

Centers for Disease Control and Prevention

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

Implementation Research Consortium to Accelerate Impact of Health Department-Delivered HIV Prevention Activities

RFA-PS-21-002

Application Due Date: 01/28/2021

Implementation Research Consortium to Accelerate Impact of Health Department-Delivered HIV Prevention Activities

RFA-PS-21-002

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Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

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

Notice of Funding Opportunity (NOFO) Title

Implementation Research Consortium to Accelerate Impact of Health Department-Delivered HIV Prevention Activities

Activity Code

U01 – Research Project - Cooperative Agreement

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-PS-21-002

Assistance Listings (CFDA) Number(s)

93.941
93.084
93.943

Category of Funding Activity:

Health

NOFO Purpose

This NOFO is designed to support research to enhance the implementation of proven HIV prevention interventions by forming a collaborative research infrastructure between experts in the field. The work of the proposed research will support the goals of the Ending the HIV Epidemic national plan. It is anticipated that this NOFO will support four (4) awards for **Core Projects** and two (2) awards for **Collaborative Projects**.

Applications for **Core Projects** should describe plans to conduct an HIV prevention implementation science research project that addresses real-world HIV prevention implementation challenges experienced by health departments and health department implementing partners (e.g., community-based organizations, clinics, etc.) when carrying out evidence-based interventions. Accessing data from health departments and health department partners is essential to this project. Therefore, Principal Investigators are encouraged to create or engage in appropriate partnerships. In response to this NOFO, each **Core Project** application must describe a detailed research plan and annual budget for years one through five.

In addition to a **Core Project**, each application should also propose a **Collaborative Project**. The **Collaborative Project** should describe a project working with investigators from multiple institutions (e.g., health departments, academic institutions, or other institutions). Collaborating sites may be identified after award or named at the time of application submission, but study objectives and partner roles and relationships to the grantee and other research partners must be clearly described in the initial application.

Similar to the **Core Project**, the **Collaborative Project** should also address real-world HIV

prevention implementation challenges experienced by health departments and health department implementing partners. However, the collaborative projects should include: a) multiple institutions, b) creating or engaging in appropriate partnerships (or agree to create/engage the appropriate partnerships, if collaborating sites are identified after the award) to allow for accessing data from health departments and health department partners, and c) study design and data collection methods that are consistent across all collaborating sites using a common protocol. As outlined for the **Core Project**, the **Collaborative Project** must describe a detailed research plan and annual budget for years one through five. An applicant must be awarded a **Core Project** in order to be awarded a **Collaborative Project**.

Key Dates

Publication Date:	**To receive notification of any changes to RFA-PS-21-002, 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:	**12/17/2020**
Application Due Date:	**01/28/2021**

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:	**03/23/2021**
Secondary Review:	**04/27/2021**
Estimated Start Date:	**09/01/2021**
Expiration Date:	**01/29/2021**

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

Required Application Instructions

ELECTRONIC APPLICATION SUBMISSION VIA ASSIST IS PREFERRED

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

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

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

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

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

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

The Research Strategy component of the Research Plan is limited to 25 pages for the entire Research Strategy component of the application (25 pages includes both the Core and Collaborative Project Research Strategy).

Within the total 25-page limit for the **Research Strategy** of the **Research Plan** section of the application, the page limit for EACH project is limited as follows:

- Core Project: 15 pages
- Collaborative Project: 10 pages

Executive Summary

- **Purpose:** This NOFO is designed to support research to enhance the implementation of proven HIV prevention interventions by forming a collaborative research infrastructure between experts in the field. The work of the proposed research will support the goals of the Ending the HIV Epidemic national plan. It is anticipated that this NOFO will support four (4) awards for **Core Projects** and two (2) awards for **Collaborative Projects**.
- **Mechanism of Support:** U01 – Research Project - Cooperative Agreement.
- **Funds Available and Anticipated Number of Awards:** The estimated total funding

available, including direct and indirect costs, for the entire five (5)-year project period **(Core and Collaborative Projects)** is $15,000,000. The estimated number of awards will be four (4) for the **Core Projects** and two (2) for the **Collaborative Projects**. 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) for the **Core Projects** is $1,400,000 (with individual awards ranging from $300,000 to $350,000). The estimated total funding (direct and indirect) for the **Core Projects**, over the entire five (5)-year project period, is $7,000,000. The estimated total funding (direct and indirect) for the first year (12-month budget period) for the **Collaborative Projects** is $1,600,000 (with individual awards ranging from $750,000 to $800,000 per award. The estimated total funding (direct and indirect) for the **Collaborative Projects** over the entire five (5)-year project period is $8,000,000. The project period is anticipated to run from 09/01/2021 to 08/31/2026.
- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. "Application and Submission Information" of this announcement. **Please note:** Page limits for the Research Strategy section for **Core** and **Collaborative Projects** are different and must be followed.
- **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.** Applications may include multiple PDs/PIs (Co-PIs) and, if so, must include a Leadership Plan that describes the roles, responsibilities and working relationships of the identified PDs/PIs (Co-PIs). However, only one PD/PI may be the primary CDC contact for the award and should be listed first in the application; this contact PD/PI must be at the recipient institution and must be indicated as such in the application.
- **Number of Applications.** Only one application per institution (normally identified by having a unique DUNS number) is allowed. One application includes both a **Core Project** and a **Collaborative Project**.
- **Application Type.** New.
- **Application Materials.** See Section IV.1 for application materials. Please note that Form F is to be used when completing the application package.

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

Public Health Service Act, Section 301(a) [42 USC 241(a)] and Section 318 [42 USC 247(c)], as amended.

1. Background and Purpose

HIV persists as a serious public health challenge in the United States. It has claimed more than 700,000 lives since it was first identified almost 40 years ago [1]. According to CDC, an estimated 1.1 million adults and adolescents in the United States are currently living with HIV, with approximately 15% unaware they have HIV [1-3]. Although HIV infection rates have decreased in the United States, new diagnoses continue in every U.S. state, with 37,881 new diagnoses occurring in 2018 [1, 4]. According to a recent HIV transmission model, approximately 80% of new HIV transmissions in 2016 were from persons either unaware of their HIV infection status (38%), or persons diagnosed with HIV but not in care (43%) [5]. HIV disproportionately impacts African American and Hispanic or Latino populations compared to other races and ethnicities; in 2018, they accounted for 42.8% and 26.2% of HIV diagnoses, respectively [3]. In addition, approximately 66% of HIV diagnoses in 2018 were attributed to male-to-male sexual contact, and from 2014 through 2018, the number of HIV diagnoses for transgender persons (adults and adolescents) increased [3]. In 2018, the highest rate of HIV diagnosis was for persons aged 25–29 years (32.6/100,000), followed by the rate for persons aged 20–24 years (27.9/100,000) [3]. Regionally, the South represented more than 52% of the new HIV diagnoses in the United States in 2018 [3].

