Centers for Disease Control

National Center for HIV-AIDS, Viral Hepatitis, STD, and TB Prevention Extramural Research Program Office

Evaluation of Models of PrEP Service Delivery at Title X and STD Clinics

RFA-PS-17-004

Application Due Date: 01/17/2017

Evaluation of Models of PrEP Service Delivery at Title X and STD Clinics

RFA-PS-17-004

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Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control

Components of Participating Organizations

National Center for HIV-AIDS, Viral Hepatitis, STD, and TB Prevention Extramural Research Program Office (NCHHSTP ERPO)
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)

Funding Opportunity Announcement (FOA) Title

Evaluation of Models of PrEP Service Delivery at Title X and STD Clinics

Activity Code

U01 Research Project - Cooperative Agreement

Funding Opportunity Announcement Type

New

Funding Opportunity Announcement Number

RFA-PS-17-004

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.941
93.974

Category of Funding Activity:

Health

FOA Purpose

To evaluate the effectiveness and cost of three health services models of PrEP provision at Title X and sexually transmitted disease (STD) clinics located in communities with high rates of new HIV diagnoses. Model 1: PrEP services provided in the Title X or STD clinic. Model 2: Referral to a PrEP service provider in the community. Model 3: Navigator-assisted linkage to a PrEP service provider in the community.

Participating Organizations:

Centers for Disease Control and Prevention (CDC) http://www.cdc.gov/

Office of the Assistant Secretary for Health (OASH) http://www.hhs.gov/ash/

Components of Participating Organizations:

National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP/CDC) http://www.cdc.gov/nchhstp/Default.htm

Office of Population Affairs (OPA/OASH) http://www.hhs.gov/opa/

Key Dates

Publication Date: **To receive notification of any changes to RFA-PS-17-004, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.**

Letter of Intent Due Date: **12/14/2016**

Application Due Date: **01/17/2017**

On-time submission requires that electronic applications be error-free and made available to CDC for processing from eRA Commons on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov/eRA Commons no later than 5:00 PM U.S. Eastern Time. Note: HHS/CDC grant submission procedures do not provide a period of time beyond the application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

Scientific Merit Review: **02/21/2017**

Secondary Review: **03/22/2017**

Estimated Start Date: **07/01/2017**

Expiration Date: **01/18/2017**

Due Dates for E.O. 12372: **Due no later than 60 days after the application receipt date.**

Required Application Instructions

It is critical that applicants follow the instructions in the SF 424 (R&R) Application Guide except where instructed to do otherwise in this FOA. Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Note: The Research Strategy component of the Research Plan is limited to 25 pages.

Applications that do not comply with these instructions may be delayed or not accepted for review.

Telecommunications for the Hearing Impaired: TTY 1-888-232-6348

Executive Summary

- **Purpose:** To evaluate the effectiveness and cost of three health services models of preexposure prophylaxis (PrEP) provision at Title X and STD clinics located in communities with high rates of new HIV diagnoses. Model 1: PrEP services provided in the Title X or STD clinic. Model 2: Referral to a PrEP service provider in the community. Model 3: Navigator-assisted linkage to a PrEP service provider in the community.
- **Mechanism of Support:** Research Project - Cooperative Agreement (U01)
- **Funds Available and Anticipated Number of Awards:** The estimated total funding available, including direct and indirect costs, for the entire 4-year project period is $11,000,000. The estimated number of awards is one (1). Awards issued under this FOA are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded and the number of awards will depend upon the number, quality, duration and cost of the applications received.
- **Budget and Project Period:** The estimated total funding (direct and indirect) for the first year (12-month budget period) is $2,000,000 with individual awards ranging from $1,500,000 to $2,000,000 for the first year. The estimated total funding (direct and indirect) for the entire project

period is $11,000,000. The project period is anticipated to run from 07/01/17 to 06/30/21.

- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. "Application and Submission Information" of this announcement.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III.1 of this announcement are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.
- **Number of PDs/PIs.** There will only be one PD/PI for each application.
- **Number of Applications.** Only one application per institution (normally identified by having a unique DUNS number) is allowed.
- **Application Type.** New.
- **Special Date(s).** Not applicable.
- **Application Materials.** See Section IV.1 for application materials. Please note that Form D Research is to be used when downloading the application package. http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: 1-888-232-6348

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

Sections 301 and 318 of the Public Health Service Act [42 U.S.C. Sections 241 and 247(c)], as amended.

Section 1004 [42 U.S.C. §300a-2] of the Public Health Service Act.

1. Background and Purpose

Pre-exposure prophylaxis (PrEP) is the administration of a once daily pill (Truvada®) to reduce the risk for HIV acquisition. PrEP has been demonstrated to be a safe and highly effective HIV prevention strategy.

In recent years, the rate of new HIV diagnoses has remained stable in the United States. However, rates remain high among certain populations such as gay, bisexual, and other men who have sex with men (MSM) and persons who are black or African American. In addition, women accounted for 19% of new diagnoses in 2014. It is especially important to target young MSM and women in at-risk populations for HIV with linkage to HIV prevention and care services in order to ensure early, effective treatment for infection and to prevent new infections.

Title X clinics and STD clinics are ideal venues to identify persons at substantial risk of HIV acquisition, many of whom utilize sexual healthcare in these settings and could likely benefit from PrEP. It is estimated that in 2014, there were approximately as many heterosexual women (468,000) as MSM (492,000) with indications for PrEP in the United States. Although PrEP uptake remains low overall, it is particularly low among eligible women (Bush *et al.,* ASM/ICAAC, 2016 http://www.natap.org/2016/HIV/062216_02.htm). Women seeking care at Title X clinics are likely at higher risk of HIV acquisition than patients seen in other clinical settings, such as primary care. In 2015, 90% of the 4.0 million patients seen at Title X clinics were women, 66% had incomes at or below the federal poverty line, 67% were below the age of 30, 47% were non-white, and 32% were Hispanic. Approximately 1.8 million women were tested for chlamydia at Title X clinics in 2015, 1.9 million were tested for gonorrhea, and 444,000 were tested for syphilis. During that same year, 1.1 million men and women were tested for HIV at Title X clinics, of which 2,423 were positive

(0.22%).

In a recent study of persons who sought care in publicly-funded, urban STD clinics, among male patients, 49% were black, 21% were Hispanic, and 24% were MSM. Among female patients, 57% were black and 19% Hispanic. This study also found that 50% of persons seeking care in public STD clinics were uninsured, underscoring the importance of STD clinics as safety net providers for HIV testing and prevention services. STDs are important markers of behaviors that place individuals at increased risk for HIV acquisition. In New York City, among MSM without rectal gonorrhea or chlamydial infection, the annual HIV incidence was 2.5%, compared with 6.7% (more than 150% greater) among those diagnosed with rectal gonorrhea or chlamydial infections. In Florida, among women without a bacterial STD, the overall HIV diagnosis rate was 30 per 100,000 person years compared with 598 per 100,000 (more than 19 times higher) for women diagnosed with syphilis and 171 per 100,000 (more than 5 times higher) for women diagnosed with gonorrhea.

The United States Preventive Services Task Force and CDC recommend routine HIV testing for adults and adolescents. HIV testing is also recommended as part of routine prenatal care; however, between 15 to 16% of U.S. women are childless by age 40 and would not benefit from prenatal testing. For these women, and other populations at risk for HIV, an encounter in the Title X or STD clinic is a valuable opportunity to provide HIV testing. HIV testing then serves as a decision node for linkage to HIV care services for those who test positive, or risk assessment with PrEP as a prevention option for those who test negative.

Health Equity:

The program supports efforts to improve the health of populations disproportionately affected by HIV/AIDS, viral hepatitis, sexually transmitted diseases (STDs) and TB by maximizing the health impact of public health services, reducing disease prevalence, and promoting health equity consistent with the National HIV/AIDS Strategy available at https://www.whitehouse.gov/administration/eop/onap/nhas.

Health disparity is a particular type of health difference that is closely linked with social or economic disadvantage based on racial or ethnic group, religion, socioeconomic status, gender, mental health, cognitive, sensory, or physical disability, sexual orientation, geographic location, or other characteristics historically linked to discrimination or exclusion [HP 2020 - http://www.healthypeople.gov/2010/hp2020/advisory/PhaseI/glossary.htm]. Health disparities in HIV, viral hepatitis, STDs, and TB are inextricably linked to a complex blend of social determinants that influence which populations are most severely affected by these diseases.

Social determinants are the economic and social conditions that influence the health of individuals, communities and jurisdictions and include conditions for early childhood development; education, employment, and work; food security, health services, housing, income, and social exclusion.

