

Centers for Disease Control and Prevention

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

Minority HIV/AIDS Research Initiative (MARI) to Build HIV Prevention, Treatment and Research Capacity in Disproportionately Affected Black and Hispanic Communities and Among Historically Underrepresented Researchers

RFA-PS-16-001

Application Due Date: 10/14/2015

Minority HIV/AIDS Research Initiative (MARI) to Build HIV Prevention, Treatment and Research Capacity in Disproportionately Affected Black and Hispanic Communities and Among Historically Underrepresented Researchers

RFA-PS-16-001

TABLE OF CONTENTS

Part 1. Overview Information
- Key Dates
- Required Application Instructions
- Executive Summary

Part 2. Full Text
- Section I. Funding Opportunity Description
- Section II. Award Information
- Section III. Eligibility Information
- Section IV. Application and Submission Information
- Section V. Application Review Information
- Section VI. Award Administration Information
- Section VII. Agency Contacts
- Section VIII. Other Information

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

Minority HIV/AIDS Research Initiative (MARI) to Build HIV Prevention, Treatment and Research Capacity in Disproportionately Affected Black and Hispanic Communities and Among Historically Underrepresented Researchers

Activity Code

U01

Funding Opportunity Announcement Type

Reissue of PS11-003

Funding Opportunity Announcement Number

RFA-PS-16-001

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

93.941

Category of Funding Activity:

Health

FOA Purpose

The overall objective of this teaching/mentored award program is to prepare qualified individuals for careers that have a significant impact on the HIV/AIDS-related research needs of the nation, especially in highly-affected minority communities. The objective of the Minority HIV/AIDS Research Initiative (MARI) Award program is to provide support for a sustained period of time for intensive research training and career development under the guidance of an experienced mentor in HIV prevention research and lead to promising HIV prevention activities and researchers who could independently conduct studies in highly-affected communities.

NOTE: A summary of the Conference Call held on Thursday, August 27, 2015 with Potential Applicants for this Funding Opportunity Announcement has been added as an amendment to the FOA in Section VIII. "Other Information" on pages 32-36 and a clarification has been added on pages 2 and 10 regarding indirect cost rates.

Key Dates

Publication Date: **To receive notification of any changes to RFA-PS-16-001, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.**

Letter of Intent Due Date: 09/14/2015

Application Due Date: **10/14/2015**

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: **12/10/2015**

Secondary Review: **01/14/2016**

Estimated Start Date: **05/01/2016**

Expiration Date: **10/15/2015**

Due Dates for E.O. 12372: Executive Order 12372 does not apply to this program.

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 12 pages.

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

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

Executive Summary

- **Purpose.** The overall objective of this teaching/mentored award program is to prepare qualified individuals for careers that have a significant impact on the HIV/AIDS-related research needs of the nation, especially in highly-affected minority communities. The objective of the Minority HIV/AIDS Research Initiative (MARI) Award program is to provide support for a sustained period of time for intensive research training and career development under the guidance of an experienced mentor in HIV prevention research and lead to promising HIV prevention activities and researchers who could independently conduct studies in highly-affected communities.
- **Mechanism of Support.** Teaching/mentored cooperative agreement award (U01).
- **Funds Available and Anticipated Number of Awards.** The estimated total funding available is up to $2,400,000 for the first year and up to $9,600,000 for the entire project period of four years. The anticipated number of awards is eight**.**
- **Budget and Project Period.** The estimated total funding (direct and indirect) for the first year (12-month budget period) is $2,400,000 for 8 awards, with a ceiling of $300,000 per award. The estimated total funding (direct and indirect) for the entire project period is $9,600,000. The project period will run from 05/01/2016 to 04/30/2020. An indirect cost rate of 8% is not automatic; however, grantee institutions can elect to take an indirect cost rate of 8% should they choose to do so.
- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. Application and Submission Information of this announcement. **For this FOA, the page limit for the Research Strategy section is 12 pages.**
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III.1 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 and who meet the eligibility criteria listed in **Section III.3** of this FOA are invited to work with their institution/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. **NOTE:** CDC does not make awards to individuals directly.

- **Number of PDs/PIs.** There will only be one PD/PI for each application.
- **Number of Applications.** Each eligible institution/organization may submit more than one application, but each application must have a different PD/PI. 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 must be indicated in the application. **NOTE:** Only one application may be submitted per topic area from the same institution.
- **Special Date(s).** A conference call with all potential applicants will be held on **Thursday, August 27, 2015 at 12:00 pm ET. Phone Number: 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. 241 and 247c

1. Background and Purpose

The Minority HIV/AIDS Research Initiative (MARI) program was established in 2003 to build capacity for HIV epidemiologic and prevention research in mostly Black and Hispanic communities and among Black and Hispanic investigators working in highly-affected communities. The MARI program supports the CDC's overarching goal to promote health and reduce disease and disability by funding research that has the potential to reduce disease burden and to result in high public health impact.

The overarching national goal stated in the CDC's HIV prevention strategic plan is to reduce the number of new HIV infections in the U.S. by focusing on eliminating racial and ethnic disparities in new HIV infections. The CDC year-end HIV/AIDS surveillance report, which outlines the racial disparities in HIV/AIDS, reveals that Blacks and Hispanics together represent 65 percent of reported cases of HIV infection, but together make up only 30 percent of the U.S. population.

