The GAIN (Greater Access and Impact with NAT) Study: Improving HIV Diagnosis, Linkage to Care, and Prevention Services with HIV Point-of-Care Nucleic Acid Tests (NATs)
RFA-PS-19-001
Application Due Date: 02/15/2019
The GAIN (Greater Access and Impact with NAT) Study: Improving HIV Diagnosis, Linkage to Care, and Prevention Services with HIV Point-of-Care Nucleic Acid Tests (NATs)

RFA-PS-19-001

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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)

**Notice of Funding Opportunity (NOFO) Title**
The GAIN (Greater Access and Impact with NAT) Study: Improving HIV Diagnosis, Linkage to Care, and Prevention Services with HIV Point-of-Care Nucleic Acid Tests (NATs)

**Activity Code**
U01 Research Project - Cooperative Agreement

**Notice of Funding Opportunity Type**
New

**Agency Notice of Funding Opportunity Number**
RFA-PS-19-001

**Assistance Listings (CFDA) Number(s)**
93.941

**Category of Funding Activity:**
Health

**NOFO Purpose**
The purpose of the research supported by this notice of funding opportunity (NOFO) is to develop feasible and effective models for using HIV point-of-care (POC) nucleic acid tests (NATs) to: (1) improve pre-exposure prophylaxis (PrEP) initiation, and duration of PrEP use, among persons at high-risk for acquiring HIV infection; and (2) reduce the time between testing in community-based and clinical-based settings and linkage to HIV care, anti-retroviral therapy (ART) initiation, and viral suppression.

**Key Dates**

**Publication Date:**
To receive notification of any changes to RFA-PS-19-001, return to the synopsis page of this announcement at [www.grants.gov](http://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:**
12/14/2018

**Application Due Date:**
02/15/2019

On-time submission requires that electronic applications be error-free and made available to CDC for processing from the NIH eRA system on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov no later than 5:00 PM U.S.
Eastern Time. Applications must be submitted using the Application Submission System & Interface for Submission Tracking (ASSIST) module which is a web-based service used for the preparation and submission of grant applications to CDC through Grants.gov. ASSIST provides the ability for applicants to prepare their applications online, and offers the applicant additional capabilities including the ability to preview the application image, validate the application against required business rules, and prepopulate data from an applicant organization's records, therefore identifying issues earlier in the application submission process.

Note: HHS/CDC grant submission procedures do not provide a grace period beyond the application due date time 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:** 04/11/2019
**Secondary Review:** 05/07/2019
**Estimated Start Date:** 09/01/2019
**Expiration Date:** 02/16/2019
**Due Dates for E.O. 12372:** Due no later than 60 days after the application receipt date.

**Required Application Instructions**

**ELECTRONIC APPLICATION SUBMISSION VIA ASSIST IS PREFERRED**

It is recommended that applicants use ASSIST for the electronic preparation and submission of applications through Grants.gov to CDC. ASSIST is an alternative method to prepare and submit applications, and provides many features to facilitate the application submission process which improves data quality (e.g., pre-population of organization data, pre-submission validation of business rules, and preview of the application image used for review). Use of the Grants.gov downloadable Adobe application packages and submission process will still be supported.

It is critical that applicants follow the instructions in the [SF 424 (R&R) Application Guide](https://grants.gov) except where instructed to do otherwise in this NOFO. Conformance to all requirements (both in the Application Guide and the NOFO) 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:** The purpose of the research supported by this notice of funding opportunity (NOFO) is to develop feasible and effective models for using HIV point-of-care (POC) nucleic acid tests (NATs) to: (1) improve pre-exposure prophylaxis (PrEP) initiation, and duration of PrEP use, among persons at high-risk for acquiring HIV infection; and (2) reduce the time between testing in community-based and clinical-based settings and linkage to HIV care, anti-retroviral therapy (ART), and viral suppression.
- **Mechanism of Support:** U01 - Research Project - Cooperative Agreement.
- **Funds Available and Anticipated Number of Awards:** The estimated total funding available, including direct and indirect costs, for the entire five (5)-year project period is $9,000,000. The anticipated number of awards is up to three (3). Awards issued under this NOFO 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 $1,800,000 with an average individual award ranging from $600,000 to $900,000 for the first year. The estimated total funding (direct and indirect) for the entire five (5)-year project period is $9,000,000. The project period is anticipated to run from 09/01/2019 to 08/31/2024.
- **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/oranizations 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.
- **Application Materials.** See Section IV.1 for application materials. Please note that Form E is to be used when completing the application package.
- **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
Public Health Service Act, Section 301(a) [42 U.S.C. 241(a)], as amended and Section 317(k)(2) [42 U.S.C. 247b(k)(2)], as amended.

1. Background and Purpose

In 2016, HIV infection was diagnosed in 39,782 people in the United States. Black/African American (26%) and Hispanic/Latino gay, bisexual, and other men who have sex with men (MSM) (18%) were among the most affected groups (1). Pre-exposure prophylaxis (PrEP) can prevent HIV acquisition among persons at risk (2). To prevent the emergence of drug-resistant HIV strains, prior to initiating PrEP, persons must be tested for HIV to ensure that they are not infected. Current rapid point-of-care (POC) technologies do not reliably detect the earliest HIV infections and lab-based testing can introduce delays while patients wait for test results. During this time, patients can drop out of care and are still at high-risk to become HIV infected. Direct molecular detection of HIV through nucleic acid tests (NATs) can identify early HIV infections, which have high potential for transmission. NATs that are used at the point-of-care (POC NAT) can provide results in 60 to 90 minutes. Obtaining timely molecular test results from a POC NAT in clinics or community settings can expand prevention as well as HIV treatment services, improve our reach into disproportionately affected populations, and provide opportunities to approach the goal of no new HIV infections (2-4).

In 2015, the U.S. Food and Drug Administration (FDA) first approved and granted Clinical Laboratory Improvement Amendments (CLIA) waivers for multiple POC NATs to diagnose influenza, streptococcus, and RSV infections. Devices used to perform these POC NATs can also be used to detect HIV-1 nucleic acid. Outside of the U.S., several POC NAT platforms are approved for HIV diagnosis and quantification. However, in the United States (U.S.), available POC testing with FDA-approved tests can only detect HIV p24 antigen and antibodies, which are only measurable days to weeks after nucleic acid detection. In the future, it is anticipated that the FDA will approve HIV POC NATs to diagnose and monitor HIV infections in the U.S.; until then, these tests can be used in a research capacity in community and clinical settings.

In PrEP clinics, systematic use of an HIV POC NAT to test at-risk persons, regardless of whether they have symptoms of acute HIV infection or not, would facilitate the identification of uninfected individuals who would benefit from initiating PrEP within a single care visit. To expedite PrEP initiation, rapid creatinine tests could also be implemented to assess renal function (a recommended safety test). HIV POC NATs could also facilitate more expedient treatment for persons diagnosed with an HIV infection.

Community-based settings can reach populations at disproportionate risk for HIV, such as black/African American and Hispanic/Latino MSM, who may not regularly access HIV testing in clinical settings. The use of HIV POC NATs may reduce the time between testing and PrEP initiation among persons at high risk, and may reduce the time between testing and treatment initiation or re-engagement for those who are diagnosed with HIV. Further, an HIV POC NAT to detect viral load at the time of diagnosis may provide information on the risk of progression of disease, and for transmission to sex and drug-sharing partners, that might improve motivation to link to HIV treatment.