Health equity is a desirable goal that entails special efforts to improve the health of those who have experienced social or economic disadvantage. It requires:

- Continuous efforts focused on elimination of health disparities, including disparities in health and in the living and working conditions that influence health, and
- Continuous efforts to maintain a desired state of equity after particular health disparities are eliminated.

Programs should use data, including social determinants data, to identify communities within their jurisdiction that are disproportionately affected by HIV, viral hepatitis, STDs and TB and related diseases and conditions, and plan activities to help eliminate health disparities. In collaboration with partners and appropriate sectors of the community, programs should consider social determinants of health in the development, implementation, and evaluation of program specific efforts and use culturally appropriate interventions that are tailored for the communities for which they are intended.

Healthy People 2020 and other National Strategic Priorities

This evaluation is designed to identify effective methods to increase access to, and use of, clinical HIV prevention services and aligns with the following strategic priorities:

- Healthy People 2020 goals: Reduce New Infections (HIV-2, HIV-3); Increase HIV Testing and Prevent Risk (HIV-9, HIV-13, HIV-14, HIV-18).
- National HIV/AIDS Strategy: Goal 1 [*Reducing New HIV Infections*]; Goal 3 [*Reducing HIV-related Disparities and Health Inequities*].
- CDC Winnable Battles Goal: Reduce HIV infections.

Public Health Impact

Developing best practices for implementing PrEP in Title X and STD clinics clinics will increase access to important HIV prevention clinical services for populations at substantial risk of acquiring HIV. Models will demonstrate best practices to link at-risk individuals to PrEP services and care.

Relevant Work

1. U.S. Public Health Service. Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United States- 2014, a Clinical Practice Guideline. http://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf

2. National HIV/AIDS Strategy. Office of National AIDS Policy. 2015. https://www.aids.gov/federal-resources/national-hiv-aids-strategy/nhas-update.pdf

3. Hall H. I., Song R., Rhodes P., Prejean J., An Q., *et al.* Estimation of HIV incidence in the United States. JAMA 2008;300:520-9.

4. CDC HIV Surveillance Report, 2014. (Accessed December 15, 2015, at http://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-us.pdf)

5. Hoover K.W., Parsell B.W., Leichliter J.S., Habel M.A., Tao G., *et al.* Continuing need for sexually transmitted disease clinics after the affordable care act. AJPH 2015;105.

6. Fowler, C. I., Gable, J., Wang, J., and Lasater, B. (2015, August). Family Planning Annual Report: 2014 National Summary. Research Triangle Park, NC: RTI International.

7. Martinez G., Daniels K., Chandra A. Fertility of Men and Women Aged 15-44 in the United States: National Survey of Family Growth, 2006-2010. National Health Statistics Reports 2012; 51: 1-27.

8. Monte L.M., Ellis R.R. Fertility of Women in the United States: 2012. U.S. Census Bureau, Current Population Survey 2014.

9. Pathela P., Braunstein S. L., Blank S., Schillinger J. A. HIV incidence among men with and those without sexually transmitted rectal infections: estimates from matching against an HIV case registry. Clin Infect Dis 2013;57:1203-9.

10. Peterman T. A., Newman D. R., Maddox L., Schmitt K., Shiver S. Risk for HIV following a diagnosis of syphilis, gonorrhea or chlamydia: 328,456 women in Florida, 2000-2011. Int J STD AIDS 2015;26:113-9.

11. Smith D.K., Van Handel M., Wolitski R.J., Stryker J.E., Hall H.I., *et al.* Estimated Percentages and Numbers of Adults with Indications for Pre-exposure Prophylaxis to Prevent HIV Acquisition — United States, 2015. MMWR 2015; 64:1291-1295.

2. Approach

Whenever possible, applications should include objectives written in the SMART format (e.g., Specific, Measurable, Achievable, Realistic and Time-bound).

Objectives/Outcomes

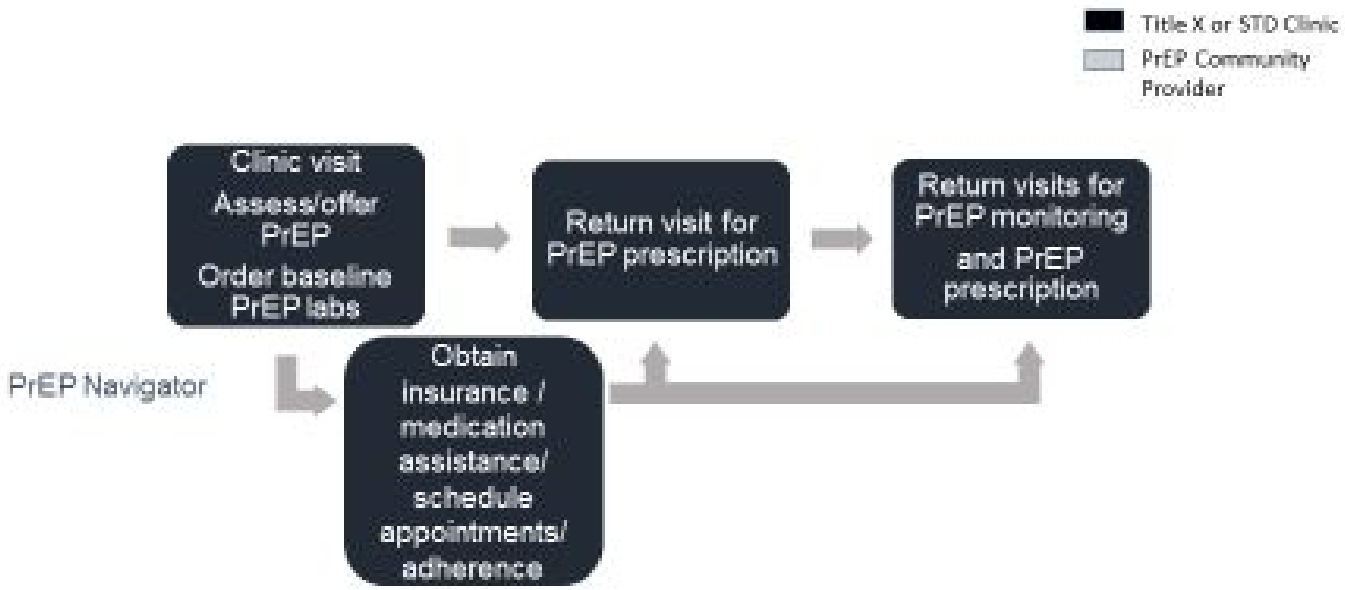
The objective of this health services research evaluation is to compare models of PrEP service delivery in order to identify best practices for successful PrEP service delivery and improve PrEP uptake among persons at substantial risk of HIV acquisition.

PrEP service delivery models

The application will describe a strategy to implement and evaluate three PrEP service delivery models (below) in Title X and STD clinic settings. The application will describe the selection of at least three Title X and at least three STD clinics in which PrEP services will be provided. Clinics should be located in geographically diverse areas and reach underserved populations at substantial risk of acquiring HIV as defined by the 2014 PrEP guidelines (http://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf) and serving an at least 50% minority population.

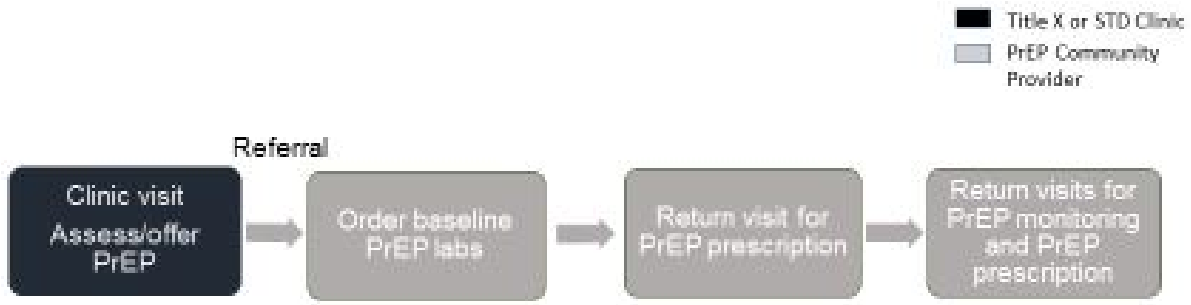
Applications should include a brief description of each clinic, including the clinic type location, a description of the population typically served by the clinic, the number of patients seen each month, the estimated number of PrEP-eligible patients, and what (if any) PrEP services are offered. Clinics are not required to have historically-provided PrEP services. Applications should describe a plan to provide appropriate technical assistance to clinics and other partners that will be providing clinical, laboratory, counseling, and patient navigation services in order to introduce or scale up PrEP services in clinics including, but not limited to: screening, navigation, and PrEP clinical management; billing for HIV testing and PrEP services; and assisting patients in enrolling in insurance and applying for PrEP assistance.

