Centers for Disease Control and Prevention

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

Evaluation of New HIV Testing Technologies in Clinical Settings with High HIV Incidence
RFA-PS-20-001
Application Due Date: 04/14/2020
Evaluation of New HIV Testing Technologies in Clinical Settings with High HIV Incidence
RFA-PS-20-001
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Part 1. Overview Information

Participating Organization(s)
Centers for Disease Control and Prevention

Components of Participating Organizations
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

Notice of Funding Opportunity (NOFO) Title
Evaluation of New HIV Testing Technologies in Clinical Settings with High HIV Incidence

Activity Code
U01 - Research Project - Cooperative Agreement

Notice of Funding Opportunity Type
New

Agency Notice of Funding Opportunity Number
RFA-PS-20-001

Assistance Listings (CFDA) Number(s)
93.941

Category of Funding Activity:
Health

NOFO Purpose
The purpose of this Notice of Funding Opportunity (NOFO) is to develop and implement protocols and recruitment strategies to evaluate the performance (sensitivity and specificity) of HIV tests under development, and/or newly available HIV tests, for use in point-of-care settings in the United States using fresh (unprocessed) specimens such as whole blood and oral fluid.

Key Dates
Publication Date: To receive notification of any changes to RFA-PS-20-001, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.

Letter of Intent Due Date: 03/16/2020

Application Due Date: 04/14/2020

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).

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**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](#) 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.**

**Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.**

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

Executive Summary
• **Purpose:** The purpose of this Notice of Funding Opportunity (NOFO) is to develop and implement protocols and recruitment strategies to evaluate the performance (sensitivity and specificity) of HIV tests under development, and/or newly available HIV tests, for use in point-of-care settings in the United States using fresh (unprocessed) specimens such as whole blood and oral fluid. Test sensitivity early in infection, when the antibody response is developing, and during conditions that might affect the detection of an analyte (HIV RNA, antigenic protein or antibody), is of particular interest; for example, determining test sensitivity in patients taking medications for antiretroviral therapy (ART) or HIV pre-exposure prophylaxis (PrEP). Therefore, protocols should address strategies for recruitment of patients with early HIV infection before they initiate ART, patients with HIV infection using ART, and HIV negative patients taking PrEP.

• **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 three (3)-year project period is $3,600,000. The number of awards will be up to three (3). Awards issued under this NOFO are contingent upon the availability of funds and receipt of 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 made, will depend upon the number, quality, duration and cost of the applications received.

**Please note:** All funds for the entire three (3)-year project period will be awarded in the first year; therefore, annual expenditures by the recipient may vary from year to year to complete project objectives but cannot exceed the total award amount. Although there will be no non-competing continuation application required on an annual basis, annual progress reports will be required.

• **Budget and Project Period:** The estimated total funding (direct and indirect) will be $3,600,000 with individual awards ranging from $900,000 to $1,800,000. All funds for the project will be awarded in the first year; thus, the estimated total funding (direct and indirect) for the first year, and the entire project period, for all recipients combined will be $3,600,000. The project period is anticipated to run from 09/30/2020 to 09/29/2023.

• **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. Application and Submission Information of this announcement.

• **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III 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.

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**Part 2. Full Text**

**Section I. Funding Opportunity Description**

**Statutory Authority**

Public Health Service Act, Sections 301(a) [42 USC 241] and 317(k)(2) [42 USC 247b], as amended.

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**1. Background and Purpose**

An estimated 38,000 new HIV infections occur each year in the United States (1). In 2016-2017, most new infections occurred among young black/African American and Hispanic/Latino men who have sex with men (MSM), and more than half of new HIV infections were reported in southern states and Washington, DC (2). The first few weeks after HIV infection, referred to as the acute HIV infection stage, comprise the stage when there is no detectable HIV-specific antibody response and HIV infection can only be detected by testing for HIV virus directly. The early detection of HIV infection, particularly during the acute stage, serves a public health need because those with acute infection have large amounts of circulating HIV virus and thereby have an increased risk of transmitting infection (3). Recent studies have shown that early initiation of antiretroviral treatment confers both clinical and public health benefits (4).

CDC recommends the use of point-of-care (POC) HIV tests whenever it is not feasible to do more sensitive laboratory-based testing. POC tests are useful in identifying HIV infections in hard to reach populations and have been widely used in a variety of venues such as mobile clinics, pride events, bars, clubs and bathhouses (6,7).

Use of the latest testing technologies can help identify HIV infections earlier, so that treatment and prevention is promptly offered and is more effective. Several new HIV tests have recently been approved (or will soon be approved) by the US Food and Drug Administration (FDA) to be used with unprocessed patient specimens (e.g., whole blood obtained via venipuncture or finger stick or oral fluid swabbed from the mouth). Some of the new tests can detect early infection by testing for the HIV virus itself, either using molecular techniques (molecular POC nucleic acid tests) or by direct detection of an antigenic component of the virus, such as p24 (POC antigen test). Other new tests can detect an early antibody response sooner than older HIV antibody tests. Determining the relative sensitivity and specificity of available HIV tests during the earliest stages of infection, including the acute stage and during development of an antibody response, while also maximizing the number of persons with previously undiagnosed infection who are identified and linked to HIV medical care, will require an examination of new HIV testing technologies in populations (e.g., MSM) and geographic areas with high HIV incidence.