The purpose of the research supported by this NOFO is to develop feasible and effective models for using HIV POC NATs to: (1) improve PrEP initiation, and duration of PrEP use, among
persons at high-risk for acquiring HIV infection; and (2) reduce the time between testing in community-based and clinical-based settings and linkage to HIV care, ART initiation, and viral suppression.

References


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 disproportionally 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 study, which is designed to develop feasible and effective models for the use of HIV POC NATs to improve: (1) pre-exposure prophylaxis (PrEP) initiation among person at high-risk for acquiring HIV infection; and (2) viral suppression among persons diagnosed with HIV infection, aligns with:

- Healthy People 2020 goals related to reducing new HIV infections, increasing HIV testing, and increasing access to care for persons with HIV infection:
  - HIV-1: Reduce the number of new HIV diagnoses.
  - HIV-2: Reduce the number of new HIV infections among adolescents and adults.
  - HIV-6: Reduce new AIDS cases among adolescent and adult men who have sex with men.
  - HIV-9: Reduce the proportion of persons with a diagnosis of Stage 3 HIV (AIDS) within 3 months of diagnosis of HIV infection.
  - HIV-13: Increase the proportion of persons living with HIV who know their serostatus.
  - HIV-14: Increase the proportion of adolescents and adults who have been tested for HIV in the past 12 months.
  - HIV-14.1: Increase the proportion of adolescents and adults who have ever been tested for HIV.
  - HIV-14.2: Increase the proportion of men who have sex with men (MSM) who report having been tested for HIV in the past 12 months.
  - HIV-19: Increase the proportion of persons who are linked to HIV medical care within 3 months of HIV diagnosis.
  - HIV-20: Increase the percentage of newly diagnosed persons with diagnosed HIV infection who are retained in continuous HIV medical care.
  - HIV-21: Increase the proportion of persons with an HIV diagnosis in medical care who were prescribed anti-retroviral therapy for the treatment of HIV infection at any time in the 12-month measurement period.
  - HIV-22: Increase the percentage of persons with diagnosed HIV infection who are virally suppressed.

- National Goals 1 [Reducing New HIV Infections]; 2 [Increase Access to Care and Improve Health Outcomes for People Living with HIV]; and 3 [Reducing HIV-related Disparities and Health Inequities]


**Public Health Impact**
Direct molecular detection of HIV is a critical component of HIV prevention strategies but current lab-dependent technologies: 1) introduce delays into HIV treatment and PrEP provision; 2) force healthcare providers to make clinical decisions with incomplete test result information; and 3) often introduce gaps in service delivery during which time people may drop out of care. HIV POC NATs have the potential to improve HIV diagnosis, treatment, care, and prevention services.

This NOFO seeks to assess how best to integrate HIV POC NAT technologies into community-based and clinical-based HIV testing. If demonstrated to be efficacious for HIV prevention, the data collected from this NOFO will provide evidence to support the utilization and scaling up of HIV POC NATs to improve HIV testing, linkage to care, viral suppression, and PrEP initiation outcomes in the United States, especially among the most affected populations.

**Relevant Work**

This notice of funding opportunity builds upon work conducted by CDC:

1. CDC published a federal register notice on an opportunity to collaborate with manufacturers of nucleic acid tests to evaluate their performance:


Since that time, CDC has presented work, generated through this collaboration, evaluating the performance of several simplified automated nucleic acid tests:


2. CDC is evaluating the performance and implementation of POC NATs through Project DETECT, conducted in a Seattle STD clinic. More information about DETECT:


   b) Evaluation of New HIV Testing Technologies in a Clinical Setting with High Incidence: Rationale, Study Design and Preliminary Results from Project DETECT, 2016 HIV Diagnostics Conference: [https://custom.cvent.com/BEED90636AE44DD0A76741F3CCF3692C/files/4ed4a58483b64239b05bf4edc3532f6a.pdf](https://custom.cvent.com/BEED90636AE44DD0A76741F3CCF3692C/files/4ed4a58483b64239b05bf4edc3532f6a.pdf)

3. CDC funded THRIVE (Targeted Highly-Effective Interventions to Reverse the HIV Epidemic) through the cooperative agreement CDC-RFA-PS15-1509 which supports state and local health departments to develop and implement demonstration projects for provision of comprehensive
HIV prevention, care, behavioral health, and social services for MSM of color by creating collaboratives with funded CBOs and unfunded clinics, health care providers, and behavioral and social service providers in their jurisdictions: https://www.cdc.gov/hiv/research/thrive/about.html

4. CDC funded PrIDE (PrEP Implementation, Data to Care, and Evaluation) through the cooperative agreement CDC-RFA-PS15-1506, which supports 12 state and local health departments to develop and implement demonstration projects to expand uptake of pre-exposure prophylaxis and data-to-care services for MSM and transgender persons of color: https://www.cdc.gov/hiv/research/demonstration/projectpride.html

2. **Approach**

The purpose of the research supported by this NOFO is to develop a model to implement HIV POC NATs in two distinct, but collaborating, settings (community-based and clinical-based HIV testing sites).

The application should:

1. Propose one or more HIV POC NATs for use during the study that are either FDA-approved, or an investigational device (please note: an investigational device exemption [IDE] may be required, depending on what additional testing is performed in parallel).
2. Describe working with CDC and the other NOFO awardees to finalize which HIV POC NATs will be used for the study when the study protocol is finalized after award.
3. Describe how the award recipient will work with CDC and the HIV POC NAT device manufacturer(s) to develop training for each of the proposed settings.
4. Describe collecting data related to the study objectives on clinical outcomes, the real world test performance compared with the reference (gold) standard, patient perspectives, and cost data.
5. Describe how the HIV prevention study objectives will be evaluated by randomizing the provision of HIV POC NATs at the site level to early versus delayed start groups. This study design has been successfully used to evaluate HIV adherence interventions.

The clinical outcome goal at both the community-based and clinical HIV testing sites is to evaluate whether implementation of HIV POC NATs will: a) increase the initiation of, and duration of time on, PrEP among HIV-negative eligible persons; and b) reduce the time from diagnosis to linkage to HIV care among persons with HIV infection.

**For the community-based HIV testing sites**, applicants are encouraged to include community testing sites that focus on providing HIV prevention services to African American/black and Hispanic/Latino MSM. All sites should aim to start data collection prior to implementing the HIV POC NAT (pre-implementation phase) and during the provision of HIV POC NAT (implementation phase) so that the outcomes can be compared with and without HIV POC NAT. Applicants are encouraged to propose an optimal method to evaluate the impact of the HIV POC NAT in this setting. CDC will work with awardees to develop a standard approach for evaluating outcomes.