- ***Model 1: Direct PrEP provision in Title X and STD clinics***: Clinical providers will implement PrEP screening tools to identify individuals attending the clinic who are at substantial risk for HIV acquisition and potentially eligible for PrEP. Once identified, clinical providers at the Title X or STD clinic will offer PrEP, prescribe PrEP, and conduct all necessary counseling and navigation services and PrEP follow up appointments.

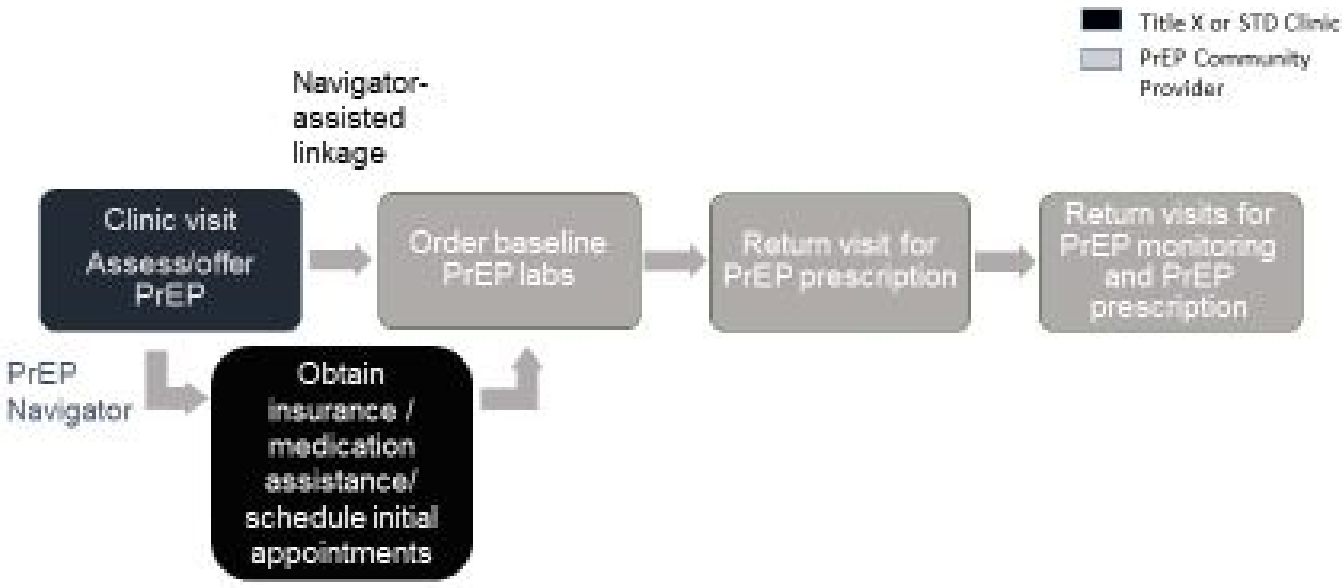


- ***Model 2: Passive referral to external PrEP service provider(s):*** Clinical providers will implement PrEP screening tools to identify individuals attending the clinic who are at substantial risk for HIV acquisition who would benefit from PrEP. Once identified, clinic staff will refer patients to local clinical partner(s) that provide PrEP services, such as a Federally Qualified Health Center (FQHC),

primary care center, or infectious disease clinic/HIV specialist, where clinical management will take place.



- ***Model 3: <u>Active linkage</u> to external PrEP service provider(s):*** As in Model 2, clinical providers will implement PrEP screening tools to identify individuals attending the clinic who are at substantial risk for HIV acquisition who would benefit from PrEP. Once identified, clinic staff will refer patients to local clinical partner(s) that provide PrEP services, such as a FQHC, primary care center, or infectious disease clinic/HIV specialist where clinical management will take place. In addition, patient navigators will be employed to assist patients with linkage to the PrEP provider and PrEP initiation. Navigation services should, at a minimum, support patients through PrEP initiation but may also extend beyond initiation to provide further support for PrEP adherence and retention. Services provided by the patient navigators may include scheduling the first PrEP appointment, providing reminders for the first PrEP appointment and subsequent appointments, and providing support services such as assistance with health insurance enrollment.



All models should include appropriate risk reduction counseling to all persons testing for HIV, referral to appropriate HIV and STD treatment services for persons testing positive for HIV or an STD, and clinic billing for PrEP and PrEP-related services. At all sites, existing resources should be leveraged to pay for clinical and lab services to ensure PrEP service delivery models can be sustained beyond the evaluation period.

Target Population

The target population includes men and women, ages 18 years and older, attending Title X or STD clinics who are at substantial risk of HIV acquisition, as defined by the 2014 US Public Health Service PrEP guidelines (http://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf). At least 50% of the individuals receiving services under this cooperative agreement must be from ethnic and/or racial minority groups. Applications should describe the use of appropriate epidemiologic data to identify clinics that primarily serve populations with a high rate of new HIV diagnoses.

All applications should describe the design of models of HIV prevention that are accessible and available to persons regardless of age, gender, race, ethnicity, sexual orientation, gender identity, or socio-economic status. Additionally, all activities should result in measurable improvements in HIV prevention among the target population of underserved subpopulations of MSM of color, including but not limited to individuals with disabilities, and individuals with limited English proficiency.

Collaboration/Partnerships

CDC/NCHHSTP (http://www.cdc.gov/nchhstp/Default.htm) and OASH/OPA (http://www.hhs.gov/opa/) are participating organizations/components of participating organizations for this FOA.

Required partnerships:

- External PrEP provider(s) to whom PrEP-eligible patients at Title X and STD clinics can be referred. In order to maximize choice for referred patients, collaborations should be developed with multiple PrEP providers whenever possible. Collaborations should include data sharing agreements to ensure appropriate evaluation data can be collected for referred patients.
- A healthcare organization, health department, or laboratory, to provide necessary clinical and laboratory data to evaluate the health service models; including at least three Title X clinics and at least three STD clinics.
- Clinics who will be providing PrEP services.

Evidence of collaboration with the required partners must be provided in the application via letters of support from the collaborating partners. Place letters in the Letters of Support section of the PHS 398 Research Plan section of the FOA.

In addition, where appropriate, awardees should collaborate with other CDC-funded programs to apply lessons learned for quality PrEP care and other HIV prevention and care services.

Evaluation/Performance Measurement

As part of the application, the PI should include measurable goals and aims based on a four-year research project period. The grantee will establish specific, measurable, achievable, realistic and time-phased (SMART) project objectives for each activity described in the application's project plan, and develop and implement project performance measures that are based on specific programmatic objectives.

Also, funded PIs must submit an annual progress report showing activities and outcomes based on their overall research goals and timeline.

The primary evaluation outcome is the number and percent of PrEP-eligible patients initiated on PrEP.

Additional outcomes include:

1. PrEP screening and initiation outcomes, including:

- Number of patients seen at the clinic
- Number of HIV tests performed
- Number of persons provided with risk reduction counseling
- Number of persons screened for PrEP indications
- Number of persons eligible for PrEP
- Number of persons referred to PrEP services
- Number of persons initiated on PrEP provided with recommended laboratory testing (e.g., HIV, hepatitis B, STDs, creatinine)
- Number of persons provided with PrEP adherence counseling
- Number of persons enrolled in health insurance/Medicaid (among uninsured)
- Number of persons enrolled in payment assistance plan
- Number of persons initiated on PrEP

2. Ongoing PrEP outcomes among persons enrolled in PrEP, including:

- Number of persons attending scheduled follow up visits
- Number of persons provided with PrEP adherence counseling at follow-up visits
- Number of persons provided with HIV and STD risk reduction counseling at follow-up visits
- Number of persons provided with recommended laboratory testing (e.g., HIV, hepatitis B, STDs, creatinine) at follow-up visits
- Number of persons requiring and provided with health insurance assistance at follow up visits

3. PrEP patient health and behavioral outcomes, including:

- Number of new HIV infections
- Number of incident STD infections (syphilis, gonorrhea, and chlamydia, hepatitis C, hepatitis B)
- Risk behavior

4. Cost of PrEP service delivery models

5. Patient and provider satisfaction

6. Documentation of lessons learned

Applications should clearly describe a research strategy to: (1) evaluate outcomes for the three models in Title X and STD clinical settings; (2) describe successes, challenges and best practices for each of the three models in Title X and STD clinic settings; and (3) compare the relative strengths and weaknesses of the three models in Title X and STD clinic settings.

Research strategies may employ a mix of quantitative and qualitative methods, as appropriate. Applications may also include additional evaluation elements in the research strategy not listed above that would contribute to the development of best practices for implementing each PrEP service delivery model.

