Centers for Disease Control and Prevention

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

Minority HIV Research Initiative (MARI) to Support Epidemiologic and Implementation Science Research in Racial/Ethnic Minority Communities Disproportionately Affected by HIV and Build Research Capacity Among Historically Underrepresented Researchers

RFA-PS-21-001

Application Due Date: 10/23/2020

Minority HIV Research Initiative (MARI) to Support Epidemiologic and Implementation Science Research in Racial/Ethnic Minority Communities Disproportionately Affected by HIV and Build Research Capacity Among Historically Underrepresented Researchers

RFA-PS-21-001

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Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

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

Notice of Funding Opportunity (NOFO) Title

Minority HIV Research Initiative (MARI) to Support Epidemiologic and Implementation Science Research in Racial/Ethnic Minority Communities Disproportionately Affected by HIV and Build Research Capacity Among Historically Underrepresented Researchers

Activity Code

U01 - Research Project - Cooperative Agreement

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-PS-21-001

Assistance Listings (CFDA) Number(s)

93.943
93.941

Category of Funding Activity:

Health

NOFO Purpose

The purpose of this Notice of Funding Opportunity (NOFO) is to support promising epidemiologic and implementation science research in racial/ethnic minority communities disproportionately affected by HIV while strengthening the capacity for conducting such research among investigators working in these communities. The NOFO supports Centers for Disease and Control and Prevention's (CDC's) goals to promote health and reduce disease and disability by funding research that has the potential to result in high public health impact.

The NOFO is aligned with the federal initiative for Ending the HIV Epidemic (EHE) by 2030. The EHE plan encompasses the following four key strategies: (i) diagnose all individuals with HIV as early as possible; (ii) treat people with HIV rapidly and effectively to reach sustained viral suppression; (iii) prevent new HIV transmissions by using proven interventions, including PrEP and syringe services programs (SSPs); (iv) respond quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.

The goals of the NOFO are:

1. To build capacity in epidemiologic and implementation science research related to HIV prevention and services in minority communities by partnering with early-career investigators to address pertinent research questions with potential for accelerating the progress to Ending the HIV Epidemic by 2030.
2. To foster investigator-initiated research by early-career investigators at academic institutions, who serve minority communities disproportionately affected by HIV

infections, that complements and extends programmatic activities by the local and state departments of health toward Ending the HIV Epidemic by 2030.

Key Dates

Publication Date:	**To receive notification of any changes to RFA-PS-21-001, 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:	**09/14/2020**
Application Due Date:	**10/23/2020**

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

Note: HHS/CDC grant submission procedures do not provide a grace period beyond the application due date time to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

Scientific Merit Review:	**12/15/2020**
Secondary Review:	**01/26/2021**
Estimated Start Date:	**05/01/2021**
Expiration Date:	**10/24/2020**
Due Dates for E.O. 12372:	**Executive Order 12372 does not apply to this program.**

Required Application Instructions

ELECTRONIC APPLICATION SUBMISSION VIA ASSIST IS PREFERRED

It is recommended that applicants use ASSIST for the electronic preparation and submission of applications through Grants.gov to CDC. ASSIST is an alternative method to prepare and

submit applications, and provides many features to facilitate the application submission process which improves data quality (e.g., pre-population of organization data, pre-submission validation of business rules, and preview of the application image used for review). Use of the Grants.gov downloadable Adobe application packages and submission process will still be supported.

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

Note: The Research Strategy component of the Research Plan is limited to 12 pages.

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

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

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

Executive Summary

- **Purpose:** The purpose of this Notice of Funding Opportunity (NOFO) is to support promising epidemiologic and implementation science research in racial/ethnic minority communities disproportionately affected by HIV while strengthening the capacity for such research among investigators working in these communities. The NOFO supports CDC's goals to promote health and reduce disease and disability by funding research that has the potential to result in high public health impact.
- **Mechanism of Support:** U01 - Research Project - Cooperative Agreement. This is a teaching/mentored cooperative agreement.
- **Funds Available and Anticipated Number of Awards:** The estimated total funding available, including direct and indirect costs, for the entire three (3)-year project period is $10,500,000. The number of awards is estimated to be up to ten (10). Awards issued under this NOFO are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded, and the number of awards, will depend upon the number, quality, duration and cost of the applications received.
- **Budget and Project Period:** The estimated total funding (direct and indirect) for the first year (12-month budget period) is $3,500,000, with individual awards estimated to be up to $350,000 for the first year. The estimated total funding (direct and indirect) for the entire three (3)-year project period will be $10,500,000. The project period is anticipated to run from 05/01/2021 to 04/30/2024. 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. Setting an indirect cost rate at 8% is not required.

- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. "Application and Submission Information" of this announcement.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III. of this announcement are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.
- **Number of PDs/PIs.** There will only be one PD/PI (Project Director/Principal Investigator) for each application. Each application must identify 5-10% effort by a local, senior investigator as a mentor who can realistically devote support and mentorship to the PD/PI and the research project based on the proposal and letters of support.
- **Number of Applications.** Applicant organizations may submit more than one application, provided that each application is scientifically distinct, has a different PD/PI and a different primary mentor.
- **Application Type.** New.
- **Application Materials.** See Section IV.1 for application materials. Please note that Forms-F are to be used when completing the application package.

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

Public Health Service Act Sections 301 [42 USC 241], 317 [42 USC 247b(k)(2)], and 318 [42 USC 247c], as amended.

1. Background and Purpose

The purpose of this NOFO is to support promising epidemiologic and implementation science research in racial/ethnic minority communities disproportionately affected by HIV while strengthening the capacity for high-impact research among underrepresented racial/ethnic minority investigators working in these communities. The NOFO supports CDC's goals to promote health and reduce disease and disability by funding research that has the potential to result in high public health impact.

The NOFO is aligned with the federal initiative for Ending the HIV Epidemic (EHE) by 2030. In particular, the NOFO supports CDC's HIV prevention strategic plan to reduce the number of new HIV infections in the U.S. by focusing on eliminating racial and ethnic disparities in new HIV infections. CDC's HIV surveillance report revealed that, in 2018, blacks/African Americans and Hispanics/Latinos accounted for 69% of HIV diagnoses but comprised only 31% of the U.S. population. This statistic highlights the urgent need for HIV epidemiologic, health services and implementation research in minority communities to effectively intervene

on modifiable risk factors and reduce the rates of new HIV infections.

The proposals for this three (3)-year project should focus on relevant and consequential epidemiology or implementation research projects that (a) have a potential to advance knowledge and practice in support of Ending the HIV Epidemic in the United States by 2030, (b) relate to addressing racial/ethnic disparities in HIV and advancing health equity, (c) inform or extend the programmatic work by the local and state health departments and local non-governmental organizations, and (c) if successful, have a potential to be sustainable, relevant and scalable to communities and populations outside of the study sites. Consultation and collaboration with local and state health department programs and community-based organizations from the outset of the project is encouraged to maximize the opportunities that the knowledge gained, and the effective strategies developed, will be incorporated into local programming related to Ending the HIV Epidemic.