For all community-based testing sites, the application should describe procedures to:

- Enroll participants who meet eligibility to initiate PrEP prior to their HIV testing.
- Conduct rapid HIV antigen/antibody or antibody-only testing.
• For people who test HIV-negative but are eligible for PrEP, the application should describe how the testing site will:
  o Provide counseling and education on the benefits of PrEP.
  o Facilitate same-day PrEP referrals, if feasible.
  o Implement evidence-based strategies to improve initiation of PrEP. This may include navigation services, same-day or flexible PrEP appointments, assistance with medication assistance programs, or accelerated health insurance initiation, but must be consistent across testing sites.
• For people with HIV infection (either a new diagnosis or a previous diagnosis), the application should describe how the testing site will:
  o Provide counseling and education on the benefits of HIV treatment.
  o Implement evidence-based strategies to improve linkage to HIV care. This may include navigation services, same-day or flexible HIV care appointments, assistance with medication assistance programs, or accelerated health insurance initiation but must be consistent across testing sites.

In addition, once testing sites implement the HIV POC NAT study intervention, the application should describe procedures to:

• Provide HIV POC NAT testing to all enrolled participants.
  o If phlebotomy is available, investigators are encouraged to obtain an EDTA whole blood tube for lab-based HIV-1 NAT testing for all enrolled participants. This testing is not required for participants, if not feasible.
• For people with a negative or undetectable HIV POC-NAT result, the application should describe procedures to:
  o Provide counseling and education on the benefits of PrEP that incorporates the HIV POC NAT result.
  o Facilitate same-day PrEP initiation utilizing the HIV POC NAT result.
    ▪ PrEP may be initiated at the HIV testing site with a starter pack and follow-up at the PrEP clinic or a same-day appointment at the PrEP clinic may be provided.
    ▪ POC creatinine testing may also be utilized (optional).
• For people with a positive or detectable HIV POC NAT result, the application should describe procedures to:
  o Provide counseling and education on the benefits of HIV treatment that incorporates the HIV POC NAT result.
  o Implement evidence-based strategies to improve linkage to HIV care that incorporates the HIV POC NAT result.
  o Utilize the HIV POC result to facilitate rapid (same day, if possible) HIV treatment.

For the clinical HIV testing sites, the application should describe how these clinical sites will provide PrEP (directly, or at an affiliated clinic) and how they will partner with the community-based HIV testing study sites to facilitate PrEP initiation referred from the community (although community referrals do not have to go to the study clinic). All sites should aim to start data collection prior to implementing the HIV POC NAT (pre-implementation phase) and during the
provision of HIV POC NAT (implementation phase) so that the outcomes can be compared with and without HIV POC NAT. Applicants are encouraged to propose an optimal method to evaluate the impact of the HIV POC NAT in this setting. CDC will work with awardees to develop a standard approach for evaluating outcomes.

For all clinical HIV testing sites, the application should describe procedures to:

- Enroll participants who meet eligibility to initiate PrEP prior to their HIV testing.
- Conduct lab-based HIV antigen/antibody testing, including supplemental testing, for repeatedly reactive results as recommended in the APHL/CDC testing algorithm (https://www.cdc.gov/hiv/testing/laboratorytests.html).
- For people who test HIV-negative and are eligible for PrEP, the application should describe how the clinical HIV testing site will:
  - Provide comprehensive introduction to PrEP, including counseling and education on the benefits of PrEP.
  - Provide baseline standard lab testing, as recommended in CDC’s PrEP guidelines (https://www.cdc.gov/hiv/risk/prep/index.html).
  - Initiate PrEP based on the clinic’s standard protocol.
  - Implement evidence-based strategies to improve PrEP adherence. This may include electronic reminders, navigation services, flexible PrEP appointments, assistance with medication assistance programs, or accelerated health insurance initiation, but must be consistent across testing sites.
- For people with HIV infection (either a new diagnosis or a previous diagnosis), the application should describe how the clinical HIV testing site will:
  - Provide counseling and education on the benefits of HIV treatment.
  - Implement evidence-based strategies to improve linkage to HIV care. This may include navigation services, same-day or flexible HIV care appointments, assistance with medication assistance programs, or accelerated health insurance initiation, but must be consistent across testing sites.
- For people who enrolled in the study and initiated PrEP, but experienced an interruption in medications of more than one week, the application should describe how the clinical HIV testing site will:
  - Provide comprehensive PrEP adherence counseling and education on the benefits of PrEP.
  - Reassess for PrEP indications and provide HIV testing as recommended in CDC’s PrEP guidelines.
  - Re-initiate PrEP based on the clinic’s standard protocol.

In addition, once clinical testing sites implement the HIV POC NAT study intervention, the application should describe procedures to:

- Provide HIV POC NAT testing to all enrolled participants.
  - Obtain an EDTA whole blood tube for lab-based HIV-1 RNA viral load testing for all enrolled participants.
- For people with a negative or undetectable HIV POC NAT result, the application should describe how the clinical HIV testing site will:
  - Provide counseling and education on the benefits of PrEP that incorporates the
HIV POC NAT result.
  o Facilitate same-day PrEP initiation utilizing the HIV POC NAT result.
    ▪ PrEP may be initiated with a starter pack or a prescription for PrEP.
    ▪ POC creatinine testing may also be utilized (optional).
  • For people with a positive or detectable HIV POC NAT result, the application should describe how the clinical HIV testing site will:
    o Provide counseling and education on the benefits of HIV treatment that incorporates the HIV POC NAT result.
    o Implement evidence-based strategies to improve linkage to HIV care that incorporates the HIV POC NAT result.
    o Utilize the HIV POC NAT result to facilitate rapid (same day, if possible) HIV treatment.
  • For people who have enrolled in the study and initiated PrEP, but experienced an interruption in medications of more than one week, the application should describe how the clinical HIV testing site will:
    o Provide HIV POC NAT testing.
    o Re-initiate PrEP immediately, if PrEP is still indicated, and the HIV POC NAT result is negative or undetectable.

Participants should be contacted at one week after PrEP initiation (by phone, if possible) to discuss any early complications with PrEP and to provide adherence support. Participants should be asked to return for a PrEP clinic visit at one month, and then at least every three months, for clinical evaluation, adherence discussions, and routine HIV, STD, and creatinine testing. Once clinics have implemented HIV POC NAT testing, these results should be used to maintain PrEP adherence by linking HIV POC NAT testing to adherence counseling, especially for any participant with reported episodes of non-adherence, medication discontinuation, or missed clinic visits.

Evaluation of the Performance of HIV POC NATs

If multiple HIV POC NAT devices are available, award recipients should conduct head-to-head evaluations of HIV POC NATs using fingerstick blood specimens at additional clinical sites. This activity would achieve two additional goals: 1) to evaluate the sensitivity of HIV POC NATs over a range of HIV-1 viral load values and 2) to compare at least two different candidate HIV POC NATs, using fingerstick blood specimens. To achieve these objectives, it is likely that recruitment of HIV-infected participants with and without suppression from an HIV care clinic would be required. These participants would not contribute to the primary study outcomes, as those participants would have the additional burden of multiple HIV POC NATs performed. Thus, award recipients interested in conducting a head-to-head evaluation of two (2) or more HIV POC NATs, using fingerstick blood specimens, should include a description of how to conduct this activity in the application and include a proposal to conduct this component in a separate clinic outside of the main implementation and outcomes study.