Although it has been known for some time that ART can affect the ability of tests to detect HIV antibodies, particularly in oral fluid specimens (8,9), recent data suggest that initiation of ART very early in infection, before a mature antibody response has been established (10), can lead to
either undetectable or transiently detectable HIV antibodies. Further, patients using HIV PrEP, who nonetheless become HIV-infected, have been shown to also exhibit abnormal antibody response patterns as well as false-negative nucleic acid test (NAT) results. Because the goals of the HIV elimination strategy (2) rely on early ART initiation and expansion of PrEP coverage, issues with test performance in treated populations are expected to be observed more frequently. Cohorts of patients currently taking ART or PrEP are needed to further evaluate characteristics of HIV test performance in these populations.

Novel HIV tests that purport to distinguish recent (e.g., within the past year) infection, from more long-term infections, are currently being used for HIV surveillance and to prioritize case finding in sub-Saharan Africa (11). These technologies could prove useful to focus attention on sources of ongoing HIV transmission to bring the epidemic to an end. However, novel POC tests that categorize the recency of infection have yet to be evaluated in clinical settings in the United States.

The purpose of this Notice of Funding Opportunity (NOFO) is to develop and implement protocols and recruitment strategies to evaluate the performance (sensitivity and specificity) of HIV tests under development, and/or newly available HIV tests, for use in point-of-care settings in the United States using fresh (unprocessed) specimens such as whole blood and oral fluid. Test sensitivity early in infection, when the antibody response is developing, and during conditions that might affect the detection of an analyte (HIV RNA, antigenic protein or antibody), is of particular interest; for example, determining test sensitivity in patients taking medications for antiretroviral therapy (ART) or HIV pre-exposure prophylaxis (PrEP). Therefore, protocols should address strategies for recruitment of patients with early HIV infection before they initiate ART, patients with HIV infection using ART, and HIV negative patients taking PrEP.

**Research Objectives of the NOFO:**

The overall project should address the following research objectives:

1. Develop and implement recruitment strategies and procedures to: (a) identify appropriate study participants to evaluate the differences in sensitivity (including acute HIV infection sensitivity) and specificity of the newest HIV tests in real time using fresh whole blood and oral fluid specimens; and (b) compare results to the currently recommended CDC laboratory algorithm (12). Patients with exposure to either early ART or PrEP should be oversampled in order to evaluate HIV test performance in these populations as well.
2. Evaluate the seroconversion sensitivity of the newest HIV tests through serial follow-up of study participants with discordant baseline test results.
3. Evaluate the diagnostic and clinical performance of nucleic acid (molecular) tests to determine the applicability of this technology for use in a variety of clinical and POC settings.
4. Collect matched demographic, behavioral and clinical data from participants to assess the impact of these factors on HIV test performance, including the use of behavioral and clinical data to categorize the timing of exposure for those with newly diagnosed infection.
5. Develop panels of specimens with accompanying demographic, clinical and behavioral data for evaluations of laboratory-based HIV tests.
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 disproportionately affected by HIV, viral hepatitis, STDs and TB and related diseases and conditions, and plan activities to help eliminate health disparities. In collaboration with partners and appropriate sectors of the community, programs should consider social determinants of health in the development, implementation, and evaluation of program specific efforts and use culturally appropriate interventions that are tailored for the communities for which they are intended.

**Healthy People 2020 and other National Strategic Priorities**

**Healthy People 2020**

For additional details on the Healthy People 2020 goals listed above, visit http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=22

This project is designed to: (1) evaluate the tests under study using unprocessed specimens and (2) evaluate the seroconversion sensitivity of new HIV tests through serial follow-up; it specifically addresses, or contributes to, the following Healthy People 2020 goals:

- *HIV-2*: (Measurable) Reduce the number of new HIV infections among adolescents and adults.
- *HIV-19*: (Measurable) Increase the percentage of persons with newly diagnosed HIV infection linked to HIV medical care (had a routine HIV medical visit) within one month of their HIV diagnosis.
- *HIV-20*: (Measurable) Increase the percentage of newly diagnosed persons with diagnosed
HIV infection who are retained in continuous HIV medical care.

- **HIV-22**: (Measurable) Increase the percentage of persons with diagnosed HIV infection who are virally suppressed.
  - **HIV-22.1**: (Measurable) Increase the percentage of persons aged 13 years and older with diagnosed HIV infection who are virally suppressed.
  - **HIV-22.2**: (Measurable) Increase the percentage of youth with diagnosed HIV infection who are virally suppressed.
  - **HIV-22.3**: (Measurable) Increase the percentage of persons who inject drugs (PWID) with diagnosed HIV infection who are virally suppressed.
- **HIV-23**: (Developmental) Reduce the proportion of persons with an HIV diagnosis receiving HIV services who were homeless or unstably housed in the 12-month measurement period.