Significant achievements have been made in the fight against HIV due to the development of effective biomedical treatment and prevention strategies. The availability of antiretroviral therapy (ART) has helped persons living with HIV achieve viral suppression, improve their health and substantially reduce transmission of the infection to others, such that a person who is properly treated and achieves and maintains viral suppression can expect to achieve a nearly normal lifespan and have effectively no risk of transmitting HIV to their partners. However, not everyone is benefitting from the new treatment and prevention options [1, 6]. Specifically, in 2018, only 79% of blacks/African Americans were prescribed ART, compared with 85% of Hispanics or Latinos and 82% of whites, and an estimated 56% of blacks/African Americans had sustained viral suppression, compared with 67% of Hispanics or Latinos and 69% of whites [7].

Similarly, the use of pre-exposure prophylaxis (PrEP) among high-risk HIV-negative individuals has been successful in reducing HIV transmission. In the United States, approximately 1.1 million persons had indications for PrEP in 2015 [8] and, whereas PrEP use has increased over time, only 18.1% of persons with PrEP indications were prescribed PrEP in 2018 [4]. PrEP coverage (number prescribed/number with indications) is lower among highest priority populations including blacks/African Americans (5.9%) and Hispanics or Latinos (10.9%) as compared to whites (42.1%) [4]. In addition, a meta-analysis found that only 24.5% of men who have sex with men (MSM) who met CDC's PrEP indications reported ever using it in 2016 [9]. Moreover, compared to other MSM, black MSM were more likely to report barriers to PrEP such as stigma and concerns about efficacy and medical decision-making [10]. Black and Hispanic MSM were significantly less likely than white MSM to be aware of PrEP, to have

discussed PrEP with a healthcare provider, or to have used PrEP within the past year [11]. Modeling has been used to indicate the number of persons needed to treat with PrEP in order to prevent one HIV infection. Findings show that universal PrEP use by MSM would be effective in reducing HIV prevalence and incidence among MSM; however, targeted use of PrEP by black and Latino MSM, especially those ≤25 years of age, would have a greater impact on HIV prevention [12].

By direction of the President, the U.S. Department of Health and Human Services (HHS) launched *The Ending the HIV Epidemic: A Plan for America (EHE)* in 2019 to address this ongoing public health crisis, with the goals of first reducing numbers of incident infections in the United States by 75% within 5 years, and then by 90% within 10 years [1]. With the advances made in biomedical and scientific research over many years, substantial important treatment and prevention tools are now available to end the HIV epidemic. Thus, the emphasis of the initiative is not in developing new tools; rather it is in scaling up existing ones (e.g., rapid tests, treatment as prevention [TasP], PrEP, etc.) for individuals and communities who need them but are not being reached. Specifically, in addition to working to accelerate progress by directing new funds to those communities affected by HIV in a phased approach, starting with the areas with the highest burden, *EHE* is focusing on four strategic pillars including: diagnosing all individuals with HIV as early as possible after infection; treating HIV infection rapidly and effectively to achieve sustained viral suppression; preventing at-risk individuals from acquiring HIV infection, including the use of PrEP; and rapidly detecting and responding to emerging clusters of HIV infection to further reduce new transmissions (https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview). Although this project is not funded with EHE dollars, the intent is to align the research projects with EHE goals.

Achieving EHE goals will require leveraging highly successful programs, including critical scientific advances in HIV prevention, diagnosis, treatment, and outbreak response, and coordinating resources across funded entities. Success will also require dedicated partnerships between researchers and multiple stakeholders including city, county, tribal, and state health departments and other agencies to implement and enhance the uptake and effectiveness of evidence-based interventions, including interventions currently available in the continuum of HIV testing, prevention, and care, to maximize community impact (https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview).

CDC recently released two funding announcements for the initial phase of EHE - RFA-PS-19-1906: "Strategic Partnerships and Planning to Support Ending the HIV Epidemic in the United States" and RFA-PS-20-2010: "Integrated HIV Programs for Health Departments to Support Ending the HIV Epidemic in the United States". Both funding announcements are directed to health departments (HDs) for planning for, and implementation of, evidence-based and innovative strategies that expand prevention, care, and treatment programs to individuals and communities with highest burden of HIV.

Transferring Evidence-Based Interventions (EBIs), and evidence-informed strategies, into practice settings is often fraught with challenges, and these challenges limit successful implementation and ultimately reduce the impact of the interventions on prevention [13]. Barriers to successful implementation can be posed by resource allocation, organizational structure, intervention adaptability, and the capacity of systems, providers, or operational tools needed to target EBIs and evidence-informed strategies to the persons at highest risk for HIV. Implementation science is an approach to understanding the magnitude of, determinants of, and

strategies most helpful to close the gap between evidence and implementation of effective interventions as routine health practices in real-world settings. Generalizable knowledge generated from implementation research is essential to the effective planning, design, and delivery of HIV prevention and care services at the local level that are vital to the EHE's success. Science advanced by this NOFO will serve to foster implementation science and generalizable knowledge within the testing, treatment, and prevention pillars of EHE.

References

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3. Centers for Disease Control and Prevention. *HIV Surveillance Report, 2018 (Updated)*; vol.31. http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. Published May 2020. Accessed July 7, 2020.
4. Centers for Disease Control and Prevention. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data — United States and 6 dependent areas, 2018. HIV Surveillance Supplemental Report 2020;25(No. 2). http://www.cdc.gov/hiv/library/reports/ hiv-surveillance.html. Published May 2020. Accessed July 7, 2020.
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8. Smith, D.K., *et al*. Estimates of adults with indications for HIV pre-exposure prophylaxis by jurisdiction, transmission risk group, and race/ethnicity, United States, 2015. Annals of Epidemiology 2018;28(12):850–857.
9. Kamitani, E., *et al*., Increasing prevalence of self-reported HIV preexposure prophylaxis use in published surveys: a systematic review and meta-analysis. AIDS, 2018. 32(17): p. 2633-2635.
10. Lelutiu-Weinberger, C. and S.A. Golub, Enhancing PrEP Access for Black and Latino Men Who Have Sex With Men. J Acquir Immune Defic Syndr, 2016. 73(5): p. 547-555.
11. Kanny, D., *et al*., Racial/Ethnic Disparities in HIV Preexposure Prophylaxis Among Men Who Have Sex with Men - 23 Urban Areas, 2017. MMWR Morb Mortal Wkly Rep, 2019. 68(37): p. 801-806.
12. Elion, R.A., *et al*., Estimated Impact of Targeted Pre-Exposure Prophylaxis: Strategies for Men Who Have Sex with Men in the United States. Int J Environ Res Public Health, 2019. 16(9).
13. Riley, W.T., Behavioral and Social Sciences at the National Institutes of Health: adoption of research findings in health research and practice as a scientific priority.

Transl Behav Med, 2017. 7(2): p. 380-384.

Health Equity:

The program supports efforts to improve the health of populations disproportionately affected by HIV/AIDS, viral hepatitis, sexually transmitted diseases (STDs) and TB by maximizing the health impact of public health services, reducing disease prevalence, and promoting health equity consistent with the National HIV/AIDS Strategy available at https://www.whitehouse.gov/administration/eop/onap/nhas.

