

Centers for Disease Control and Prevention

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

Early HIV Treatment to Optimize Patient Health and HIV Prevention
RFA-PS-16-006
Application Due Date: 02/19/2016

Early HIV Treatment to Optimize Patient Health and HIV Prevention

RFA-PS-16-006

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

Funding Opportunity Announcement (FOA) Title

Early HIV Treatment to Optimize Patient Health and HIV Prevention

Activity Code

U18 Research Demonstration – Cooperative Agreements

Funding Opportunity Announcement Type

New

Funding Opportunity Announcement Number

RFA-PS-16-006

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

93.941

Category of Funding Activity:

Health

FOA Purpose

To support the conduct of a mixed-methods health services research study to assess models for the implementation of immediate antiretroviral therapy (ART) for persons with newly diagnosed acute and early HIV infection. Models will be implemented and evaluated in 2 to 3 HIV care settings. These implementation studies will allow a better understanding of clinical outcomes and patients' experiences with immediate initiation of antiretroviral (ARV) treatment, including: 1) time to viral suppression and the proportion of patients who remain virally suppressed 12 months after their diagnosis, 2) retention in HIV care, 3) satisfaction with clinical care, 4) changes in HIV transmission risk behavior, and 5) laboratory markers of HIV infection.

NOTE: This FOA has been amended in red text to include a Summary of the Conference Call with Potential Applicants held on January 12, 2016 (Section VIII, pages 31 to 34) and to correct FOA language to state that letters of support are required from a healthcare organization, health department AND laboratory (Section III.5, page 10).

Key Dates

Publication Date:	**To receive notification of any changes to RFA-PS-16-006, 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:	**01/14/2016**
Application Due Date:	**02/19/2016**

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

Scientific Merit Review: **05/24/2016**

Secondary Review: **06/16/2016**

Estimated Start Date: **09/30/2016**

Expiration Date: **02/20/2016**

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

Required Application Instructions

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

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

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

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

Executive Summary

- **Purpose.** To support the conduct of a mixed-methods health services research study to assess models for the implementation of immediate antiretroviral therapy (ART) for persons with newly diagnosed acute and early HIV infection. Models will be implemented and evaluated in two to three HIV care settings. These implementation studies will allow a better understanding of clinical outcomes and patients' experiences with immediate initiation of antiretroviral (ARV) treatment, including: 1) time to viral suppression and the proportion of patients who remain virally suppressed 12 months after their diagnosis, 2) retention in HIV care, 3) satisfaction with clinical care, 4) changes in HIV transmission risk behavior, and 5) laboratory markers of HIV infection.
- **Mechanism of Support.** Cooperative Agreement.
- **Funds Available and Anticipated Number of Awards.** Estimated total funding available, to include direct and indirect costs for the entire project period, is $14,850,000. The project period will be for four years. There will be up to three awards. Awards issued under this FOA are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded and the number of awards will depend upon the number, quality, duration and cost of the applications received.
- **Budget and Project Period.** The estimated funding (direct and indirect) for each award for the first year (12-month budget period) will be $495,000. An estimated $4,950,000 total funding (direct and indirect) will be available for each award for the entire four-year project period, with a maximum award of $495,000 for year 1, $1,650,000 for year 2, $1,980,000 for year 3, and $825,000 for year 4. The project period will run from 09/30/16 to 09/29/20.
- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. "Applicaiotn and Submission Information" of this announcement.

- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III.1. of this announcement are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.
- **Number of PDs/PIs.** There will only be one PD/PI per application. If necessary, Co-PI(s) may be listed in the application but only one PI may be the primary CDC contact for the award and this must be indicated in the application.
- **Number of Applications.** Each eligible applicant institution may submit only one application.
- **Application Type.** New.
- **Special Date(s).** A potential applicant conference call will be held on **Tuesday, January 12, 2016** at 12:00 noon Eastern Time. The bridge number is 1-866-662-8986; passcode 8378091.
- **Application Materials.** See **Section IV.1** for application materials. Please note that Form C is to be used when downloading the application package: http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at TTY: (770) 488-2783.