For appropriate indicators, applications should describe how program baseline measures will be established. For example, historical program data can be used; or, if data is not available, clinics can plan a pre-intervention baseline data collection period prior to implementing models.

Translation Plan

The results of this evaluation will be made available to a wide range of potential users and stakeholders. Key findings will be presented at national meetings and published in peer-review journals. Findings related to effective health services models for PrEP provision will also be disseminated to clinicians, the public health workforce, and community-based stakeholders to inform their efforts to implement these models.

Section II. Award Information

Funding Instrument Type: Cooperative Agreement

A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

Application Types Allowed:

New - An application that is submitted for funding for the first time. Includes multiple submission attempts within the same round.

Estimated Total Funding: $11,000,000

Year 1: $2,000,000

Year 2: $3,000,000

Year 3: $3,000,000

Year 4: $3,000,000

Anticipated Number of Awards: 1

Award ceiling and floor are for the first 12-month budget period for an individual award.

Awards issued under this FOA are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Award Ceiling: $2,000,000 Per Budget Period

Award Floor: $1,500,000 Per Budget Period

Total Project Period Length: 4 year(s)

Throughout the project period, CDC's commitment to continuation of awards will depend on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and CDC's determination that continued funding is in the best interest of the Federal government.

HHS/CDC grants policies as described in the HHS Grants Policy Statement (http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:

State governments
County governments
City or township governments
Special district governments
Independent school districts
Public and State controlled institutions of higher education
Native American tribal governments (Federally recognized)
Public housing authorities/Indian housing authorities

Native American tribal organizations (other than Federally recognized tribal governments)
Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education
Private institutions of higher education

Additional Eligibility Category:

The following types of Higher Education Institutions are always encouraged to apply for CDC support as Public or Private Institutions of Higher Education:

Hispanic-serving Institutions
Historically Black Colleges and Universities (HBCUs)
Tribally Controlled Colleges and Universities (TCCUs)
Alaska Native and Native Hawaiian Serving Institutions

Nonprofits Other Than Institutions of Higher Education:

Nonprofits (Other than Institutions of Higher Education)

Governments:

Eligible Agencies of the Federal Government
U.S. Territory or Possession

Other:

Native American tribal organizations (other than Federally recognized tribal governments)
Faith-based or Community-based Organizations
Regional Organizations
Bona Fide Agents: a Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms" when submitting via www.grants.gov.

2. Foreign Organizations

Foreign Organizations are not eligible to apply.

Foreign components of U.S. Organizations are not eligible to apply.

For this announcement, applicants may not include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

3. Special Eligibility Requirements

Applicant organizations that request funding above the ceiling amount of the award will not be forwarded to peer review or considered for funding.

Applications submitted under this funding opportunity announcement must not include activities that overlap with simultaneously-funded research under other awards.

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

- Applications are expected to describe direct service delivery at Title X and STD clinics, or to demonstrate a formal collaboration with at least 3 clinics of each type which provide these services. Evidence of collaboration must be provided through letters of support with the collaborating clinics. The letters of support must be placed in the Letters of Support section of the PHS 398 Research Plan Component of the application.

- Applications must provide evidence of collaboration with a healthcare organization, health department, or laboratory, to provide necessary clinical and laboratory data to evaluate the health service models. Evidence of this collaboration must be in the form of letters of support that are placed in the Letters of Support section of the PHS 398 Research Plan Component of the application.

- Applications must demonstrate that investigators have experience conducting human subjects research and have access to an institutional review board (IRB) which can approve evaluation protocols; otherwise, the application must provide evidence of collaboration, via a letter of support, with a partner institution that can provide IRB approval and appropriate research guidance and oversight. The letter of support must be placed in the Letters of Support section of the PHS 398 Research Plan Component of the application.

- Applications must include letter(s) of support from external PrEP provider(s) to whom PrEP-eligible patients at Title X and STD clinics can be referred. The letter(s) of support should include data sharing agreements to ensure that appropriate evaluation data can be collected for referred patients and must be placed in the Letters of Support section of the PHS 398 Research Plan Component of the application.

Applications that do not meet the responsiveness criteria listed above will be considered nonresponsive will not move forward to peer review or be eligible for funding.

6. Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https://eportal.nspa.nato. int/AC135Public/Docs/US%20Instructions%2 0for%20NSPA%20NCAGE.pdf
- System for Award Management (**SAM**) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, https://www.sam.gov/portal/SAM/#1.
- Grants.gov

- eRA Commons

All applicant organizations must register with **Grants.gov**. Please visit www.Grants.gov at least 30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The "one-time" registration process will take three to five days to complete. However, it is best to start the registration process at least two weeks prior to application submission.
All Program Directors/Principal Investigators (PD/PIs) **must** also work with their institutional officials to register with the **eRA Commons** or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization. **All registrations must be successfully completed and active before the application due date**. Applicant organizations are strongly encouraged to start the registration process at least four (4) weeks prior to the application due date.

7. Universal Identifier Requirements and System for Award Management (SAM)

All applicant organizations **must obtain** a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the US D&B D-U-N-S Number Request Web Form or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number.
Additionally, all applicant organizations must register in the **System for Award Management (SAM)**. Organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM internet site at https://www.sam.gov/index.html.
If an award is granted, the grantee organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the grantee organization.

8. Eligible Individuals (Project Director/Principal Investigator) in Organizations/Institutions

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Project Director/Principal Investigator (PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for HHS/CDC support.

9. Cost Sharing

This FOA does not require cost sharing as defined in the HHS Grants Policy Statement (http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

10. Number of Applications

As defined in the HHS Grants Policy Statement,(http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf), applications received in response to the same funding opportunity announcement generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit. HHS/CDC will not accept any application in response to this FOA that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

Only one application per institution (normally identified by having a unique DUNS number) is allowed.

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity from www.Grants.gov.
If access to the Internet is not available or if the applicant encounters difficulty accessing the forms on-line, contact the HHS/CDC Office of Grants Services (OGS) Technical Information Management Section (TIMS) staff at (770) 488-2700 or ogstims@cdc.gov for further instructions. Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Time. CDC Telecommunications for the hearing impaired or disabled is available at: TTY 1-888-232-6348.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide.htm and here: http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf, except where instructed in this Funding Opportunity Announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.
The forms package associated with this FOA includes all applicable components, mandatory and optional. Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow the instructions in the SF 424 (R&R) Application Guide to ensure you complete all appropriate "optional" components.
In conjunction with the SF424 (R&R) components, CDC grants applicants should also complete and submit additional components titled "PHS398." Note the PHS398 should include assurances and certifications, additional data required by the agency for a complete application. While these are not identical to the PHS398 application form pages, the PHS398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete application to CDC will include SF424 (R&R) and PHS398 components. These forms can be downloaded from http://grants.nih.gov/grants/forms.htm

3. Letter of Intent

Due Date for Letter of Intent: **12/14/2016**

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows CIO staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. "Overview Information", prospective applicants are asked to submit a letter of intent that includes the following information:

Name of the Applicant

Descriptive title of proposed research

Name, address, and telephone number of the PD(s)/PI(s)

Names of other key personnel

Participating institutions

Number and title of this funding opportunity announcement

The letter of intent should be sent to:

Gregory Anderson, MPH, MS

Extramural Research Program Office

Office of the Associate Director of Science

National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

1600 Clifton Road, MS E-60

Atlanta, GA 30333

Telephone: 404-718-8833

Fax: 404-718-8822

Email: GAnderson@cdc.gov

4. Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this FOA in Grants.gov includes all applicable components for this FOA, required and optional.

5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of 16 components. Not all 16 components of the Research Plan apply to all Funding Opportunity Announcements (FOAs). Specifically, some of the following 16 components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide.htm and here: http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Funding Opportunity Announcement Description).

Follow the page limits stated in the SF 424 (R&R) unless otherwise specified in the FOA. As applicable to and specified in the FOA, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

1. Introduction to Application (for Resubmission and Revision ONLY) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the FOA.