Health disparity is a particular type of health difference that is closely linked with social or economic disadvantage based on racial or ethnic group, religion, socioeconomic status, gender, mental health, cognitive, sensory, or physical disability, sexual orientation, geographic location, or other characteristics historically linked to discrimination or exclusion [HP 2020 - http://www.healthypeople.gov/2010/hp2020/advisory/PhaseI/glossary.htm]. Health disparities in HIV, viral hepatitis, STDs, and TB are inextricably linked to a complex blend of social determinants that influence which populations are most severely affected by these diseases.

Social determinants are the economic and social conditions that influence the health of individuals, communities and jurisdictions and include conditions for early childhood development; education, employment, and work; food security, health services, housing, income, and social exclusion.

Health equity is a desirable goal that entails special efforts to improve the health of those who have experienced social or economic disadvantage. It requires:

- Continuous efforts focused on elimination of health disparities, including disparities in health and in the living and working conditions that influence health, and
- Continuous efforts to maintain a desired state of equity after particular health disparities are eliminated.

Programs should use data, including social determinants data, to identify communities within their jurisdiction that are disproportionately affected by HIV, viral hepatitis, STDs and TB and related diseases and conditions, and plan activities to help eliminate health disparities. In collaboration with partners and appropriate sectors of the community, programs should consider social determinants of health in the development, implementation, and evaluation of program specific efforts and use culturally appropriate interventions that are tailored for the communities for which they are intended.

Healthy People 2030 and other National Strategic Priorities

This announcement aims to accelerate evidence-informed decision making and performance improvements to HIV prevention strategies. Several Healthy People 2020 (HP 2020) objectives are supported through this NOFO. The HP 2020 objectives supported by this announcement include:

Reduce new HIV infections

- HIV-1 Reduce the number of new HIV diagnoses

- HIV-2 Reduce the number of new HIV infections among adolescents and adults
- HIV-3 Reduce the rate of HIV transmission among adolescents and adults
- HIV-4 Reduce new AIDS cases among adolescents and adults
- HIV-5 Reduce new AIDS cases among adolescent and adult heterosexuals
- HIV-6 Reduce new AIDS cases among adolescent and adult men who have sex with men
- HIV-7 Reduce new AIDS cases among adolescents and adults who inject drugs
- HIV-8 Reduce perinatally acquired HIV and AIDS cases
- HIV-24 Reduce the percentage of young gay and bisexual males in grades 9 through 12 who engage in HIV-risk behaviors

Increase HIV testing and prevent HIV risk

- HIV-9 Reduce the proportion of persons with a diagnosis of Stage 3 HIV (AIDS) within 3 months of diagnosis of HIV infection
- HIV-13 Increase the proportion of persons living with HIV who know their serostatus
- HIV-14 Increase the proportion of adolescents and adults who have been tested for HIV in the past 12 months
- HIV-16 Increase the proportion of substance abuse treatment facilities that offer HIV/AIDS education, counseling, and support
- HIV-17 Increase the proportion of sexually active persons who use condoms
- HIV-18 Reduce the proportion of men who have sex with men (MSM) who reported unprotected anal intercourse with a partner of discordant or unknown status during their last sexual encounter

Increase access to care and improve health outcomes for people living with HIV

- HIV-10 (Developmental) Increase the proportion of HIV-infected adolescents and adults who receive HIV care and treatment consistent with current standards
- HIV-11 Increase the proportion of persons surviving more than 3 years after a diagnosis with AIDS
- HIV-12 Reduce deaths from HIV infection
- HIV-19 Increase the percentage of persons with newly diagnosed HIV infection linked to HIV medical care (had a routine HIV medical visit) within one month of their HIV diagnosis
- HIV-20 Increase the percentage of newly diagnosed persons with diagnosed HIV infection who are retained in continuous HIV medical care
- HIV-21 (Developmental) 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 percentage of persons with diagnosed HIV infection who are virally suppressed
- HIV-23 (Developmental) Reduce the proportion of persons with an HIV diagnosis receiving HIV services who were homeless or unstably housed in the 12-month measurement period

Public Health Impact

This program would establish a research consortium coordinated with health department programming and associated collaborative partnerships to efficiently conduct HIV prevention implementation research with real-world HIV prevention implementation challenges experienced by health departments and health department implementing partners in mind. Implementation science is a key element of the EHE initiative, emphasizing the need to learn how to best implement existing tools and effective interventions in a way that decreases new HIV infections in jurisdictions and states with greatest HIV burden. Whereas individual program evaluation and demonstration projects help to improve programs, and can identify lessons that worked in that program, they do not produce generalizable knowledge; in part, because they do not employ the study designs or collect the data needed to do so. A research consortium with **Core** and **Collaborative Projects** will allow for more efficient and strategic evaluation of implementation strategies that best facilitate dissemination and adoption of effective HIV prevention tools.

By identifying best practices for implementing and disseminating effective HIV prevention strategies, the proposed research consortium can have a major public health impact in HIV-vulnerable populations and communities. First, by focusing on implementation science, the research consortium should inform how best to deliver evidence-based strategies that will improve service delivery to consumers and increase access to, and uptake of, effective strategies. Second, a research consortium where researchers can work together to identify critical HIV prevention needs of health departments and their implementation partners across their communities, and the most appropriate ways to address those needs, increases the chances of asking relevant scientific questions that will have a public health impact. Third, using a research consortium model can also lead to future and sustainable collaborations that will inform research-to-practice models and foster quality improvement of programs. Finally, because the multi-site findings from the **Collaborative Projects** may be more generalizable than a single-site study, the potential for greater public health impact is substantially increased by making the findings more useful to health departments, HIV prevention researchers, and Federal agencies.

Relevant Work

This NOFO builds on previously funded programs including:

1. RFA-PS-18-1802: Integrated HIV Surveillance and Prevention Programs for Health Departments (https://www.cdc.gov/hiv/funding/announcements/ps18-1802/index.html)

2. CDC HIV Prevention Demonstration Projects with Health Departments (https://www.cdc.gov/hiv/research/demonstration/)

3. NIMH/CDC collaboration on PrIDE: RFA-PS-15-1506 (https://grants.nih.gov/grants/guide/pa-files/PA-16-199.html)

2. Approach

Applications may include multiple PDs/PIs (or Co-PIs) and, if so, must include a **Leadership Plan** that describes the roles, responsibilities and working relationships of the PDs/PIs (or Co-PIs). However, only one PD/PI may be the primary CDC contact for the award; this contact

PD/PI must be at the recipient institution and must be indicated as such in the application.

Each application MUST address a **Core Project** and a **Collaborative Project** in a single application. Each **Core Project** and each **Collaborative Project** and its accompanying budget must be clearly identified in the application using clear headings/identifiers **(see Section IV.2 of this NOFO for more detailed information regarding application format)**.

The approach to this award is multi-fold and includes the following key components. Each component is critical in the successful application and completion of this award.