These statistics highlight the urgent need for HIV epidemiologic and prevention research in minority communities that are at risk for HIV infection.

The goals of the MARI program are:

1. To build HIV prevention research capacity in minority communities in which little research has been conducted by partnering with and developing new investigators in these communities to address pertinent research questions.

2. To engage in career development and provide research opportunities for new investigators from mostly Black and Hispanic communities through collaboration with the Division of HIV/AIDS Prevention at CDC. This will be achieved by encouraging these scientists to develop independent research skills needed to gain experience in HIV epidemiologic and prevention research, to present the results of their research at national

conferences and to publish their results in peer-reviewed journals.

3. To develop and conduct HIV epidemiologic prevention research, in the form of limited case-controlled, cross-sectional or qualitative projects that have public health relevance to communities highly-affected by the HIV epidemic.

Therefore, the overall objective of this teaching/mentored award program is to prepare qualified individuals for careers that have a significant impact on the HIV/AIDS-related research needs of the nation, especially in highly-affected minority communities. The objective of the Minority HIV/AIDS Research Initiative Award program is to provide support for a sustained period of time for intensive research training and career development under the guidance of an experienced mentor in HIV prevention research and lead to promising HIV prevention activities and researchers who could independently conduct studies in highly-affected communities.

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 http://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

Research proposed as part of this teaching/mentored award will support the following Healthy People 2020 objectives related to HIV:

HIV-2, Reduce the number of new infections among adolescents and adults;

HIV-3, Reduce the rate of HIV transmission among adolescents and adults;

HIV-9, Reduce the proportion of persons with a diagnosis of Stage 3 HIV (AIDS) within 3 months of diagnosis of HIV infection;

HIV-13, Increase the proportion of persons living with HIV who know their serostatus;

HIV-14, Increase the proportion of adolescents and adults who have ever been tested for HIV;

HIV-19, Increase the proportion of persons who are linked to HIV medical care (had a routine HIV medical visit) within 3 months of HIV diagnosis;

HIV-21, Increase the proportion of persons with an HIV diagnosis in medical care who were prescribed antiretroviral therapy for the treatment of HIV infection at any time in the 12-month measurement period;

HIV-22, Increase the proportion of persons with an HIV diagnosis in medical care with a viral load <200 copies/mL at the last test during the 12-month measurement period.

The Healthy People 2020 site is available at: https://www.healthypeople.gov/2020/topics-objectives/topic/hiv .

The research conducted as part of the Minority HIV/AIDS Research Initiative (MARI) aligns with all 3 goals of the National HIV/AIDS Strategy (NHAS):

- Reducing HIV incidence (MARI projects consist of several studies that provide HIV prevention information to populations at risk of HIV exposure, which increases their abilities to protect themselves from acquiring new HIV infection)
- Increasing access to care and optimizing health outcomes (MARI projects have consisted of evaluations of providing home-based HIV services to at-risk populations, HIV-infected homeless populations, rural populations and other projects within highly-affected communities of color which serve to ensure increased access to HIV prevention and care)
- Reducing HIV-related health disparities (MARI is focused on supporting HIV prevention and research activities in disproportionately-affected communities of color by investigators who are fully engaged in those communities).

Additional details about the national HIV/AIDs Strategy are available here: https://www.whitehouse.gov/administration/eop/onap/nhas.

Also, this HIV prevention FOA supports a CDC Winnable Battles goal to reduce new HIV infections in the United States. More information about CDC's Winnable Battles are available at: http://www.cdc.gov/winnablebattles/HIV/.

Public Health Impact

The US National HIV/AIDS Strategy (NHAS) has as one of its major goals the reduction of HIV-related health disparities and notes that to achieve this goal we must diversify the HIV workforce and increase culturally-relevant HIV prevention interventions. This objective is also consistent with the first-ever Department of Heath and Human Services' Action Plan to Reduce Health Disparities. Increasing the number of racial/ethnic minority scientists serving disproportionately-affected communities: (1) diversifies the workforce, (2) may increase the credibility of research findings and confidence in research-driven initiatives among minority communities that have a history of medical research-related distrust, and (3) creates opportunities to increase the portfolio of HIV prevention interventions for disproportionately-affected communities; all are vital to achieving NHAS and Department of Health and Human Services goals.

Relevant Work

This FOA builds upon previous awards to MARI with historically underrepresented researchers working in highly-affected minority communities. An update about MARI and relevant publications by MARI investigators can be found in the following report: http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2013.301345

2. Approach

Applicants must submit investigator-initiated proposals that address one of the following six research topic areas for high-impact HIV prevention in disproportionately-affected communities. In the application, applicants must state which topic the application will address.

Topic 1: Optimizing HIV continuum of care outcomes for disproportionately-affected men who have sex with men (MSM), especially Blacks/African Americans and Hispanics/Latinos.

Black/African American MSM in the U.S. have been disproportionately affected by HIV since the beginning of the epidemic in the 1980s, although studies show that Black/African-American men do not engage in more risk-associated behaviors than White men, and are just as consistent about condom use and HIV testing. Yet disparities in HIV incidence and prevalence between Black/African-American and White MSM in the U.S. remain largely unexplained. Racial/ethnic disparities have been noted at all stages of the HIV care continuum – only 33 percent of HIV-positive Black MSM were retained in care, compared with 51 percent of White MSM; and only 16 percent of Black MSM were virally suppressed, compared with 34 percent of White MSM.