2. Specific Aims – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.

3. Research Strategy – the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and timeline.

4. Inclusion Enrollment Report (Renewal and Revision applications ONLY)

5. Progress Report Publication List (for Continuation ONLY)

Human Subjects Section

6. Protection of Human Subjects

7. Inclusion of Women and Minorities

8. Targeted/Planned Enrollment Table (for New Application ONLY)

9. Inclusion of Children

Other Research Plan Sections

10. Vertebrate Animals

11. Select Agent Research

12. Multiple PD/PI Leadership Plan.
13. Consortium/Contractual Arrangements
14. Letters of Support
15. Resource Sharing Plan(s)
16. Appendix

Component 4 (Inclusion Enrollment Report) applies only to Renewal and Revision applications for clinical research. Clinical research is that which is conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies). Follow the page limits in the SF 424 (R&R) Application Guide unless otherwise specified in the FOA. All instructions in the SF424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf must be followed along with any additional instructions provided in the FOA.
Applicants that plan to collect public health data must submit a Data Management Plan (DMP) in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application. A DMP is required for each collection of public health data proposed. Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds.
The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include:
• Descriptions of the data to be produced in the proposed project
• How access will be provided to the data (including provisions for protection of privacy, confidentiality, security, intellectual property, or other rights)
• Use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use
• Plans for archival and long-term preservation of the data, or explaining why long-term preservation and access cannot be justified
Examples of DMPs may be found here: University of California https://dmp.cdlib.org/, or USGS, http://www.usgs.gov/datamanagement/plan/dmplans.php

Please note the new requirement for a Data Management Plan (DMP) in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application (see immediately above).

Letters of Support Section:

• Applications are expected to describe direct service delivery at Title X and STD clinics, or to demonstrate a formal collaboration with at least 3 clinics of each type which provide these services. Evidence of collaboration must be provided through letters of support with the collaborating clinics. The letters of support must be placed in the Letters of Support section of the PHS 398 Research Plan Component of the application.

• Applications must provide evidence of collaboration with a healthcare organization, health department, or laboratory, to provide necessary clinical and laboratory data to evaluate the health service models. Evidence of this collaboration must be in the form of letters of support that are placed in the Letters of Support section of the PHS 398 Research Plan Component of the application.

• Applications must demonstrate that investigators have experience conducting human subjects research and have access to an institutional review board (IRB) which can approve evaluation protocols; otherwise, the application must provide evidence of collaboration via a letter of support with a partner institution that can provide IRB approval and appropriate research guidance and oversight. The letter of support must be placed

in the Letters of Support section of the PHS 398 Research Plan Component of the application.

• Applications must include letter(s) of support from external PrEP provider(s) to whom PrEP-eligible patients at Title X and STD clinics can be referred. The letter(s) of support should include data sharing agreements to ensure that appropriate evaluation data can be collected for referred patients and must be placed in the Letters of Support section of the PHS 398 Research Plan Component of the application.

6. Appendix

Do not use the appendix to circumvent page limits. A maximum of 10 PDF documents are allowed in the appendix. Additionally, up to 3 publications may be included that are not publically available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

7. Page Limitations

All page limitations described in this individual FOA must be followed. For this specific FOA, the Research Strategy component of the Research Plan narrative is limited to 25 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 25 pages for all appendices.

8. Format for Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff. Applicants should ensure that all attachments are uploaded to the system.
CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf.

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit in advance of the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.
Organizations must submit applications via Grants.gov (http://www.grants.gov), the online portal to find and apply for grants across all Federal agencies. The eRA Commons systems retrieve the application from Grants.gov and check the application against CDC business rules. If no errors are found, the application will be assembled in the eRA Commons for viewing by the applicant before moving on for further CDC processing.
If errors are found, the applicant will be notified in the eRA Commons. They must make required changes to the local copy of their application and submit again through Grants.gov.
Applicants are responsible for viewing their application in the eRA Commons to ensure accurate and successful submission.
Once you can see your application in the Commons, be sure to review it carefully as this is what the reviewer will see. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (http:// grants.nih. gov/grants /guide/url_ redirect .htm? id=11123).
Information on the submission process is provided in the SF424 (R&R) Application Guide.
Note: HHS/CDC grant submission procedures do not provide a period of time beyond the grant application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e. error correction window).
The application package is not complete until it has passed the Grants.gov/eRA Commons validation process. This process and email notifications of receipt, validation or rejection may take two (2) business days.

Applicants are strongly encouraged to allocate additional time prior to the submission deadline to submit their applications and to correct errors identified in the validation process. Applicants are encouraged also to check the status of their application submission to determine if the application packages are complete and error-free. Applicants who encounter system errors when submitting their applications must attempt to resolve them by contacting the Grants.gov Contact Center (1-800-518-4726; support@grants.gov). If the system errors cannot be resolved, applicants must contact TIMS at 770-488-2700; ogstims@cdc.gov for guidance at least 3 calendar days before the deadline date.
After submission of your application package, applicants will receive a "submission receipt" email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. This validation process may take as long as two (2) business days. A third and final e-mail message is generated once the applicant's application package has passed validation and the grantor has confirmed receipt of the application.

Unsuccessful Submissions: If an application submission was unsuccessful, ***the applicant*** must:
1. Track his/her submission and verify the submission status (tracking should be done initially regardless of rejection or success).
    a. If the status states "***rejected***," do #2a or #2b.
2. Check his/her emails from both Grants.gov and eRA Commons for rejection notices.
    a. If the deadline has passed, he/she should email the Grant Management Specialist listed in the FOA (pgotim@cdc.gov) explaining why the submission failed. b. If there is time before the deadline, he/she should correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **01/17/2017**

Electronically submitted applications must be submitted no later than 5:00 p.m., ET, on the listed application due date.

10. Intergovernmental Review (E.O. 12372)

Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order 12372 (http://www.archives.gov/federal-register/codification/executive-order/12372.html). This order sets up a system for state and local review of proposed federal assistance applications. You should contact your state single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your state's process. Click on the following link to get the current SPOC list: http://www.whitehouse.gov/omb/grants_spoc/.

11. Funding Restrictions

All HHS/CDC awards are subject to the federal regulations, 45 CFR 75, terms and conditions,and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.
For more information on expanded authority and pre-award costs, go to:
http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf .
CDC requires that mechanisms for, and cost of, public health data sharing be included in grants,cooperative agreements, and contracts. The cost of sharing or archiving public health data may also be included as part of the total budget requested for first-time or continuation awards.
Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Resource Sharing Plan(s) section of the PHS398 Research Plan Component of the application.
Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds (for example, privacy and

confidentiality considerations, embargo issues).
Awardees who fail to release public health data in a timely fashion will be subject to procedures normally used to address lack of compliance (for example, reduction in funding, restriction of funds, or award termination) consistent with 45 CFR 74.62 or other authorities as appropriate. For further information, please see: http://www.cdc.gov/grants/additionalrequirements/index.html for revised AR-25.

1) The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project outcomes and not merely serve as a conduit for an award to another party or provider who is ineligible.

2) Funds relating to the conduct of research involving human subjects will be restricted until the appropriate assurances and Institutional Review Board (IRB) approvals are in place. Copies of all current local IRB approval letters and local IRB approved protocols (and CDC IRB approval letters, if applicable) will be required to lift restrictions.

3) Projects that involve the collection of information, identical record keeping or reporting from 10 or more individuals and are funded by a cooperative agreement and constitute a burden of time, effort, and/or resources expended to collect and/or disclose the information will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA).

4) On September 24, 2014, the Federal government issued a policy for the oversight of life sciences "Dual Use Research of Concern" (DURC) and required this policy to be implemented by September 24, 2015. This policy applies to all New and Renewal awards issued on applications submitted on or after September 24, 2015, and to all non-competing continuation awards issued on or after that date. CDC awardee institutions and their investigators conducting life sciences research subject to the Policy have a number of responsibilities that they must fulfill. Institutions should reference the policy, available at http://www.phe.gov/s3/dualuse, for a comprehensive listing of those requirements.

Non-compliance with this Policy may result in suspension, limitation, or termination of USG funding, or loss of future US Government (USG) funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

5) Please note new information regarding the inclusion of a Data Management Plan (DMP) in applications described above under "Funding Restrictions" and also in AR-25 in the Additional Requirements section of this FOA (http://www.cdc.gov/grants/additionalrequirements/index.html). Funding restrictions may be imposed, pending submission and evaluation of a Data Management Plan.

12. Other Submission Requirements and Information

- Applications are expected to describe direct service delivery at Title X and STD clinics, or to demonstrate a formal collaboration with at least 3 clinics of each type which provide these services. Evidence of collaboration must be provided through letters of support with the collaborating clinics. The letters of support must be placed in the Letters of Support section of the PHS 398 Research Plan Component of the application.

- Applications must provide evidence of collaboration with a healthcare organization, health department, or laboratory to provide necessary clinical and laboratory data to evaluate the health service models. Evidence of this collaboration must be in the form of letters of support that are placed in the Letters of Support section of the PHS 398 Research Plan Component of the application.

- Applications must demonstrate that investigators have experience conducting human subjects research and have access to an institutional review board (IRB) which can approve evaluation protocols; otherwise, the application must provide evidence of collaboration via a letter of support with a partner institution that can provide IRB approval and appropriate research guidance and oversight. The letter of support must be placed in the Letters of Support section of the PHS 398 Research Plan Component of the application.