As part of this activity, applications should describe procedures to:
  • Identify at least one clinical site at which at least two (2) HIV POC NATs could be evaluated per year.
Applications should describe the ability to work with CDC to identify tests to be included in this evaluation, noting that the tests being implemented may change as frequently as annually over the time of the award.

- Recruit participants with HIV infection to participate in the evaluation of the HIV POC NATs and ensure that at least 200 participants are recruited per year and that at least 50% of all recruited participants have a detectable HIV-1 viral load, based on results of laboratory-based HIV-1 RNA testing.
- Conduct at least two fingerstick HIV POC NATs on each participant. Additional HIV testing (such as rapid HIV testing) may be performed (optional).
- Collect an EDTA whole blood tube for lab-based HIV-1 RNA testing for all enrolled participants.
- For people with a positive or detectable HIV POC NAT result, the application should describe how the study clinic will:
  - Provide counseling and education on the benefits of HIV treatment and achieving viral suppression that incorporates the HIV POC NAT result.
  - Implement evidence-based strategies to improve HIV care to achieve viral suppression that incorporates the HIV POC NAT result.
  - Utilize the HIV POC NAT result to facilitate rapid (same day, if possible) HIV treatment.

In both community and clinical settings, the HIV POC NAT performance should be compared within-individual to the gold standard reference test of a lab-based FDA-approved HIV-1 RNA viral load assay. Among persons with an unknown HIV infection status at the time of testing using standard diagnostic testing, the HIV POC NAT sensitivity (including acute HIV infection sensitivity), specificity, positive predictive value, and negative predictive value should be calculated. Among persons with HIV infection who receive an HIV-1 viral load test, the agreement of HIV POC NAT quantitative or semi-quantitative results (copies of HIV-1 detected per mL) to the lab-based HIV-1 viral load result should be calculated.

The application should describe how a survey will be conducted with a subset of participants and staff at the HIV testing sites and the PrEP clinics. The survey should evaluate participant experience and satisfaction with the HIV POC NAT and if the information from this test influenced their decision regarding PrEP or ART initiation. The survey should also evaluate the participant’s risk factors for HIV infection and any barriers to initiating PrEP or ART. The staff interview should evaluate their experience and satisfaction with providing the HIV POC NAT. Information on cost to perform the HIV POC NAT should be collected, including a time-in-motion evaluation, to accurately capture the staff time required to perform the assay and to inform a cost-effectiveness analysis.

Participant incentives are not required or encouraged for participants who receive HIV POC NAT testing, and are followed for the main outcomes of initiating PrEP and linking to HIV care, unless incentives are already provided as standard of care at the HIV testing site. Participants who complete additional activities, such as a survey or interview, or who receive testing with multiple HIV POC NAT devices, could receive an incentive to compensate for their time.

Applicants are encouraged to use the HIV POC NAT device in other settings, such as HIV treatment clinics and during field outreach to HIV-infected persons who are out-of-care (e.g., health department data-to-care, care coordination, or partner services activities), although these
activities are not required. In HIV treatment clinics, HIV-infected people who are not known to have viral suppression, could receive HIV POC NAT testing in addition to their comprehensive HIV clinical care. This testing would provide more data on the agreement of the HIV POC NAT result and the lab-based HIV-1 viral load. In addition, the result might be used to tailor adherence messages. Participants with a detectable HIV POC NAT could receive motivational counseling either to initiate same-day antiretroviral treatment or to improve adherence. With health department field-based testing of persons who are HIV infected but not receiving care, the HIV POC NAT result might be used as an additional motivator to re-link to care.

Applications should provide a detailed description of the proposed study implementation that includes:

- Specific target populations for selected community-based and clinical testing settings should be based on evidence of recruitment sites and strategies that have demonstrated success at reaching a high volume of testing and yield of positive HIV tests among persons not currently achieving viral suppression. For example, African American / black and Hispanic / Latino men who have sex with men are at disproportionate risk for HIV infection and may more readily access HIV testing services that are community-based and tailored to their unique needs: https://www.cdc.gov/hiv/testing/nonclinical/index.html. Also, see Table 3a of CDC’s 2016 HIV Surveillance Report: https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2016-vol-28.pdf.
- Description of the process for consenting, screening, and enrolling participants.
- Description of a plan to compare outcomes with and without the HIV POC NAT.
- Description of the proposed HIV testing procedures.
- Description of the implementation of the promising and evidence-based strategies planned for linkage to HIV care and PrEP. Strategies offered should be the same for both study arms (i.e., the pre-implementation phase and the HIV POC NAT implementation phase).
- Description of appropriate incentive plans for completion of study activities.
- Description of the process for collecting baseline information on participant demographics, HIV testing and treatment history.
- Description of the process for collecting follow-up data on study participants’ linking to PrEP services.
- Description of a plan for tracking HIV testing, referrals, and linkages for HIV care and prevention.
- Description and justification of the proposed study design, including sample size for a main outcome such as increased PrEP initiations, power, and effect size.
  o The study should enroll at least 700 people at-risk for HIV infection and the application should propose a sample size calculation that clearly lists the underlying assumptions and describes the statistical methods used.
- Description of a plan for documenting costs associated with the provision of HIV POC NATs in community- and clinical-based HIV testing sites compared with standard care.
• Description of a plan for collecting and analyzing qualitative data (e.g., from key informant interviews and focus groups) on the process of implementing HIV POC NAT testing in non-clinical settings. In addition to the key outcomes, identify:
  o External social and/or structural factors that facilitate and/or inhibit implementation of HIV POC NATs.
  o Internal barriers and facilitators to implementation of HIV POC NATs.
  o Costs associated with service delivery.
• Description of the proposed data management plan detailing data access and sharing of the data at completion of the research study.
• Description of a quality assurance plan. The quality assurance (QA) plan, to be developed during the first year, should include a thorough written description of all project activities in the form of a Standard Operating Procedure Manual that will describe policies and procedures for testing, referral and linkage to HIV services. A QA manager should be identified in the application.
• Description of plans to disseminate findings and develop tools of promising practices and lessons learned.
• The application should describe plans for submitting annual progress reports and other written reports to CDC as specified in the NOFO.
• The application should describe plans for a Publication Committee for the study that includes representatives from all of the awardees, CDC, and other key partners to determine rules for authorship of publications, abstracts and presentations and select targeted journals.

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

HIV POC NATs will become an option for HIV diagnostics and clinical patient monitoring in the U.S. but the optimal public health roles for these assays remain undefined. This project provides the opportunity to measure the potential public health impact of this new technology in two settings: community-based and clinical HIV testing sites. The primary objective of this NOFO is to develop a feasible and effective model for the use of HIV POC NATs to improve PrEP initiation among person at high-risk for acquiring HIV infection. Additional objectives are to evaluate if: 1) use of HIV POC NATs for HIV-infected persons results in more persons linking to HIV treatment; and 2) use of HIV POC NATs for persons on PrEP results in a longer duration of time on PrEP.