**Other Strategic Priorities**

- The White House national initiative "Ending the HIV Epidemic: A Plan for America", particularly the DIAGNOSE strategy: *Diagnose all individuals with HIV as early as possible after infection.*

**Public Health Impact**

CDC provides guidelines for HIV testing and diagnosis in the United States, as well as programmatic technical guidance for its partners. Because of the critical importance of detecting HIV infection as early as possible, CDC monitors and updates these guidance documents to reflect advancements in HIV testing technology and the availability of new tests. Although manufacturers seeking approval of HIV tests conduct studies to demonstrate device safety and effectiveness, clinical trials are not designed to evaluate important aspects that determine the public health impact of these tests. Moreover, they do not evaluate multiple tests head-to-head to yield relative performance data that is helpful in guiding testing strategies. Therefore, this NOFO will support test evaluations to understand the differences in sensitivity and specificity of the newest HIV serologic tests, using unprocessed specimens collected from infected individuals who are in the acute or early stages of disease.

This research NOFO is to assess the relative performance of these new POC HIV tests, particularly among persons who: (a) present diagnostic challenges, including those exposed to HIV PrEP; (b) those with very recent HIV infection (before the development of a mature antibody response); and (c) those achieving viral suppression before developing an antibody response, among others.

Test performance and questionnaire data will be used to inform HIV testing guidelines and provide information to HIV test providers about the appropriate use of different HIV testing
technologies in different settings, and for different populations (e.g., for highest risk persons as well as the general population). Diagnosing HIV infection as early as possible, and using appropriate HIV tests to monitor those using PrEP or ART to optimize the preventive effects of these interventions, are key components of the HIV elimination strategy. Test performance data will help inform the choice of test technology and allow these technologies to be tailored to the strategies needed to end the HIV epidemic.

Relevant Work

1. Time From HIV Infection to Earliest Detection for 4 FDA-Approved Point-Of-Care Tests, CROI 2018; http://www.croiconference.org/sessions/time-hiv-infection-earliest-detection-4-fda-approved-point-care-tests


2. Approach

CDC updates HIV testing guidance on an ongoing basis to reflect advancements in HIV testing technology and is committed to independent evaluations of the performance of new HIV tests in head-to-head comparisons with existing technology to inform this guidance. For point-of-care tests, test performance should be evaluated in settings where they are intended to be used,
employing a variety of unprocessed specimens and with patients representing the likely population of persons seeking HIV testing (including those at high-risk of recent infection), or undergoing ongoing monitoring while receiving HIV ART or PrEP. This NOFO aims to support the evaluation of HIV tests when conducted in clinical settings with high HIV incidence, and with large populations of patients receiving both PrEP and ART care. Under this cooperative agreement, protocols should be developed with technical assistance and consultation from CDC scientists and other partners (e.g., local health departments, local laboratories).

In this study, the recipient should identify and recruit participants in specific target populations and conduct multiple POC tests using unprocessed specimens, including oral fluid and finger stick blood, as well as anticoagulated whole blood from venipuncture. The recipient should also collect blood for laboratory-based comparator tests against which POC tests will be evaluated. If individual POC test results are not concordant (i.e., not all positive or all negative), the recipient will enroll participants with discrepant results in follow-up testing until these discrepant results are resolved. Finally, in order to provide detailed and standardized risk behavior data for each study participant, CDC will provide technical assistance to implement an approved questionnaire that will be administered by the recipient(s). Data collected via this questionnaire will be used to quantify the HIV risk behaviors that participants engage in around the time of infection and describe changes in risk behavior associated with diagnosis.

The application should describe the approach for meeting the research objectives, including the identification of study clinical sites, the recruitment of participants into the study, the process for conducting point-of-care (POC) and laboratory testing, any additional follow-up clinic visits for evaluating the performance of new testing technologies, and the procedures for data and specimen collection, including the following activities:

**Study sites**

- Describe the clinical site(s) where the HIV tests under evaluation will be conducted as well as potential partner sites from which participants will be referred for study enrollment at the clinic site.
- Describe any prior experience with evaluations of HIV tests at potential study sites.
- Consider the current standard of care for HIV testing, and describe how this standard will be modified, if necessary, so that the comparator for evaluations of POC tests will include the CDC laboratory algorithm, including an antigen/antibody screening test and, when indicated, an HIV-1/HIV-2 differentiation test and an HIV-1 nucleic acid test (12).
- Describe the current standard of care for monitoring patients receiving either ART or PrEP, and the type of viral load test used for monitoring HIV-infected patients; these tests will serve as the gold standard for any evaluations of qualitative, quantitative or semi-quantitative POC NATs.

**Recruitment procedures for one or more of the following groups of patients**

Note that here, and elsewhere, the proposed sample sizes are per recipient, per year (i.e., if there are two awards, the total sample for the entire project for each year would be expected to double relative to the numbers listed below; and, for a given recipient, the sample size projection for the total five (5)-year project period would be expected to be five times greater than what is listed below).
1. The application should describe strategies to recruit HIV infected participants for the evaluation of the sensitivity of the tests under investigation. In each study year, at least 200 participants known to be infected with HIV should be recruited including:

(a) Newly diagnosed (within the prior 90 days) patients who have and have not started ART.
(b) Patients not currently taking ART (who have not taken even one dose in the past 30 days).
(c) Patients taking ART who have not yet achieved viral suppression, based on the CDC definition of a viral load <200 copies/ml.
(d) Patients taking ART who are considered to have achieved viral suppression, based on the CDC definition of a viral load <200 copies/ml.

The target for the mix of populations (a. through d. above) will be determined each year by the recipient in consultation with CDC.