Applications addressing this topic may wish to consider the following research gap questions:

1) What are some strategies (including considerations of social and structural determinants of health) to improve linkage and retention in care for persons living with HIV who face multiple barriers to effective care and treatment? Also consider clinical approaches that include multiple disciplines.

2) How can interventions strengthen use of antiretroviral treatments and reaching viral suppression among disproportionately affected racial/ethnic minority MSM?

3) What are some additional HIV testing strategies for identifying persons with acute HIV infections in clinical and non-clinical settings?

4) How can programs that provide free and/or low-cost HIV medications be scaled up and effectively delivered to persons who desire to be on treatment?

Topic 2: Effective implementation science strategies for HIV prevention, early diagnosis of acute infection, and treatment: expanding upon what works in highly-affected Black/African-American and Hispanic/Latino MSM communities.

Implementation science focuses on how to improve the uptake, translation and implementation of research into common practices. These efforts build the evidence base for HIV programs and maximize the impact of HIV education and prevention. Disproportionately-affected minority communities may benefit from increased implementation science efforts to more strategically evaluate promising HIV prevention and treatment interventions.

Applications addressing this topic may wish to consider the following research gap questions:

1) How do we improve access to HIV services among persons not currently reached by HIV services?

2) How do we effectively engage highly-affected communities in HIV education and prevention strategies that engage families, providers and community facilities (centers, churches)?

3) What strategies can be considered to deliver and use the 4th generation HIV tests for more timely diagnoses of acute HIV infection and early initiation of treatment?

Topic 3: Developing networks of young, Black/African-American men who have sex with men (YBMSM) for HIV education, prevention and care using social determinants of health (SDH) and empowerment-driven approaches that are most relevant for successful HIV prevention, care and treatment.

Among gay and bisexual men, Black/African-American gay and bisexual men—especially those who are

younger—are the group most affected by HIV. Young African-American men who have sex with men (MSM) aged 13 to 24 years are especially affected by HIV. In 2010, they accounted for approximately 4,800 new HIV infections—more than twice as many estimated new infections as either young White or young Hispanic/Latino gay and bisexual men. Addressing this alarming epidemic among YBMSM requires a multifaceted approach that considers social and structural determinants of health, stigma, homophobia and discrimination.

Applications addressing this topic may wish to consider the following research questions:

1) What do YBMSM suggest as engaging and effective HIV prevention and treatment strategies for them and/or their networks?

2) What are sustainable, cost-effective, and culturally-tailored strategies for incorporating SDH solutions into HIV prevention and treatment approaches for YBMSM?

Topic 4: Increasing access to and uptake of treatment as prevention (TasP) and pre-exposure prophylaxis (PrEP) for communities of color: innovative strategies.

Data show that successfully engaging persons living with HIV in effective treatment can decrease HIV transmission to uninfected partners by up to 96% (treatment as prevention). Data also show that pre-exposure prophylaxis (PrEP) can be an effective strategy for decreasing the chance of acquiring HIV by up to 92% (if exposed) among uninfected, at-risk persons. These evidence-based solutions have not been fully implemented in disproportionately-affected Black/African-American and Hispanic/Latino communities.

Applications addressing this topic may wish to consider the following research gap questions:

1) What are new approaches to increase dialogue and administration of PrEP for at-risk persons in disproportionately-affected Black/African-American and Hispanic/Latino communities (at the patient level or at the provider level)?

2) What are strategies to increasingly engage highly-affected communities in strengthening understanding of and buy-in for treatment as prevention for persons living with HIV infection?

Topic 5: Developing strategies to more effectively engage and retain Black/African-American and Hispanic/Latina women in HIV care: cross-specialty and interdisciplinary approaches.

Women comprise 25% of persons living with HIV in the United States. Among women, Black/African-Americans and Hispanic/Latinas are disproportionately affected, with HIV diagnoses rates that are 19 and 3.5 times, respectively, higher than the rate for non-Hispanic White women. Data suggest that women are less often engaged in regular HIV care and less often achieve viral suppression.

Applications addressing this topic may wish to consider the following research gap questions:

1) What are promising approaches to effectively engage Black/African-American and Hispanic/Latina women in sustained HIV care?

2) What data are needed to increase engagement of women at each stage of the continuum of care?

Topic 6: Investigator-initiated, innovative projects.

We anticipate that investigators working in affected Black/African-American and Hispanic/Latino communities, including MSM communities, will have their own ideas for HIV prevention research in their communities. Strong, innovative applications that address research topics outside of the CDC-suggested research areas (above), but that are specific to addressing the HIV epidemic in highly-affected Black/African-American, Hispanic/Latino, Native American and MSM communities, will also be considered.

The applicants should demonstrate that they have been actively working in and with disproportionately-affected populations as part of their HIV prevention activities.

Objectives/Outcomes

Each application should provide detailed descriptions of the research goals based on the above stated topics of MARI (to engage disproportionately-affected minority populations in culturally-tailored, effective HIV prevention research strategies).

The following logic model summarizes the strategies and outcomes of MARI as a mentored, teaching award for HIV prevention.