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

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

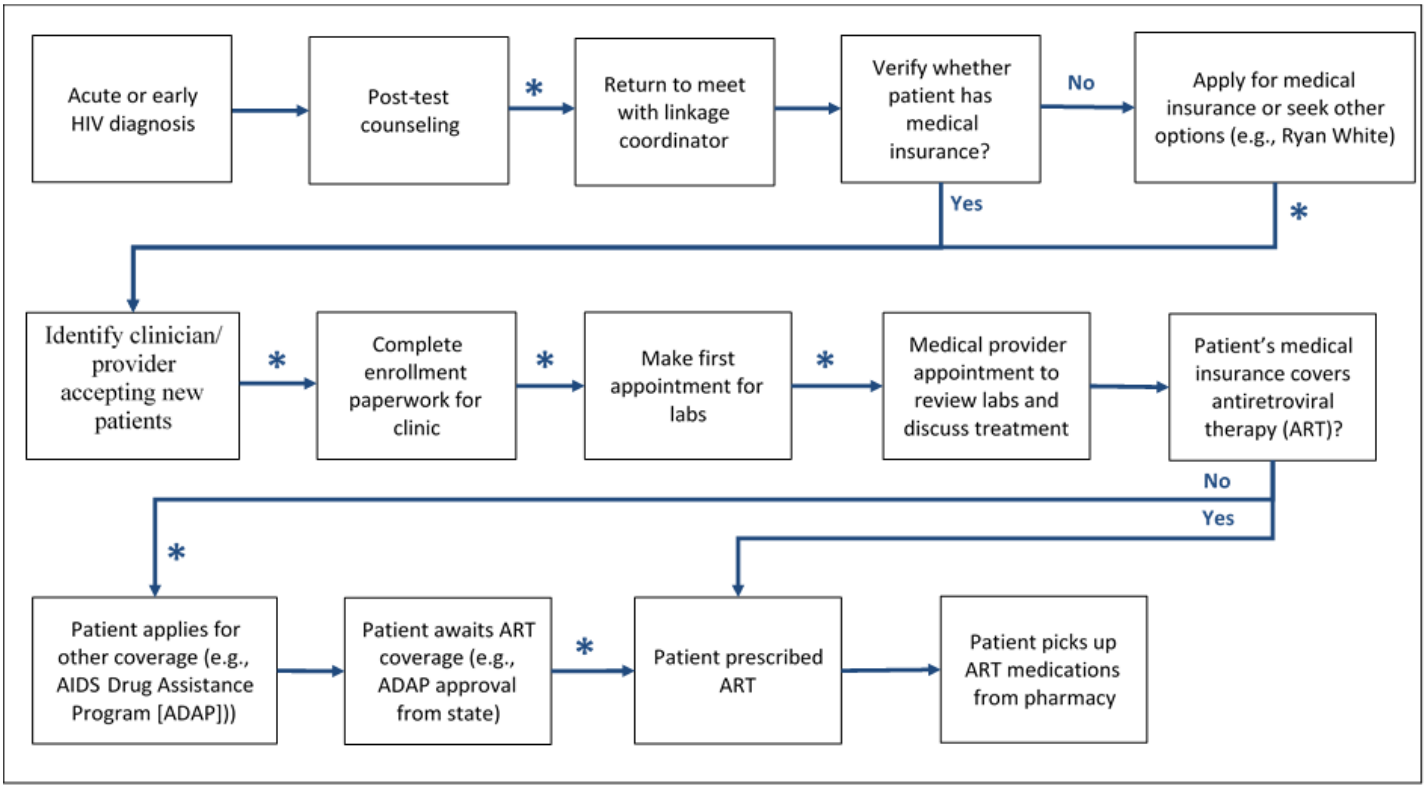
1. Background and Purpose

An estimated 1.1 million people were living with HIV in the United States in 2011 and the incidence of HIV infection among young men who have sex with men (MSM), especially young black MSM, has been increasing. Advances in antiretroviral therapy (ART) have dramatically decreased HIV-related morbidity and mortality and substantially reduced the risk of HIV transmission through suppression of HIV viremia. Persons with acute and early HIV infection (the stage of disease immediately after infection with the virus) are an important group to prioritize for treatment for a number of reasons. First, patients receiving HIV treatment early in the course of infection can gain substantial clinical benefit. Early treatment improves laboratory markers of disease progression and can decrease the severity of acute disease, lower the viral set point, and preserve immune function, which can improve the ability of an individual's immune system to control the virus on its own, in certain situations. Second, initiation of ART has been shown to be a strong correlate of retention in HIV care among treatment-naïve participants entering care and thus, early treatment might improve retention in life-saving HIV care. Lastly, the high viral load characteristic of early HIV infection contributes disproportionately to HIV transmission; modeling studies have demonstrated that early treatment can reduce the number of new HIV infections by nearly 50%.

To achieve these health benefits, and to prevent further HIV transmission, a priority of the National HIV/AIDS Strategy is to increase the number of people who know their HIV status and access HIV care and ART in the United States. Unfortunately, as of 2011, only 40% of the persons diagnosed with HIV infection were engaged in HIV care and an estimated 30% of all HIV-infected persons had achieved viral suppression, highlighting the need for systematic improvement in how treatment is provided. Modern antiretroviral medications are safe, conveniently dosed (once daily pills), have a high threshold to viral resistance, and can achieve viral suppression in two weeks; these characteristics make the benefits of acute and early HIV treatment achievable. Unfortunately, with the current standard of care, there are typically lengthy delays

(often on the order of several months for a variety of reasons such as enrollment in an insurance plan – see Figure 1) in initiating antiretroviral therapy. In one study evaluating treatment outcomes among persons diagnosed with acute HIV infection, the median time for 50% of the cohort to achieve viral suppression was 10 months. These delays happened during a period when significant immunological damage was occurring and when there was maximum risk for further HIV transmission. Models of immediate HIV treatment (e.g., Figure 2) at the time of HIV diagnosis are needed to improve both access to, and benefit from, HIV treatment.

Figure 1. Existing process for initiation of antiretroviral therapy for persons newly diagnosed with acute or early HIV infection



This example of existing patient flow identifies several potential points for delay in initiating antiretroviral therapy (ART) for those with newly diagnosed acute or early HIV infection. Steps marked with an asterisk (*) represent instances when patients are required to wait and/or return to complete the next step in the process, highlighting several potential points for loss to follow-up. Depending on the patient's medical coverage and existing resources in the community, patients may be required to wait weeks to months before initiating ART.

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

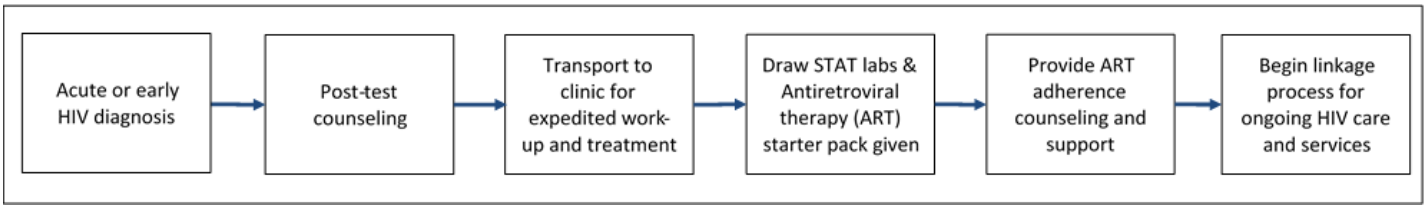
Identifying effective methods to increase access to, and use of, clinical HIV prevention and treatment services aligns with the following:

- Healthy People 2020 goals related to reducing new HIV infections, increasing HIV testing, and increasing access to care for persons with HIV infection.
- National HIV/AIDS Strategy Goals: 1) Reducing New HIV Infections; 2) Increase access to care and improve health outcomes for people living with HIV; and 3) Reducing HIV-related Disparities and Health Inequities.
- CDC Winnable Battles Goal: Reduce HIV infections.