I. Research Priorities

For both **Core** and **Collaborative Projects**, applications should focus on implementation strategies specific to the Diagnose, Treat or Prevent pillars of the *EHE* initiative and address challenges health departments face in bringing effective prevention to populations in need. Some examples of implementation challenges within the pillars that are of interest might include, but are not limited to: evaluation of different community-based testing strategies or approaches to identifying undiagnosed persons ("diagnose"); strategies to better support re-linking people with HIV back into care or to retaining persons in HIV care ("treat"); or strategies to enhance PrEP uptake and persistence ("prevent"). Cross-cutting issues of interest include, but are not limited to, stigma, approaches for rural or marginalized populations (including homeless populations, young trans women and gay men of color, African American women, people of color in rural areas, aging populations, people who inject drugs), and integrating behavioral/mental health issues. Strategies to enhance program delivery, address health care providers, or structural issues (e.g., improving access to care and treatment, policies to reduce healthcare system barriers, and integrating efforts of surveillance, prevention and treatment of HIV) are also of interest. Applications should focus on areas where there is capacity to achieve the greatest reach and impact for the populations disproportionately affected by HIV and for whom data indicate are not being sufficiently reached with effective prevention.

II. Guidance for Developing Research Plan and Activities

A. CORE PROJECT. Each **Core Project** proposal should describe a research project that is designed to be implemented and analyzed by an individual awardee institution.

The **Core Project** research plan should provide both a high-level overview of the entire (5) five-year project period and a detailed description of the first year of the award. The proposals should include a detailed description of the research goals and objectives. Proposals should also incorporate an explanation of the relevance to one or more of the research priorities listed above. There should be a clearly described implementation problem/gap and associated research question(s), study design, research methods, and implementation outcomes as well as a logic model provided in the application. Applications are expected to describe the HIV prevention implementation research issue, why previous implementation approaches have not worked, justify why the proposed approach could work, and propose a timeline. Each application should include a logic model with an outline of the anticipated short-term, intermediate, and long-term project-specific outcomes.

Applications should also make specific reference to the Integrated HIV Prevention and Care plan or any other relevant jurisdictional EHE plan or equivalent (e.g., Getting to Zero

plan) for the jurisdiction in which they are working, and how the proposed research ideas support these goals. The proposal should include a work plan that directly responds to issues, strategies and activities outlined in either local EHE or other relevant plans. Applications should propose specific, measurable, achievable, realistic, and time-based (SMART) process and/or outcomes for the implementation research ideas. In addition, a concise description of how the recipient's plans to implement and monitor each implementation activity should be included in the work plan. The work plan can be uploaded as a separate attachment to be submitted as part of the application. Name the file "work plan" and upload the document(s) as a PDF file under "Other Attachments".

B. COLLABORATIVE PROJECT. The goal of this project is to build science-based partnerships in order to bridge gaps in implementing evidence-based interventions in HIV prevention.

Collaborative Project proposals should describe a research project that includes more than one institution working together on a common protocol to address common implementation challenges in HIV. The **Collaborative Project** should consist of one primary recipient institution and one or more subcontracting institution(s). Either the primary institution or one or more of its subcontracting sites should have access to health department data in the implementing jurisdictions needed to perform the objectives of the implementation research study. Collaborating sites may be named at the time of application submission, or identified after award, but study objectives and partner roles and relationships to the grantee and other research partners must be clearly described in the application. If named after award, the collaborating sites may also be institutions funded for a **Core Project**. The funded recipient for the **Collaborative Project** will be required to participate in an HIV prevention Implementation Science consortium (see below) and collaborating sites may also participate in the consortium. The collaborating sites must provide a letter of commitment that delineates the expertise, roles, responsibilities, and commitments of each consortium team member before work can commence.

III. Consortium Working Groups

The Consortium will be comprised of representatives from the funded **Core** and **Collaborative Projects**. The Consortium will provide scientific support to **Core** and **Collaborative Projects** as well as aid in the development of the collaborative research infrastructure. As part of the collaborative research infrastructure, co-investigators with expertise in various fields will be expected to participate in additional working groups to aid the development of research in their respective fields. These working groups may revolve around particular subject matter (e.g., PrEP, Data-to-Care specific workgroups) or programmatic domains (e.g., data sharing or facilitating training). Working Groups will work collaboratively to serve in an advisory role to individual investigators by providing scientific and technical support. Well-developed Working Groups are integral to the Consortium's success but will not serve as an advisory group to CDC.

Objectives/Outcomes

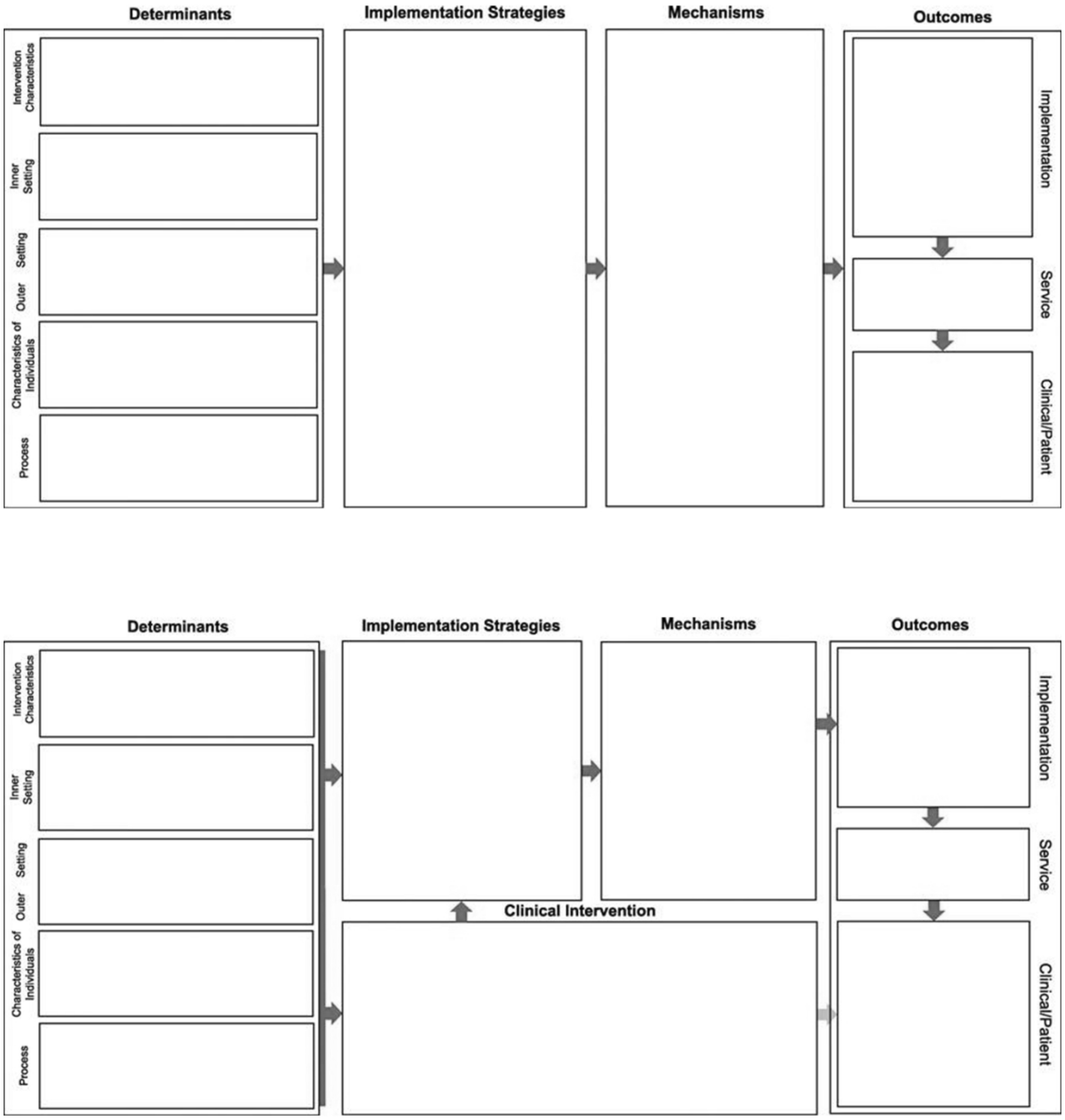
Whenever possible, applications should include objectives written in the SMART format (e.g., Specific, Measurable, Achievable, Realistic and Time-bound).