NOTE: Applicants must submit an ***investigator-initiated proposal*** and define one or more research questions the project will address. Each application must clearly specify the following four (4) aspects for the proposed project:

1) Type of research project [*chose one*]

- Original epidemiologic research (including designing and conducting observational and interventional studies related to HIV prevention or services)
- Implementation science research (including using existing evidence-based or evidence-informed HIV-related interventions in new populations or settings and optimizing intervention uptake, effectiveness and efficiency)*

* See: https://www.cdc.gov/hiv/effective-interventions/index.html

https://www.cdc.gov/hiv/research/interventionresearch/compendium/index.html

2) The Ending the HIV Epidemic Initiative strategy to which the project relates [*chose all that apply*]:

- Diagnose all individuals with HIV as early as possible
- Treat people with HIV rapidly and effectively to reach sustained viral suppression
- Prevent new HIV transmissions by using proven interventions, including PrEP and syringe services programs (SSPs)
- Respond quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them

3) The target population for the proposed project, within these priority groups [*chose all that apply*]:

- Racial/ethnic minority gay, bisexual and other men who have sex with men (MSM)
- Racial/ethnic minority cis-gender women
- Racial/ethnic minority transgender women
- Racial/ethnic minority heterosexual men

4) Racial/ethnic minority populations that project will focus on [*chose all that apply*]:

- Black/African American
- Hispanic/Latino
- Asian/Pacific Islander
- American Indian/Alaska Native
- Multiple races

In developing their own specific research proposal suitable for their target population, the applicants may be guided by some general questions relevant to the four (4) strategies for Ending the HIV Epidemic (EHE) in the United States by 2030, below. However, please note that this list of questions is not exhaustive. Applicants are encouraged to propose projects related to EHE that they believe may have most relevance for and impact in their selected communities.

1. Diagnose all individuals with HIV as early as possible.

a. What HIV testing strategies might be effective for identifying persons with early HIV infections and for reducing the percentage of people with undiagnosed HIV in clinical and non-clinical settings? Consider options including laboratory-based testing, point-of-care and mobile testing and self-testing.
b. How can public health engage effectively with partners (e.g., corrections, social service agencies, homeless shelters, STD clinics) to improve timely diagnosis of HIV and subsequent navigation/linkage to care?
c. What enhancements to social network testing or partner-services testing approaches are promising for diagnosing HIV in hard-to-reach populations?

2. Treat people with HIV rapidly and effectively to reach sustained viral suppression

a. How can initiating ART immediately (or as soon as possible) and other immediate ART programs be scaled up and effectively delivered?
b. What types of community-driven or health-services focused interventions could improve the antiretroviral adherence and reaching viral suppression in a target population?
c. What support systems and multidisciplinary approaches could improve linkage and retention in care for people with HIV who face multiple barriers (including social, structural) to treatment and durable suppression? Consider, for example, integrated case management, data-to-care, or other novel approaches (e.g., telemedicine programs using videoconferencing).
d. How do we increase access to and uptake of HIV care among people who had HIV diagnosed but currently are not in HIV care or accessing any HIV-related services?

3. Prevent new HIV transmissions by using proven interventions, including PrEP and syringe services programs (SSPs).

a. What approaches (at the patient-level or provider/clinic-level) increase awareness of and prescription of PrEP and retention in PrEP services for at-risk persons? Consider navigation to and maintenance of PrEP through various care delivery services (e.g., community health centers, telemedicine combined with pharmacy services).
b. How do we effectively engage communities with high incidence of HIV infection and

traditionally low PrEP uptake in PrEP promotion and other HIV prevention strategies that involve families, service providers or community entities (e.g., federally qualified health centers, LGBTQ centers, faith-based settings)?

c. What approaches can be used to increase the awareness and understanding of HIV treatment as prevention and that being undetectable is prevention in racial/ethnic minority populations?
d. What culturally appropriate strategies increase engagement in SSPs and uptake of HIV prevention tools/strategies among people with substance use or injection drug use risk?

4. Respond quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.

a. How can local and state health departments engage with communities of color for more effective HIV outbreak response and control?
b. What are the informational gaps around analysis of molecular data for outbreak detection and control and how can this information be appropriately disseminated within the communities with assistance of various public health partners?
c. What barriers experienced by communities of color might impact outbreak response (e.g., mistrust of government and/or medical/public health systems, experiencing disproportionate harms from policing or immigration enforcement, reduced access to care) and how can these barriers be mitigated?
d. How can local and state health departments identify community-based organizations, providers, and other partners for outbreak response and more effectively engage with racial/ethnic communities either experiencing or at risk of experiencing HIV outbreaks? How do we stimulate and establish effective partnerships in this public health area?

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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.

Other National Public Health Priorities

The activities under this NOFO will also support multiple national public health priorities:

- Ending the HIV Epidemic: A Plan for America: https://www.hiv.gov/federal-response/ending- the-hiv-epidemic/overview The new initiative seeks to reduce the number of new HIV infections in the United States by 75 percent within five years, and then by at least 90 percent within 10 years, for an estimated 250,000 total HIV infections averted.
- The HHS Strategic Plan, FY 2018-2022: https://www.hhs.gov/about/strategic-plan/strategic- goal-2/index.html
- National HIV/AIDS Strategy: Update 2020: https://www.hiv.gov/federal-response/national-hiv- aids-strategy/nhas-update
- CDC Division of HIV/AIDS Prevention Strategic Plan 2017-2020: https://www.cdc.gov/hiv/pdf/dhap/cdc-hiv-dhap-external-strategic-plan.pdf
- CDC National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)

Strategic Plan Through 2020: https://www.cdc.gov/nchhstp/docs/NCHHSTP-Strategic-Plan-through- 2020-508.pdf
- HIV Care Continuum: https://www.hiv.gov/federal-response/policies-issues/hiv-aids-care-conti nuum
- CDC Winnable Battles goal to reduce new HIV infections in the United States: http ://www.cdc.gov/winnablebattles/HIV/.

Additional details about previous CDC-funded mentored research to address disparities in HIV are available here: https://www.cdc.gov/hiv/dhap/eb/mari/index.html

Public Health Impact

Since 2003, CDC has sought to build capacity for HIV epidemiologic and prevention research in black and Hispanic/Latino communities and among black and Hispanic/Latino investigators working in communities with high prevalence and incidence of HIV by supporting the Minority HIV Research Initiative (MARI) Award program. The MARI program has demonstrated success in preparing qualified early-career scientists for careers that have a significant impact on the HIV-related research needs of the nation, especially in racial/ethnic and sexual minority (e.g., men who have sex with men and transgender) communities. The award provides support for intensive research training and career development under the guidance of an experienced local mentor in HIV prevention research. This leads to promising HIV prevention programs and independent research activities in communities disproportionately affected by HIV. The NOFO supports CDC's overarching goal to promote health and reduce disease and disability.