Public Health Impact

The development of a health service model for expedited ART would improve patient flow by decreasing the number of steps, and the time interval, from diagnosis of HIV infection to initiation of treatment, shown in Figure 2. Administration of immediate ART could substantially reduce the time to viral suppression, providing clinical benefits to the patient and reducing risk of HIV transmission, while awaiting linkage to ongoing HIV care. Additional potential benefits include increased retention in care, decreased risk behavior, and increased patient satisfaction with care.

Figure 2. Proposed process for initiation of immediate antiretroviral therapy for persons newly diagnosed with acute or early HIV infection



Relevant Work

- Masciotra S. Evaluation of Determine™ HIV-1/2 Ag/Ab combo in the context of acute HIV screening; CROI 2015 http://www.croiconference.org/sessions/evaluation-determinetm-hiv-12-agab-combo-context-acute-hiv-screening
- HIV laboratory testing guidance http://www.cdc.gov/hiv/pdf/guidelines_testing_recommendedLabTestingAlgorithm.pdf
- Rosenberg ES. Race and age disparities in HIV incidence and prevalence among MSM in Atlanta, GA; CROI 2014: http://www.croiwebcasts.org/console/player/22065?mediaType=slideVideo&;
- HIV incidence report, 2007-2010 http://www.cdc.gov/hiv/pdf/statistics_hssr_vol_17_no_4.pdf
- HIV Surveillance Report 2013 http://www.cdc.gov/hiv/pdf/g-l/hiv_surveillance_report_vol_25.pdf
- HIV treatment guidelines http://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf
- Starting antiretroviral treatment early improves outcomes for HIV-infected individuals http://www.nih.gov/news/health/may2015/niaid-27.htm

2. Approach

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

Objectives/Outcomes

The objective of the proposed health services research study is to support the development of health services models for immediate antiretroviral (ARV) treatment of persons with newly diagnosed acute or early HIV infection, by implementing and evaluating a model in up to three HIV care venues. These implementation studies will allow a better understanding of clinical outcomes, patients' perspectives and behavior with immediate initiation of ARV treatment, including: 1) time to viral suppression and the proportion of patients who remain virally suppressed 12 months after their diagnosis, 2) patient retention in HIV care, 3) patient satisfaction with clinical care, 4) changes in HIV transmission risk behavior, and 5) laboratory markers of HIV infection.

These innovative models should be implemented and evaluated at two to three clinical HIV care sites with the following objectives and outcomes:

- Targeting immediate HIV treatment in disproportionately affected groups (e.g., men who have sex with men [MSM], racial and ethnic minorities).
- Identifying and enrolling persons with acute or early HIV infection. Applicants should partner with HIV testing programs that provide either frequent HIV testing (at least every 6 months) or pre-exposure prophylaxis to persons at high risk of HIV acquisition, especially MSM. Gay and bisexual men are disproportionately affected by HIV and an early treatment protocol will need to be effective in this population to have a national impact on the HIV epidemic.
- Conducting a post-test counseling process with assessment of patients assessed for, and offering, immediate ART.
- Assessing and addressing behavioral health and social services needs (e.g., mental health, substance abuse, or housing issues).
- Assessing and addressing additional barriers (e.g., health insurance coverage, clinic enrollment processes).
- Increasing access to same-day or walk-in HIV clinical services.
- Conducting STAT laboratory tests (e.g., CBC and renal and liver function tests) that might be necessary before ART can be initiated, and rapid HIV-specific laboratory tests (e.g., CD4, viral load, and HIV genotype) that are necessary but may not be available at the time of ART initiation.
- Developing a sustainable plan to provide same-day medication starter packs.
- Developing protocols to alter the ART regimen, if HIV drug resistance is detected via rapid HIV-specific laboratory testing.
- Providing adherence support.

- Seamlessly transitioning patients from the immediate treatment program into an ongoing HIV care program without disruptions of ART or HIV care provision.
- Administering a pre- and post-survey (approximately 20 inutes) to a subset of patients (25%) before enrollment and at a later time after ART has been initiated, to understand patient risk factors for HIV, decision-making processes regarding whether or not to enroll in treatment or to defer treatment to a later time, satisfaction with the decision chosen, as well as additional behavioral health and social services and adherence support.

Applications should describe model(s) to provide early (preferably same-day using starter packs; see Figure 2 as an example) treatment for persons newly diagnosed with acute or early HIV infection. Applications should address, in detail, strategies to achieve a streamlined and patient-centered approach to HIV treatment for persons with acute or early HIV infection. Models may be compared to existing standards for linkage to HIV care and treatment initiation. Applications should describe a detailed plan to evaluate patient outcomes.

Target Population

The objective of the proposed health services research study is to support the development of health services models for immediate antiretroviral (ARV) treatment of persons with newly diagnosed acute or early HIV infection, by implementing and evaluating a model in up to three HIV care venues. These innovative models should be implemented and evaluated at two to three clinical HIV care sites and target immediate HIV treatment in disproportionately affected groups (e.g., men who have sex with men [MSM], racial and ethnic minorities).

Collaboration/Partnerships

Collaborations and partnerships with clinics providing primary HIV care and ART for young black MSM are strongly recommended. Also, eligible applicants should collaborate with healthcare facilities or health departments with the capacity to provide all necessary HIV clinical services and obtain relevant laboratory tests for this proposed study.

Evaluation/Performance Measurement

As part of the application, the PI should include measurable goals and aims based on a four-year research project period. The grantee will collaborate with CDC to: 1) establish specific, measurable, achievable, realistic and time-phased (SMART) project objectives for each activity described in the applicant's project plan, and 2) develop and implement project performance measures that are based on specific programmatic objectives. Also, funded PIs must submit an annual progress report showing their activities and outcomes based on their overall research goals and timeline. For more information on required Reporting, please see Section VI of this FOA.

The successful grantee will implement a health services model for immediate ART for persons diagnosed with acute or early HIV infection, and collect data to evaluate. The grantee will prepare a sampling plan; study protocol; data collection instruments; data management and security plan; data quality assurance and data analysis procedures; and OMB and IRB applications for the study. In this research study, the grantee will evaluate the following key outcomes:

- Proportion of patients who remain virally suppressed 12 months after their diagnosis;
- Retention in HIV care;
- Patient satisfaction with clinical care;
- Changes in HIV transmission risk behavior;
- Laboratory markers of viral suppression.