Purpose: The overall objective of this teaching/mentored Award program is to prepare qualified early-career scientists for careers that have a significant impact on the HIV/AIDS-related research needs of the nation, especially in highly-affected racial/ethnic and sexual minority (LGBT) communities. The objective of the Minority HIV/AIDS Research Initiative (MARI) Award program is to provide support for a sustained period of time for intensive research training and career development under the guidance of an experienced mentor in HIV prevention research leading to promising HIV prevention activities and programs and research independence in communities disproportionately affected by HIV.			
Strategies	**Outcomes**		
	Short-term	**Intermediate**	**Long-term**
<u>Strategy 1</u>: Work with early-career investigators to develop research protocols and respond to human subjects inquiries to conduct high-impact HIV prevention research in communities that are disproportionately affected by HIV, especially Black/African American, Hispanic/Latino, and MSM communities. (Year 1) *<u>Strategy 2</u>: Provide training and technical assistance to funded MARI investigators in support of study implementation, data dissemination, writing scientific abstracts and manuscripts, and presenting at scientific conferences (Years 2-4)*	*1. Increased funded research training and capacity building for historically underrepresented HIV prevention scientists doing community-level research.* *2. Increased engagement by affected, minority communities as part of HIV research and developing effective interventions.* *3. Improved capacity of historically underrepresented, highly-affected communities to engage in developing solutions for HIV education and prevention.*	*1. Improved capacity of historically-underrepresented, highly-affected communities to engage in developing solutions for HIV education and prevention.* *2. For the target population, improved sexual health self-efficacy, awareness and skills regarding HIV prevention.* *3. Improved skills for successfully presenting at national and international scientific conferences and publishing research findings in peer-reviewed journals.* *4. Improved ability to navigate academic and research pathways for career progression.*	*1. Reduced HIV incidence in affected communities.* *2. Increased access to care and treatment for persons living with HIV infection.* *3. Reduced HIV-related health disparities.* *4. Sustainable HIV prevention research capacity in minority communities by partnering with and developing new investigators in these communities to address pertinent research questions.* *5. Improved health equity for a diverse HIV scientific workforce.*

Strategy 3: To develop cost-effective, culturally-tailored, and sustainable HIV prevention interventions for communities highly affected by the HIV epidemic. (Years 3-4)			*6. More successful attempts for larger, federally-funded HIV and health disparities research, such as NIH grants.* *7.Inform local and federal policy-makers as it relates to HIV prevention in highly-affected communities.*

Target Population

This FOA focuses on populations that are disproportionately-affected by HIV infections (MSM, Blacks/African Americans and Hispanic/Latinos), as stated in the National HIV/AIDS Strategy and is consistent with the National HIV Surveillance Report, which can be found here: http://www.cdc.gov/hiv/library/reports/surveillance/2013/surveillance_Report_vol_25.html

Collaboration/Partnerships

The PI may choose to collaborate with partners (optional) who are also subject matter experts for their HIV prevention research proposal. The application should include letters of support that indicate a Memorandum of Understanding (MOU) will be developed with each proposed partner after receiving an award. The letters of support should include: 1) specific roles and responsibilities of each partner, 2) names and titles of individuals who will be committed to this project, 3) a description of how progress will be measured, and 4) whether any funding will go to the proposed partner. This may be separate from the local senior mentor who will be supported at the 5-10% level on the proposal budget.

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.

Translation Plan

As a teaching/mentored award, MARI PIs are supported in their data analyses, abstract/manuscript writing, and data dissemination efforts. Dissemination plans should include efforts with local communities, as well as presentations at national and international scientific meetings and publication of results in peer-reviewed journals.

Section II. Award Information

Funding Instrument Type: Cooperative Agreement

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

Application Types Allowed:

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

Estimated Total Funding: $9,600,000

Year 1: up to $300,000

Year 2: up to $300,000

Year 3: up to $300,000

Year 4: up to $300,000

Estimated total funding available for the first year is up to $2,400,000.

Anticipated Number of Awards: 8

An indirect cost rate of 8% is not automatic; however, grantee institutions may elect to take an indirect cost rate of 8% should they choose to do so.

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

Award Ceiling: $300,000 Per Budget Period

Award Floor: $0 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
For profit organizations other than small businesses

Small businesses
Others (see text field entitled "Additional Information on Eligibility" for clarification)

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

Foreign institutions and components of foreign institutions are not eligible to apply.

Documentation of the following five requirements must be included in the application. This includes, but is not limited to, documentation in the PI's biosketch indicating involvement in HIV/AIDS research and/or HIV/AIDS-related publications and letters of support in the application's Appendix.

The PI from the applying institution must be able to meet and demonstrate the following five requirements:

1) Possess a research or health-professional master's or doctorate-level degree from an accredited school/program;

2) Never have been a Principal Investigator on an HHS HIV research award for $250,000 or greater;

3) Be knowledgeable about HIV/AIDS epidemiology and prevention, as well as have basic and documented research experience in, or related to, the field of HIV/AIDS, STD, and racial/ethnic or sexual minorities;

4) Have a documented history of working in Black/African-American, Hispanic/Latino, or Native American communities and ability to access study populations from these communities that are affected by HIV;

5) Demonstrate engagement to partner and apply with a local senior investigator who is able to devote 5-10% full-time effort to the project as a mentor. A letter of support from the mentor is required in the application appendix.

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

N/A

6. Required Registrations

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

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https://eportal.nspa.nato. int/AC135Public/Docs/US%20Instructions%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.

Each eligible institution/organization may submit more than one application, provided that each application is scientifically distinct and has a different PD/PI. 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 must be indicated in the application.
NOTE: Only one application may be submitted per topic area from the same institution.