• Applications must include letter(s) of support from external PrEP provider(s) to whom PrEP-eligible patients at Title X and STD clinics can be referred. The letter(s) of support should include data sharing agreements to ensure that appropriate evaluation data can be collected for referred patients and must be placed in the Letters of Support section of the PHS 398 Research Plan Component of the application.

Application Submission
Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.**
Applicants must complete all required registrations before the application due date. Section III.6 "Required Registrations" contains information about registration.
For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically (http://grants.nih.gov/grants/guide /url_ redirect.htm? id=11144).

Important reminders: All PD/PIs must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to CDC.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.
See more resources to avoid common errors and submitting, tracking, and viewing applications: http:// grants.nih. gov/grants/ Electronic Receipt /avoiding _errors.htm or http:// grants. nih.gov/grants/ Electronic Receipt/submit _app.htm
Upon receipt, applications will be evaluated for completeness by the CDC Office of Grants Services (OGS) and responsiveness by OGS and the Center, Institute or Office of the CDC. Applications that are incomplete and/or nonresponsive will not be reviewed.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the CDC mission (http:// www.cdc.gov/ about/ organization/ mission.htm), all applications submitted to the CDC in support of public health research are evaluated for scientific and technical merit through the CDC peer review system.

Overall Impact
Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria
Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Does the application discuss the importance of PrEP for HIV prevention in persons at substantial risk of HIV acquisition?

Does the application demonstrate awareness of facilitators and barriers to utilization of PrEP services by at-risk populations at Title X and/or STD clinics?

If successful, do the research results have the potential to be sustainable beyond the project period and scalable and reach a large portion of the population at risk?

Investigator(s)

Are the PD/PIs, collaborators, and other researchers well suited to the project? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Does the application's proposed team include personnel with research expertise appropriate to the specific population and the proposed evaluation methods?

Have previous research results provided high quality outputs and contributed to improvements in public health practice and population health?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Is the proposed research innovative and yet offer reasonable potential for concrete applications of interest and value to public health?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?
If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Does the application demonstrate an understanding of the research objectives as reflected in the specific evaluation design and methods of the research proposal?

Does the application propose to implement the three PrEP service delivery models in at least three Title X and at least three STD clinics?

Does the application demonstrate that the clinics are located in diverse geographic regions and serve populations at substantial risk of acquiring HIV who have not had historical access to PrEP services?

Does the application support claims using appropriate epidemiologic data, including the rate of new HIV diagnoses in the population served?

Does the applicant directly operate three Title X and three STD clinics, or if not, provide evidence through letters of support with at least three Title X and three STD clinics?

Does the application describe how existing resources will be leveraged to ensure sustainability beyond the project period?

Does the application demonstrate capacity to implement each of the PrEP service delivery models in listed clinic(s)?

Does the application provide evidence of collaboration with an appropriate number of PrEP providers for referral of PrEP-eligible patients?

Does the application propose a research approach that would identify facilitators and barriers and demonstrate best practices for the delivery of each of the PrEP service delivery models Title X or STD clinics?

Does the application provide plans for recruitment, engagement, and retention of the target population of persons at substantial risk of HIV acquisition?

Does the application provide a plan for ensuring all sites provide required clinical and counseling services, including risk reduction counseling, and medication adherence support for persons who initiate PrEP?

Does the application provide a plan for collection of clinical and laboratory data necessary to evaluate the model and all outcomes listed in the FOA?

Does the application provide a plan for implementation of the patient and staff satisfaction surveys?

Does the application provide a plan to provide confidentiality assurance of patients' clinical and lab data, and survey data?

Does the applicant institution have an internal institutional review board (IRB)? If the applicant institution does not have an internal IRB, is there a formal collaboration through a letter of support with a partner institution that can provide IRB approval and appropriate research guidance and oversight?

Does the application provide evidence of collaboration through a letter of support with a healthcare organization, health department, or clinical laboratory to provide necessary laboratory services to evaluate the health service models?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Does the application provide estimates of the number of clients in their clinic population who are eligible for PrEP?

Does the application describe adequate access to qualified personnel with realistic and sufficient time commitments relative to each phase of the evaluation timeline?

Does the application provide a description of personnel responsibilities, percentage of time commitment, lines authority and supervisory reporting?

Does the application describe its capacity for evaluation, administration, data management, and statistical support for the research?

Does the application describe how services will be provided to at least 50% of individuals from racial and/or ethnic minorities?

2. Additional Review Criteria

As applicable for the project proposed, *reviewers will evaluate* the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but *will not give separate scores* for these items.

Protections for Human Subjects

If the research involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46 , the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements (http://www.cdc.gov/grants/additionalrequirements/index.html).

If your proposed research involves the use of human data and/or biological specimens, you must provide a justification for your claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research (http:// www.cdc.gov /maso Policy /Policy_women.pdf and http:// www.gpo.gov /fdsys /pkg /FR-1995-09-15 /pdf/95-22950.pdf #page=1) and the policy on the Inclusion of Persons Under 21 in Research (http:// www.cdc.gov /maso /Policy /policy496.pdf).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For

additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

Biohazards
Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Dual Use Research of Concern
Reviewers will identify whether the project involves one of the agents or toxins described in the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern, and, if so, whether the applicant has identified an IRE to assess the project for DURC potential and develop mitigation strategies if needed.
For more information about this Policy and other policies regarding dual use research of concern, visit the U.S. Government Science, Safety, Security (S3) website at: http://www.phe.gov/s3/dualuse. Tools and guidance for assessing DURC potential may be found at: http://www.phe.gov/s3/dualuse/Pages/companion-guide.aspx.

3. Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but *will not give scores* for these items, and should not consider them in providing an overall impact/priority score.

Please note new information regarding the inclusion of a Data Management Plan (DMP) in applications described below under "Resource Sharing Plan(s)" and also in AR-25 in the Additional Requirements section of this FOA (http://www.cdc.gov/grants/additionalrequirements/index.html). Funding restrictions may be imposed, pending submission and evaluation of a Data Management Plan.

Resource Sharing Plan(s)
HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: http://www.cdc.gov/grants/additionalrequirements/index.html
New additional requirement: CDC requires awardees for projects and programs that involve data collection or generation of data with federal funds to develop and submit a Data Management Plan (DMP) for each collection of public health data.
Investigators responding to this funding opportunity announcement should include a detailed DMP in the Resource Sharing Plan(s) section of the PHS 398 Research Plan Component of the application. The AR-25 outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.
The DMP should be developed during the project planning phase prior to the initiation of collecting or generating public health data and will be submitted with the application. The submitted DMP will be evaluated for completeness and quality at the time of submission.
The DMP should include, at a minimum, a description of the following:
• Type of data to be produced in the proposed project;
• Mechanisms for providing access to and sharing of the data (including provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights);
• Use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
• Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified.
Applications submitted without the required DMP may be deemed ineligible for award unless submission of

DMP is deferred to a later period depending on the type of award, in which case, funding restrictions may be imposed pending submission and evaluation.

Budget and Period of Support Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: http://www.cdc.gov/grants/interestedinapplying/applicationresources.html

4. Review and Selection Process

Applications will be evaluated for scientific and technical merit by an appropriate peer review group, in accordance with CDC peer review policy and procedures, using the stated review criteria.
As part of the scientific peer review, all applications:

- Will undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review), will be discussed and assigned an overall impact/priority score.

- Will receive a written critique.

Applications will be assigned to the appropriate HHS/CDC Center, Institute, or Office. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

- Pending the scientific merit of the applications and the availability of funding, preference may be given to proposed projects that provide geographic diversity.

Review of risk posed by applicants.
Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.
In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.
CDC’s framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this funding opportunity announcement.
In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items

such as the following:
(1) Financial stability;
(2) Quality of management systems and ability to meet the management standards prescribed in this part;
(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
(4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and
(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.
CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

5. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) and other pertinent information via the eRA Commons.

Section VI. Award Administration Information

1. Award Notices

Any applications awarded in response to this FOA will be subject to the DUNS, SAM Registration, and Transparency Act requirements. If the application is under consideration for funding, HHS/CDC will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement (http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the Grants Management Officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions as described in Section IV.11. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be allowable as an expanded authority, but only if authorized by CDC.