2. The application should also describe recruitment strategies for the evaluation of test specificity, including prioritizing participants currently taking or initiating PrEP. The application should describe how, in each study year, a sample of at least 500 participants not known to be HIV-infected (e.g., those seeking HIV testing, or with a possible exposure to HIV since their last documented HIV-negative test result) will be recruited, including at least 50 patients initiating or taking HIV PrEP. Participants in this group should be allowed to re-enroll no more than every 90 days, and repeat enrollments should be documented such that all study visits for a participant can be linked at the end of the study.

**Testing with novel HIV testing technologies at each study visit**

- The application should describe how clinic clients, who consent to participate in the study, will have anti-coagulated (EDTA) whole blood, oral fluid and dried-blood spot specimens collected for the evaluation of the new HIV screening and diagnostic tests.
- The application should describe how staff will operationalize a protocol to perform multiple POC HIV tests, including those still under investigation for FDA approval, on unprocessed specimens, in real time.
- The application should describe the investigator's ability to change the tests under evaluation, depending on the performance of the tests during the study, and the availability of new tests over time. The tests being used may change as frequently as annually over the period of performance of the award as long as the objectives and specific aims remain within the scope of activities originally proposed.
- The application should describe the process for providing a baseline behavioral survey, developed with technical assistance from CDC, that will supply detailed and standardized risk behavior data. Data collected via this survey will be used to quantify the HIV risk behaviors that participants engage in around the time of infection, and describe changes in risk behavior associated with diagnosis.

**Specimen collection at each study clinic visit**
• The application should describe the ability of clinic staff and partner laboratories to collect, process, and store specimens (e.g., dried-blood spots, oral fluid, and/or EDTA plasma processed from whole blood specimens) until they can be used in evaluations of laboratory-based HIV tests.

• At a minimum, each recipient should aim to collect and store specimens from 800 HIV-infected participants with positive HIV test results on all screening tests, as well as 1500 specimens from participants with negative HIV test results on all screening tests during the five (5)-year period of performance.

Serial follow-up visits after the first study clinic visit

The application should describe how participants with at least one reactive HIV screening test result, and at least one non-reactive HIV screening test result (i.e., discordant screening result), will be invited to continue with follow-up visits to resolve test discrepancies and to assess seroconversion sensitivity for all tests. It is expected that study participants with discordant test results at their first study visit will comprise a mix of: (a) those having falsely reactive HIV test results, (b) those in the process of seroconverting after the acute stage of infection, and (c) possibly those in the process of achieving viral suppression. The application should provide estimates of the expected number of participants with discordant results that could be identified in each study year, based either on past studies conducted in the potential clinic population, or information about test results from the past two years of data at the proposed study clinics.

• The application should describe the proposed follow-up schedule for each category of discordant test results and the consent and enrollment plan for serial follow-up. For example, study participants in the process of seroconversion might require several closely spaced study visits in the first 30 to 60 days after enrollment. The application should also describe a plan for re-contacting participants who fail to return for a scheduled follow-up visit, and how investigators will document how the plan was implemented when necessary.

• The application should describe the testing and specimen collection procedures at each follow-up visit. At a minimum, the recipient will collect specimens appropriate to run the POC tests currently under evaluation; remnant specimens (i.e., EDTA plasma) may be processed, aliquotted, and stored for shipment to CDC for further test evaluations, as warranted.

• The application should demonstrate the recipient's prior experience with: (a) research studies involving clinical follow-up in their clinic population; and (b) electronic information management systems which either already collect, or which can be modified to collect, the clinical and risk information required to fulfill the objectives of the NOFO.

• The application should also describe how a behavioral survey, created with technical assistance from CDC, will be administered during follow-up. At a minimum, when all tests become concordant (i.e., at the last serial follow-up visit), participants should complete a final behavioral survey to identify any behavioral changes during their time of follow-up. This survey should contain the same domains as the baseline survey administered to participants in the first study visit, with additional questions about disclosure of study HIV test results to recent sex partners, and risk behaviors during the
follow-up period.

**Laboratory testing for comparison to POC tests under study**

Laboratory-based HIV testing using the CDC recommended algorithm and, for those participants with at least one reactive HIV test, a quantitative HIV-1 viral load, should serve as the gold standard comparison for HIV test performance in this study. As indicated in the site selection criteria, an ideal study clinical site should already be performing these tests routinely for patients seeking HIV testing and for those receiving ongoing HIV or PrEP care. If the study clinical site(s) do not routinely offer this laboratory testing, the recipient should identify a partner laboratory that conducts either an algorithm that includes an antigen/antibody laboratory immunoassay, an HIV-1/HIV-2 differentiation test, and a nucleic acid test, or pooled nucleic acid testing of all persons who screen HIV-negative on site. The identified partner should be able to run these tests on the entire study population, with negative test results on all tests under evaluation as the reference standard for the evaluation of the new test technologies. This, or another partner laboratory, should be able to perform a quantitative HIV-1 viral load test for all study participants identified, with a reactive result on at least one (1) test under evaluation, indicating possible HIV infection. The application should describe the process for specimen handling, timeline from specimen collection to receipt of these gold standard test results, and the proposed process for notifying study participants of any discrepancies between laboratory test results and those from the POC tests.

