Smith, Melissa Thomas-Proctor

HICSB: Kristen Hess, Sonia Singh, Omar Whiteside, Qian An, Eduardo Valverde, Alexa Oster, Benjamin Laffoon

EB: Kashif Iqbal, Cal Ham, Dawn Smith

CBB: Kathleen Green, Vasavi Thomas

OHE: Lamont Scales, MA

4. Institution(s) or other entity(ies) funding the project:

Centers for Disease Control and Prevention

5. Project goals:

Support health departments in the U.S. to implement Pre-Exposure prophylaxis (PrEP) and Data to Care demonstration projects prioritizing MSM and transgender persons at high risk for HIV infection, particularly persons of color, recognizing that the population with the highest incidence of HIV in the U.S. is young Black MSM. PrEP (marketed as Truvada®) is an antiretroviral medication that is proven to significantly reduce the risk of HIV acquisition among sexually active adults. Data to Care" is a strategy for identifying, engaging and re-engaging persons living with HIV who are not in HIV medical care. Data to Care uses laboratory reports received by a health department's HIV surveillance program, and a range of other data sources as markers of HIV care, analyzes these reports to confidentially identify HIV-diagnosed individuals who are not engaged in HIV medical care or have not achieved viral suppression. Once clients are engaged or re-engaged into HIV care, they are offered antiretroviral medication to suppress their HIV-1 viral load, improve health outcomes and reduce transmission risk among people living with HIV (PLWH).

6. Project objectives:

Category 1: Implement PrEP demonstration projects to: (1) increase the number of MSM and transgender persons requesting PrEP for HIV prevention; (2) increase the number who are prescribed PrEP and (3) reduce the number of new HIV infection among MSM and transgender persons.

Category 2: Implement Data to Care demonstration projects to: (1) increase the percentage of MSM and transgender persons diagnosed with HIV who are engaged in care (2) increase the percentage of MSM and transgender persons diagnosed with HIV who have a suppressed viral load (3) reduce the number of new HIV diagnoses among MSM and transgender persons and (4) increase survival of MSM and transgender persons diagnosed with HIV.

7. Public health (program or research) needs to be addressed:

Category 1: PrEP Support Demonstration Projects Targeting MSM and Transgender Persons at Substantial Risk of Acquiring HIV: This project will support activities to strengthen or enhance the ability to identify MSM and transgender persons who stand to benefit the most from PrEP, refer appropriate candidates to PrEP providers in the jurisdiction, and increase the number of providers knowledgeable and capable of offering PrEP to MSM and transgender persons at high risk for HIV infection, particularly persons of color. PrEP-related activities must be implemented as part of a comprehensive HIV prevention program that includes, when indicated, referral to prevention, screening and treatment services for STD, viral hepatitis, substance abuse, and mental health services

Category 2: Data to Care Demonstration Projects that use Surveillance data sources to identify MSM and Transgender persons not in HIV care: This project will support activities that expand or enhance their ability to use HIV surveillance data and other data sources, as appropriate, to improve clinical outcomes along the HIV continuum of care for MSM and transgender persons.

8. Population(s) or groups to be included:

The PrIDE Demonstration projects will prioritize men who have sex with men and transgender persons at high risk for HIV infection, particularly persons of color and MSM and TG persons who are HIV-diagnosed.

9. Project methods:

Project PrIDE supports health departments to implement PrEP and Data to Care demonstration projects and therefore, has no research methods. Specific activities for grantee's funded to implement Category 1: PrEP will strengthen or enhance the jurisdiction's ability to identify MSM and transgender persons who stand to benefit the most from PrEP, and include referring appropriate candidates to PrEP providers in the jurisdiction, and increasing the number of providers knowledgeable and capable of offering PrEP to MSM and transgender persons at high risk for HIV infection, particularly persons of color. Activities for grantee's funded to implement Category 2: Data to Care will support expanding or enhancing their ability to use HIV surveillance data and other data sources, as appropriate, to improve clinical outcomes along the HIV continuum of care for MSM and transgender persons.

Activities for both categories [Category 1: PrEP Implementation and Category 2: Data to Care] may include creating new or expand existing partnerships with community-based organizations, LGBT organizations, private health care providers, clinics and community health centers including STD clinics that serve MSM and transgender persons; identifying and convening Community Advisory Boards to inform program planning and implementation processes; developing provider buy-in and support; develop local evaluation framework for activities; and assuring compliance with CDC/NCHHSTP Security and Confidentiality Guidelines across all programs and reviewing state and local laws and regulations affecting collection and use of HIV surveillance
Data (for data to care).

10. Selection, inclusion, or sampling of participants (persons or entities):

Not applicable

11. Incentives to be provided to participants:

Not applicable

12. Plans for data collection and analysis:

The PrIDE Monitoring and Evaluation plan will involve process and outcome data across the 12 funded jurisdictions. Grantees are expected to allocate up to 10% of their total budget to local evaluation. Program performance will be assessed using short and intermediate outcome measures. CDC will work collaboratively with grantees to develop key evaluation questions, establish relevant measures, and identify data sources for routine reporting.

13. Confidentiality protections:

Grantees are expected to assure compliance with the CDC/NCHHSTP Security and Confidentiality Guidelines across all programs.