2. CDC Administrative Requirements

Overview of Terms and Conditions of Award and Requirements for Specific Types of Grants
All HHS/CDC grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the NoA. For these terms of award, see the HHS Grants Policy Statement Part II: Terms and Conditions of Award (http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).
Awardees must comply with the administrative requirements (AR) outlined in 45 Code of Federal Regulations (CFR) Part 75, as appropriate, as well as any additional requirements included in the FOA. Specific requirements that apply to this FOA are the following:

AR-1: Human Subjects Requirements

AR-2: Inclusion of Women and Racial and Ethnic Minorities in Research

AR-3: Animal Subjects Requirements

AR-7: Executive Order 12372 Review

AR-8: Public Health System Reporting Requirements

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2020

AR-12: Lobbying Restrictions

AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities

AR-14: Accounting System Requirements

AR-15: Proof of Non-profit Status

AR-16: Security Clearance Requirement

AR-21: Small, Minority, And Women-owned Business

AR-22: Research Integrity

AR-23: Compliance with 45 C.F.R. Part 87

AR-25: Data Management and Access

AR-26: National Historic Preservation Act of 1966

AR-28: Inclusion of Persons Under the Age of 21 in Research

AR-29: Compliance with EO13513, “;Federal Leadership on Reducing Text Messaging while Driving”;, October 1, 2009

AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973

AR 31 - Distinguishing Public Health Research and Public Health Nonresearch

AR 32 –; FY 2012 Enacted General Provisions

AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

AR-34: Language Access for Persons with Limited English Proficiency

ARs applicable to HIV/AIDS Awards:

AR-4: HIV/AIDS Confidentiality Provisions

AR-5: HIV Program Review Panel Requirements

AR-6: Patient Care

For more information on the Code of Federal Regulations, visit the National Archives and Records Administration at: http://www.archives.gov/.

To view brief descriptions of relevant CDC requirements visit: http://www.cdc.gov/grants/additionalrequirements/index.html

3. Additional Policy Requirements

The following are additional policy requirements relevant to this FOA:

HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items and Printing Publications This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy

apply to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website at:http://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html.
Federal Funding Accountability and Transparency Act of 2006 Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252, requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single, publicly accessible website, www.usaspending.gov. For the full text of the requirements, please review the following website: https://www.fsrs.gov/.
Plain Writing Act The Plain Writing Act of 2010, Public Law 111-274 was signed into law on October 13, 2010. The law requires that federal agencies use "clear Government communication that the public can understand and use" and requires the federal government to write all new publications, forms, and publicly distributed documents in a "clear, concise, well-organized" manner. For more information on this law, go to: http://www.plainlanguage.gov/plLaw/index.cfm.
Tobacco and Nutrition Policies The CDC supports implementing evidence-based programs and policies to reduce tobacco use and secondhand smoke exposure, and to promote healthy nutrition. CDC encourages all awardees to implement the following *optional* evidence-based tobacco and nutrition policies within their organizations. These policies build on the current federal commitment to reduce exposure to secondhand smoke, which includes The Pro-Children Act, 20 U.S.C. 7181-7184 that prohibits smoking in certain facilities that receive federal funds.
Tobacco:

- Tobacco-free indoors – no use of any tobacco products (including smokeless tobacco) or electronic cigarettes in any indoor facilities under the control of the applicant.
- Tobacco-free indoors and in adjacent outdoor areas – no use of any tobacco products or electronic cigarettes in any indoor facilities, within 50 feet of doorways and air intake ducts, and in courtyards under the control of the applicant.
- Tobacco-free campus – no use of any tobacco products or electronic cigarettes in any indoor facilities and anywhere on grounds or in outdoor space under the control of the applicant.

Nutrition:

- Healthy food service guidelines that at a minimum align with Health and Human Services and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations for cafeterias, snack bars, and vending machines in any facility under the control of the recipient organization and in accordance with contractual obligations for these services. The following are resources for healthy eating and tobacco free workplaces:

- http://www.gsa.gov/graphics/pbs/ Guidelines_for_Federal_Concessions_and_Vending_Operations.pdf
- http://www.cdc.gov/tobacco/basic_information/healthy_people/toolkit/index.htm
- http://www.cdc.gov/obesity/strategies/food-serv-guide.html

Applicants should state whether they choose to participate in implementing these two optional policies. However, no applicants will be evaluated or scored on whether they choose to participate in implementing these optional policies.

Pilot Program for Enhancement of Employee Whistleblower Protections All applicants will be subject to a term and condition that applies the terms of 48 CFR section 3.908 to the award and requires that grantees inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

Copyright Interests Provision This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH)

Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.
The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

Language Access for Persons with Limited English Proficiency Recipients of federal financial assistance 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. Recipients of federal financial assistance must take the reasonable steps to provide meaningful access to their programs by persons with limited English proficiency.

Dual Use Research of Concern On September 24, 2014, the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern was released. Grantees (foreign and domestic) receiving CDC funding on or after September 24, 2015 are subject to this policy. Research funded by CDC involving the agents or toxins named in the policy, must be reviewed to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. This review must be completed by an Institutional Review Entity (IRE) identified by the funded institution.
Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR). The award recipient must maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant, cooperative agreement or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.
If a project is determined to be DURC, a risk/benefit analysis must be completed. CDC will work collaboratively with the award recipient to develop a risk mitigation plan that the CDC must approve. The USG policy can be found at http://www.phe.gov/s3/dualuse.
Non-compliance with this Policy may result in suspension, limitation, restriction or termination of USG funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

Data Management Plan(s)
CDC requires that all new collections of public health data include a Data Management Plan (DMP). For purposes of this announcement, "public health data" means digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation. This new requirement ensures that CDC is in compliance with the following; Office of Management and Budget (OMB) memorandum titled "Open Data Policy–Managing Information as an Asset" (OMB

M-13-13); Executive Order 13642 titled “Making Open and Machine Readable the New Default for Government Information”; and the Office of Science and Technology Policy (OSTP) memorandum titled “Increasing Access to the Results of Federally Funded Scientific Research” (OSTP Memo).
The AR-25 http://www.cdc.gov/grants/additionalrequirements/index.html outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

4. Cooperative Agreement Terms and Conditions

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Part 75, and other HHS, PHS, and CDC grant administration policies. The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial CDC programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; CDC Project Officers are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and HHS/CDC as defined below.

The PD(s)/PI(s) will have the primary responsibility for:

- Complying with the responsibilities for extramural investigators for the Data Management and Access Additional Requirement (AR-25) described at: http://www.cdc.gov/grants/additionalrequirements/index.html
- Ensuring the protection of human subjects through ethical review of all protocols involving human subjects at the local institution and at CDC and obtaining the appropriate Institutional Review Board approvals for all institutions or individuals engaged in the conduct of the research project.
- Working with CDC scientists to obtain OMB-PRA approvals, as needed.
- PUBLICATIONS/PRESENTATIONS: Publications, journal articles, presentations, etc. produced under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate, for example: “This publication (journal article, etc.) was supported by the Cooperative Agreement Number above from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention or the Office of the Assistant Secretary for Health”. In addition, the PI/PD must provide to CDC Program abstracts or manuscripts prior to any publication related to this funding. The awardee will not seek to publish or present results or findings from this project without prior clearance and approval from CDC.
- Complying with the responsibilities for the PI as described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf).
- Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.
- Awardees will participate in annual meetings of the awardees, will provide representation to the Executive Steering Committee (ESC, see below) and will support any other committees, task forces, and advisory panels related to the project, as needed and will participate in regularly scheduled conference calls with the awarding agencies. Project budgets should include travel for participation in these activities.

CDC and OASH Federal Staff Responsibilities. CDC and OASH staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

- CDC will assist the PI, as needed, in complying with the responsibilities for extramural investigators for the Data Management and Access Additional Requirement (AR-25) described at: http://www.cdc.gov/grants/additionalrequirements/index.html
- CDC will prepare the paperwork necessary for submission of research protocols to the CDC Institutional Review Board for review, as needed.
- CDC will obtain Office of Management and Budget approval per the Paperwork Reduction Act, if necessary.
- CDC will assist the PI, as needed, in complying with the PI responsibilities described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf
- Reviewing changes in sites or protocols throughout the duration of the project period.
- CDC and OASH staff will provide technical assistance for activities of the awardee, and will coordinate activities with federal and non-federal agencies outside of the project awardees. A project Executive Steering Committee (ESC) with representation from CDC and OASH and the project sites will be organized to facilitate regular communication among awardees, OASH and CDC. The ESC also may engage members who provide substantive scientific, programmatic, or clinical knowledge from academia, government, private industry or other relevant sectors.
- CDC and OASH will serve as resources to provide: scientific/programmatic support in the development and modification of evaluation protocols and the design of project activities; advice in the selection of sources or resources; advice in management and technical performance; and assistance in the preparation of publications, as warranted.
- CDC and OASH will participate in the monitoring of issues relating to evaluation data collection and monitoring of data integrity and quality control through consideration of the annual reports, site visits, patient logs, etc. This review may include, but is not limited to, compliance with the evaluation protocol, meeting evaluation targets, adherence to uniform data collection procedures, and the timeliness and quality of data reporting as needed to the administration and evaluation core.