Translation Plan

The results of this research will be made available to a wide range of potential users and stakeholders. Key findings will be presented at national meetings and published in peer-review journals. Findings related to effective health services models for immediate ART for acute and early HIV infection will also be disseminated to clinicians, the public health workforce, and community-based stakeholders to inform their efforts to implement these models. In addition, findings related to self-reported risk behaviors of people living with HIV (PLWH) who initiate immediate ART, compared to usual care, will inform both HIV prevention efforts.

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: $14,850,000

Year 1: $1,485,000 for up to 3 awards;

Year 2: $4,950,000 for up to 3 awards;

Year 3: $5,940,000 for up to 3 awards;

Year 4: $2,475,000 for up to 3 awards.

Estimated total funding available for the first year (12-month budget period) is $1,485,000 for up to 3 awards.

Estimated total funding available for the entire four-year project period is $14,850,000 for up to 3 awards.

Anticipated Number of Awards: 3

The ceiling for an individual award is $495,000, including direct and indirect costs, for the first 12-month budget period.

The floor for an individual award is $300,000, including direct and indirect costs, for the first 12-month budget period.

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

Award Ceiling: $495,000 Per Budget Period

Award Floor: $300,000 Per Budget Period

Total Project Period Length: 4 year(s)

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

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

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:

State governments
County governments
City or township governments
Special district governments
Independent school districts
Public and State controlled institutions of higher education
Native American tribal governments (Federally recognized)
Public housing authorities/Indian housing authorities
Native American tribal organizations (other than Federally recognized tribal governments)
Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education
Private institutions of higher education
Others (see text field entitled "Additional Information on Eligibility" for clarification)

Additional Eligibility Category:

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

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

Nonprofits Other Than Institutions of Higher Education:

Nonprofits (Other than Institutions of Higher Education)

Governments:

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

Other:

Native American tribal organizations (other than Federally recognized tribal governments)
Faith-based or Community-based Organizations
Regional Organizations

Bona Fide Agents: a Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms" when submitting via www.grants.gov.
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 http:// ecfr.gpoaccess.gov /cgi/t/text/ text-idx?c=ecfr& sid=512ff78311f427c00454772dcf21523a&rgn=div8 &view=text&node=48:1.0.1.6.34.0.1.18& idno=48

2. Foreign Organizations

Foreign Organizations are not eligible to apply.

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

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

3. Special Eligibility Requirements

Additional Information on Eligibility

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

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

- Applications submitted under this funding opportunity announcement must not include activities that overlap with simultaneously-funded research already awarded to applicants under other awards.
- The application must include evidence of the investigative team’s research experience in HIV diagnostics, HIV treatment and primary care.
- The application must include a letter of support showing evidence of collaboration with a healthcare organization, health department, and laboratory to provide the necessary clinical and laboratory data to evaluate the health service models.

6. Required Registrations

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

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

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

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

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

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

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

9. Cost Sharing

This FOA does not require cost sharing as defined in the HHS Grants Policy Statement (http:// www.hhs.gov/ asfr/ ogapa/ aboutog/ hhsgps107.pdf).

10. Number of Applications

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

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

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity from www.Grants.gov.

If access to the Internet is not available or if the applicant encounters difficulty accessing the forms on-line, contact the HHS/CDC Procurement and Grants Office Technical Information Management Section (TIMS) staff at (770) 488-2700 or pgotim@cdc.gov for further instructions. Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Time. CDC Telecommunications for the hearing impaired or disabled is available at: TTY 1-888-232-6348.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/ 424/SF424_RR_Guide_General_VerC.pdf), except where instructed in this Funding Opportunity Announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

The forms package associated with this FOA includes all applicable components, mandatory and optional. Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow the instructions in the SF 424 (R&R) Application Guide to ensure you complete all appropriate “optional” components.

In conjunction with the SF424 (R&R) components, CDC grants applicants should also complete and submit additional components titled “PHS398.” Note the PHS398 should include assurances and certifications, additional data required by the agency for a complete application. While these are not identical to the PHS398 application form pages, the PHS398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete application to CDC will include SF424 (R&R) and PHS398 components. These forms can be downloaded from http://grants.nih.gov/grants/forms.htm

3. Letter of Intent

Due Date for Letter of Intent: **01/14/2016**

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

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

Name of the Applicant

Descriptive title of proposed research
Name, address, and telephone number of the PD(s)/PI(s)
Names of other key personnel
Participating institutions
Number and title of this funding opportunity

The letter of intent should be sent to:

Gregory Anderson, MPH, MS

Extramural Research Program Office

Office of the Associate Director of Science

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

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

1600 Clifton Road, MS E-60

Atlanta, GA 30333

Telephone: 404-718-8833

Fax: 404-718-8822

Email: GAnderson@cdc.gov

4. Required and Optional Components

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

5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of 16 components. Not all 16 components of the Research Plan apply to all Funding Opportunity Announcements (FOAs). Specifically, some of the following 16 components are for Resubmissions or Revisions only. See Part I, Section 5.5 of the SF 424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Funding Opportunity Announcement Description).
Follow the page limits stated in the SF 424 unless otherwise specified in the FOA. As applicable to and specified in the FOA, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

1. Introduction to Application (for Resubmission and Revision ONLY) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the FOA.
2. Specific Aims – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health. **3. Research Strategy** – the research strategy

should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and timeline. **4. Inclusion Enrollment Report** (Renewal and Revision applications ONLY) **5. Progress Report Publication List** (for Continuation ONLY)

Human Subjects Section

6. Protection of Human Subjects 7. Inclusion of Women and Minorities 8. Targeted/Planned Enrollment Table (for New Application ONLY) **9. Inclusion of Children**

Other Research Plan Sections

10. Vertebrate Animals 11. Select Agent Research 12. Multiple PD/PI Leadership Plan. 13. Consortium/Contractual Arrangements 14. Letters of Support 15. Resource Sharing Plan(s) 16. Appendix

Component 4 (Inclusion Enrollment Report) applies only to Renewal and Revision applications for clinical research. Clinical research is that which is conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies). Follow the page limits in the SF 424 **unless otherwise specified in the FOA.**

All instructions in the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) must be followed along with any additional instructions provided in the FOA.