Implementation Science (IS) Research Issues. As a key component of the EHE initiative, IS

research is needed to identify critical implementation strategies to improve the delivery, reach, uptake, fidelity, and sustainability of HIV clinical and behavioral prevention services in order to substantially reduce annual new infections, particularly among those not currently being reached with effective prevention services. Implementation science research evaluates the use of strategies to integrate interventions into real-world settings to improve patient access and use, and subsequently, outcomes. Implementation science research focuses on understanding barriers and facilitators, mechanisms, and processes that affect implementation, and evaluates strategies to improve implementation. Implementation science research assesses the extent to which contextual factors that function as determinants of implementation, such as lack of expertise among staff, can be addressed by a specific implementation strategy. Implementation strategies, in general, are those methods or techniques used to enhance the dissemination, adoption, use/uptake, reach/penetration, fidelity, or sustainability of a program, service, or intervention (hereafter referred to as a public health program). Implementation strategies are typically "independent" of the specific public health programs being implemented, in that they comprise the key elements for integrating or expanding a program within a given setting. Mechanisms of action are processes or events through which an implementation strategy operates, such as a training program to increase staff expertise (strategy) which improves staff knowledge, changes attitudes, or increases self-efficacy and confidence in ability to deliver the program with fidelity. Implementation outcomes include measures of the extent to which a public health program is adopted and delivered with fidelity in a given setting (see Figure 1).

The logic models depicted in Figure 1 are intended to be examples of appropriate formats; other formats are acceptable.

Figure 1. Implementation Research Logic Models



Smith, J.D., Li, D.H. & Rafferty, M.R. The Implementation Research Logic Model: a method for planning, executing, reporting, and synthesizing implementation projects. Implementation Sci 15, 84 (2020).

A wide range of frameworks and models have been developed to structure IS research approaches; online tools can assist applicants (i.e., consortium teams) in identifying the framework(s) most appropriate for their specific research topic (https://dissemination-implementation.org/).

Applications should propose **Core** and **Collaborative Projects** that use IS research methods (e.g., approaches, measures) to address implementation challenges that are improved by the understanding of factors that impact HIV prevention programs and services in their

jurisdictions. For example, IS research questions related to the Diagnose and Treat pillars of EHE might include identifying which factors affect the extent to which routine opt-out HIV screening in healthcare and other institutional settings is implemented according to operational guidance, is delivered by staff with adequate training and support, does not add undue burden to existing workflows, and is acceptable to the client population and/or mitigates barriers to access that they might otherwise encounter. Such research questions may also focus, for example, on comparing strategies of rapid linkage to HIV medical care for persons newly diagnosed and/or for persons with indications of PrEP. Such studies could examine differences in implementation components, such as specific messages provided to the client, characteristics of the messenger (e.g., experience and skill in communicating with diverse populations), program staffing and resource allocation, and methods of outreach. Additionally, research questions could focus on identifying strategies to improve health equity in terms of accessibility to services for priority groups with disproportionately high HIV burden. These examples of IS research questions serve to illustrate how programs can be strengthened and identified using an IS approach and are not intended to be definitive for the purposes of responding to this funding opportunity. Qualitative measures (e.g., individual interviews and focus groups, content analysis of program documents) and quantitative measures (e.g., electronic medical record abstraction, survey methods, clinical and laboratory assessments of patients) may be used in each research project. Each proposed study will use an IS framework (e.g., Consolidated Framework for Implementation Research [CFIR] [1], Theoretical Domains Framework [TDF] [2], Promoting Action on Research Implementation in Health Services [PARIHS] [3], RE-AIM [4], Proctor Outcomes Model [5,6]) to define the key domains of implementation and measurement. Data should be collected on implementation-relevant strategies, hypothesized mechanisms of change and implementation outcomes (e.g., fidelity to intervention model, uptake of tools by providers, exposure/reach to clients, sustainability/feasibility of the implementation model). Examples of possible IS designs include formative research to further define the implementation barriers or standardize the implementation model, observational studies to understand the critical implementation components involved in a given intervention mode, and between- and within-group (including pre/post) comparisons or controlled trials of different implementation strategies for a public health program, strategy, or service.

References

1. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4:50.
2. Birken SA, Powell BJ, Presseau J, *et al*. Combined use of the Consolidated Framework for Implementation Research (CFIR) and the Theoretical Domains Framework (TDF): a systematic review. Implement Sci. 2017;12(1):2.
3. Stetler CB, Damschroder LJ, Helfrich CD, Hagedorn HJ. A guide for applying a revised version of the PARIHS framework for implementation. Implement Sci. 2011;6:99.
4. Gaglio B, Shoup JA, Glasgow RE. The RE-AIM framework: a systematic review of use over time. Am J Public Health. 2013;103(6):e38-46.
5. Proctor E, Silmere H, Raghavan R, *et al*. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Health. 2011;38(2):65-76.
6. Proctor EK, Landsverk J, Aarons G, Chambers D, Glisson C, Mittman B:

Implementation research in mental health services: An emerging science with conceptual, methodological, and training challenges. Adm Policy Ment Health 2009, 36:24–34.

Target Population

Study outcomes of the award will be assessed at the level of health department staff and systems, HIV prevention community partner staff and systems, and related infrastructure components that influence or impact HIV prevention implementation in the jurisdictions, as appropriate, given the proposed research focus. Target populations will be defined accordingly from this group of entities. Programs conducted by these entities, which the research questions focus on, should serve priority groups identified in local HIV prevention plans (i.e., Integrated HIV Prevention and Care and/or EHE Plans) and reflect the need for the proposed IS research. Process level assessment inputs for enhancing HIV implementation may include target populations of HD and HIV prevention partner organization staff, and community members intended to eventually benefit from application of implementation research findings.

