

Centers for Disease Control and Prevention

NATIONAL CENTER FOR HIV, VIRAL HEPATITIS, STDS AND TB PREVENTION

Enhancing Telehealth Strategies to Support Retention and Adherence to Antiretroviral Therapy (ART)

RFA-PS-23-002

03/17/2023

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Overview

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

Components of Participating Organizations:

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

Notice of Funding Opportunity (NOFO) Title

Enhancing Telehealth Strategies to Support Retention and Adherence to Antiretroviral Therapy (ART)

Activity Code

U01 – Research Project - Cooperative Agreements

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-PS-23-002

Assistance Listings Number(s)

93.084

Category of Funding Activity

HL - Health

NOFO Purpose

Telehealth services such as TeleART are becoming more widely implemented; however, to date, there is a dearth of evidence of effectiveness of TeleART for antiretroviral therapy (ART) adherence and retention in HIV care in the U.S. The purpose of the research supported by this Notice of Funding Opportunity (NOFO) is to evaluate the effectiveness of an enhanced telehealth program to improve adherence to ART, while also exploring the "implementability" of enhanced telehealth practice into routine care using a hybrid effectiveness-implementation

research design. The study should: 1) evaluate the effectiveness of an enhanced telehealth program for maintenance of HIV medication adherence among clinically stable people with HIV (PWH) and 2) identify potential implementation facilitators and challenges by evaluating the delivery of these strategies. Furthermore, the study should evaluate the cost and cost-effectiveness of providing telehealth to patients on ART, and evaluate program enhancements that include, but may not be limited to, biospecimen sample self-collection and the use of specialized staff such as community health workers and patient navigators. This enhanced telehealth program should focus on groups disproportionately affected by HIV and other persons for whom social determinants of health (e.g., stigma, discrimination, poverty, and low socioeconomic status) limit their engagement in HIV care and treatment. Specifically, African American cis-gender women, and/or Black or Hispanic/Latino gay, bisexual and other men who have sex with men, and/or transgender women, are groups of interest. The research supported by this NOFO should support Ending the HIV Epidemic in the U.S. (EHE) goals and should build on CDC's Division of HIV Prevention telehealth activities.

Key Dates

Publication Date:

To receive notification of any changes to RFA-PS-23-002, 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:

The LOI date will generate once the Synopsis is published if Days or a Date are entered.
02/17/2023

Application Due Date:

03/17/2023
03/17/2023

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 11:59 PM U.S. Eastern Time.

Applicants will use a system or platform to submit their applications through Grants.gov and eRA Commons to CDC. ASSIST, an institutional system to system (S2S) solution, or Grants.gov Workspace are options. ASSIST is a commonly used platform because it provides a validation of all requirements prior to submission and prevents errors.

For more information on 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 http://grants.nih.gov/support/index.html.

- E-mail: commons@od.nih.gov
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552
- Hours: Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding Federal holidays

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:
05/24/2023

Secondary Review:
06/20/2023

Estimated Start Date:
09/01/2023

Expiration Date:
03/18/2023

Required Application Instructions

It is critical that applicants follow the instructions in the How to Apply - 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 20 pages.

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

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

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

Executive Summary

- **Purpose:** Telehealth services such as TeleART are becoming more widely implemented; however, to date, there is a dearth of evidence of effectiveness of TeleART for antiretroviral therapy (ART) adherence and retention in HIV care in the U.S. The purpose of the research supported by this Notice of Funding Opportunity (NOFO) is to evaluate the effectiveness of an enhanced telehealth program to improve adherence to ART, while also exploring the "implementability" of enhanced telehealth practice into routine care using a hybrid effectiveness-implementation research design. The study should: 1) evaluate the effectiveness of an enhanced telehealth program for maintenance of HIV medication adherence among clinically stable people with HIV (PWH) and 2) identify potential implementation facilitators and challenges by evaluating the delivery of these strategies. Furthermore, the study should evaluate the cost and cost-effectiveness of providing telehealth to patients on ART, and evaluate program enhancements that include, but may not be limited to, biospecimen sample self-collection and the use of specialized staff such as community health workers and patient navigators. This enhanced telehealth program should focus on groups disproportionately affected by HIV and other persons for whom social determinants of health (e.g., stigma, discrimination, poverty, and low socioeconomic status) limit their engagement in HIV care and treatment. Specifically, African American cis-gender women, and/or Black or Hispanic/Latino gay,

bisexual and other men who have sex with men, and/or transgender women, are groups of interest. The research supported by this NOFO should support Ending the HIV Epidemic in the U.S. (EHE) goals and should build on CDC's Division of HIV Prevention telehealth activities.

- **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 four (4)-year project period is $3,600,000. The estimated number of awards is two (2). Awards issued under this NOFO are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded, and the number of awards will depend upon the number, quality, duration, and cost of the applications received.
- **Budget and Project Period:** The estimated total funding (direct and indirect) for the first year (12-month budget period) is $900,000, with individual awards ranging from $350,000 to $450,000 for the first year. The estimated total funding (direct and indirect) for the entire four (4)-year project period is $3,600,000. The project period is anticipated to run from 9/01/2023 to 08/31/2027.
- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. "Application and Submission Information" of this announcement.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III. of this announcement are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. **NOTE:** CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.
- **Number of PDs/PIs.** There will only be one PD/PI for each application.
- **Number of Applications.** Only one application per institution (normally identified by having a unique entity identifier [UEI] number) is allowed.
- **Application Type.** New.
- **Application Materials.** See Section IV.1 for application materials. Please note that SF424 (R&R) FORMS-H is to be used when completing the application package. Please see https://grants.nih.gov/grants/how-to-apply-application-guide.html