**Transmitting collected data**

- The application should describe how investigators will collect, clean, and store all study data including:
  - POC test results for the tests under evaluation.
  - Laboratory test results for comparison to the POC tests.
  - Behavioral data collected via questionnaires created with CDC technical assistance.
  - A process for linking data collected at the first study visit to all follow-up study visits (for those enrolled for follow-up of discordant test results, and those not known to be infected with HIV, who participate in the study more than once).
- The recipient should work with CDC to develop procedures for data quality control and secure storage, reporting, and transmittal of data.
- The application should describe the procedures to ensure completeness of the data. At a minimum, the recipient should ensure all consent information is 100% complete, survey data are 80% complete, and all performance data on test results is 100% complete prior to submission to CDC.
- The recipient will work with CDC to ensure that data are available for public use according to the requirements for sharing public health data.

**Patient specimen processing, storage and shipment procedures**

Applications should describe standard operating procedures for collection, labeling, processing, storage and shipment of all specimens to be collected during the first study visit and the serial follow-up visits. The description should include plans for: a) collection and labeling of fresh unprocessed specimens (oral fluid and EDTA whole blood) used for the point-of-care screening
tests at the clinical site; b) labeling, processing and shipping, when required, of specimens for testing with the laboratory test(s) described above as the reference standard for the evaluation of the new test technology; and c) labeling, processing and shipping, when required, of specimens for which any other HIV test was reactive so that these specimens can be tested with a quantitative HIV-1 viral load test. The application should include descriptions of how remnant specimens may be aliquoted, stored and shipped to CDC, as warranted (not to exceed quarterly).

CDC and the recipient will work together to develop consent forms to cover the collection and storage of biologic specimens for this project. Consent forms will contain the following language, or some variation of the following language, with the same intent: "This research study is part of a cooperative agreement with the U.S. Centers for Disease Control and Prevention. Remnants from patient specimens collected as part of this study may be sent to CDC and possibly to other institutions for additional testing. These research tests include, but are not limited to, the development or evaluation of tests to detect HIV infection and other tests for research purposes only. The research tests will not be those that test for genetic problems and the blood will not be used for cloning or commercial purposes. You may choose not to have your blood stored for future research and still be part of the study. Your name and/or other directly identifiable information will not be shared outside of the research study site. All links to your name and other directly identifiable information will be removed before the specimens are transferred to the CDC. Since all tests on remnant specimens are for research purposes only and will be conducted after the link to your identifying information has been removed, no individual results will be given back to you or go into your medical record."

Objectives/Outcomes
The overall project should address the following research objectives:

1. Develop and implement recruitment strategies and procedures to: (a) evaluate the differences in sensitivity (including acute HIV infection sensitivity) and specificity of the newest HIV tests in real time, using fresh whole blood and oral fluid specimens and (b) compare to the recommended CDC laboratory algorithm. Patients with exposure to either early ART or PrEP should be oversampled in order to evaluate HIV test performance in these populations as well.

2. Evaluate the seroconversion sensitivity of the newest HIV tests through serial follow-up of study participants with discordant baseline test results.

3. Evaluate the diagnostic and clinical performance of nucleic acid (molecular) tests to determine the applicability of this technology for use in a variety of clinical and POC settings.

4. Collect matched demographic, behavioral and clinical data from participants to assess the impact of these factors on HIV test performance, including the use of behavioral and clinical data to categorize the timing of exposure for those with newly diagnosed infection.

5. Develop panels of specimens with accompanying demographic, clinical and behavioral data for evaluations of laboratory-based HIV tests.

Primary study outcomes are:

- Assess sensitivity of POC tests under study in at least 200 participants known to be
infected with HIV in each study year.

- Assess specificity of POC tests under study in at least 500 participants not known to be infected with HIV in each study year.
- Assess performance (concordance with a reference standard viral load) of POC NAT tests.
- Increase the number of (oral fluid, plasma, dried-blood spot, etc.) specimens in storage for evaluations of new laboratory-based HIV tests.

**Secondary study outcomes are:**

- Increase the number of well-characterized panels of specimens with POC test results and behavioral data that can be used to evaluate the seroconversion sensitivity of the newest HIV tests through serial follow-up of study participants with discordant baseline test results.
- Evaluate the performance of tests under evaluation (in terms of sensitivity and specificity) in specific populations including persons who initiate ART early in infection and those taking PrEP.

**Target Population**

The following groups should be approached for participation through convenience sampling if they are 18 years of age or older, able to consent to study participation, and able to complete the computer-assisted self-interview in English or Spanish:

- Newly diagnosed (within the prior 90 days) patients who have and have not started ART.
- Patients not currently taking ART (who have not taken even one dose in the past 30 days).
- Patients taking ART who have not yet achieved viral suppression based on the CDC definition of a viral load of <200 copies/ml.
- Patients taking ART who are considered to have achieved viral suppression based on the CDC definition of a viral load of <200 copies/ml.
- Patients not known to be HIV-infected (e.g., those seeking HIV testing or with a possible exposure to HIV since their last documented HIV-negative test result). Participants in this group should be allowed to re-enroll no more than every 90 days.

**Collaboration/Partnerships**

The recipient should work collaboratively with other project partners to develop and implement the study through consultation and by gathering technical assistance. These partners may include other clinics, non-clinical HIV test providers, clinical or commercial laboratories, and the relevant State or local health department.