The CDC and HHS will benefit from work conducted under this NOFO because the novel epidemiologic and implementation science research by minority early-career investigations will be informed, in part, by the priorities of the local and state health department executing Ending the HIV Epidemic plans. The collaborations between early-career investigators working in communities disproportionately affected by HIV and the relevant local and state health departments present new opportunities to address unmet needs and facilitate research-to-program innovation and translation. The resultant MARI research projects are primed to produce "innovatively disruptive" strategies and culturally tailored solutions, for underserved communities that may have been previously outside of the reach of local public health. In that way, MARI projects help close the implementation gaps in the adoption and dissemination of high impact HIV prevention throughout the nation.

This NOFO advances public health practice and delivery by directly engaging communities in research; by supporting development and adaptation of interventions informed by persons at risk of HIV; and by diversifying the HIV prevention research and care workforce with trained researchers from historically underrepresented communities. Collaborations with local health department partners and community-based organizations from the outset of the project are encouraged to maximize the incorporation of knowledge gained and effective strategies into local programming toward Ending the HIV Epidemic.

Relevant Work

This research NOFO builds upon previous awards to historically underrepresented researchers working in minority communities with high prevalence and incidence of HIV. An update about the program and relevant publications can be found in the following report: http://ajph.aphap

ublications.org/doi/abs/10.2105/AJPH.2013.301345

Applicants may also refer to related NOFOs for programmatic efforts related to Ending the HIV in the United States:

- PS19-1906: Strategic Partnerships and Planning to Support Ending the HIV Epidemic in the United States: https://www.cdc.gov/hiv/funding/announcements/ps19-1906/index.html
- PS20-2010: Integrated HIV Programs for Health Departments to Support Ending the HIV Epidemic in the United States: https://www.cdc.gov/hiv/funding/announcements/ps20-2010/index.html

2. Approach

The following **logic model** summarizes the strategies and outcomes of the NOFO:

LOGIC MODEL: The purpose of this NOFO is to support promising epidemiologic and implementation science research in racial/ethnic minority communities disproportionately affected by HIV while strengthening the capacity for such high-impact research among under represented racial/ethnic minority investigators working in these communities.

Strategies and Activities	**Intended Short-Term and Intermediate Outcomes**		**Intended Long-term Outcomes**
	Community and human capital development	**Research and implementation**	
1: Funded investigators will engage with community stakeholders, relevant health departments and local mentors to propose and develop epidemiologic and implementation science research projects for Ending the HIV Epidemic in their communities.	1.1. Increased engagement of historically under-represented minority communities in HIV research and developing or adapting effective interventions.	1.1. Experience gained, lessons learned and successful completion of an epidemiologic study or implementation science research project for evidence-based or evidence-informed intervention for priority populations at funded MARI sites.	A. Reduced HIV infections in racial/ethnic minority populations disproportionately affected by HIV. B. Improved health outcomes for racial/ethnic minority persons living with diagnosed HIV infection. C. Reduced HIV-related health

			disparities.
2: Funded investigators will develop and implement protocols to conduct high-impact HIV research in communities disproportionately affected by HIV, especially black/African American, Hispanic/Latino, and MSM communities.	2.1. Increased funded research training for historically underrepresented HIV prevention scientists doing community-level research.	2.1. Increased portfolio of promising novel interventions and adapted existing evidence-based or evidence-informed interventions for communities by HIV.	D. Sustainable HIV prevention research capacity in historically underrepresented minority communities. E. Improved health equity for a diverse HIV scientific workforce.
	2.2. Improved capacity of minority communities to engage in developing solutions for HIV prevention and services	2.2. Increased number of persons who are tested for HIV and diagnosed earlier with HIV infection.	
3. Funded investigators will receive training and technical assistance from local and CDC mentors in support of study implementation, data dissemination, writing scientific abstracts and manuscripts, and presenting at scientific conferences.	3.1. Improved skills of funded investigators for presenting at national and international scientific conferences and publishing research findings in peer-reviewed journals.	2.3. Increased number of persons linked to and accessing HIV care with rapid treatment and achieving sustained viral suppression. 2.4. Increased number of persons accessing PrEP and SSP services.	
	3.2. More successful attempts for larger, federally funded HIV and health disparities research, such as NIH grants.	2.5. Increased engagement of communities of color in HIV outbreak preparedness and response	
	3.3. Improved ability of funded investigators to navigate academic and research pathways for career progression.		

Objectives/Outcomes

Each application should provide detailed descriptions of research goals and research questions and explain the proposed project's relevance to one or more of the Ending the HIV Epidemic strategies. Each application should clearly outline the anticipated short-term and intermediate project-specific outcomes (intended results) to be achieved by the end of the project. The application should present specific, measurable, achievable, realistic and time-phased (SMART) project objectives. The application should clearly indicate if the proposed three (3)-year project will represent original epidemiologic research or implementation science research related to an existing evidence-based or informed intervention (please refer to: https://www.cdc.gov/hiv/effective-interventions/index.html and specify which intervention).

Given public health crises that can arise (i.e., COVID-19), each applicant is encouraged to

consider how recruitment and the informed consent process for study participants, administration of surveys, and delivery of potential interventions, could be done by means other than in-person contact, if necessary; for example, by using electronic telecommunications technologies (e.g., videoconferencing, the internet, live streaming, telemedicine, and texting, mobile apps and other e-health interventions) to support proposed project activities.

Target Population

This NOFO focuses on populations that are at the highest risk for and disproportionately affected by HIV, consistent with data in the CDC's HIV Surveillance Report: https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2018-vol-30.pdf. Applicants are encouraged to use additional data (including social determinants data) and materials available in the jurisdiction where the work is proposed (e.g., HIV care and prevention council plans, health department's Ending the Epidemic plans) to justify the selection of the target population that can benefit from participating in the project and its anticipated outcomes. The application should demonstrate that the investigators have been actively working in and with people in the disproportionately affected population as part of their HIV prevention research, program implementation or clinical activities to date. The application should provide justification and supporting data for the target population as being disproportionately affected by HIV in the geographic area for the proposed projects and explain how the proposed research addresses gaps for and needs of the target population in that area.

Collaboration/Partnerships

The Project Director/Principal Investigator (PD/PI) may choose to collaborate with partners who are also subject matter experts for their original epidemiologic research or implementation science research proposal. Consultation with local health department HIV/STD surveillance and prevention programs and with community-based organizations during the preparation of the proposal is encouraged so that the proposed research addresses known HIV prevention, implementation and services gaps. The application should include letters of support that indicate a Memorandum of Understanding (MOU) will be developed with each proposed partner after receiving the 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. These collaborations may be separate from the local senior mentor who will be supported at the 5-10% effort level in the proposal budget.