Collaboration/Partnerships

The goal of this NOFO is to build partnerships to bridge the gap between IS research and health department unanswered IS questions. In order to effectively meet this need, consultation and partnership with a state or local health department (HD) is strongly encouraged. Applications should demonstrate an understanding of HD IS needs and processes related to data collection, and applications that include HD representatives as collaborators, or even as co-principal investigators, are strongly encouraged. If multiple PDs/PIs (or Co-PIs) are proposed, the application must include a Leadership Plan that describes the roles, responsibilities, and working relationships of the PDs/PIs (or Co-PIs). Only one PD/PI may be the primary CDC contact for the award, must be at the recipient institution, and the contact must be clearly indicated in the application.

Consortium Collaboration - During the consortium meetings and IS research process, CDC expects recipients to coordinate, as needed, with various relevant groups and stakeholders, including, but not limited, to Health Resources and Services Administration (HRSA) funded entities, sexually transmitted disease (STD) programs, viral hepatitis programs, TB programs, school-based programs, other surveillance programs, laboratory units, other health agencies, tribal governments and/or tribally designated organizations, community-based organizations, community health centers, Bureau of Primary Health Care funded recipients, lesbian, gay, bisexual and transgender (LGBT) health centers, STD and TB clinics, hospitals, specialty clinics, other non-governmental organizations, and criminal justice and correctional facilities implementing comprehensive HIV programs focused on ending the HIV epidemic in the respective jurisdictions.

Evaluation/Performance Measurement

The application should include measurable goals and aims based on a five (5)-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.

The application should include an evaluation plan consistent with the proposed research and the stated purpose and outcomes of this announcement. Among other elements and evaluation activities, the evaluation and performance measurement plan should include the following elements:

Process-level measures: The consortium and jurisdictional teams will be assessed annually for **process-level functioning**, with member-level feedback applied to improve consortium progress in working together.

Annual **site-level reports** will be submitted that describe jurisdictional issues and accomplishments, including a summary of jurisdictional successes and lessons learned, and those successes and lessons learned from cross-jurisdictional collaborative activities. Descriptive data will be included that describe numbers by study for enrollment and completion as well as key findings when available.

Outcome-level measures: Project **outcome-level assessment** will be IS-related and specific to each study and issues being addressed therein. Examples of implementation outcomes that could be assessed include acceptability or uptake of services by prioritized community members; HIV prevention-related HD or community partner staff perceptions, attitudes, and skills; relationship-level variables between HD staff, partner staff, and key community representatives; infrastructure-level factors such as policies, clinic or center environmental issues, or other physical mechanisms impacting HIV prevention implementation. Applications should include well-defined outcomes in the context of the proposed research focus. Specific outcomes and measures will vary depending on the proposed research questions.

Translation Plan

Projects should be designed with valuable tools in mind as products. These products should support implementation of HIV prevention programs and activities that are in alignment with the goals of EHE. Products should be able to be scaled to a broad level beyond the jurisdictions in which the research was conducted. Specifics will vary based on the focus of the proposed research. When feasible, products from completed IS studies shall be shared with others, either through peer-to-peer interactions with other health departments or dispersed through entities and mechanisms available to health departments and HIV prevention professionals in the US (e.g., NASTAD, CDC). To the greatest extent possible, study tools should be created in a format that are easily translated for broader use.

Findings should be disseminated through relevant conference presentations, meetings, and publications. Additional unique means of sharing study findings directly with implementers are expected to be proposed. Further, consideration should be given to dissemination of lessons learned by the consortium that would be beneficial to other implementers. Potential additional products should be described in the application, including such materials as annual reports of consortium accomplishments.

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: $15,000,000

Estimated Total Funding (including direct and indirect costs) for the Core and Collaborative Projects during the entire five (5)-year period of performance: $15,000,000

Estimated Total Funding (including direct and indirect costs) for the Core Projects only during the entire five (5)-year period of performance: $7,000,000

Estimated Total Funding (including direct and indirect costs) for the Collaborative Projects only during the entire five (5)-year period of performance: $8,000,000

Estimated total funding available for the first year (first 12-month budget period), including direct and indirect costs, for four Core Projects: $1,400,000

Estimated total funding available for the first year (first 12-month budget period), including direct and indirect costs, for two Collaborative Projects: $1,600,000

Project Ceilings: $350,000 per Core Project award and $800,000 per Collaborative Project award (first budget period only).

Project Floors: $300,000 per Core Project award and $750,000 per Collaborative Project award (first budget period only).

Award Ceiling per budget period per award: $1,150,000 (Core plus Collaborative Project)

Award Floor per budget period per award: $300,000 (Core Project only)

Anticipated Number of Awards: 4
Anticipated number of awards: Four (4) Core Projects and two (2) Collaborative Projects

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

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

Award Ceiling:	$1,150,000 Per Budget Period
Award Floor:	$300,000 Per Budget Period
Total Period of Performance Length:	5 year(s)

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

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

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:

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

Additional Eligibility Category:

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

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

Nonprofits (Other than Institutions of Higher Education):

Nonprofits (Other than Institutions of Higher Education)

Governments:

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

Other:

Faith-based or Community-based Organizations
Regional Organizations
Bona Fide Agents: A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms."
Federally Funded Research and Development Centers (FFRDCs): FFRDCs are operated, managed, and/or administered by a university or consortium of universities, other not-for-profit or nonprofit organization, or an industrial firm, as an autonomous organization or as an identifiable separate operating unit of a parent organization. A

FFRDC meets some special long-term research or development need which cannot be met as effectively by an agency's existing in-house or contractor resources. FFRDC's enable agencies to use private sector resources to accomplish tasks that are integral to the mission and operation of the sponsoring agency. For more information on FFRDCs, go to https://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

N/A

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

If the application exceeds the ceilings for the first 12-month budget period indicated in Section II. of this NOFO, HHS/CDC will consider the application non-responsive and it will not enter the review process. HHS/CDC will notify the applicant that the application did not meet the submission requirements if the application requests funding greater than the following:

$350,000 per Core Project and $800,000 per Collaborative Project (first 12-month budget period only, including direct and indirect costs).

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://cage.dla.mil/

- 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/index.html .
- Grants.gov
- eRA Commons

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

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

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

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

DUNS number to the recipient organization.

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

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

9. Cost Sharing

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

10. Number of Applications

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

Only one application per institution (normally identified by having a unique DUNS number) is allowed. One application includes both a **Core Project** and a **Collaborative Project**.

Applications may include more than one PD/PI; however, the first PD/PI listed on the application will be the contact PD/PI for all correspondence. Any additional PDs/PIs are permitted, but should be referred to and listed as Co-PIs.

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.

IMPORTANT NOTE:

- In both the **Research Strategy** and **Project Summary/ Abstract (Description)** sections, the application should clearly list each proposed project by name (i.e., identify the proposed project as the **Core Project** or the **Collaborative Project**).
- Each application must apply for both a **Core Project** and a **Collaborative Project**.