Research objectives

1. In community-based and clinical-based testing sites, evaluate if use of HIV POC NATs lead to an increased number of persons initiating PrEP among those who test HIV negative, and whether the use of HIV POC NATs at PrEP clinical visits improves a person’s duration time on PrEP to over 12 months.
2. In community-based and clinical-based testing sites, evaluate if use of HIV POC NATs lead to an increased number of persons linking to HIV care, starting anti-retroviral drugs, and achieving viral suppression among those who test HIV positive.
3. Assess the feasibility, acceptability, and implementation facilitators and barriers for patients and providers of using HIV POC NATs in community-based and clinical-based testing sites.
4. Assess the patient and provider satisfaction and convenience of using an HIV POC NAT.
5. Document the cost of using HIV POC NATs in community-based and clinical-based testing sites compared with standard of care.
6. Assess the performance of HIV POC NATs compared to a reference laboratory NAT.

The scientific knowledge gained through this research study should inform the development of best practices for using HIV POC NATs in community-based and clinical-based testing sites to expedite PrEP initiation for persons at substantial risk of HIV infection. It should determine whether the use of HIV POC NATs expedite PrEP initiation and increases the number of persons who link to HIV treatment.

The research study should provide data on real-world test performance of HIV POC NATs when used on unprocessed blood specimens. It should also provide patient and provider perspectives on its use. Finally, the research project should provide information on the costs of using HIV POC NATs for HIV diagnosis and monitoring, which can be compared with existing standard HIV tests.

**Expected outcomes by activity include the following:**

1. **Implement HIV POC NAT testing at community-based HIV testing sites**
   - Increased PrEP initiations among eligible persons compared with standard care.
   - Increased PrEP initiations among eligible African American / black and Hispanic / Latino men who have sex with men compared with standard care.
   - Decreased time between HIV testing and PrEP initiation compared with standard care.
   - Increased duration of time with increased percentages of persons on PrEP at 6 months and 12 months compared with standard care.
   - Increased linkage to HIV clinical care, ART initiation, and viral suppression among persons diagnosed with HIV infection (new or previously diagnosed) compared with standard care.
   - Decreased time between HIV testing and HIV treatment initiation compared with standard care.

2. **Implement HIV POC NAT testing at clinical HIV testing sites**
   - Increased PrEP initiations among eligible persons compared with standard care.
   - Increased PrEP initiations among eligible African American / black and Hispanic / Latino men who have sex with men compared with standard care.
   - Decreased time between HIV testing and PrEP initiation compared with standard care.
   - Increased duration of time with increased percentages of persons on PrEP at 6 months and 12 months compared with standard care.
   - Increased linkage to HIV clinical care, ART initiation, and viral suppression among persons diagnosed with HIV infection (new or previously diagnosed) compared with standard care.
   - Decreased time between HIV testing and HIV treatment initiation compared with standard care.
3. **Describe the performance of the HIV POC NATs compared with the gold standard reference test of a lab-based, FDA-approved HIV-1 RNA viral load assay**
   - The HIV POC NATs sensitivity to diagnose HIV infection should exceed 95%.
   - The HIV POC NATs specificity should exceed 99%.
   - Among persons with HIV infection, the paired difference between HIV POC NATs and lab-based HIV-1 viral load results should be less than 0.3 log10 when greater than 1,000 HIV-1 copies/mL are detected.

4. **Conduct a survey with a subset of participants and staff to evaluate their experience and satisfaction with HIV POC NATs**
   - More than 80% of participants surveyed report a positive patient-centered experience with the HIV POC NAT testing experience.
   - More than 80% of staff surveyed report a positive experience with conducting HIV POC NAT testing.

5. **Collect information on cost to perform the HIV POC NATs including a time-in-motion evaluation**
   - HIV POC NATs are cost effective in a model that accounts for the cost data and study data on additional HIV infections detected and additional persons who initiated PrEP and sustained PrEP use.

**Target Population**


The target populations for this study are persons at high-risk for acquiring HIV infection and HIV-positive persons who are not virally suppressed, including those who are newly identified and those who are out of care. Selected non-clinical, community-based testing settings should be based on demonstrated success at conducting a high volume of testing and reaching persons at high-risk for acquiring HIV infection and HIV-positive persons not currently achieving viral suppression. African American/black and Hispanic/Latino MSM are at disproportionate risk for HIV infection and may more readily access HIV testing services that are community-based and tailored to their unique needs: [https://www.cdc.gov/hiv/testing/nonclinical/index.html](https://www.cdc.gov/hiv/testing/nonclinical/index.html). Also, see Table 3a of CDC’s 2016 HIV surveillance report: [https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2016-vol-28.pdf](https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2016-vol-28.pdf).

**Collaboration/Partnerships**

Award recipients are expected to form a collaboration among at least three partners, including:

- A community-based organization with a history of providing HIV prevention services to African American/black and Latino/Hispanic MSM.
- A major HIV clinical care provider with: a) clinics that provide HIV testing and PrEP; b) the capacity to provide all of the necessary clinical services; and c) the capacity to obtain relevant laboratory tests for this proposed study.
- A local or state health department that leads public health HIV prevention in the proposed...
jurisdiction.

Letters of collaboration or a memorandum of understanding (MOU) from these partners that indicate support for participating in this project should be submitted with the application. The application should describe how the collaborating partners will work together to implement the strategies and to sustain the outcomes of this project. The application should also describe how the collaborating partners will efficiently use existing resources and how information will be exchanged during the project.

Applications should provide a detailed description of plans to select and establish partnerships with relevant agencies (e.g., academic institutions, health departments, community-based organizations, HIV/STD care clinics, community health centers, etc.) that includes:

- Description of plans to establish a credible presence in the community to reach the target population and to facilitate successful completion of the proposed project activities.
- Demonstration of partnerships established through subcontracts and/or memoranda of agreement (MOAs) with health departments, hospitals, clinics, providers, laboratories, and/or HIV service organizations for testing, diagnostics, follow-up, navigation services, and treatment, as needed. MOAs with HIV and PrEP providers should describe their experience and ability to prescribe ART and/or PrEP.
- Letters of collaboration from the research partners and a description of how and why the collaborating agencies were selected. Letters of collaboration should include:
  - A statement of the collaborating agency’s role in the project.
  - A statement of their resources and commitment to the success of the study, including any skills or experience that may make them uniquely qualified to serve as a study partner.
  - Intent to enter into formal agreements for participation (e.g., MOUs, contracts) for the entire project period.
  - Collaborating agencies that will facilitate community-based testing should also include in their letters of collaboration:
    - Description of previous or proposed recruitment sites and strategies that have a high volume of testing and yield of positive HIV tests. High yield may be interpreted as relative to expected rate of diagnosis based on the prevalence in the population. Diagnostic yield refers to the proportion of positive results (newly diagnosed HIV infection) relative to the total number of tests performed. Higher yield indicates that a program is reaching those most at risk of an undiagnosed infection.
    - Description of existing or proposed community-based HIV testing strategies that target vulnerable populations, including details about the types of POC rapid tests used. Description should also include how CDC’s recommended testing algorithms are applied (https://www.cdc.gov/hiv/testing/laboratorytests.html). The application should document that funds will be used to cover the costs of rapid HIV test kits for the duration of this study.
    - Description of how testing strategies will follow CDC’s guidelines for testing in non-clinical settings, which includes guidelines for targeting and recruitment. See: https://www.cdc.gov/hiv/pdf/testing/cdc_hiv_impleme
Evaluation/Performance Measurement
The application should include measurable goals and aims based on a five (5)-year research project period. The application should include specific, measurable, achievable, realistic and time-phased (SMART) project objectives for each activity described in the application’s project plan, and describe the development and implementation of project performance measures based on specific programmatic objectives.