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 (PGO TIMS) staff at (770) 488-2700 or pgotim@cdc.gov for further instructions. Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Standard 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.

3. Letter of Intent

Due Date for Letter of Intent: **09/14/2015**

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 above and 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 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

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 12 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 CDC PGO 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: **10/14/2015**

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)

This initiative is not subject to intergovernmental review (http:// www. whitehouse.gov/ omb/ grants_spoc).

11. Funding Restrictions

All HHS/CDC awards are subject to the terms and conditions, cost principles, and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.
For more information on expanded authority and pre-award costs, go to: http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf.

Funds relating to the conduct of research involving human subjects will be restricted until the appropriate assurances and Institutional Review Board approvals are in place.

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).

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 Procurement and Grants Office (PGO) and responsiveness by PGO 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?

Are the proposed study activities likely to have a positive impact on HIV prevention? Is the proposed target population at high risk for acquiring or transmitting HIV, including current behavioral determinants, cultural and social norms, and risk behaviors for acquisition or transmission of HIV?

Investigator(s)

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

Do the investigators demonstrate an understanding of the research objectives of this announcement as evidenced by the quality of the proposed research plan and specific study design? Do the investigators have a thorough understanding of HIV prevention approaches? Do the investigators demonstrate familiarity with and have documented access to communities most adversely and disproportionately affected by the HIV/AIDS epidemic? Do the investigators have a documented history of working in Black, Hispanic and Native American communities and ability to access study populations from these communities? Do the investigators demonstrate knowledge of issues faced by Black, Hispanic and/or Native American communities affected by HIV? Do the investigators demonstrate ability to recruit study population and obtain valid data through the use of culturally appropriate methods and instruments? Do the investigators have the appropriate training and skills to implement culturally-relevant HIV prevention research with the proposed target population? Are the investigators able to carry out the proposed research as demonstrated by the experience of the PI and the proposed research team and organizational setting? Do the investigators have the assistance or sub-contractual involvement of a community- or faith-based organization, governmental agency or other agency in order to fulfill the terms of the study that they are proposing? Do the investigators possess a research or a health-professional master's or doctorate-level degree from an accredited school/program? Do the investigators have documented research experience in, or related to, the field of HIV/AIDS, STD, or underserved or impoverished, minority communities? Do the investigators have the ability to establish effective and well-defined working relationships with community advisory boards (CABs), community-based organizations (CBOs) or similar entities which will ensure appropriateness of proposed research and implementation of the proposed activities? Do the investigators demonstrate efforts to develop this relationship by submitting letters of support or equivalent statement(s) as part of the application? Do the letters of support specify the role of the CAB, CBO, or other entity in supporting the proposed research? Do the investigators have documented basic capacity/support in data management and analysis? Do the investigators have a history of service to racial/ethnic minority communities that are disproportionately affected by HIV?

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 novel approach to HIV prevention for the target population that is culturally appropriate?

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 clearly state which research topic is being addressed from the list of topics 1-6? Are study questions within the CDC-suggested research categories and do they address gaps in the HIV/AIDS research literature or build on the findings of previously conducted research in highly-affected communities? Does the application demonstrate applicability and relevance of study objectives to minority communities? Does the application have a realistic and plausible detailed plan of approach that is substantiated based on prior experience with research activities with the target population? Does the application provide plans for recruitment and outreach of study participants from the proposed target population? How feasible is the study plan to sample, recruit, and enroll study participants in a culturally-appropriate manner and design study instruments that are culturally-appropriate to target populations? Is the application's timeline realistic and feasible? Is the plan to analyze data appropriate? Does the plan provide for protecting the privacy of the study participants and ensuring confidentiality of the research data? Does the study plan demonstrate that plans for recruitment and outreach for study participants will include establishing partnerships with communities? Does the study plan show evidence of establishing a partnership with at least one community organization to consult on all aspects of conducting the study and to link participants with prevention and medical services as needed? How feasible are the plans to involve the study population, their advocates, or service providers in the development of research activities and to inform them of research results? Is there community support for implementing and evaluating the proposed research as evidenced by letters of support from agencies representing or serving the proposed target population? Does the study plan include an evaluation plan with measures of effectiveness? Do the measures of effectiveness relate to performance goals of this announcement? Are the measures of effectiveness objective and quantitative and do they measure the intended outcome? Does the application consider cost-effectiveness as part of the final analysis? Does the application consider the sustainability of the proposed research, if an intervention is proposed? Do the investigators provide an overall budget for the total project period and a detailed budget for Year 1? Does the approach implement culturally and linguistically competent methodology within the study design?

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?

Is there evidence of institutional support? Does the planned location for the study have access to adequate numbers of the proposed target population? Do the investigators have access to qualified personnel with realistic and sufficient percentage-time commitments relative to each phase of the study timeline? Does the study plan demonstrate baseline epidemiologic, behavioral, clinical, administrative and management experience needed to conduct the proposed research? Is there evidence that the investigators and staff have experience working with the target population of study participants? Do the investigators provide a description of duties, percentage time commitments, and responsibilities of project personnel including clear lines of authority and supervisory capacity over the behavioral, administrative, data management, and statistical aspects of the research? How adequate are the plans for facilities, equipment, assessment programming, data processing, and analysis capacity, and systems for management of data security and participant privacy in achieving the research objectives?