Consultation and partnering with the local health department for the duration of the project is encouraged to maximize opportunities that knowledge gained, and effective strategies developed, will be incorporated sustainably into further local programming toward Ending the HIV Epidemic in the jurisdiction.

Evaluation/Performance Measurement

The application should include measurable goals and aims based on a three (3)-year research project period. The application should describe specific, measurable, achievable, realistic and time-phased (SMART) project objectives for each activity described in the application's project plan and describe the development and implementation of project performance measures based on specific programmatic objectives.

Ascertaining and reporting the number of persons who were engaged and served as part of research project screening, interventions and service provision is expected in the annual progress report. This includes reporting the number of persons tested for HIV, number of persons linked to HIV care, number of persons who achieved viral suppression, and number of persons referred to or prescribed PrEP, as a result of the project, whenever applicable. Please refer to the logic model for intended short-term, mid-term and long-term outcomes. Proposed type and scale of evaluation and monitoring activities as well as staffing or resources should be specified.

All applications should include a detailed study plan, and implementation science projects should include implementation science design, monitoring and evaluation framework. If the proposed implementation research project aims to evaluate implementation strategies for improving the integration of a proven intervention, the application should also specify the implementation logic model and which implementation outcomes will be measured in the project.

Translation Plan

In this mentored award/cooperative agreement, MARI PD/PIs are supported in their data analyses, abstract/manuscript writing, and data dissemination efforts by their local mentors and by CDC. Dissemination plans should be well thought out and include efforts with local communities, presentations to the local and state health departments, presentations at national and international scientific meetings, and publication of results in peer-reviewed journals. Attendance and presentations at CDC seminars, group site visits, and symposia, online or in person, to share interim findings is also encouraged. Attending initial (kick-off) and annual group meetings with other MARI-funded Principal Investigators to promote the development of methodologically rigorous epidemiologic research and implementation science, research findings dissemination, peer-based learning, and networking among investigators should be budgeted by investigators in the application in years 1-3 to attend these meetings in Atlanta, Georgia.

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:	$10,500,000

Estimated total funding available for the first year (first 12 months), including direct and

indirect costs: $3,500,000

Estimated total funding available for the entire period of performance, including direct and indirect costs: $10,500,000

Anticipated Number of Awards: 10

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

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

Award Ceiling:	$350,000 Per Budget Period
Award Floor:	$0 Per Budget Period
Total Period of Performance Length:	3 year(s)

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

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

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:	State governments County governments City or township governments Special district governments Independent school districts Public and State controlled institutions of higher education Native American tribal governments (Federally recognized) Public housing authorities/Indian housing authorities Native American tribal organizations (other than Federally recognized tribal governments) Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher

education
Private institutions of higher education
For profit organizations other than small businesses
Small businesses

Additional Eligibility Category:

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

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

Nonprofits (Other than Institutions of Higher Education):

Nonprofits (Other than Institutions of Higher Education)

Governments:

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

Other:

Faith-based or Community-based Organizations
Regional Organizations
Bona Fide Agents: A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms."

Federally Funded Research and Development Centers (FFRDCs): FFRDCs are operated, managed, and/or administered by a university or consortium of universities, other not-for-profit or nonprofit organization, or an industrial firm, as an autonomous organization or as an identifiable separate operating unit of a parent organization. A FFRDC meets some special long-term research or development need which cannot be met as effectively by an agency's existing in-house or contractor resources. FFRDC's enable agencies to use private sector resources to accomplish tasks that are integral to the mission and operation of the sponsoring agency. For more information on FFRDCs, go to https://gov.ecfr.io/cgi-bin/searchECFR

2. Foreign Organizations

Foreign Organizations are not eligible to apply.

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

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

3. Additional Information on Eligibility

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/.
- Grants.gov
- eRA Commons

All applicant organizations must register with Grants.gov. Please visit www.Grants.gov at least 30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The "one-time" registration process will take three to five days to complete. However, it is best to start the registration process at least two weeks prior to application submission.

All Program Directors/Principal Investigators (PD/PIs) must also work with their institutional officials to register with the eRA Commons or ensure their existing Principle Investigator (PD/PI) eRA Commons account is affiliated with the eRA commons account of the applicant organization. All registrations must be successfully completed and active before the application due date. Applicant organizations are strongly encouraged to start the eRA Commons registration process at least four (4) weeks prior to the application due date. ASSIST requires that applicant users have active eRA Commons account in order to prepare an application. It also requires that the applicant organization's Signing Official have an active eRA Commons Signing Official account in order to initiate the submission process. During the submission process, ASSIST will prompt the Signing Official to enter their Grants.gov Authorized Organizational Representative (AOR) credentials in order to complete the submission, therefore the applicant organization must ensure that their Grants.gov AOR credentials are active.

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

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

SAM internet site at https://www.sam.gov/index.html.
If an award is granted, the recipient organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the recipient organization.

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

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

9. Cost Sharing

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

10. Number of Applications

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

Each eligible institution/organization can submit more than one application, but each application must have a different PD/PI and a different senior local mentor. If necessary, co-PI(s) can be listed in the application but only one PD/PI can be the primary CDC contact for the award, and this must be indicated in the application.

In addition, the PD/PI from the applicant institution should be able to meet and demonstrate the following within the application:

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

2) Never have been a primary investigator on an HHS HIV research award for $350,000 or greater;

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

4) Have a documented history of working in racial/ethnic minority communities disproportionately affected by HIV; ability to access study populations from these communities; and propose a study with participants in their own local community;

5) Are able to devote a substantial effort to the project (i.e., minimum 50% effort in the first year of funding with possible subsequent reductions up to a minimum of 25% effort in the last

year of funding to ensure completion of analyses and dissemination of findings);

6) Able to collaborate and apply with a local senior investigator (i.e., senior mentor) who is able to devote 5-10% of their full-time effort to the project as a mentor and intends to serve as mentor for three (3) years. **A letter of support from the mentor is required.**

Section IV. Application and Submission Information

1. Address to Request Application Package

In order to use ASSIST, applicants must visit https://public.era.nih.gov/assist where you can login using your eRA Commons credentials, and enter the Notice of Funding Opportunity Number to initiate the application, and begin the application preparation process.
If you experience problems accessing or using ASSIST, you can refer to the ASSIST Online Help Site at: https://era.nih.gov/erahelp/assist. Additional support is available from the NIH eRA Service desk via:

- E-mail: http://grants.nih.gov/support/index.html
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552. The NIH eRA Service desk is available Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding federal holidays.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide.htm and here: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general-forms-f.pdf, except where instructed in this Notice of Funding Opportunity to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review. The package associated with this NOFO includes all applicable mandatory and optional forms. Please note that some forms marked optional in the application package are required for submission of applications for this NOFO. Follow the instructions in the SF-424 (R&R) Application Guide to ensure you complete all appropriate “optional” components.
When using ASSIST, all mandatory forms will appear as separate tabs at the top of the Application Information screen; applicants may add optional forms available for the NOFO by selecting the Add Optional Form button in the left navigation panel.