Translation Plan
HIV POC NATs should become an option for HIV diagnostics and clinical monitoring in the U.S. but the optimal public health role remains undefined. The results of this research should be made available to a wide range of potential users and stakeholders. Key findings should be presented at national and international meetings and published in peer-review journals. Findings related to the effective implementation of HIV POC NATs in community-based and clinical settings should be disseminated to the public health community, clinicians, and community-based stakeholders to inform their efforts to sustainably implement these testing models. In addition, findings related to the patient and implementing staff experiences with HIV POC NATs should inform recommendations for how to provide and best utilize HIV POC NATs.

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: $9,000,000

Estimated total funding available per year:
Year 1: $1,800,000
Year 2: $1,800,000
Year 3: $1,800,000
Year 4: $1,800,000
Year 5: $1,800,000
Estimated total funding available for the first year (first 12-month budget period), including direct and indirect costs: $1,800,000

Estimated total funding available for the entire five (5)-year project period, including direct and indirect costs: $9,000,000

Anticipated Number of Awards: 3

It is anticipated there will be up to three (3) awards.

The ceiling and floor amounts listed below are for the first 12-month budget period only.

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

Award Ceiling: $900,000 Per Budget Period
Award Floor: $0 Per Budget Period
Total Period of Performance Length: 5 year(s)

Throughout the Period of Performance, 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 NOFO.

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
For profit organizations other than small businesses
Small businesses

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:

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."
Federally Funded Research and Development Centers (FFRDCs): FFRDCs are operated, managed, and/or administered by a university or consortium of universities, other not-for-profit or nonprofit organization, or an industrial firm, as an autonomous organization or as an identifiable separate operating unit of a parent organization. A FFRDC meets some special long-term research or development need which cannot be met as effectively by an agency's existing in-house or
contractor resources. FFRDC's enable agencies to use private sector resources to accomplish tasks that are integral to the mission and operation of the sponsoring agency. For more information on FFRDCs, go to https://dap.dau.mil/acquiped/Pages/ArticleDetails.aspx?aid=5e3079b8-44f2-43df-a0e7-9f379e8c48ed

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
N/A

4. Justification for Less than Maximum Competition
N/A

5. Responsiveness
N/A

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%20for%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/.
- 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 Principle Investigator (PD/PI) 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 eRA Commons registration process at least four (4) weeks prior to the application due date. ASSIST requires that applicant users have active eRA Commons account in order to prepare an application. It also requires that the applicant organization's Signing Official have an active eRA Commons Signing Official account in order to initiate the submission process. During the submission process, ASSIST will prompt the Signing Official to enter their Grants.gov Authorized Organizational Representative (AOR) credentials in order to complete the submission, therefore the applicant organization must ensure that their Grants.gov AOR credentials are active.

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 recipient 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 recipient 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, (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf), applications received in response to the same Notice of Funding Opportunity 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 NOFO 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
In order to use ASSIST, applicants must visit https://public.era.nih.gov/assist where you can login using your eRA Commons credentials, and enter the Notice of Funding Opportunity Number to initiate the application, and begin the application preparation process. If you experience problems accessing or using ASSIST, you can refer to the ASSIST Online Help Site at: https://era.nih.gov/erahelp/assist. Additional support is available from the NIH eRA Service desk via:
- E-mail: http://grants.nih.gov/support/index.html
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552. The NIH eRA Service desk is available Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding federal holidays.

2. Content and Form of Application Submission
It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide.htm and here: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf except where instructed in this Notice of Funding Opportunity 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 package associated with this NOFO includes all applicable mandatory and optional forms. Please note that some forms marked optional in the application package are required for submission of applications for this NOFO. Follow the instructions in the SF-424 (R&R) Application Guide to ensure you complete all appropriate “optional” components. When using ASSIST, all mandatory forms will appear as separate tabs at the top of the Application Information screen; applicants may add optional forms available for the NOFO by selecting the Add Optional Form button in the left navigation panel.
Please include all of the eight (8) mandatory forms listed below in the application package:

**Mandatory**

1. SF424(R&R)[V2.0];
2. PHS 398 Cover Page Supplement [V4.0];
3. Research and Related Other Project Information [V1.4];
4. Project/Performance Site Location(s) [V2.0];
5. Research and Related Senior/Key Person Profile (Expanded) [V2.0];
6. Research and Related Budget [V1.4];
7. PHS 398 Research Plan [V4.0];
8. PHS Human Subjects and Clinical Trials Information [V1.0].

Please include the one (1) optional form listed below, if applicable, in the application package:

**Optional**

1. R&R Subaward Budget Attachment(s) Form 5 YR 30 ATT.

**3. Letter of Intent**

Due Date for Letter of Intent: **12/14/2018**

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 CDC 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 institution
- 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 notice of funding opportunity (NOFO)

The letter of intent should be sent to:
- Gregory Anderson, MPH, MS
- Extramural Research Program Office
- Office of the Associate Director of Science
4. Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this NOFO in Grants.gov includes all applicable components for this NOFO, required and optional. In ASSIST, all required and optional forms will appear as separate tabs at the top of the Application Information screen.

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 components. Not all components of the Research Plan apply to all Notices of Funding Opportunities (NOFOs). Specifically, some of the following components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/generalforms-e.pdf and https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Notice of Funding Opportunity Description).

Follow the page limits stated in the SF 424 unless otherwise specified in the NOFO. As applicable to and specified in the NOFO, 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 NOFO.

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 time line.

4. Progress Report Publication List (for Continuation ONLY)

Other Research Plan Sections

5. Vertebrate Animals
6. Select Agent Research
7. Multiple PD/PI Leadership Plan.
8. Consortium/Contractual Arrangements
9. Letters of Support
10. Resource Sharing Plan(s)
11. Authentication of Key Biological and/or Chemical Resources
12. Appendix

All instructions in the SF424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf must be followed along with any additional instructions provided in the NOFO.

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: According to the Additional Requirement-25 (AR-25) (https://www.cdc.gov/grants/additionalrequirements/ar-25.html), investigators who 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 as follows:

The DMP must describe how investigators will make data readily available. Investigators 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. A Data Management Plan (DMP) is required for each collection of public health data proposed. The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include the following five elements:

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;
- Mechanisms for, or limitations to, providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security,
intellectual property, or other rights - this section should address access to identifiable and de-identified data);
- Statement of the 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 (this section should address archiving and preservation of identifiable and de-identified data).

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 NOFO must be followed. For this specific NOFO, 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 50 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** [https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf) and here: [https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf](https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf).

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are strongly encouraged to allocate additional time and submit in advance of the deadline to ensure they have time to make any corrections that might be necessary for successful submission. This includes the time necessary to complete the application resubmission process that may be necessary, if errors are identified during validation by Grants.gov and the NIH eRA systems. The application package is not complete until it has passed the Grants.gov and NIH eRA Commons submission and validation processes.