6. Appendix

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

7. Page Limitations

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

8. Format for Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff. Applicants should ensure that all attachments are uploaded to the system.

CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide (Part I, Section 2) (http://grants.nih.gov/ grants/funding/424/ SF424_RR_Guide_General_VerC.pdf).

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit in advance of the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications via Grants.gov (http://www.grants.gov), the online portal to find and apply for grants across all Federal agencies. The eRA Commons systems retrieve the application from Grants.gov and check the application against CDC business rules. If no errors are found, the application will be assembled in the eRA Commons for viewing by the applicant before moving on for further CDC

processing.
If errors are found, the applicant will be notified in the eRA Commons. They must make required changes to the local copy of their application and submit again through Grants.gov.
Applicants are responsible for viewing their application in the eRA Commons to ensure accurate and successful submission.
Once you can see your application in the Commons, be sure to review it carefully as this is what the reviewer will see. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (http:// grants.nih. gov/grants /guide/url_redirect .htm? id=11123).
Information on the submission process is provided in the SF424 (R&R) Application Guide.
Note: HHS/CDC grant submission procedures do not provide a period of time beyond the grant application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e. error correction window).
The application package is not complete until it has passed the Grants.gov/eRA Commons validation process. This process and email notifications of receipt, validation or rejection may take two (2) business days.
Applicants are strongly encouraged to allocate additional time prior to the submission deadline to submit their applications and to correct errors identified in the validation process. Applicants are encouraged also to check the status of their application submission to determine if the application packages are complete and error-free. Applicants who encounter system errors when submitting their applications must attempt to resolve them by contacting the Grants.gov Contact Center (1-800-518-4726; support@grants.gov). If the system errors cannot be resolved, applicants must contact TIMS at 770-488-2700; pgotim@cdc.gov for guidance at least 3 calendar days before the deadline date.
After submission of your application package, applicants will receive a "submission receipt" email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. This validation process may take as long as two (2) business days. A third and final e-mail message is generated once the applicant's application package has passed validation and the grantor has confirmed receipt of the application.

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

Due Date for Applications: **02/19/2016**

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

10. Intergovernmental Review (E.O. 12372)

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

11. Funding Restrictions

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

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).

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

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

12. Other Submission Requirements and Information

Application Submission

Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.**

Applicants must complete all required registrations before the application due date. Section III.6 "Required Registrations" contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically (http://grants.nih.gov/grants/guide /url_ redirect.htm? id=11144).

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

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

If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.

See more resources to avoid common errors and submitting, tracking, and viewing applications: http:// grants.nih. gov/grants/ Electronic Receipt /avoiding_ errors.htm or http:// grants. nih.gov/grants/ Electronic Receipt/submit_ app.htm

Upon receipt, applications will be evaluated for completeness by the CDC Office of Grants Services (OGS) and responsiveness by OGS and the Center, Institute or Office of the CDC. Applications that are incomplete and/or nonresponsive will not be reviewed.

Section V. Application Review Information

1. Criteria

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

Overall Impact

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

Scored Review Criteria

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

Significance

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

Does the application discuss the importance of early ART for optimal health outcomes and prevention of HIV transmission?

Does the application demonstrate awareness facilitators and barriers to utilization of HIV prevention and care services by at-risk populations, including young black MSM?

Investigator(s)

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

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

Does the application demonstrate access to qualified personnel with realistic and sufficient time commitments relative to each phase of the study timeline?

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

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 propose a health services model that demonstrates an understanding of the facilitators and barriers to prompt initiation of ART?

Does the application propose a health services model that can overcome these barriers to decrease the time interval between diagnosis of acute or early HIV infection and viral suppression?

Approach

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

Does the application demonstrate an understanding of the research objectives for this FOA as reflected in the specific study design and methods of the research proposal?

Does the application provide plans for recruitment, engagement, and retention of the target population of persons with newly diagnosed acute and early HIV infection?

Does the application provide a plan for medication adherence support?

Does the application provide a plan for collection of clinical and lab data necessary to evaluate the model?

Does the application provide a plan for implementation of the patient survey?

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

Environment

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

Does the application provide estimates of the number of MSM and rate of new HIV diagnoses, stratified by race and ethnicity, in the community?

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

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.

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.

As part of the Biohazards assessment, reviewers will evaluate whether the research proposed qualifies as Dual Use Research of Concern. Despite its value and benefits, certain types of research conducted for legitimate purposes can be utilized for both benevolent and harmful purposes. Such research is called "dual use research." Dual use research of concern is a subset of dual use research defined as: "life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security." The United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern articulates the practices and procedures required to ensure that dual use research of concern is identified at the institutional level and risk mitigation measures are implemented as necessary.

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.

2. Additional Review Criteria

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

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

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

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

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

Vertebrate Animals The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort,

distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

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

Dual Use Research of Concern Reviewers will identify whether the project involves one of the agents or toxins described in the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern, and, if so, whether the applicant has identified an IRE to assess the project for DURC potential and develop mitigation strategies if needed.
For more information about this Policy and other policies regarding dual use research of concern, visit the U.S. Government Science, Safety, Security (S3) website at: http://www.phe.gov/s3/dualuse. Tools and guidance for assessing DURC potential may be found at: http://www.phe.gov/s3/dual-use/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 Plans HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: http://www.cdc.gov/grants/additionalrequirements/index.html. Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

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

4. Review and Selection Process

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

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

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

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

- Relevance of the proposed project to program priorities.

5. Anticipated Announcement and Award Dates

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

Section VI. Award Administration Information

1. Award Notices

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

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

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

2. CDC Administrative Requirements

Overview of Terms and Conditions of Award and Requirements for Specific Types of Grants

All HHS/CDC grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the NoA. For these terms of award, see the HHS Grants Policy Statement Part II: Terms and Conditions of Award (http://www.hhs.gov/ asfr/ogapa/aboutog/hhsgps107.pdf).