Letters of Support should be placed in the PHS 398 Research Plan "Other Research Plan Section" of the application under "9. Letters of Support".

Please include all of the eight (8) mandatory forms listed below in the application package:

Mandatory

1. SF424(R&R);
2. PHS 398 Cover Page Supplement;
3. Research and Related Other Project Information;
4. Project/Performance Site Location(s);
5. Research and Related Senior/Key Person Profile (Expanded);
6. Research and Related Budget;

7. PHS 398 Research Plan;
8. PHS Human Subjects and Clinical Trials Information.

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

Optional

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

3. Letter of Intent

Due Date for Letter of Intent: **09/14/2020**

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

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

Name of the Applicant Institution

Descriptive title of proposed research

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

Names of other key personnel

Participating institutions

Number and title of this notice of funding opportunity

The letter of intent should be sent to:

Gregory Anderson, MPH, MS

Extramural Research Program Office

Office of the Associate Director of Science

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

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

1600 Clifton Road, MS US8-1

Atlanta, GA 30333

Telephone: 404-718-8833

Fax: 404-718-8822

Email: GAnderson@cdc.gov

4. Required and Optional Components

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

5. PHS 398 Research Plan Component

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

1. **Introduction to Application** (for Resubmission and Revision ONLY) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the NOFO.
2. **Specific Aims** – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.
3. **Research Strategy** – the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and time line.
4. **Progress Report Publication List** (for Continuation ONLY)

Other Research Plan Sections

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

All instructions in the SF424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general-forms-f.pdf and here: http://grants.nih.gov/grants/how-to-apply-application-guide.htm must be followed along with any additional instructions

provided in the NOFO.
Applicants that plan to collect public health data must submit a Data Management Plan (DMP) in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application. A DMP is required for each collection of public health data proposed. Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds.
The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include:
• A description of the data to be collected or generated in the proposed project;
• Standards to be used for the collected or generated data;
• Mechanisms for, or limitations to, providing access to and sharing of the data (include a description of
provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights -
this section should address access to identifiable and de-identified data);
• Statement of the use of data standards that ensure all released data have appropriate documentation that
describes the method of collection, what the data represent, and potential limitations for use; and
• Plans for archiving and long-term preservation of the data, or explaining why long-term preservation
and access are not justified (this section should address archiving and preservation of identifiable and deidentified
data).
Examples of DMPs may be found here: USGS, http://www.usgs.gov/products/data-and-tools/data-management/data-management-plans

Letters of Support should be placed in the PHS 398 Research Plan "Other Research Plan Section" of the application under "9. Letters of Support".

Please note: According to the Additional Requirement-25 (AR-25) (https://www.cdc.gov/grants/additionalrequirements/ar-25.html), investigators who plan to collect public health data must submit a Data Management Plan (DMP) in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application as follows:

The DMP must describe how investigators will make data readily available. Investigators who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds. A Data Management Plan (DMP) is required for each collection of public health data proposed. The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include **the following five elements**:

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

- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified (this section should address archiving and preservation of identifiable and de-identified data).

6. Appendix

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

7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 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. Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

8. Format for Attachments

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

9. Submission Dates & Times

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

applicant must correct errors before their application can be submitted.
Applicants are responsible for viewing their application in ASSIST after submission to ensure accurate and successful submission through Grants.gov. If the submission is not successful and post-submission errors are found, then those errors must be corrected and the application resubmitted in ASSIST.
Applicants are able to access, view, and track the status of their applications in the eRA Commons.
Information on the submission process is provided in the SF-424 (R&R) Application Guidance and ASSIST User Guide at https://era.nih.gov/files/ASSIST_user_guide.pdf.
Note: HHS/CDC grant submission procedures do not provide a grace period beyond the grant application due date time to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e. error correction window).
Applicants who encounter problems when submitting their applications must attempt to resolve them by contacting the NIH eRA Service desk at:
Toll-free: 1-866-504-9552; Phone: 301-402-7469
http://grants.nih.gov/support/index.html
Hours: Mon-Fri, 7 a.m. to 8 p.m. Eastern Time (closed on federal holidays)

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

It is important that applicants complete the application submission process well in advance of the due date time.
After submission of your application package, applicants will receive a "submission receipt" email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. A third and final e-mail message is generated once the applicant's application package has passed validation and the grantor agency has confirmed receipt of the application.

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

1. Track submission and verify the submission status (tracking should be done initially regardless of rejection or success).

    a. If the status states "rejected," be sure to save time stamped, documented rejection notices, and do #2a or #2b

2. Check emails from both Grants.gov and NIH eRA Commons for rejection notices.

    a. If the deadline has passed, he/she should email the Grants Management contact listed in the Agency Contacts section of this announcement explaining why the submission failed.
    b. If there is time before the deadline, correct the problem(s) and resubmit as soon as

possible.

Due Date for Applications: **10/23/2020**

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

10. Intergovernmental Review (E.O. 12372)

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 federal regulations, 45 CFR 75, terms and conditions, and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.
In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability (https://www.cdc.gov/grants/additionalrequirements/ar-35.html).
For more information on expanded authority and pre-award costs, go to: https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.
CDC requires that mechanisms for, and cost of, public health data sharing be included in grants, cooperative agreements, and contracts. The cost of sharing or archiving public health data may also be included as part of the total budget requested for first-time or continuation awards.
Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Resource Sharing Plan(s) section of the PHS398 Research Plan Component of the application.
Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds (for example, privacy and confidentiality considerations, embargo issues).
Recipients who fail to release public health data in a timely fashion will be subject to procedures normally used to address lack of compliance (for example, reduction in funding, restriction of funds, or award termination) consistent with 45 CFR 74.62 or other authorities as appropriate. For further information, please see: https://www.cdc.gov/grants/additionalrequirements/ar-25.html for revised AR-25.

Additional Funding Restrictions:

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

all current local IRB approval letters and local IRB approved protocols (and CDC IRB approval letters, if applicable) will be required to lift restrictions.

2) Funds relating to the conduct of research involving vertebrate animals will be restricted until the appropriate assurances and Institutional Animal Care and Use Committee (IACUC) approvals are in place. Copies of all current local IACUC approval letters and local IACUC approved protocols will be required to lift restrictions.