Recipients should collaborate with a sufficient number of clinical (e.g., large HIV clinics, and/or PrEP clinics) and non-clinical (e.g., community-based organizations offering HIV testing) partners to obtain study referrals and recruitment to achieve the study sample size. Recipients should include in their application a description of how the partner sites were selected, including a description of the minimum criteria to participate (e.g., provide a minimum number of referrals to the study per month).

If the study clinical site(s) do not routinely offer laboratory testing, the recipient should identify a
partner laboratory that conducts either: (a) an algorithm that includes an antigen/antibody laboratory immunoassay, an HIV-1/HIV-2 differentiation test and a nucleic acid test; or (b) pooled nucleic acid testing of all those who screen HIV-negative on site. The partner laboratory should be able to run these tests on the entire study population using negative test results on all tests under evaluation as the reference standard for the evaluation of the new test technologies. This or another partner laboratory should be able to perform a quantitative HIV-1 viral load test for all study participants identified with a reactive result on at least one test under evaluation, indicating possible HIV infection. Finally, the recipient should identify a partner laboratory able to properly process, aliquot, store and ship frozen biologic materials from this study on dry ice for testing.

Letters of Support
The application should include Letters of Support from each non-federal partner that will collaborate in the study. The letters should include estimates of the total number of participants from each of the proposed target populations that the partner site can refer annually. The recipient and proposed project partners should establish policies to confidentially share data during the study. Examples of the types of data that may need to be shared include prior HIV test results and information about referred patients’ exposure to ART and/or PrEP. Letters from project partners should state what data will be shared with the recipient and other study partners for this study or that approval to share data is anticipated.

The application should also include letters from the proposed project laboratory or laboratories indicating which tests the laboratory or laboratories will use for the CDC diagnostic algorithm and for quantitative HIV-1 viral load monitoring.

Memorandum of Understanding and Contracts
Post-award, the recipient should formalize collaborations with all project partners in the form of Memoranda of Understanding (MOU) and/or contracts. The MOU and/or contract should clearly convey the objectives of the project, how the project objectives will be accomplished, recommended strategies for patient referral to the study and data sharing policies (including data that will be collected and who will collect the data). The recipient should include in the MOU the timeline of the collaboration, frequency of project communications, and methods of communication.

Evaluation/Performance Measurement
The application should include measurable goals and aims based on a five (5)-year research project period. The application should establish 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
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 performance of HIV tests should be disseminated to the public health community, clinicians, CDC-awardees, and community-based
stakeholders to inform their efforts in selecting and using these tests.

**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:** $3,600,000
*Estimated total funding available for the entire project period, including direct and indirect costs: $3,600,000*

Year 1: $3,600,000
Year 2: N/A
Year 3: N/A

**Estimated Total Funding per award, including direct and indirect costs:** $900,000 to $1,800,000 per recipient for the entire three (3)-year project period. Note that all funds will be awarded in year one. Applications should list proposed annual budgets that are appropriate for the proposed workplans.

**Anticipated Number of Awards:** 3

**Please note:** The award ceiling and floor listed below are per recipient per three (3)-year project period. The statement below: "Award ceiling and floor are for the first 12-month budget period only." is embedded NOFO template language that cannot be changed and is not applicable to this NOFO.

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

Award ceiling and floor are for the first 12-month budget period only.

**Award Ceiling:** $1,800,000 Per Project Period
**Award Floor:** $900,000 Per Project Period

**Total Period of Performance Length:** 3 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  
Others (see text field entitled "Additional Information on Eligibility" for clarification)

Additional Eligibility Category:

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."

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. Additional Information on Eligibility

Additional Eligibility Categories:

- Private Non-profit Institutions of Higher Education
- The following types of Higher Education Institutions are always encouraged to apply for CDC support as Public or Private Non-profit Institutions of Higher Education:
  - Historically Black Colleges and Universities (HBCUs)
  - Tribally Controlled Colleges and Universities (TCCUs)
  - Alaska Native and Native Hawaiian Serving Institutions
  - Hispanic-serving Institutions

- 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://gov.ecfr.io/cgi-bin/searchECFR?ob=r&idno=&q1=FFRDC&r=&SID=1510a9feb7999d185d40b026ad998cc0&mc=true](https://gov.ecfr.io/cgi-bin/searchECFR?ob=r&idno=&q1=FFRDC&r=&SID=1510a9feb7999d185d40b026ad998cc0&mc=true)

4. Justification for Less than Maximum Competition
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.ns.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.

Letters of Support from partner companies or organizations should be placed in the PHS 398 Research Plan "Other Research Plan Section" of the application under "9. Letters of Support".

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
3. Letter of Intent

Due Date for Letter of Intent: **03/16/2020**

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” and immediately above, 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
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 US8-1
Atlanta, GA 30333
Telephone: 404-718-8833
Fax: 404-718-8822
Email: GAnderson@cdc.gov

4. Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this 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 http://grants.nih.gov/grants/how-to-apply-application-guide.htm 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/generalforms-e.pdf and here: http://grants.nih.gov/grants/how-to-apply-application-guide.htm 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:
• 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 deidentified data).
Examples of DMPs may be found here: USGS, [http://www.usgs.gov/products/data-and-

**Please note:** The Federal government must be given a royalty-free, nonexclusive, and
irrevocable license for the Federal government to reproduce, publish, or otherwise use the data
collected as a result of this funding and to authorize others to do so for Federal purposes, e.g., to
make it available in government-sponsored databases for use by other researchers (45 CFR
Section 75.322 [b]).