Organizations must submit applications using the ASSIST web-based application preparation and submission process. 

ASSIST will validate applications before submission. If the system detects errors, then the
Applicant must correct errors before their application can be submitted.

Applicants are responsible for viewing their application in ASSIST after submission to ensure accurate and successful submission through Grants.gov. If the submission is not successful and post-submission errors are found, then those errors must be corrected and the application resubmitted in ASSIST.

Applicants are able to access, view, and track the status of their applications in the eRA Commons.


Note: HHS/CDC grant submission procedures do not provide a grace period beyond the grant application due date time 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).

Applicants who encounter problems when submitting their applications must attempt to resolve them by contacting the NIH eRA Service desk at:
Toll-free: 1-866-504-9552; Phone: 301-402-7469
http://grants.nih.gov/support/index.html
Hours: Mon-Fri, 7 a.m. to 8 p.m. Eastern Time (closed on federal holidays)

Problems with Grants.gov can be resolved by contacting the Grants.gov Contact Center at:
Toll-free: 1-800-518-4726
https://www.grants.gov/web/grants/support.html
support@grants.gov
Hours: 24 hours a day, 7 days a week (closed on federal holidays)

If the applicant encounters problems that prevent the ability to submit an application which cannot be resolved by Grants.gov or NIH eRA Service Desks, then applicants must contact CDC Technical Information Management Section (TIMS) at 770-488-2700; ogstims@cdc.gov for guidance at least 3 calendar days before the deadline date. Therefore, it is important that applicants complete the application submission process well in advance of the due date time.

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. A third and final e-mail message is generated once the applicant’s application package has passed validation and the grantor agency has confirmed receipt of the application.

Unsuccessful Submissions: If an application submission was unsuccessful, the applicant must:

1. Track 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 emails from both Grants.gov and NIH eRA Commons for rejection notices.
   a. If the deadline has passed, he/she should email the Grants Management contact listed in the Agency Contacts section of this announcement and ogstims@cdc.gov explaining why
the submission failed.

b. If there is time before the deadline, correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: 02/15/2019

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: https://www.whitehouse.gov/wp-content/uploads/2017/11/Intergovernmental_-Review_-SPOC_01_2018_OFFM.pdf.

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. In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability (https://www.cdc.gov/grants/additionalrequirements/ar-35.html).

For more information on expanded authority and pre-award costs, go to: https://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).

Recipients 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: https://www.cdc.gov/grants/additionalrequirements/ar-25.html for revised AR-25.

Additional Funding Restrictions:

1. Funds related 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.
2. Funds relating to the conduct of research involving vertebrate animals will be restricted until the appropriate assurances and Institutional Animal Care and Use Committee (IACUC) approvals are in place. Copies of all current local IACUC approval letters and local IACUC approved protocols 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 grantee 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 United States Government (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.
5. Please note the requirement for 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 NOFO (https://www.cdc.gov/grants/additional requirements/ar-25.html). Funding restrictions may be imposed, pending submission and evaluation of a Data Management Plan.

12. Other Submission Requirements and Information
Risk Assessment Questionnaire Requirement
CDC is required to conduct pre-award risk assessments to determine the risk an applicant poses to meeting federal programmatic and administrative requirements by taking into account issues such as financial instability, insufficient management systems, non-compliance with award conditions, the charging of unallowable costs, and inexperience. The risk assessment will
include an evaluation of the applicant’s CDC Risk Questionnaire, located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, as well as a review of the applicant’s history in all available systems; including OMB-designated repositories of government-wide eligibility and financial integrity systems (see 45 CFR 75.205(a)), and other sources of historical information. These systems include, but are not limited to: FAPIIS (https://www.fapiis.gov/), including past performance on federal contracts as per Duncan Hunter National Defense Authorization Act of 2009; Do Not Pay list; and System for Award Management (SAM) exclusions.

CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-1132 annually. This questionnaire, which is located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, along with supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. If your organization has completed CDC’s Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization representative to include the original submission date, organization’s EIN and DUNS.

When uploading supporting documentation for the Risk Questionnaire into this application package, clearly label the documents for easy identification of the type of documentation. For example, a copy of Procurement policy submitted in response to the questionnaire may be labeled using the following format: Risk Questionnaire Supporting Documents _ Procurement Policy.

**Duplication of Efforts**

Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual’s time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual’s effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award. Report Submission: The applicant must upload the report under “Other Attachment Forms.” The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap.”

**Please note** the new requirement for a Risk Assessment Questionnaire (described above) that should be uploaded as an attachment in the "12. Other Attachments" section of the "RESEARCH & RELATED Other Project Information" section 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://era.nih.gov/erahelp/ASSIST/

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?

- How well does this application describe the need to integrate HIV POC NATs into community-based and clinical testing settings?
- Does the application explain how the introduction of HIV POC NATs in these settings may affect disparities in HIV-related health outcomes among black/African American and Hispanic/Latino MSM?
- How likely is it that the project will be able to leverage the use of HIV POC NATs to improve linkage to HIV clinical care, PrEP initiation, and duration of time on PrEP in the proposed settings?

**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?

- Do the investigators demonstrate prior experience with clinical research?
- Do the investigators have experience with protecting human subjects from research harm?
- Do the investigators have experience in the development of a protocol for data collected...
from the public that required approval from the Office of Management and Budget (OMB) as described in the Paperwork Reduction Act?

- Do the investigators have experience evaluating investigational test devices as defined by the Food and Drug Administration?
- Do the investigators describe relevant experience with HIV service delivery settings, such as community-based and clinical testing sites and PrEP clinics?
- Do the investigators describe relevant experience in conducting research on HIV prevention services for black/African American and Hispanic/Latino MSM?

## 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?

- How well does the application describe an intervention model that leverages HIV POC NATs in combination with other innovative strategies to improve the overall HIV service delivery process?
- How well does the application describe a standardized, comprehensive service model for both the immediate intervention and delayed start study arms?
- Does the project described in the application have the potential to increase efficiency or lead to cost savings?

## 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 describe the clinics where the study will be implemented, including patient populations studied and a description of the outcome measures of interest (e.g., number and proportion of eligible patients initiating PrEP, duration of time on PrEP, number and proportion of patients with newly diagnosed HIV initiating ART within 30 days, etc.)?
- Does the approach section of the application describe the current standard of practice at the proposed study sites, including clearly defined procedures for HIV testing prior to PrEP initiation and HIV viral load monitoring?
- Does the approach section of the application describe how laboratory results are
securely recorded and stored?
- Does the application describe procedures for initiation of PrEP and/or antiretroviral therapy and the extent to which these will be enhanced and standardized across settings as part of the study?
- Does the approach describe a study design that is both rigorous and practical, including plans for site randomization, client recruitment, clinical and self-report data collection, and data storage and analysis?
- Does the approach section of the application describe mechanisms to collect information on HIV test results and linkage to care in community sites, and clinical outcomes including documentation of PrEP initiation, duration of time on PrEP, linkage to HIV care, and ART initiation that are appropriate to document the proposed study outcomes?
- Does the approach section of the application describe methods to minimize participant attrition for study follow-up?