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

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

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

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

12. Other Submission Requirements and Information

Risk Assessment Questionnaire Requirement

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

for Award Management (SAM) exclusions.
CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-1132 annually. This questionnaire, which is located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, along with supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. Upload the questionnaire and supporting documents as an attachment in the "12. Other Attachments" section of the "RESEARCH & RELATED Other Project Information" section of the application. If your organization has completed CDC's Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization representative to include the original submission date, organization's EIN and DUNS.

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

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

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

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

Applicants must complete all required registrations before the application due

date. Section III.6 "Required Registrations" contains information about registration.

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

Important reminders:
All PD/PIs must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to CDC.
The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.
If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.

See more resources to avoid common errors and submitting, tracking, and viewing applications:

- http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm
- http://grants.nih.gov/grants/ElectronicReceipt/submit_app.htm
- https://era.nih.gov/files/ASSIST_user_guide.pdf
- http://era.nih.gov/erahelp/ASSIST/

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

Section V. Application Review Information

1. Criteria

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

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

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

Significance

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

- Does the work address a scientific problem of importance to public health research and/or practice?
- Are the proposed study activities likely to improve HIV-related prevention, care or services for people being screened for or enrolled in the study?
- 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?
- Does the study relate to biomedical interventions (e.g., PrEP use, HIV treatment) or other interventions (e.g., SSPs) which are included in local or national EHE plans?
- If successful, do the research results have the potential to be scalable and reach a large portion of the population at risk?

Investigator(s)

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

- 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 and strategies for Ending the HIV Epidemic?
- Do the investigators demonstrate familiarity with and have documented access to

communities most adversely and disproportionately affected by HIV?

- Do the investigators have a documented history of working in racial/ethnic minority communities and ability to access study populations from these communities?
- Do the investigators demonstrate knowledge of issues faced by racial/ethnic minority communities and their target populations as relevant to their proposed work?
- 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-related epidemiologic or implementation science research with the proposed target population?
- Does the application identify a 5-10% effort senior investigator as a mentor who can realistically devote support and mentorship to the PD/PI and the research project based on the proposal and letters of support?
- Are the investigators able to carry out the proposed research (including recruitment, implementation, data management, analysis, and dissemination) as demonstrated by the experience of the PD/PI and the proposed research team and organizational setting?
- Do the investigators require 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 seek consultation from or engagement with the state or local health department in the development and conduct of the project in their proposed geographic?
- Do the investigators possess a research or a health-professional masters or doctorate-level degree from an accredited school/program?
- Is there confirmation in the application that the PD/PI has never been a Principal Investigator on an HHS HIV research award for $350,000 or greater?
- Do the investigators have documented research experience in, or related to, the field of HIV, 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 have a history of service to racial/ethnic minority communities that are disproportionately affected by HIV?
- Does the project engage a junior or mid-career investigator with substantial effort (at least 50% effort in the first year, with possible reduction in effort during later years) as the primary investigator and a local site senior investigator (5-10% effort) as an additional resource for the junior investigator to help with scientific protocol development and provide local guidance as needed, within the parameters of the goals of the NOFO (previously funded MARI junior or mid-career investigators are eligible to serve as a local senior investigator for a new applicant)
- Do the investigators conduct data collection and analysis activities rather than contracting it to an outside source?
- Do the investigators have the ability to implement culturally and linguistically competent methodology within the study design?
- Do the investigators have a history of service to racial/ethnic minority communities that

are disproportionately affected by HIV?
- Do the investigators have linkages to the targeted population?
- Are the investigators indigenous to historically underrepresented black/African American, Hispanic/Latino, or Native American communities?
- Are the investigators based in close geographic proximity to the location of the proposed research activities?

Innovation

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

- Is the proposed research innovative and does it have a reasonable potential for concrete application to Ending the HIV Epidemic efforts by the CDC and its partners?
- Do the investigators propose a novel approach to HIV prevention or service provision for the target population that is culturally appropriate?
- Is this approach likely to have a broader population-level impact and be scalable to other populations outside of study sites?

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 address the following four aspects for the proposed project: (1) does the project represent original epidemiologic research or does it represent implementation science research (including an application of an existing evidence-based or evidence-informed intervention and which one); (2) does the project relate to one or more strategies for Ending the HIV Epidemic Initiative, and which strategy or strategies; (3) is the target population for the project one of the priority racial/ethnic groups for reducing HIV-related health disparities, to include MSM, cis-gender women, transgender women, and heterosexual men, and which group; (4) does the project focus on a racial/ethnic minority population or populations to include: Black/African American, Hispanic/Latino, Asian/Pacific Islander, American Indian/Alaska Native, multiple races/ethnicities?
- Do the study questions address gaps in the HIV prevention and epidemiologic research

literature or build on the findings of previously conducted research or programmatic experience in highly affected communities (with appropriate references to existing scientific work)?

- Is the proposed project informed by the priorities specified in the jurisdictional plan for Ending the HIV Epidemic or other needs assessments or plans for comprehensive prevention and care in the geographic area where the project is proposed?
- 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 their prior experience with research activities with the target population?
- Does the application outline the anticipated short-term and intermediate project-specific outcomes (intended results) to be achieved by the end of the project?
- Does the application provide plans for recruitment and outreach of study participants from the proposed target population?
- Is the study plan feasible to sample, recruit, and enroll, and retain study participants in a culturally appropriate manner and design study instruments that are culturally appropriate to target populations?
- Does the application anticipate and offer any contingency plans, alternative strategies or innovative solutions, should there be challenges in recruitment and retention of the desired study population?
- Is the application?s timeline realistic and feasible to complete the project within the three (3)-year period?
- Is the plan to manage and analyze data appropriate and 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?
- Is the study plan feasible 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?
- Is there a local public health awareness of and support for the proposed project as evidenced by letters of support from the health department?
- 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?
- If an implementation science research project is proposed, is it presented with an appropriate implementation science design, monitoring and evaluation framework?

- Does the application consider the scalability and sustainability of the proposed research, if an intervention is proposed?
- Are plans for dissemination of the project and translation of results stated, including potential ways that the project results might inform programmatic activities by the state and local health departments for Ending the HIV Epidemic?
- Do the investigators provide an overall budget for the total project period and a detailed budget for Year 1 that includes travel expenses for the PI to attend a two-day meeting in Atlanta, Georgia?
- Does the approach implement culturally and linguistically competent methodology within the study design?
- Does the application 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
- Does the project demonstrate strong community partnerships and access to predominantly Black/African American, Hispanic/Latino, or Native American communities that are disproportionately affected by HIV?
- Are the proposed projects cross-sectional or pilot (time-limited) in nature and require no more than three (3) years of funding?
- Does the proposed research include SMART objectives and approaches?
- Does the proposed research have strong potential for broader population-level impact?
- Can the proposed research be scalable to other populations outside of the study sites and alter service delivery and public health practice?