14. Other ethics concerns (e.g., incentives, risks, privacy, or security):

Not applicable

15. Projected time frame for the project:

September 30, 2015 – September 29, 2018

16. Plans for publication and dissemination of the project findings:

Plans for publications and dissemination of project findings will be prepared in conjunction with project officers and shared via the PrIDE website, conferences, peer-reviewed and other publications and other reports. Peer-reviewed publications will be in line with the PrIDE publication agreement developed by the Pr IDE team.

17. Appendices — including informed consent documents, scripts, data collection instruments, focus group guides, fact sheets, or brochures:

Not applicable

18. References (to indicate need and rationale for project):

The following are some references included in the FOA:
Grant RM, Lama JR, Anderson PL, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. N Engl J Med. Dec 30 2010;363(27):2587-2599.

Grant, RM., Anderson PL, McMahan V, et al. "Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: a cohort study." The Lancet infectious diseases. 2014. Doi: 10.1016/S1473-3099(14)70847-3.

Herbst JH, Jacobs ED, Finlayson TJ, et al. Estimating HIV prevalence and risk behaviors of transgender persons in the United States: A systematic review. AIDS Behav. 2008;12:1-17.

Johnson AS, Hall HI, Hu X, Lansky A, Holtgrave DR, Mermin J. Trends in Diagnoses of HIV Infection in the United States, 2002-2011. JAMA. 2014; 312(4):432-434. doi:10.1001/jama.2014.8534.

Purcell D, Johnson CH, Lansky A, et al. Estimating the population size of men who have sex with men in the United States to obtain HIV and syphilis rates. The Open AIDS Journal 2012; 6:98–107.

Sevelius JM, et al. HIV/AIDS programming in the United States: Considerations affecting transgender women and girls. Women's Health Issues. 2011:21-6S; S278-S282.

Sweeney P, Gardner LI, Buchacz K, Garland PM, Mugavero MJ, Bosshart JT, et al. Shifting the paradigm: Using HIV surveillance data as a foundation for improving HIV care and preventing HIV infection. Milbank Quarterly 2013; 91: 558–603.

PROJECT APPROVAL

Choose one of the following options (Division or Center/OD Project)

☐ DIVISION PROJECT

NCHHSTP BRANCH AND DIVISION ADS REVIEW AND APPROVAL (Sign electronically by clicking next to the X and following the prompts)

X _____ Yuko Mizuno ACS

Branch Chief or Branch Science Officer

X _____

Division ADS, Acting ADS, or Deputy ADS

☐ CENTER/OD PROJECT

NCHHSTP OD OFFICE REVIEWS AND APPROVALS (Sign electronically by clicking next to the X and following the prompts)

X _____

Office Associate Director or Designee

X _____

NCHHSTP ADS or Designee

NCHHSTP ADS/Deputy ADS or ADLS Review and Approval

Project Title: Click to add your answer. The space will expand as you type.

Date received in NCHHSTP ADS or ADLS office: Click to add date ADS/ADLS office received. March 16, 2016

Date received by NCHHSTP Deputy ADS or ADLS: Click to enter date ADS/ADLS Deputy received.

Select the checkbox for each applicable comment for Nos. 1–5 or select the checkbox for No. 6 if all of the comments apply. Additional applicable comments may be added to No. 7. If additional information is required before approval can be granted, select No. 8.

☐ 1. This project is approved by NCHHSTP/CDC and CDC (per CDC policies and federal regulations) for CDC staff participation.

☐ 2. Participating partners and sites must obtain project review and approval, according to their institutional policies and procedures and according to local, national, and international regulations and laws, including 45 CFR 46 regulations and state laws. CDC project officers must maintain a current copy of local sites' approvals in project records.

☐ 3. CDC investigators and project officers need to adhere to the highest ethics standards of conduct and to respect and protect the privacy, confidentiality, autonomy, data, welfare, and rights of participants and integrity of the project. All applicable country, state, and federal laws and regulations must be followed.

☐ 4. Informed consent or script is needed as required by laws and regulations. Information conveyed in an informed consent or script process needs to address all applicable required elements of informed consent. Consent of employees in related projects about their institutions needs to include a statement that their voluntary participation or withdrawal would not affect their employment status or opportunities.

☐ 5. OMB Paperwork Reduction Act determination by the NCHHSTP OMB/PRA Coordinator might be needed for this project.

☐ 6. All previous comments apply.

☐ 7. **Other applicable comments:** Type your comment in the box. The space will expand as you type.

1–6 apply | Submit to NCHHSTP ADS office before Project initiation, copies of partner(s)' IRB/institutional approvals

☐ 8. **More information is required before approval is granted:** Explain what additional information is requested by typing in the box. The space will expand as you type.

Date Information was requested: Click to add date information requested

Date Information was received: Click to add date information received.

Approval must be granted by the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Associate Director for Science (ADS), Acting ADS, or Deputy ADS, or for laboratory-associated projects, by the Associate Director for Laboratory Science (ADLS) or Acting ADLS.

Project Title: Click to add your answer. The space will expand as you type.

March 18, 2016

X Salaam Semaan

NCHHSTP ADS, Acting ADS, or Deputy ADS

Or

X

NCHHSTP ADLS or Designee