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/od/pgo/funding/grants/additional_req.shtm#ar1).

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.

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.

Applications will be rank ordered by priority score within each topic area, 1-6. Applications with a priority score between 10 and 60 will be eligible for funding consideration.

Funding recommendations for eligible applications will then take into consideration the following program priorities, in rank order of preference (most important to least important priority):

Funding Preferences

1. Topic area diversity: This FOA will attempt to fund at least one award in each CDC-suggested research topic area, 1-6.
2. Geographic diversity: This FOA will attempt to fund applicants based on proposals that target research

in geographic regions that are disproportionately-affected by HIV. Please refer to the following link for further information on disproportionately-affected areas: http://www.cdc.gov/hiv/statistics/basics/geographicdistribution.html

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 74 or Part 92, 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-3: Animal Subjects Requirements
- AR-9: Paperwork Reduction Act Requirements
- AR-10: Smoke-Free Workplace Requirements
- AR-11: Healthy People 2020
- AR-12: Lobbying Restrictions
- AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities
- AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

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

ARs applicable to HIV/AIDS Awards:

AR-4: HIV/AIDS Confidentiality Provisions

AR-5: HIV Program Review Panel Requirements

AR-6: Patient Care

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.archives.gov/.

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

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/ asfr/ogapa/acquisition/ effspendpol_ memo.html)

Federal Funding Accountability and Transparency Act of 2006

Public Law 109-282, the Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), 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 Web site, www.USASpending.gov (http:// 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 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/nutrition/index.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.

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 at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), 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:

- Working 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.
- Pairing with HIV epidemiologic and prevention researchers at CDC for additional mentorship and help with the timely development of protocols and study instruments, submission of protocols to required human subjects review boards, conduct of investigations, and to analyze, present and publish study results.
- Demonstrating that research will occur in racial/ethnic and/or sexual minority and/or impoverished populations at risk for HIV infection by including in their research proposal applicable state or local surveillance data in indicating high rates of HIV/AIDS among the target population in the proposed research population.
- Collaborating with local senior researchers, CDC researchers and community-based organizations or similar community liaisons (as needed) for the duration of the project period on several activities such as development of data collection instruments, specimen collection protocols, and data management procedures.
- Identifying, recruiting, obtaining informed consent from, and enrolling an adequate number of study participants as determined by the study protocols and the program requirements.
- Following study participants as determined by the study protocols.
- Establishing procedures to protect the privacy of the study participants and the confidentiality of the research data.
- Obtaining the appropriate local Institutional Review Board approvals for all institutions or individuals participating in the research project.
- Working with CDC scientists to obtain OMB-PRA approvals, as needed.
- Performing laboratory tests (when appropriate) and data analysis as determined in the study protocols.
- Presenting at national or international meetings and publishing research findings in peer-reviewed scientific literature.
- Participating in conference calls with CDC project officer(s) and research team.
- Attending initial and annual meetings with other MARI- funded grantees in Atlanta to promote research dissemination and networking among investigators and budgeting for such travel in years 2-4.
- 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.
- 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.

CDC staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below. In this teaching/mentored cooperative agreement, a Center Project Officer (PO) will be a mentor/teacher with scientific and programmatic involvement during the conduct of the

project through scientific and technical assistance, advice, and coordination. As such, the PO will:

- Provide mentorship for the recipient/junior or mid-level investigator.
- Provide technical assistance as needed in the design and conduct of the research.
- Facilitate and assist in the development of a research protocol for Institutional Review Board (IRB) review by all cooperating institutions participating in the research project. CDC will determine if local IRB review and approval is sufficient for the study protocol.
- Assist, as needed, in designing a data management system.
- Assist in the analysis of research information and the presentation and publication of research findings as warranted.
- Conduct site visits to ensure that venues are properly selected, collaborations outlined in proposals are successful, the community is involved in the research activities, and investigators are following the research protocol.
- Conduct initial and annual meetings of MARI-funded investigators in Atlanta or via teleconference to facilitate the exchange of research progress among recipients and to offer additional technical expertise for the conduct of research.

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.

In the Yearly Non-Competing Grant Progress Report, include all current IRB protocols and approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. If the protocol involves human subjects, please provide a copy of the most recent local IRB and CDC IRB protocols and approval letters. If any IRB approvals are still pending at the time of APR due date, indicate the status in your narrative.

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.

2. Annual Federal Financial Reporting

The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through eRA Commons within 90 days after the end of the calendar quarter in which the budget period ends. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data.

Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining

the reason and date by which the Grants Officer will receive the information. **All CDC Financial Expenditure data due on/after October 1, 2012 must be submitted using the FFR via the eFSR/FFR system in the eRA Commons.** All Federal Reporting in the Payment Management System is unchanged. All new submissions should be prepared and submitted as FFRs.
CDC's implementation of the FFR retains a financial reporting period that coincides with the budget period of a particular project. However, **the due date for annual FFRs will be 90 days after the end of the calendar quarter in which the budget period ends**. Note that this is a change in due dates of annual FFRs and may provide up to 60 additional days to report, depending upon when the budget period end date falls within a calendar quarter. For example, if the budget period ends 1/30/2012, the annual FFR is due 6/30/2012 (90 days after the end of the calendar quarter of 3/31/2012). Due dates of final reports will remain unchanged. The due date for final FFRs will continue to be 90 days after the project period end date.
Grantees must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, grantees must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).
FFR (SF 425) instructions for CDC grantees are now available at http:// grants.nih.gov/ grants/forms.htm. For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: http://www.cdc.gov/grants/interestedinapplying/applicationresources.html
FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) (https://public.era.nih.gov/chl/public/search/commonsRegisteredOrgs.era). CDC recommends that this one time registration process be completed at least 2 weeks prior to the submittal date of a FFR submission.
Organizations may verify their current registration status by running the "List of Commons Registered Organizations" query found at: http://era.nih.gov/commons/. Organizations not yet registered can go to https:// commons. era.nih.gov/ commons/ registration/ registration Instructions. jsp for instructions. It generally takes several days to complete this registration process. This registration is independent of Grants.gov and may be done at any time.
The individual designated as the PI on the application must also be registered in the Commons. The PI must hold a PI account and be affiliated with the applicant organization. This registration must be done by an organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide found at: http:// era.nih.gov/ commons /index.cfm.

3. Final Reports: Final reports should provide sufficient detail for CDC to determine if the stated outcomes for the funded research have been achieved and if the research findings resulted in public health impact based on the investment. The grantee's final report should include:

- Research Aim/Project Overview: The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.
- Translation of Research Findings: The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the project period. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.
- Public Health Relevance and Impact: This section should address improvements in public health as

measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.

- Publications; Presentations; Media Coverage: Include information regarding all publications, presentations or media coverage resulting from this CDC funded activity. Please include any additional dissemination efforts that did or will result from the project.

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)
Procurement and Grants Office
Telephone 770-488-2700
Email: PGOTIM@cdc.gov
Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Standard Time

Program Official/Scientific Research Contact:

Amy Yang, 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: 404-718-8836

Fax: 404-718-8822

Email: AYang@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:

Shirley Byrd
Procurement and Grants Office
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
2920 Brandy Wine Road, MS E-15
Atlanta, GA 30341
Telephone: 770-488-2591
Fax: 770-488-2868
Email: SKByrd@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. 241 and 247c.

Summary of the Conference Call held on Thursday, August 27, 2015 with Potential Applicants for Funding Opportunity Announcement (FOA): PS16-001 "Minority HIV/AIDS Research Initiative (MARI) to Build HIV Prevention, Treatment and Research Capacity in Disproportionately Affected Black and Hispanic Communities and Among Historically Underrepresented Researchers."

Introductory Comments

Any scientific or technical questions should be addressed to the Scientific Program Officer, Dr. Amy Yang (AYang@cdc.gov). Any questions on financial, grants management, or eligibility aspects should be addressed to the Grants Management Officer, Ms. Shirley Byrd (SKByrd@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 FOA at 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.

Required Registrations

Please see Part 2, Section III, #6 "Required Registrations" for information on required registrations.

Other Tips

Letters of Intent are 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.

Please submit your application at least five days before the deadline to allow for error correction. No extensions will be granted due to 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 criteria. These 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". Applicants must submit proposals that address ONE of the six research topic areas described. Applicants must state which topic the application will address. No clear indication of the topic area to be addressed may disqualify the application from being reviewed.

Please remember that the Research Strategy section of the Research Plan is limited to 12 pages. Also remember to submit a 4-year Research Plan and a budget for each year.

It is anticipated that there will be 8 awards. The estimated total funding (direct and indirect) available for Year 1 is $2,400,000 (spread across the 8 awards). The estimated total funding (direct and indirect) for the entire project period is $9,600,000 (spread across the 8 awards). The ceiling amount is $300,000 per award for the first year, including direct and indirect costs. Awards issued under this FOA are contingent upon the availability of funds.

Questions and Answers:

1. Question: Does the description of our training plans fall under the 12-page limit for the Research Strategy section of the Research Plan?

Answer: You should include at least some information in the application about your training plans and your relationship with your mentor. This information could be included in the Letter of Support or in the Appendix which would not count against the 12-page Research Strategy limit. However, at a minimum, you should refer to the Letter of Support or Appendix in the Research Strategy section of the application so that reviewers are aware of where to find this information. A Letter of Support from the mentor is required to be in the application's Appendix. Most of your Research Strategy narrative should focus on describing the actual research proposed.

2. Question: How much should the application focus on research versus training?

Answer: This FOA is a teaching/mentored cooperative agreement. The application should include your mentor/mentee plan, such as how often to meet or what activities a mentor would be involved in when helping a mentee, but the majority of the 12-page Research Strategy narrative should focus on the research proposed.

3. Question: Can we have more than one mentor?

Answer: You are only required to have one local mentor. Up to two local mentors are allowed and their total effort can add up to 10%. You need to be aware that you only have a maximum of $300,000. You will also have a CDC mentor. Be clear about what each mentor's role will be in the project.

4. Question: What is meant by "local" mentor? Can the mentor be from out-of-state?

Answer: Local mentor means a subject matter expert who will work with you at your local site. The mentor can be from out-of-state but should be within the United States.

5. Question: Because this is a mentored grant, can you have any other concurrent mentoring grants?

Answer: You can have a concurrent training grant as long as all eligibility requirements are met.

6. Question: Are collaborators allowed?

Answer: Yes, but only one Principal Investigator is allowed per application.

7. Question: Is there salary support for mentors?

Answer: Yes, mentors need to commit 5-10% of time and effort; the salary support can be included within the $300,000 budget.