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 an adequate number of persons in 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?
- Is there institutional support and a plan for hiring, retaining and replacing study staff, as

needed, to meet project goals within required timelines?

- Are there adequate plans for facilities, equipment, assessment programming, data processing and analysis capacity, and systems for management of data security and participant privacy to achieve the research objectives?
- Are there letters of support or equivalent statement(s) as part of the application to specify the role of the CAB, CBO, or other governmental or non-governmental entity to support the proposed research?

2. Additional Review Criteria

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

Protections for Human Subjects

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

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

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

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research (https://www.cdc.gov/maso/Policy/Policy_women.pdf and the policy on the Inclusion of Persons Under 21 in Research (https://www.cdc.gov/maso/Policy/policy496.pdf).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following four points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the

appropriateness of the species and numbers proposed; 3) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 4) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (https://grants.nih.gov/grants/olaw/VAChecklist.pdf).

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

Dual Use Research of Concern
Reviewers will identify whether the project involves one of the agents or toxins described in the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern, and, if so, whether the applicant has identified an IRE to assess the project for DURC potential and develop mitigation strategies if needed.

For more information about this Policy and other policies regarding dual use research of concern, visit the U.S. Government Science, Safety, Security (S3) website at: http://www.phe.gov/s3/dualuse. Tools and guidance for assessing DURC potential may be found at: http://www.phe.gov/s3/dualuse/Pages/companion-guide.aspx.

3. Additional Review Considerations

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

Resource Sharing Plan(s)
HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: https://www.cdc.gov/grants/additionalrequirements/ar-25.html

New additional requirement: CDC requires recipients for projects and programs that involve data collection or generation of data with federal funds to develop and submit a Data Management Plan (DMP) for each collection of public health data.

Investigators responding to this Notice of Funding Opportunity should include a detailed DMP in the Resource Sharing Plan(s) section of the PHS 398 Research Plan Component of the application. The AR-25 outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

The DMP should be developed during the project planning phase prior to the initiation of collecting or generating public health data and will be submitted with the application. The submitted DMP will be evaluated for completeness and quality at the time of submission.

The DMP should include, at a minimum, a description of the following:

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;
- Mechanisms for, or limitations to, providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights - this section should address access to identifiable and de-identified data);
- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified (this section should address archiving and preservation of identifiable and de-identified data).

Applications submitted without the required DMP may be deemed ineligible for award unless submission of DMP is deferred to a later period depending on the type of award, in which case, funding restrictions may be imposed pending submission and evaluation.

Budget and Period of Support

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

The budget can include both direct costs and indirect costs as allowed.

Indirect costs could include the cost of collecting, managing, sharing and preserving data.

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

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

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

4. Review and Selection Process

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

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

- Will receive a written critique.

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

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

Applications will be rank ordered by priority score and the acceptable funding range determined. Funding recommendations may then take into consideration the following program priorities, in rank order of preference (most important to least important):

1) Topic area diversity: At least one award in each of the four pillars for Ending the HIV Epidemic:

- Diagnose all individuals with HIV as early as possible
- Treat people with HIV rapidly and effectively to reach sustained viral suppression
- Prevent new HIV transmissions by using proven interventions, including PrEP and syringe services programs (SSPs)
- Respond quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them

2) Project diversity: At least one award for original epidemiologic research and at least one award for implementation science research*.

* See: https://www.cdc.gov/hiv/effective-interventions/index.html

https://www.cdc.gov/hiv/research/interventionresearch/compendium/index.html

Review of risk posed by applicants.
Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to

review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.

In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Recipient Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.

CDC’s framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this Notice of Funding Opportunity.

In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:

(1) Financial stability;
(2) Quality of management systems and ability to meet the management standards prescribed in this part;
(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
(4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and
(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

5. Anticipated Announcement and Award Dates

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

Section VI. Award Administration Information

1. Award Notices

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

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

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

2. CDC Administrative Requirements

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

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

Specific requirements that apply to this NOFO are the following:

AR-1: Human Subjects Requirements

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

AR-3: Animal Subjects Requirements

AR-8: Public Health System Reporting Requirements

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2020

AR-12: Lobbying Restrictions

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

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

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

AR-22: Research Integrity

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

AR-25: Policy on Public Health Research and Non-research Data Management and Access

AR-26: National Historic Preservation Act of 1966

AR-27: Conference Disclaimer and Use of Logos

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

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

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

AR 31 - Distinguishing Public Health Research and Public Health Nonresearch

AR 32 – FY 2012 Enacted General Provisions

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

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

AR-36: Certificates of Confidentiality

ARs applicable to HIV/AIDS Awards:

AR-4: HIV/AIDS Confidentiality Provisions

AR-5: HIV Program Review Panel Requirements

AR-6: Patient Care

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

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

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

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

all funds appropriated by Congress. For more information, visit the HHS website at: https://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html.

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

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

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

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

and the PubMed Central identification number (PMCID) thereafter.

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

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

Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR). The award recipient must maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant, cooperative agreement or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.

If a project is determined to be DURC, a risk/benefit analysis must be completed. CDC will work collaboratively with the award recipient to develop a risk mitigation plan that the CDC must approve. The USG policy can be found at http://www.phe.gov/s3/dualuse.

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

Data Management Plan(s)
CDC requires that all new collections of public health data include a Data Management Plan (DMP). For purposes of this announcement, "public health data" means digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation.

This new requirement ensures that CDC is in compliance with the following; Office of Management and Budget (OMB) memorandum titled "Open Data Policy–Managing Information as an Asset" (OMB M-13-13); Executive Order 13642 titled "Making Open and Machine Readable the New Default for Government Information"; and the Office of Science and Technology Policy (OSTP) memorandum titled "Increasing Access to the Results

of Federally Funded Scientific Research" (OSTP Memo).

The AR-25 https://www.cdc.gov/grants/additionalrequirements/ar-25.html outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.
Certificates of Confidentiality: Institutions and investigators are responsible for determining whether research they conduct is subject to Section 301(d) of the Public Health Service (PHS) Act. Section 301(d), as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255 (42 U.S.C. 241(d)), states that the Secretary shall issue Certificates of Confidentiality (Certificates) to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. In furtherance of this provision, CDC supported research commenced or ongoing after December 13, 2016 in which identifiable, sensitive information is collected, as defined by Section 301(d), is deemed issued a Certificate and therefore required to protect the privacy of individuals who are subjects of such research. Certificates issued in this manner will not be issued as a separate document, but are issued by application of this term and condition to this award. See Additional Requirement 36 to ensure compliance with this term and condition. The link to the full text is at: https://www.cdc.gov/grants/additionalrequirements/ar-36.html.