Awardees must comply with the administrative requirements (AR) outlined in 45 Code of Federal Regulations (CFR) Part 75, as appropriate, as well as any additional requirements included in the FOA. Specific requirements that apply to this FOA are the following:

Generally applicable ARs:

AR-1: Human Subjects Requirements

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

AR-7: Executive Order 12372 Review

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2010

AR-12: Lobbying Restrictions

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

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

AR-17: Peer and Technical Reviews of Final Reports of Health Studies –; ATSDR

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

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Release and Sharing of Data

AR-26: National Historic Preservation Act of 1966

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

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

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

AR 31 - Distinguishing Public Health Research and Public Health Nonresearch

AR 32 –; FY 2012 Enacted General Provisions

Organization Specific ARs:

AR-8: Public Health System Reporting Requirements

AR-15: Proof of Non-profit Status

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

For more information on the Code of Federal Regulations, visit the National Archives and Records Administration at: http://www.access.gpo.gov/nara/cfr/cfr-table-search.html

To view brief descriptions of relevant CDC requirements visit: http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm

Additional Policy Requirements

The following are additional policy requirements relevant to this FOA:

Dual Use Research of Concern (DURC)

On September 24, 2014, the Federal government issued a policy for the oversight of life sciences “Dual Use Research of Concern” (United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. September 24, 2014. DURC is defined as life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. The fundamental aim of this oversight policy is to preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.

The DURC policy applies to recipients in the United States that receive Federal funding for life sciences research and that conduct or sponsor research involving one or more of the 15 agents or toxins listed in the policy. This policy also applies to foreign recipients that receive Federal funding to conduct or sponsor research involving one of these 15 agents or toxins. Research funded by CDC involving these agents or toxins 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 may be completed by an Institutional Review Entity (IRE) identified by the funded institution. Many institutions task their Institutional Biosafety Committees with this responsibility.

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 or cooperative agreement 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. For example, CDC may request that the institution periodically review a project for its DURC potential, propose any modifications to the risk mitigation plan, and share any resulting manuscripts with their Program Official prior to submitting the manuscript to a journal. CDC's Institutional Biosecurity Board (IBB) is responsible for approval of all DURC risk mitigation plans. The award recipient is responsible for adhering to the risk mitigation plan, as approved by CDC.

3. Additional Policy Requirements

The following are additional policy requirements relevant to this FOA:

HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items and Printing Publications This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy apply to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website at:http://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html.

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

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

Tobacco and Nutrition Policies The CDC supports implementing evidence-based programs and policies to reduce tobacco use and secondhand smoke exposure, and to promote healthy nutrition. CDC encourages all awardees to implement the following *optional* evidence-based tobacco and nutrition policies within their organizations. These policies build on the current federal commitment to reduce exposure to secondhand smoke, which includes The Pro-Children Act, 20 U.S.C. 7181-7184 that prohibits smoking in certain facilities that receive federal funds.

Tobacco:

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

Nutrition:

- Healthy food service guidelines that at a minimum align with Health and Human Services and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending

Operations for cafeterias, snack bars, and vending machines in any facility under the control of the recipient organization and in accordance with contractual obligations for these services. The following are resources for healthy eating and tobacco free workplaces:

- http://www.gsa.gov/graphics/pbs/ Guidelines_for_Federal_Concessions_and_Vending_Operations.pdf
- http://www.cdc.gov/nccdphp/dnpao/hwi/toolkits/tobacco/index.htm
- http://www.cdc.gov/obesity/strategies/food-serv-guide.html

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

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

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

Language Access for Persons with Limited English Proficiency Recipients of federal financial assistance from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. Recipients of federal financial assistance must take the reasonable steps to provide meaningful access to their programs by persons with limited English proficiency.

Dual Use Research of Concern On September 24, 2014, the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern was released. Grantees (foreign and domestic) receiving CDC funding on or after September 24, 2015 are subject to this policy. Research funded by CDC involving the agents or toxins named in the policy, must be reviewed to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. This review must be completed by an Institutional Review Entity (IRE) identified by the funded institution.

Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR). The award recipient must maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant, cooperative agreement or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.
If a project is determined to be DURC, a risk/benefit analysis must be completed. CDC will work collaboratively with the award recipient to develop a risk mitigation plan that the CDC must approve. The USG policy can be found at http://www.phe.gov/s3/dualuse.
Non-compliance with this Policy may result in suspension, limitation, restriction or termination of USG funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

4. Cooperative Agreement Terms and Conditions of Award

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 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:

- 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.
- Plan, direct, and execute the proposed research project with CDC staff substantially involved as a partner.
- Develop research protocols in collaboration with CDC staff and submit for local IRB review and approval. Protocol development activities will include the development of screening and HIV testing procedures, data collection instruments, specimen collection protocols, data management procedures and procedures to maintain the confidentiality of study records.
- Obtain a Certificate of Confidentiality from CDC.
- Identify, recruit, obtain informed consent from, enroll, and follow study participants as determined by study protocols and program requirements.
- Link study participants to indicated clinical care as determined by study protocols.
- Conduct interviews, counseling, specimen collection and shipping, medical record abstraction, and academic detailing, as determined by study protocols.
- Perform data analyses and submit study findings for publication in a peer-reviewed journal and presentation at scientific meetings.
- Agree to collaborate and share data with CDC, and transfer data for analysis at specified intervals.
- Participate in conference calls with CDC project officers and research team.
- Host CDC project officer(s) for site visits.
- Ensure the protection of human subjects through ethical review of all protocols involving human subjects at the local institution and at CDC and obtain the appropriate Institutional Review Board

approvals for all institutions or individuals engaged in the conduct of the research project.
- Work with CDC scientists to obtain OMB-PRA approvals, as needed.
- PUBLICATIONS/PRESENTATIONS: Publications, journal articles, presentations, etc. produced under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate, for example: "This publication (journal article, etc.) was supported by the Cooperative Agreement Number above from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention". In addition, the PI/PD must provide to CDC Program abstracts or manuscripts prior to any publication related to this funding. The grantee will not seek to publish or present results or findings from this project without prior clearance and approval from CDC.
- Comply with the responsibilities for the PI as described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC).