8. Question: If the research will take place in two or three cities, can the people in charge of the project in those cities be co-investigators?

Answer: It is OK for you to have other staff managing the sites in other cities, but for the purposes of this grant, they will not be considered Co-PIs. You need to make it clear that you are the PI.

9. Question: The Background section of the FOA states that you want to do limited case-control and cross-sectional studies, but it doesn't say anything about interventions. Can we use an interventions study?

Answer: If you are using the intervention to answer a research question, that could be OK.

10. Question: What does it mean by "limited case-controlled" project?

Answer: The "limited case-controlled" project described in the Background section of the FOA means a small case-control study (comparing persons with and without a disease or exposure) within the budget.

11. Question: Since this is a training grant, do you allow an indirect cost rate of 8%?

Answer: An indirect cost rate of 8% is not automatic; however, grantee institutions may elect to take an 8% indirect cost rate should they choose to do so.

12. Question: Is there any flexibility in the ceiling amount between years?

Answer: No.

13. Question: Are you looking for intervention-type studies?

Answer: It is open to any research study as long as it addresses one of the six topic areas.

14. Question: Do you want us to have an extensive record of accomplishments in our field? Do you want someone who is midway in career development or more mature?

Answer: It is a mentoring grant, but we do want to make sure you have a proven record of experience and background working in the field and with the populations that are the focus of the proposed study.

15. Question: How do you identify a qualified investigator? Publications? Experience?

Answer: That will be determined by the reviewers based upon your biosketch. The minimum requirement is a Master's degree and some experience in the field. Please see the requirements listed in the FOA.

16. Question: What kind of documentation is appropriate to show never having been a PI on an HHS HIV research award for $250,000 or greater? Is a letter OK?

Answer: Yes - the more clarification you can provide, the better.

17. Question: Are studies with Native-American populations allowed?

Answer: Yes. Please read carefully each of the six topic areas because different populations are described in each.

18. Question: How many applications did you receive for prior FOAs?

Answer: We cannot discuss the specific number, but it is fair to say that we generally receive far more applications than we have awards.

19. Question: How is the mentor evaluated in terms of their HIV experience? Is their track record in other grants considered?

Answer: Reviewers will determine that by looking at everything submitted, especially the biosketches.

20. Question: Will the letter of intent be reviewed?

Answer: No, it is used to estimate reviewer requirements. Please include the letter of intent information requested in the FOA.

21. Question: Because there is no limit or suggestions of how to address the training plan, should we include additional skills we have that might help us prove that we have experience?

Answer: Yes, but the focus should be on the research you propose to do.

22. Question: Please clarify the second eligibility criterion that states that an eligible applicant must never have been a PI on an HHS HIV research award of $250,000 or greater.

Answer:

a. The $250,000 award limit means the total amount of HHS HIV research awards received up to the application due date (10/14/2015). For example, an investigator received a 3-year HHS HIV research award of $255,000, spanning years 2014 to 2017. By the application due date, the PI had received only $160,000 of the $255,000 total award. The PI is therefore eligible to apply to this FOA. However, if the PI also received another HHS HIV research award of $100,000 by the application due date, the PI would not be eligible ($160,000 plus $100,000 = $260,000 which is greater than $250,000 in total awards).

b. "Research" does not include training, education or non-research awards.

c. The investigator is eligible to apply if the HHS awards received are $250,000 or greater but were not for HIV research.

d. Awards that are from agencies other than HHS do not count against the $250,000 total.

23. Question: The project we are proposing is a hybrid between two topics. Which one should we submit it under?

Answer: It is up to the investigator to state which topic best fits their application. This FOA will attempt to fund at least one qualified application per topic. Investigators should select their topic area based on their own best judgement.

24. Question: Do we need to address all questions listed underneath a topic area?

Answer: It is not required to address all; it is up to the applicant to address some or all.

25. Question: What is the minimum and maximum percent of effort for a PI?

Answer: There is no specification in the FOA regarding the percent effort required for a PI. As this is a teaching/mentored cooperative agreement, a substantial amount of effort is expected from the PI (e.g., 50% minimum effort for the first year). There is no maximum percent effort required for the PI. In contrast, the mentor's effort is expected to be 5-10%.

26. Question: Where in the application should we identify which priority topic area we plan to address? Also, can we identify two priority areas?

Answer: You must identify the topic area at the beginning of your research proposal. You must not identify more than one topic area, as each application will be reviewed and compete with the applications in that topic category. Please make your best judgement regarding in which topic area your proposal fits.

27. Question: According to the FOA, the support letter for collaborators should indicate that a Memorandum of Understanding (MOU) will be developed, including specific roles and responsibilities, names and titles of individuals committed to the project, a description of how progress will be measured, and how funding will be allocated. Could you help us understand if this would apply for our recruitment sites? Or if a regular support letter would be sufficient?

Answer: If the recruitment sites are your collaborators, they should provide a letter of support as described in the FOA. Within this letter, there should be a commitment that an MOU will be developed, should the applicant be awarded funds.

28. Question: In looking at the funding opportunity announcement, it is unclear to me if an applicant must identify as either African-American or Latino/a in order to be eligible for the program. Can you clarify this?

Answer: This FOA does not require applicants to identify their ethnicity. The FOA intends to solicit applications regarding studies of HIV on minority populations including African-Americans, Latinos, Native Americans, etc. (as described in the research topics).