Areas of Joint Responsibility include:

- The awardee and the Project ESC will cooperate to ensure the timely and broad dissemination of lessons learned, to inform researchers and health care systems engaged in research in health care settings.
- The Project ESC will facilitate these joint activities and, in particular, provide facilitation of research protocols, human subjects and other regulatory protocols (including adverse event reporting), data harmonization, manuscript and other information dissemination planning, and initial clearance of manuscripts or other dissemination products, as warranted.

Additionally, a Scientific Program Officer in the NCHHSTP Extramural Research Program Office (ERPO) will be responsible for the normal scientific and programmatic stewardship of the award as described below:

- Named in the Notice of Award as the Program Official to provide overall scientific and programmatic stewardship of the award;
- Serve as the primary point of contact on official award-related activities including an annual review of the awardee's performance as part of the request for continuation application;
- Make recommendations on requests for changes in scope, objectives, and or budgets that deviate from the approved peer-reviewed application;
- Carry out continuous review of all activities to ensure objectives are being met;
- Attend committee meetings and participate in conference calls for the purposes of assessing overall progress, and for program evaluation purposes; and

- Monitor performance against approved project objectives.

5. Reporting

Awardees will be required to submit the Non-Competing Continuation Grant Progress Report (PHS 2590) annually and financial statements as required in the HHS Grants Policy Statement.
A final progress report, invention statement, equipment inventory list and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement.
Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity depend upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.
The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.
Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients: **1) information on executive compensation when not already reported through the SAM Registration; and 2) similar information on all sub-awards/ subcontracts/ consortiums over $25,000.** It is a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the HHS Grants Policy Statement (http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

A. Submission of Reports

The Recipient Organization must provide HHS/CDC with an original, plus one hard copy of the following reports:

1. **Yearly Non-Competing Grant Progress Report**, (use form PHS 2590, posted on the HHS/CDC website, www.grants.gov and at http:// grants.nih.gov/grants/ funding/2590/ 2590.htm, **is due 90 to 120 days prior to the end of the current budget period.** The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.
2. **Annual Federal Financial Report (FFR)** SF 425 is required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which the budget period ends.**
3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the project period.**

B. Content of Reports

1. Yearly Non-Competing Grant Progress Report: The grantee's continuation application/progress shoul include

- Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the PHS 2590 (http:// grants1.nih.gov/ grants/funding/ 2590/2590.htm) http:// grants.nih.gov/grants/ funding/2590/2590.htm: Detailed narrative report for the current budget period that directly addresses

progress towards the Measures of Effectiveness included in the current budget period proposal.

- Research Aims: list each research aim/project

a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned
b) Leadership/Partnership: list project collaborations and describe the role of external partners.

- Translation of Research (1 page maximum). When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that were translated into public health policy or practice and how the findings have been or may be adopted in public health settings. Or, if they cannot be applied yet, this section should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. *Questions to consider in preparing this section include*:

- How will the scientific findings be translated into public health practice or inform public health policy?
- How will the project improve or effect the translation of research findings into public health practice or inform policy?
- How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs or practices?
- How will the findings advance or guide future research efforts or related activities?

- Public Health Relevance and Impact (1 page maximum). This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques, inform policy, or use of technology in public health. *Questions to consider in preparing this section include*:

- How will this project lead to improvements in public health?
- How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
- How will the findings, results, or recommendations contributed to documented or projected reductions in morbidity, mortality, injury, disability, or disease?

- Current Budget Period Financial Progress: Status of obligation of current budget period funds and an estimate of unobligated funds projected provided on an estimated FFR.

- New Budget Period Proposal:

- Detailed operational plan for continuing activities in the upcoming budget period, including updated Measures of Effectiveness for evaluating progress during the upcoming budget period. Report listed by Research Aim/Project.
- Project Timeline: Include planned milestones for the upcoming year (be specific and provide deadlines).

- New Budget Period Budget: Detailed line-item budget and budget justification for the new budget period. Use the CDC budget guideline format.

- Publications/Presentations: Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the

project, simply indicate “Not applicable: No publications or presentations have been made."

- IRB Approval Certification: Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.

- Update of Data Management Plan: The DMP is considered a living document that will require updates throughout the lifecycle of the project. Investigators should include any updates to the project’s data collection such as changes to initial data collection plan, challenges with data collection, and recent data collected. Applicants should update their DMP to reflect progress or issues with planned data collection and submit as required for each reporting period.

- Additional Reporting Requirements:

N/A

2. Annual Federal Financial Reporting The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through eRA Commons within 90 days after the end of the calendar quarter in which the budget period ends. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data.
Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information. **All CDC Financial Expenditure data due on/after October 1, 2012 must be submitted using the FFR via the eFSR/FFR system in the eRA Commons.** All Federal Reporting in the Payment Management System is unchanged. All new submissions should be prepared and submitted as FFRs.
CDC's implementation of the FFR retains a financial reporting period that coincides with the budget period of a particular project. However, **the due date for annual FFRs will be 90 days after the end of the calendar quarter in which the budget period ends**. Note that this is a change in due dates of annual FFRs and may provide up to 60 additional days to report, depending upon when the budget period end date falls within a calendar quarter. For example, if the budget period ends 1/30/2012, the annual FFR is due 6/30/2012 (90 days after the end of the calendar quarter of 3/31/2012). Due dates of final reports will remain unchanged. The due date for final FFRs will continue to be 90 days after the project period end date.
Grantees must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, grantees must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).
FFR (SF 425) instructions for CDC grantees are now available at http:// grants.nih.gov/ grants/forms.htm. For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: https://era.nih.gov/registration_accounts.cfm
FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) (https:// commons. era.nih.gov/ commons/). CDC recommends that this one time registration

process be completed at least 2 weeks prior to the submittal date of a FFR submission.
Organizations may verify their current registration status by running the "List of Commons Registered Organizations" query found at: https://era.nih.gov/registration_accounts.cfm. Organizations not yet registered can go to https:// commons. era.nih.gov/ commons/ registration/ registration Instructions. jsp for instructions. It generally takes several days to complete this registration process. This registration is independent of Grants.gov and may be done at any time.
The individual designated as the PI on the application must also be registered in the Commons. The PI must hold a PI account and be affiliated with the applicant organization. This registration must be done by an organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide found at: http:// era.nih.gov/ commons /index.cfm.
3. Final Reports: Final reports should provide sufficient detail for CDC to determine if the stated outcomes for the funded research have been achieved and if the research findings resulted in public health impact based on the investment. The grantee's final report should include:

- Research Aim/Project Overview: The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.
- Translation of Research Findings: The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the project period. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.
- Public Health Relevance and Impact: This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.•
- Publications; Presentations; Media Coverage: Include information regarding all publications, presentations or media coverage resulting from this CDC funded activity. Please include any additional dissemination efforts that did or will result from the project.
- Final Data Management Plan: Applicants must include an updated final Data Management Plan that describes the data collected, the location of where the data is stored (example: a repository), accessibility restrictions (if applicable), and the plans for long term preservation of the data.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading or navigating forms)
Contact Center Phone: 800-518-4726
Email: support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking application status, post

submission issues, FFR submission)
Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
Email: commons@od.nih.gov
Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time

CDC Technical Information Management Section (TIMS)
Telephone 770-488-2700
Email: ogstims@cdc.gov
Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Time

Scientific/Research Contact(s)

Paul Smutz, PhD

Extramural Research Program Office

Office of the Associate Director for Science

National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

1600 Clifton Road, MS E-60

Atlanta, GA 30333

Telephone: 404-718-8830

Fax: 404-718-8822

Email: wsmutz@cdc.gov

David M. Johnson

Operations and Management Officer

Office of Population Affairs

Office of the Assistant Secretary for Health

U.S. Department of Health and Human Services

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Email: david.johnson@hhs.gov

Peer Review Contact

Gregory Anderson, MPH, MS

Extramural Research Program Office

Office of the Associate Director for Science

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Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road, MS E-60
Atlanta, GA 30333
Telephone: 404-718-8833
Fax: 404-718-8822
Email: GAnderson@cdc.gov

Financial/Grants Management Contact(s)

Portia Brewer
Office of Financial Resources
Office of Grant Services
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
2920 Brandywine Road, MS K-75
Atlanta, GA 30341
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Fax: (770) 488-8350
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Section VIII. Other Information

Other CDC funding opportunity announcements can be found at www.grants.gov.
All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

Authority and Regulations

Awards are made under the authorization of Sections of the Public Health Service Act as amended and under the Code Federal Regulations.

Sections 301 and 318 of the Public Health Service Act [42 U.S.C. Sections 241 and 247(c)], as amended.

Section 1004 [42 U.S.C. §300a-2] of the Public Health Service Act.