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

- Provide guidance and assistance in the development of data management systems and procedures compliant with federal data security policies.
- Facilitate conference calls, grantee meetings, and site visits.
- Provide technical assistance, as needed, in the design and conduct of the research.
- Facilitate and assist in the development of research protocols for IRB review.
- Obtain determination of human subjects review and, if CDC is determined to be engaged in the research, the HHS/CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.
- Assist, as needed, in designing a data management system and obtaining data security system review and approval.
- Collaborate with the grantee on the analysis and interpretation of data and on the presentation and publication of results, when the CDC contribution merits this.
- Conduct site visits to ensure that study venues are properly established, collaborations outlined in proposals are active, and the research is being conducted in compliance with the approved protocols.
- Prepare the paperwork necessary for submission of research protocols to the CDC Institutional Review Board for review, as needed.
- Obtain Office of Management and Budget approval per the Paperwork Reduction Act, if necessary.
- Assist the PI, as needed, in complying with the PI responsibilities described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC).

Areas of Joint Responsibilities include:

- Collaborate in the development of human subjects research protocols and additional documents for IRB review by all cooperating institutions participating in the project and for OMB review, if needed.

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

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

- Monitor performance against approved project objectives.

5. Reporting

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

Additional Reporting Requirements:

The frequency of other progress reporting and the reporting format will be agreed upon between the awardee and CDC. Beginning year 2, the grantee will submit to CDC twice yearly a report that includes:

- Total number of participants screened and enrolled in the study, stratified by acute vs. early HIV infection.
- Total number of participants initiated on ART.
- Total number of participants completing quarterly follow-up visits.
- Summary of laboratory testing results, including HIV viral load and CD4 cell counts.

A. Submission of Reports

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

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

required **90 days after the end of the project period.**

B. Content of Reports

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

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

- Research Aims: list each research aim/project

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

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

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

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

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

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

- New Budget Period Proposal:
    - Detailed operational plan for continuing activities in the upcoming budget period, including updated Measures of Effectiveness for evaluating progress during the upcoming budget period. Report listed by Research Aim/Project.
    - Project Timeline: Include planned milestones for the upcoming year (be specific and provide deadlines).
- New Budget Period Budget: Detailed line-item budget and budget justification for the new budget period. Use the CDC budget guideline format.
- Publications/Presentations: Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate "Not applicable: No publications or presentations have been made."
- IRB Approval Certification: Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.

Section VII. Agency Contacts

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

Application Submission Contacts

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

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking application status, post submission issues, FFR submission)
Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
Email: commons@od.nih.gov
Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time

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

Program Official / Scientific Research Contact

Paul Smutz, PhD

Extramural Research Program Office

Office of the Associate Director for Science

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

Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road, MS E-60
Atlanta, GA 30333
Telephone: 404-718-8830
Fax: 404-718-8822
Email: wsmutz@cdc.gov

Peer Review Contact

Gregory Anderson, MPH, MS
Extramural Research Program Office
Office of the Associate Director for Science
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road, MS E-60
Atlanta, GA 30333
Telephone: 404-718-8833
Fax: 404-718-8822
Email: GAnderson@cdc.gov

Financial/Grants Management Contact

Karen Zion
Office of Financial Resources
Office of Grant Services
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
2960 Brandy Wine Road, MS E-15
Atlanta, GA 30341
Telephone: (770) 488-2729
Fax: (770) 488-2828
Email: **wvf8@cdc.gov**

Section VIII. Other Information

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

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

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

Summary of the Conference Call held on Tuesday, January 12, 2016 with Potential Applicants for Funding Opportunity Announcement (FOA): PS16-006 "Early HIV Treatment to Optimize Patient Health and HIV Prevention"

Introductory Comments:

Any scientific or technical questions should be addressed to the Scientific Program Officer, Dr. Paul Smutz (WSmutz@cdc.gov). Any questions on financial, grants management, or eligibility aspects should be addressed to the Grants Management Officer, Ms. Karen Zion (wvf8@cdc.gov). Questions regarding the Peer Review process should be addressed to the Scientific Review Officer, Mr. Gregory Anderson (GAnderson@cdc.gov). Contact information can be found in the Funding Opportunity Announcement (FOA) in Part 2, Section VII. "Agency Contacts". Information on application submission is listed in Section IV. "Application and Submission Information".

Eligibility Information:

Please see Part 2, Section III. "Eligibility Information" for questions regarding eligible applicants.

Section III.3. Special Eligibility Requirements:

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

Section III.5. Responsiveness:

Please read this section carefully for a detailed explanation of responsiveness criteria.

- Applications submitted under this funding opportunity announcement must not include activities that overlap with simultaneously-funded research already awarded to applicants under other awards.
- The application must include evidence of the investigative team's research experience in HIV diagnostics, HIV treatment and primary care.
- The application must include a letter of support showing evidence of collaboration with a healthcare providing organization, a health department, and a laboratory to provide the necessary clinical, public health, and laboratory services and data to evaluate the health service models.

Required Registrations:

Please see Part 2, Section III.6. "Required Registrations" for information on required registrations. All registrations must be successfully completed and active before the application due date. Applicant organizations are strongly encouraged to start the registration process at least four (4) weeks prior to the application due date.

Other Tips and Important Dates:

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. Letters of Intent are therefore strongly encouraged. Please see Part 2, Section IV.3. "Letter of Intent" for instructions on submitting a letter of intent. Emailing the letter to Mr. Gregory Anderson at

GAnderson@cdc.gov is acceptable. Letters of Intent are due by **January 14th, 2016.**

Applications are due no later than **5 pm Eastern Time on February 19th, 2016**. Please submit your application at least five days before the deadline to allow for error correction. No extensions will be granted for applications that are rejected because of submission errors.

Potential applicants should pay close attention to Part 2, Section V.1. "Criteria" for information on application review criteria. The review criteria must be addressed – these are the criteria that will be used by reviewers to score the application. Failure to provide required information could result in an unfavorable score.

Please also pay close attention to Part 2, Section I.2. "Approach".

It is anticipated that there will be up to three awards.

The estimated total funding available for three awards is up to $1,485,000 for the first 12-month budget period and up to $14,850,000 for the entire project period of four (4) years.