**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 include evidence of partnerships with HIV prevention service organizations including, but not limited to, local health departments, community-based organizations, community health centers, and other agencies serving the target population in the service delivery area?
- Does the application describe adequate on-site staffing support to cover the multiple service delivery settings described?
- Does the application describe how the study sites were selected, including a description of whether the sites are comparable in terms of services that will be provided with a common study protocol?
- To what extent does the application select HIV prevention service settings that serve high HIV-prevalence geographic areas and populations?
- Does the application include letters of collaboration or memoranda of understanding (MOUs) from all collaborating agencies?

**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 (https://www.cdc.gov/grants/additionalrequirements/ar-1.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 (https://www.cdc.gov/maso/Policy/Policy_women.pdf) and the policy on the Inclusion of Persons Under 21 in Research (https://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 (https://grants.nih.gov/grants/olaw/VASchecklist.pdf).

**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.

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: https://www.cdc.gov/grants/additionalrequirements/ar-25.html

New additional requirement: CDC requires recipients 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 Notice of Funding Opportunity 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](http://www.cdc.gov/grants/interestedinapplying/applicationresources.html)

The budget can include both direct costs and indirect costs as allowed. Indirect costs could include the cost of collecting, managing, sharing and preserving data. Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of modified total direct costs exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.

Indirect costs on training grants are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and sub-awards in excess of $25,000.

If requesting indirect costs in the budget based on a federally negotiated rate, a copy of the indirect cost rate agreement is required. Include a copy of the current negotiated federal indirect cost rate agreement or cost allocation plan approval letter.

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**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 NOFO. 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.

Please note: Applications may receive funding preference in the following order:

First, an application that targets jurisdiction(s) in metropolitan statistical areas (MSA) with a high HIV burden, as indicated by recent HIV diagnosis rates (please see Table 28 of CDC’s 2016 HIV Surveillance Report https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2016-vol-28.pdf), may receive preference over those that do not include jurisdiction(s) with a high HIV burden.

Second, an application may receive funding preference so that no two applications are studying populations within the same HHS geographic region (https://www.hhs.gov/about/agencies/iea/regional-offices/index.html) to ensure that the models for using HIV POC NAT are feasible and effective in diverse settings.

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 Recipient 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 Notice of Funding Opportunity.

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 NOFO 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 (https://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.

Recipient 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
Administrative and National Policy Requirements, Additional Requirements (ARs) outline the administrative requirements found in 45 CFR Part 75 and the HHS Grants Policy Statement and other requirements as mandated by statute or CDC policy. Recipients must comply with administrative and national policy requirements as appropriate. For more information on the Code of Federal Regulations, visit the National Archives and Records Administration: http://www.access.gpo.gov/nara/cfr/cfr-table-search.html.

Specific requirements that apply to this NOFO 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-5: HIV Program Review Panel Requirements
AR-6: Patient Care
AR-7: Executive Order 12372 Review
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-16: Security Clearance Requirement
AR-22: Research Integrity
AR-23: Compliance with 45 C.F.R. Part 87
AR-25: Policy on Public Health Research and Non-research Data Management and Access
AR-26: National Historic Preservation Act of 1966
AR-27: Conference Disclaimer and Use of Logos
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-31: Distinguishing Public Health Research and Public Health Nonresearch
AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use
3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

**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 applies to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website at: [https://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html](https://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](http://www.usaspending.gov). For the full text of the requirements, please review the following website: [https://www.fsrs.gov/](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](http://www.plainlanguage.gov/plLaw/index.cfm).

**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](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 [https://www.cdc.gov/grants/additionalrequirements/ar-25.html](https://www.cdc.gov/grants/additionalrequirements/ar-25.html) outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

Certificates of Confidentiality: Institutions and investigators are responsible for determining whether research they conduct is subject to Section 301(d) of the Public Health Service (PHS) Act. Section 301(d), as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255 (42 U.S.C. 241(d)), states that the Secretary shall issue Certificates of Confidentiality (Certificates) to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. In furtherance of this provision, CDC supported research commenced or ongoing after December 13, 2016 in which identifiable, sensitive information is collected, as defined by Section 301(d), is deemed issued a Certificate and therefore required to protect the privacy of individuals who are subjects of such research. Certificates issued in this manner will not be issued as a separate document, but are issued by application of this term and condition to this award. See Additional Requirement 36 to ensure compliance with this term and condition. The link to the full text is at: [https://www.cdc.gov/grants/additionalrequirements/ar-36.html](https://www.cdc.gov/grants/additionalrequirements/ar-36.html).

### 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 the Extramural Investigators as described in the Policy on Public Health Research and Non-research Data Management and Access.
- 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”. In addition, the PI/PD must provide to CDC Program abstracts or manuscripts prior to any publication related to this funding. The grantee will not seek to publish or present results or findings from this project without prior clearance and approval from CDC.
- 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.

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

- Assisting the PI, as needed, in complying with the Investigator responsibilities described in the Policy on Public Health Research and Non-research Data Management and Access.
- Preparing the paperwork necessary for submission of research protocols to the CDC Institutional Review Board for review, as needed.
- Obtaining Office of Management and Budget approval per the Paperwork Reduction Act, if necessary.
Areas of Joint Responsibility include:

- For applications that are successfully funded under this NOFO, the recipient agrees that upon award, the application and the summary of reviewers’ comments for the application may be shared with the CDC staff who will provide technical assistance, as described above. The recipient organization will retain custody of and have primary rights to the information, data and software developed under this award, subject to U.S. Government rights of access and consistent with current HHS/CDC policies.

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 grantee’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

Recipients will be required to complete Research Performance Progress Report (RPPR) in eRA Commons at least annually (see https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/forms/report_on_grant.htm) 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 recipients 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 recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.

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, is due 90 to 120 days before the end of the current budget period. The RPPR form (https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf) is to be completed on the eRA Commons website. 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 (https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm) 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 period of performance.

B. Content of Reports

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

   • Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the RPPR form in eRA Commons (https://grants.nih.gov/grants/rppr/index.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

Additional information regarding the use of eRA Commons may be found at the following website:


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.

The due date for final FFRs will continue to be 90 days after the Period of Performance end date.

Recipients must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, recipients 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 recipients are now available at [https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm](https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.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://grants.nih.gov/support/index.html](https://grants.nih.gov/support/index.html)

FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) ([https://commons.era.nih.gov/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](https://era.nih.gov/registration_accounts.cfm). Organizations not yet registered can go to [https://commons.era.nih.gov/commons](https://commons.era.nih.gov/commons) 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: [https://era.nih.gov/docs/Commons>UserGuide.pdf](https://era.nih.gov/docs/Commons>UserGuide.pdf).

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 period of performance. 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 Standard Time

**Scientific/Research Contact**

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

**Peer Review Contact**

Gregory Anderson, MPH, MS
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: 404-718-8833
Fax: 404-718-8822
Email: GAnderson@cdc.gov

**Financial/Grants Management Contact**
Section VIII. Other Information

Other CDC Notices of Funding Opportunities can be found at [www.grants.gov](http://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.

Public Health Service Act, Section 301(a) [42 U.S.C. 241(a)], as amended and Section 317(k)(2) [42 U.S.C. 247b(k)(2)], as amended.