  Within the total 25-page limit for the **Research Strategy** of the **Research Plan** section of the application, the page limit for EACH project is limited as follows:

  - Core Project: 15 pages
  - Collaborative Project: 10 pages

- Throughout the **Research Strategy** and other application sections, text pertaining to a given project should be titled to begin with the words **"Core Project"** or **"Collaborative Project"** to distinguish projects from one another. The **Research Strategy** for both projects will be in one section of the application but broken down by project, sequentially (e.g., **Core Project** followed by **Collaborative Project**).
- As part of the initial scientific merit review, the **Core Project** and the **Collaborative Project** will be scored, and rank ordered separately and will each receive an overall impact score. Only applications receiving a **Core Project** will be eligible to receive a **Collaborative Project** award. It is anticipated that four (4) **Core Projects** will be awarded and two (2) **Collaborative Projects** will be awarded.
- The applicant only needs to submit one SF424R&R application for both projects; however, the budget and the budget justification needs to be listed separately for each project (i.e., two budgets and two budget justifications in one SF424R&R application).
- **Letters of Support** from partners or other organizations should be placed in the PHS 398 Research Plan "Other Research Plan Section" of the application under **"9. Letters of Support".**
- **If multiple PDs/PIs** are proposed, a Leadership Plan should be placed in the PHS 398 Research Plan "Other Research Plan Section " of the application under **"7. Multiple PD/PI Leadership Plan".**

- In addition, **a concise description** of how the recipient's plans to implement and monitor each implementation activity should be included in the work plan. The work plan should be uploaded as a separate attachment to be submitted as part of the application. Name the file "Core Project Work Plan" and "Collaborative Project Work Plan" for the **Core** and **Collaborative Projects**, respectively, and upload the document(s) as a PDF file under the **"12. Other Attachments"** section of the "RESEARCH & RELATED Other Project Information" section of the application.

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

Mandatory

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

If multiple collaborating institutions will be involved, please include in this section of the application your single IRB (sIRB) Plan:

- Describe how you will comply with the single IRB review requirement under the Revised Common Rule at 45 CFR 46.114 (b) (cooperative research). If available, provide the name of the IRB that you anticipate will serve as the sIRB of record.
- Indicate that all identified engaged institutions or participating sites will agree to rely on the proposed sIRB and that any institutions or sites added after award will rely on the sIRB.
- Briefly describe how communication between institutions and the sIRB will be handled.
- Indicate that all engaged institutions or participating sites will, prior to initiating the study, sign an authorization/reliance agreement that will clarify the roles and responsibilities of the sIRB and participating sites.
- Indicate which institution or entity will maintain records of the authorization/reliance agreements and of the communication plan.
- Note: Do not include the authorization/reliance agreement(s) or the communication plan(s) documents in your application.
- Note: If you anticipate research involving human subjects but cannot describe the study at the time of application, include information regarding how the study will comply with the single Institutional Review Board (sIRB) requirement prior to initiating any multi-site study in the delayed onset study justification.

Please include the optional form listed below, if applicable, in the application package:

Optional

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

3. Letter of Intent

Due Date for Letter of Intent: **12/17/2020**

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 CIO staff to estimate the potential review workload and plan the review.

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

Name of the applicant institution

Descriptive title of proposed research

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

Names of other key personnel

Participating institutions

Number and title of this notice of funding opportunity (NOFO)

The letter of intent should be sent to:

Gregory Anderson, MPH, MS

Extramural Research Program Office

Office of the Associate Director of Science

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

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

1600 Clifton Road, US8-1

Atlanta, GA 30333

Telephone: 404-718-8833

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

and University of California https://dmp.cdlib.org/

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.

PLEASE NOTE: If applications go beyond the page limit designated for a given section, excess pages will be removed from the application prior to peer review and may negatively affect the scoring. Please pay attention to page limits for the **Core Project** and the **Collaborative Project** described in Section IV.2 of this NOFO.

7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 25 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 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: **01/28/2021**

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

10. Intergovernmental Review (E.O. 12372)

Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order 12372 (https://www.archives.gov/federal-register/codification/executive-order/12372.html). This order sets up a system for state and local review of proposed federal assistance applications. You should contact your state single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your state's process. Click on the following link to get the current SPOC list: https://www.whitehouse.gov/wp-content/uploads/2020/04/SPOC-4-13-20.pdf.

11. Funding Restrictions

Expanded Authority:
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 and speak to your GMS.
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.

Protecting Life in Global Health Assistance:
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/additional-requirements/ar-35.html).

Public Health Data:
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.

Data Management Plan:
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/additional-requirements/ar-25.html for revised AR-25.

Human Subjects:
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.
If the proposed research project involves more than one institution and will be conducted in the United States, awardees are expected to use a single Institutional Review Board (sIRB) to conduct the ethical review required by HHS regulations for the Protections of Human Subjects Research, and include a single IRB plan in the application, unless review by a sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy or a compelling justification based on ethical or human subjects protection issues or other well-justified reasons is provided. Exceptions will be reviewed and approved by CDC in accordance with Department of Health and Human Services (DHHS) Regulations (Title 45 Code of Federal Regulations Part 46), or a restriction may be placed on the award. For more information, please contact the

scientific/research contact included on this NOFO.
Note: The sIRB requirement applies to participating sites in the United States. Foreign sites participating in CDC-funded, cooperative research studies are not expected to follow the requirement for sIRB.

Additional Funding Restrictions:

1. Awards made under this NOFO should have no scientific or budgetary overlap with other funded awards.

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

If the proposed research project involves more than one institution and will be conducted in the United States, awardees are expected to use a single Institutional Review Board (sIRB) to conduct the ethical review required by HHS regulations for the Protections of Human Subjects Research, and include a single IRB plan in the application, unless review by a sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy or a compelling justification based on ethical or human subjects protection issues or other well-justified reasons is provided. Exceptions will be reviewed and approved by CDC in accordance with Department of Health and Human Services (DHHS) Regulations (Title 45 Code of Federal Regulations Part 46), or a restriction may be placed on the award. For more information, please contact the scientific/research contact included in this NOFO. Please see Section IV.2 of this NOFO, "Content and Form of Application Submission" for guidance on sIRB Plan content.

Note: The sIRB requirement applies to participating sites in the United States. Foreign sites participating in CDC-funded, cooperative research studies are not expected to follow the requirement for sIRB.

3. 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.

4. 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).

5. On September 24, 2014, the Federal government issued a policy for the oversight of life sciences “Dual Use Research of Concern” (DURC) and required this policy to be implemented by September 24, 2015. This policy applies to all New and Renewal awards issued on applications submitted on or after September 24, 2015, and to all non-competing continuation awards issued on or after that date. CDC grantee institutions and their investigators conducting life sciences research subject to the Policy have a number of

responsibilities that they must fulfill. Institutions should reference the policy, available at http://www.phe.gov/s3/dualuse, for a comprehensive listing of those requirements. Non-compliance with this Policy may result in suspension, limitation, or termination of United States Government (USG) funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

6. Please note the requirement for inclusion of a Data Management Plan (DMP) in applications as 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 (https://grants.nih.gov/grants/how-to-apply-application-guide.html).