**Letters of Support from partner companies or organizations should be placed in the PHS
398 Research Plan "Other Research Plan Section" of the application under "9. Letters of
Support".**

### 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. Pages that exceed page limits
described in this NOFO will be removed and not forwarded for peer review, potentially
affecting an application's score.
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).

9. Submission Dates & Times

Part 1. 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
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](https://www.grants.gov/web/grants/support.html)
support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

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," be sure to save time stamped, documented rejection notices, and 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 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: 04/14/2020

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:

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 relating to the conduct of research involving human subjects will be restricted until the appropriate assurances (OHRP-approved Federal Wide Assurance [FWA]) 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. The recipient may not draw funds from the paying office under advance payment, obligate (expend) federal funds, or claim required cost sharing or matching costs for research involving human subjects at any site engaged in non-exempt research until the requirements for an FWA, IRB approval, and evidence of the training of senior/key personnel have been met. The prohibition on expenditures may extend to the whole project if that activity is not severable. The recipient must be advised that failure to comply within the stated time may result in full or partial termination of the award.

Please note: To be eligible for funding, all clinical research involving INDs, drugs approved for a different indication, or experimental combinations of drugs must meet FDA IND regulations, FDA human subjects protection requirements, and HHS human subjects requirements. As provided in the FDA regulations, an IND or IDE also may apply to biologics or devices. The FDA regulations are published in 21 CFR parts 50 and 312. Citations to FDA humans subjects protection requirements as well as FDA regulations as they pertain to use of IND or IDE can
be found here:


Award recipients must comply with these regulations, as applicable.

2) Funds relating to the conduct of research involving vertebrate animals may 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 may 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 recipient institutions and their investigators conducting life sciences research subject to the Policy have a number of responsibilities that they must fulfill. Institutions should reference the policy, available at http://www.phe.gov/s3/dualuse, for a comprehensive listing of those requirements.

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

5) Please note 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/additionalrequirements/ar-25.html). Funding restrictions may be imposed, pending submission and evaluation of a Data Management Plan.

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

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. Upload the questionnaire and supporting documents as an attachment in the "12. Other Attachments" section of the "RESEARCH & RELATED Other Project Information" section of the application. 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?

- Does the application describe the need to integrate the best HIV tests available into community-based and clinical testing settings to achieve the goal of identifying all HIV infections as soon as possible after they occur?
- Does the application explain how the introduction of HIV POC NAT into clinical settings where patients receive HIV ART or PrEP could improve outcomes for both individual patients and the public health goal of eliminating HIV transmission in the United States?
- Does the application adequately describe how the proposed project will identify and successfully recruit members of the proposed target populations in order to provide test performance data necessary to inform NOFO goals?

**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 have relevant experience with HIV clinical service delivery settings including HIV care clinics, PrEP clinics and clinical laboratories performing
appropriate HIV tests?
- Do the investigators have experience evaluating and/or implementing point-of-care HIV testing in clinical or non-clinical settings?
- Do the investigators describe relevant experience in conducting research on HIV prevention services, including HIV testing and subsequent linkage to HIV ART or PrEP care?
- Do the investigators have experience with human subjects research protections?
- Do the investigators have prior experience evaluating investigational test devices as defined by the Food and Drug Administration?

### 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?

- Does the application describe recruitment strategies or other innovative methods to ensure timely participation in the study by the proposed target populations?
- Does the application describe a standardized, comprehensive model for the evaluation of multiple point-of-care tests using unprocessed specimens collected from patients and tested in real time (e.g., multiple finger stick specimens collected in one visit)?

### 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 sources of target patient populations?
- Does the application describe the type of laboratory testing to be used for the comparison to point-of-care tests under evaluation?
- Does the approach describe how laboratory results are securely recorded and stored, and how any discordance with point-of-care results requiring follow-up will be reported to participants?
- Does the application describe the process for recruitment and consent of an appropriate mix of study participants from the target populations to achieve the samples sizes required?
• Does the application describe methods for conducting multiple point-of-care HIV tests under evaluation using unprocessed participant samples?
• Does the application describe methods for administering the study questionnaire with technical assistance from CDC?
• Does the application describe an approach to collect, process, aliquot and store samples for the study repository?
• Does the application describe a process for compiling sources of study related data and transferring data to CDC?
• Does the approach describe a study design that is both rigorous and practical, including plans for participant referral and recruitment, retention of participants with discordant results enrolled in follow-up, collection, cleaning and management of clinical and self-reported behavioral data, and data storage, analysis, and dissemination?
• Does the application describe the development of a protocol for data collection from the public that requires approval from the Office of Management and Budget (OMB) as described in the Paperwork Reduction Act?

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 adequately describe the clinical environment where the study will be conducted, including current standard of care laboratory testing that will be conducted?
• Does the application adequately describe capacity to perform the necessary laboratory components, including standard of care testing, and specimen processing, aliquoting, storage and shipment or plans to partner with a laboratory(ies) that will perform these tasks?
• Does the application describe how the study referral sites were selected, including a description of the capacity to meet proposed study sample sizes for the target populations?
• Does the application describe how the recipient will deliver data to CDC and work with CDC to disseminate data in accordance with public access policies?
• Does the application include Letters of Support from all collaborating non-Federal partner 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.