4. Cooperative Agreement Terms and Conditions

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

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

- Complying with the responsibilities for the Extramural Investigators as described in the Policy on Public Health Research and Non-research Data Management and Access
- Ensuring the protection of human subjects through ethical review of all protocols involving human subjects at the local institution and at CDC and obtaining the appropriate Institutional Review Board approvals for all institutions or individuals engaged in the conduct of the research project.
- Working with CDC scientists to obtain OMB-PRA approvals, as needed.
- PUBLICATIONS/PRESENTATIONS: Publications, journal articles, presentations, etc. produced under a CDC grant support project must bear an acknowledgment and

disclaimer, as appropriate, for example: “This publication (journal article, etc.) was supported by the Cooperative Agreement Number above from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention”. In addition, the PI/PD must provide to CDC Program abstracts or manuscripts prior to any publication related to this funding. The grantee will not seek to publish or present results or findings from this project without prior clearance and approval from CDC.

- Complying with the responsibilities for the PI as described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf).
- Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.
- 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, implementation science, and prevention researchers at CDC for additional mentorship and help with the timely development of protocols and study instruments, submission of protocols to require 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 among the target population in the proposed research population.
- Collaborating with local senior researchers, CDC researchers, and community-based organizations or similar community liaison (as needed) for duration of 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.
- 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 to promote research dissemination and networking among investigators. Investigators should budget for travel in years 1-3 should meetings occur in Atlanta, Georgia.

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

- Providing mentorship for the recipient/junior or mid-level investigator, to supplement mentorship that is expected from the local senior mentor.
- Providing technical assistance as needed in the design and conduct of the research.
- Facilitating and assisting in the development of a research protocol for Institutional Review Board (IRB) review by all cooperating institutions participating in the research project. NCHHSTP will determine if local IRB review and approval is sufficient for the study protocol and will verify if CDC staff persons are not engaged in the research.
- Assisting, as needed, in designing and maintaining a data management system.
- Assisting in the analysis of research information and the presentation and publication of research findings, as warranted.
- Conducting 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.
- Conducting initial and annual meetings of MARI-funded investigators to facilitate the exchange of research progress among recipients and to offer additional technical expertise for the conduct of research.
- Assisting the PI, as needed, in complying with the Investigator responsibilities described in the Policy on Public Health Research and Non-research Data Management and Access.
- Obtaining Office of Management and Budget approval per the Paperwork Reduction Act, if necessary.
- Assisting the PI, as needed, in complying with the PI responsibilities described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf

Areas of Joint Responsibility include:

- None; all responsibilities are divided between awardees and CDC staff as described above.

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

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

- Attend committee meetings and participate in conference calls for the purposes of assessing overall progress, and for program evaluation purposes; and
- Monitor performance against approved project objectives.

5. Reporting

Recipients will be required to complete Research Performance Progress Report (RPPR) in eRA Commons at least annually (see https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/forms/report_on_grant.htm) and financial statements as required in the HHS Grants Policy Statement.

A final progress report, invention statement, equipment inventory list and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement.

Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity depend upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.
Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients:
1) Information on executive compensation when not already reported through the SAM Registration; and
2) Similar information on all sub-awards/ subcontracts/ consortiums over $25,000. It is a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.
All recipients of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

A. Submission of Reports

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

1. **Yearly Non-Competing Grant Progress Report**, is due 90 to 120 days before the end of the current budget period. The RPPR form (https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf) is to be completed on the eRA Commons website. The progress report will serve as the non-competing

continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

2. **Annual Federal Financial Report (FFR) SF 425** (https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm) is required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which the budget period ends**.

3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the period of performance**.

B. Content of Reports

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

- Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the RPPR form in eRA Commons (https://grants.nih.gov/grants/rppr/index.htm). Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.
- Research Aims: list each research aim/project

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

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

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

- Public Health Relevance and Impact (1 page maximum). This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques, inform policy, or use of technology in public health. Questions to consider in preparing this section include:
- How will this project lead to improvements in public health?
- How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
- How will the findings, results, or recommendations contributed to documented or projected reductions in morbidity, mortality, injury, disability, or disease?

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

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

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

- Publications/Presentations: Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate “Not applicable: No publications or presentations have been made."

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

- Update of Data Management Plan: The DMP is considered a living document that will

require updates throughout the lifecycle of the project. Investigators should include any updates to the project's data collection such as changes to initial data collection plan, challenges with data collection, and recent data collected. Applicants should update their DMP to reflect progress or issues with planned data collection and submit as required for each reporting period.

- Additional Reporting Requirements:

N/A

2. Annual Federal Financial Reporting The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through eRA Commons within 90 days after the end of the calendar quarter in which the budget period ends. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data.
Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information.
The due date for final FFRs will continue to be 90 days after the Period of Performance end date.
Recipients must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, recipients must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

FFR (SF 425) instructions for CDC recipients are now available at https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm. For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: https://grants.nih.gov/support/index.html

FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) (https:// commons. era.nih.gov/ commons/). CDC recommends that this one time registration process be completed at least 2 weeks prior to the submittal date of a FFR submission.

Organizations may verify their current registration status by running the "List of Commons Registered Organizations" query found at: https://era.nih.gov/registration_accounts.cfm. Organizations not yet registered can go to https://commons.era.nih.gov/commons for instructions. It generally takes several days to complete this registration process. This

registration is independent of Grants.gov and may be done at any time.

The individual designated as the PI on the application must also be registered in the Commons. The PI must hold a PI account and be affiliated with the applicant organization. This registration must be done by an organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide found at: https://era.nih.gov/docs/Commons_UserGuide.pdf.

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

- Research Aim/Project Overview: The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.

- Translation of Research Findings: The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the period of performance. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.

- Public Health Relevance and Impact: This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.

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

- Final Data Management Plan: Applicants must include an updated final Data Management Plan that describes the data collected, the location of where the data is stored (example: a repository), accessibility restrictions (if applicable), and the plans for long term preservation of the data.

Section VII. Agency Contacts

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

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

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

Scientific/Research Contact(s)

Jocelyn Patterson Mosley, MPH, MA

Extramural Research Program Office

Office of the Associate Director for Science

National Center for HIV/AIDS, Viral Hepatitis,

STD and TB Prevention, MS US8-1

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

Telephone: 404-639-6437

Email: jpatterson@cdc.gov

Peer Review Contact(s)

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, MS US8-1

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

Telephone: 404-718-8833

Email: GAnderson@cdc.gov

Financial/Grants Management Contact(s)

Ester Edward

Office of Financial Resources/Office of Grants Services

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

2939 Brandywine Road, MS TV-2

Atlanta, GA 30341

Telephone: 770-488-2852

Email: ece9@cdc.gov

Section VIII. Other Information

Other CDC Notices of Funding Opportunities 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.

Public Health Service Act Sections 301 [42 USC 241], 317 [42 USC 247b(k)(2)], and 318 [42 USC 247c], as amended.