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 (https://www.cdc.gov/about/organization/mission.htm), all applications submitted to the CDC in support of public health research are evaluated for scientific and technical merit through the CDC peer review system.

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

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

Significance

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

this field?

- Does the application identify important implementation science research gaps specific to the challenges experienced by health departments and health department implementing partners that the proposed projects will address?
- Does the application utilize local epidemiologic or other relevant data to demonstrate the need for improved implementation strategies to facilitate better outcomes for populations that may benefit from this research?
- Are the proposed set of project activities methodologically strong, and yet realistic to accomplish, such that they will contribute significantly to HIV prevention implementation research in the United States?
- Does the application describe how results from the proposed research will advance the implementation of HIV prevention by health departments and health department implementing partners in the United States?

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 proposed PD(s)/PI(s) and collaborators have a successful track record of HIV prevention research and sound experience specifically in HIV prevention implementation research?
- Does the application demonstrate that project staff and collaborators are knowledgeable and experienced in implementation science and how it applies to HIV prevention?
- Does the application demonstrate evidence of success in implementation science via references to scientific publications and presentations at scientific conferences?
- Does the application demonstrate that project staff and collaborators are knowledgeable of the challenges experienced by health departments and health department implementing partners in HIV prevention and treatment?
- If the application includes multiple PDs/PIs (or Co-PIs), does the application include a Leadership Plan that describes the roles, responsibilities and working relationships of the PDs/PIs (or Co-PIs)?
- If the application includes multiple PDs/PIs (or Co-PIs), is only one PD/PI identified as the primary CDC contact for the award and is this contact PD/PI at the recipient institution?
- For the Collaborative Project, if collaborating partners are to be named after award, does the application indicate a plan for the identification of appropriate collaborators?
- Does the application demonstrate that the investigators have identified implementation science questions relevant to health departments and health department implementing partners?
- Do investigators, including collaborators, have sufficient time dedicated to supporting

the projects and consortium activities?
- Are the investigators well positioned to be a strong research team and active member of the consortium in the successful conduct and completion of the implementation research studies that are proposed?

Innovation

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

- Does the application clearly describe the proposed research question and any innovation that the results can lead to?
- Do proposed partnerships provide opportunities for innovation?
- Does the application challenge and seek to shift current public health practice paradigms or approaches?
- Is the proposed research innovative and yet offer reasonable potential for concrete applications of interest and value to health departments and health department implementing partners?
- Does the project have the potential to increase efficiency or lead to cost savings?

Approach

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

- Do the proposed studies address implementation issues that are broadly relevant to HIV prevention programming of health departments and health department implementing partners?
- Are outputs identified and are measures/metrics to assess implementation outcomes included?
- Does the application propose sound research methods that will lead to useful and generalizable results?
- Does the proposed research team commit to participate as a member of a consortium?
- For the Collaborative Project, does the research team commit to using a common multi-site protocol to achieve project goals?

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 the institutional support, and other resources available, adequate for the project activities proposed?
- Does the application present evidence of access to data from health departments and health department implementing partners?
- For Collaborative Projects, does the application present evidence of an environment supportive of partnerships, participation in a research consortium with other researchers, and willingness to work collaboratively on multi-site studies?
- Does the application include letters of collaboration from proposed partners that reflect their role in the project?

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://olaw.nih.gov/guidance/vertebrate-animal-section.htm).

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.

As part of the initial scientific merit review, each project (**Core Project** and **Collaborative Project**) will receive a separate overall impact score representing the scientific merit of the individual project; projects will be rank ordered separately by this score (**Core Projects** ranked with **Core Projects** and **Collaborative Projects** ranked with **Collaborative Projects**).

It is anticipated that four (4) **Core Project** awards will be made, in rank order. An applicant must be awarded a **Core Project** in order to be eligible to be awarded a **Collaborative Project**. Thus, one application will receive two independent overall impact scores for the projects proposed (one for the **Core Project** and one for the **Collaborative Project**).

Core Projects will be rank ordered by overall impact score and the acceptable funding range for **Core Projects** will be determined using these scores. Once the fundable range has been determined for the **Core Projects**, the best scoring **Collaborative Projects** from among those applications awarded a **Core Project** will be awarded, in rank order, by their overall impact

scores.

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: https://www.archives.gov/federal-register/cfr.

Specific requirements that apply to this NOFO are the following:

CDC Administrative Requirements:

AR-1: Human Subjects Requirements

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

AR-3: Animal Subjects Requirements

AR-4: HIV/AIDS Confidentiality Provisions

AR-5: HIV Program Review Panel Requirements

AR-6: Patient Care

AR-7: Executive Order 12372 Review

AR-8: Public Health System Reporting Requirements

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2020

AR-12: Lobbying Restrictions

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

AR-14: Accounting System Requirements

AR-15: Proof of Non-profit Status

AR-16: Security Clearance Requirement

AR-20: Conference Support

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

AR-22: Research Integrity

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

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

AR-26: National Historic Preservation Act of 1966

AR-27: Conference Disclaimer and Use of Logos

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

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

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

AR 31 - Distinguishing Public Health Research and Public Health Nonresearch

AR 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

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/additional-requirements/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/additional-requirements/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.
- Providing feedback on research questions and feasibility of answering prioritized questions on the research agenda with valid research designs.
- Obtaining IRB and any other regulatory or security approvals needed to conduct the study.
- Enrolling participants and collecting data.
- Developing systems to receive data from sites.
- Cleaning, analyzing and interpreting data.
- Taking a leadership role in assuring the dissemination of scientific findings in appropriate outlets.
- Working collaboratively as a member of the consortium.

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

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

- Serving as coordinators of the consortium and establishing related management and technical assistance processes.
- Encouraging continuous engagement among all consortium members.
- Participating as an active consortium technical advisor in substantive discussions of research conduct and dissemination.

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).

Please note: FFR reporting is now via the Payment Management System (PMS): https://pms.psc.gov/

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 the Payment Management System (PMS) **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 the Payment Management System (PMS) 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 is 120 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 on the Payment Management System (PMS) can be found at https://pms.psc.gov.
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://era.nih.gov/ 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, health care 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

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

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

1600 Clifton RD, NE, MS US8-1

Atlanta, GA 30329

Telephone: (404) 639-6437

Email: jpatterson@cdc.gov

Peer Review Contact

Gregory Anderson, MPH, MS

Extramural Research Program Office

Office of the Associate Director for Science

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

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

1600 Clifton RD, NE, MS US8-1

Atlanta, GA 30329

Telephone: (404) 718-8833

Email: GAnderson@cdc.gov

Financial/Grants Management Contact

Sharon Cassell

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) 488-2703

Email: zpr0@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, Section 301(a) [42 USC 241(a)] and Section 318 [247(c)], as

amended.