The ceiling and floor, respectively, for an individual award for the first 12-month budget period (including direct and indirect costs) is $495,000 and $300,000.

Questions and Answers:

1. Question: Is there a target N in terms of numbers of people enrolled?

Answer: No, there is not a required minimum number of people to enroll. The goal is to develop and demonstrate a sustainable intervention to provide immediate HIV treatment during the acute and early phase of HIV infection. Applicants should have a plan to demonstrate that the intervention is feasible and effective. Effectiveness can be demonstrated with metrics (including time to viral suppression and proportion virally suppressed) compared with an *a priori* standard of success defined by the applicant or with historical data. Power calculations should be performed to ensure that there are sufficient study population numbers to demonstrate these results.

2. Question: In the opening comments, it was mentioned that the application must include evidence of the investigative team's research experience in HIV diagnostics, HIV treatment and primary care. Is that requirement for the PI or just the other team members?

Answer: The PI does not necessarily have to have the experience so long as team members do. This experience should be clearly documented in the biosketch section of the application.

3. Question: Can study funds be used to purchase starter packs or pay for laboratory costs?

Answer: Yes, but the goal is for the program to be sustainable so these costs should probably not drive the whole budget of the project. It is expected that funds for study-related laboratory testing would be covered by the grant budget.

4. Question: Are you looking for applications from areas with a certain HIV incidence?

Answer: There is no requirement for applications to be from an area with a certain HIV incidence. However, it is important for each applicant to demonstrate that they can diagnose and identify people who will qualify for the treatment and that a sufficient number of individuals can be enrolled to obtain statistically meaningful data.

5. Question: Are you interested in comparing models to existing standards? Is this a single arm observational study or are you looking for a formal comparison?

Answer: The intent is not a randomized clinical trial but rather a single arm observational study that could be compared to existing standards (as defined by the applicant) or with historical data. The study should also be designed to show that this work is feasible and can be implemented to achieve rapid and sustained viral suppression and to prevent HIV transmissions.

6. Question: Is there any preference in terms of racial or ethnic populations that should be targeted?

Answer: There are no hard criteria in terms of racial or ethnic populations, but ideally the intervention will be shown to be effective in the most disproportionately affected populations which could include young men who have sex with men (MSM), African American or black MSM, and other disproportionately affected populations in the applicant's jurisdiction.

7. Question: It seems that the emphasis is on acute and early HIV infections. Could those with established HIV be considered for this study?

Answer: Yes, an application could make a good case for including people with established HIV infection. The emphasis of the award is on persons with acute and early HIV infection as this phase of infection is disproportionately associated with further HIV transmission and it will be important for applicants to address this phase of HIV infection. However, a strict definition of early HIV infection was not provided to give applicants flexibility in how they would identify persons with early HIV infection. In addition, applicants can provide justification for providing this intervention for persons with established HIV infection who might also benefit from immediate HIV treatment such as, but not limited to, (i) patients with a high viral load, (ii) patients with multiple anonymous partners, or (iii) patients identified through partner notification or molecular phylogenetics as being in a network at high-risk for further HIV transmission.

8. Question: In terms of the required letters of support, do we need one from a healthcare organization, one from a health department and one from a laboratory?

Answer: Yes, all involved collaborators should provide a letter of support: a healthcare organization, a health department, and a laboratory should participate in this study. The original FOA states a letter of support is required from a healthcare organization, health department OR laboratory. The FOA has now been corrected to state a letter of support is required from a healthcare organization, health department AND laboratory.

9. Question: The FOA talks about linking diagnoses to care. Does it matter if these organizations are the same or can they be separate?

Answer: These organizations (the organization that diagnoses acute and early HIV infection and the organization that provides HIV treatment) can be separate or the same.

10. Question: Can you please confirm that we should have 2 to 3 clinical sites involved per awardee?

Answer: Yes, there should be 2 to 3 clinical sites involved per awardee.

11. Question: If we could identify people who had fallen out of care, who have a high viral load and could bring them back into care, would that be a good population to study?

Answer: The application should not be structured around that population alone. That said, an applicant could make a good argument for including this patient population, using the justification that you are trying to provide this service to people who are at a high risk for HIV transmission to others within the community. The goal is to stop HIV transmission and applicants can be as innovative as possible.

12. Question: Do we need to budget for travel to meetings at CDC?

Answer: Yes. The first study meeting might be a larger one where 2 to 4 investigators would need to travel to CDC. In other years, it might only be 2 investigators that need to travel to CDC in a given year. The length of the meetings might be 2 days, once per year.

13. Question: Is the year one ceiling of $495,000 intended to cover implementation at 2 to 3 study sites?

Answer: Yes, the year one budget is smaller than for subsequent years. There is usually a phasing in of work over time because IRB and OMB approvals may take most of the first year to be established. The budget typically increases during years 2 and 3 because these approvals have been obtained and work is in full swing.

14. Question: If an institution has multiple clinical sites can that work?

Answer: Yes, each awardee should collaborate with 2 to 3 clinical sites. These clinical sites can be part of the same institution, as long as the applicant explains how they are distinct from each other.

15. Question: Can an institution participate as a collaborator in multiple applications for this award?

Answer: No,only one application may be submitted and awarded per institution, and this budget would cover work with all collaborating clinical sites.

16. Question: Is there a requirement that the applicant have multiple sites in the proposal?

Answer: Yes, the intervention needs to be implemented at 2 to 3 clinical sites. The same entity can be running those sites, but there needs to be at least two separate clinical sites involved.

17. Question: You mentioned that the ceiling for year one is $495,000. Are there ceilings for the other years?

Answer: Yes, the ceiling for year 2 is $1,650,000; for year 3 it is $1,980,000; and for year 4 it is $825,000. This is because it is expected that the work will ramp up in the middle years and then less funds will be needed in the last year when data collection is finishing and data is being analyzed.

18. Question: There is a floor of $300,000 for the first year but is there any floor for the other years?

Answer: The floor in other years is determined by the applicant based on the complexity of the work proposed. The applicant needs to decide how much money will be required to complete the work proposed.