Protectors 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 four 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) 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 4) 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:

• 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). 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.

### 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
recommendations:

- 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.

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-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-7: Executive Order 12372 Review
AR-8: Public Health System Reporting Requirements
AR-9: Paperwork Reduction Act Requirements
AR-10: Smoke-Free Workplace Requirements
AR-11: Healthy People 2020
AR-12: Lobbying Restrictions
AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities
AR-14: Accounting System Requirements
AR-15: Proof of Non-profit Status
AR-16: Security Clearance Requirement
AR-20: Conference Support
AR-21: Small, Minority, And Women-owned Business
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-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973
AR 31 - Distinguishing Public Health Research and Public Health Nonresearch
AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern
AR-34: Language Access for Persons with Limited English Proficiency
AR-36: Certificates of Confidentiality

ARs applicable to HIV/AIDS Awards:
AR-5: HIV Program Review Panel Requirements
AR-6: Patient Care

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

To view brief descriptions of relevant CDC requirements, visit: https://www.cdc.gov/grants/additional-requirements/index.html

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 apply 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.

Federal Funding Accountability and Transparency Act of 2006 Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252, requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single, publicly accessible website, www.usaspending.gov. For the full text of the requirements, please review the following website: https://www.fsrs.gov/.

Plain Writing Act The Plain Writing Act of 2010, Public Law 111-274 was signed into law on October 13, 2010. The law requires that federal agencies use "clear Government communication that the public can understand and use" and requires the federal government to write all new publications, forms, and publicly distributed documents in a "clear, concise, well-organized" manner. For more information on this law, go to: http://www.plainlanguage.gov/plLaw/index.cfm.

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. The recipient is ultimately responsible for ensuring compliance with the requirements for protection of human subjects, including compliance with the Food and Drug Administration's (FDA’s) requirements, if applicable.
- Working with CDC scientists to obtain OMB-PRA approvals, as needed.
- **PUBLICATIONS/PRESENTATIONS:** Publications, journal articles, presentations, etc. produced under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate, for example: “This publication (journal article, etc.) was supported by the Cooperative Agreement Number above from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention or HHS”. In addition, the PI/PD should provide to CDC Program abstracts or manuscripts prior to any publication related to this funding. The recipient should 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:**

- Providing technical assistance and consultation, as needed, assisting the PI in complying with the Extramural 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.
- Providing technical assistance and consultation, as needed, assisting the PI in complying

**Areas of Joint Responsibility include:**

- Monitoring project outcomes, including sample sizes of all key target populations, at regular intervals.
- Adapting recruitment strategies as necessary to meet target population goals.
- Identifying POC tests for evaluation and changing tests included in the evaluation as necessary within the scope of the originally proposed project.
- Presenting study findings at scientific meetings and other public forums, as warranted by contribution.
- Developing analysis concept proposals, working jointly to finalize these proposals and conducting the necessary and appropriate analysis of study data to produce abstracts and manuscripts summarizing study findings, as warranted by contribution.
- Ensuring a systematic process for access to study data and specimens is available to ensure public access to the study data through appropriate mechanisms according to applicable policies.
- 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 grant regulations and 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 recipient’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/rpqr/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. All recipients of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

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

1. Yearly Non-Competing Grant Progress Report, is due 90 to 120 days before the end of the current budget period. The RPPR form (https://grants.nih.gov/grants/rpqr/index.htm; https://grants.nih.gov/grants/rpqr/rpqr_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.

(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:

Although there will be no non-competing continuation application required on an annual basis, annual progress reports will be required.

When HHS funds all, or part of, a clinical study involving an IND or an IDE, the OPDIV (CDC) must be aware of any significant communications with FDA concerning the study. The recipient must report certain types of FDA communications to CDC within 72 hours of receiving a copy of, or upon being informed of the FDA communication (through the PI or another person acting on behalf of the recipient), whichever occurs first. This notification requirement applies to any of the following communications from FDA with the sponsor of the IND or IDE: All clinical research involving INDs, drugs approved for a different indication, or experimental combinations of drugs must meet FDA IND regulations, FDA human subjects protection requirements, and HHS human subjects requirements. As provided in the FDA regulations, an IND or IDE also may apply to biologics or devices. The FDA regulations are published in 21 CFR parts 50 and 312.

One copy of each publication resulting from work performed under a CDC-supported cooperative agreement must accompany the annual and final progress reports submitted to CDC. The CDC must be notified of, and provided access to, publications resulting from work under a CDC award.

The recipient’s annual progress report should also include:

• The number of study participants in each target population category for the current fiscal year and the total project period to date.
• The number of specimens collected in the current fiscal year and for the total project to date.
• A summary of the data collected and delivered to CDC during the current fiscal year and the total project period to date.

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_frr.htm](https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_frr.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 PI's 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

Scientific/Research Contact(s)
Jocelyn Patterson Mosley, MPH, MA
Extramural Research Program Office
Office of the Associate Director of Science
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
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, Sections 301(a) [42 USC 241] and 317(k)(2) [42 USC 247b], as
amended.
Primary CFDA #: 93.941
Secondary CFDA #: 93.084