Section I. Funding Opportunity Description

Statutory Authority

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

1. Background and Purpose

For over 40 years, HIV has affected millions of Americans and more than 700,000 have died. In recent years, deaths among persons with HIV have declined, while the number of people with

HIV has increased due to the impact of HIV treatment on disease progression and death. An estimated 1.2 million persons are living with HIV and approximately 13% are unaware they have HIV. Whereas anyone can acquire HIV, inequities in social and structural determinants of health (e.g., racism, stigma, discrimination, and barriers to services) result in a disproportionate number of HIV infections in specific populations, including Black cis-gender women, Black and Hispanic/Latino MSM, and transgender women. MSM are disproportionately affected by HIV infection in the United States when their estimated lifetime risk for HIV infection (one in six) is compared with heterosexual men (one in 524) and heterosexual women (one in 253). When examining differences by race/ethnicity, disparities among MSM are further exacerbated, as the estimated lifetime risk for HIV infection is one in two for Black MSM and one in four for Hispanic/Latino MSM.

For transgender persons, a 2019 systematic review and meta-analysis found that among the US transgender population, an estimated 14% of transgender women have HIV. The disparity in HIV diagnosis among transgender persons is particularly apparent because among the 3 million HIV testing events reported to CDC in 2017, the percentage of transgender people receiving an HIV diagnosis was three times the national average.

Despite making up less than 15% of the female population, Black women continue to be disproportionately impacted by HIV, accounting for nearly 60% of new HIV infections in US women. Furthermore, compared to all people with diagnosed HIV, women have lower viral suppression rates. Data from the Medical Monitoring Project and the HIV Outpatient Study demonstrate disparities in viral suppression with viral suppression being suboptimal for all women, but more so for Black and Hispanic/Latino women. The National HIV/AIDS Strategy (NHAS) lists MSM, transgender women, and cis-gender Black women to be among the priority populations to focus prevention, care and treatment interventions and resources upon for the greatest impact in reaching NHAS goals.

People with HIV (PWH) who are on antiretroviral therapy (ART) and maintain an undetectable HIV viral load can have a nearly normal life expectancy and have no risk of transmitting HIV to others through sex. Implementing biomedical interventions that reach persons with HIV (i.e., ART) in geographic areas where infections are most concentrated is central to preventing HIV infection in the United States.

In 2019, the Department of Health and Human Services (HHS) introduced the *Ending the HIV Epidemic in the U.S.* (EHE) initiative which includes four science-based strategies: Diagnose, Treat, Prevent and Respond. Efforts to address the four EHE pillars should lead to increased engagement by patients in the healthcare system. Consequently, more people should learn their HIV status and, for those who test positive, receive ART. This increase in routine screenings and patients prescribed ART can present practical challenges for health systems, including clinic congestion, protracted patient waiting times and abbreviated interactions with clinicians, potentially affecting the quality of patient services, and leading to reductions in medication adherence and poor health outcomes.

Achieving the EHE goal of reducing the number of new HIV infections in the US by 90% by 2030 necessitates increasing ART retention and adherence. However, due to structural and social

determinants of health, people disproportionately affected by HIV, may experience barriers to medication adherence. PWH have cited numerous barriers to retention in care, including stigma, discrimination, distance to clinic, and competing priorities.

TeleART with Multi-month Prescription Refills (MMPR)

Differentiated models of care or service delivery (DSD) have been developed to increase or improve patient access to care, while reducing the burden on health systems and clinicians. For example, prior to the relatively recent move towards multi-month prescription refills (MMPRs), which were introduced to optimize the efficiency of HIV service delivery, many clinically stable patients on ART (defined as a patient receiving ART for at least 1 year with no adverse drug reactions requiring regular monitoring) had to visit a clinic monthly, regardless of their disease progression and comorbidities. MMPRs eliminate the previous need for monthly clinic and/or community facility visits. Findings from PEPFAR-funded countries show that in resource-limited settings, MMPRs reduce patient burden (e.g., time spent at a clinic, travel costs, and work or school hours lost) while improving adherence, and increasing the likelihood patients will be virally suppressed, when compared to patients not using MMPRs.

In response to the global SARS-CoV-2 (COVID-19) pandemic, telehealth practices are now more widely used to deliver medical services, including HIV prevention and treatment. Even before the pandemic, HIV care and prevention agencies were implementing telehealth services to small urban and rural locations. As such, many patients may already be receiving telehealth services, including TeleART, and for clinically stable patients, TeleART with multi-month prescription refills may have replaced in person clinic visits as "standard practice". However, whereas telehealth services such as TeleART with multi-month prescription refills are becoming more widely implemented, to date there is a dearth of evidence for the effectiveness of TeleART for ART adherence in the US.

Whereas MMPRs have helped, continuing to require in-person clinic visits to conduct routine labs and screenings means that clinicians allocate considerable time consulting with virally suppressed patients, which reduces the time clinicians have available for patients who may require additional clinical attention for HIV-specific or primary care. Hence, additional strategies are needed to further support patients in maintaining adherence and viral suppression, while decreasing patient burden and redirecting clinical resources to those patients who need them most. The research supported by this NOFO should identify strategies for implementing telehealth services that improve the efficiency of service delivery for patients, reduce burden on clinics, maintain patient engagement and adherence, and are acceptable to PWH on ART. This research should evaluate the potential additive benefit of other strategies that may enhance TeleART, including, but not limited to, biospecimen sample self-collection for HIV-related tests in the home/community setting, and integrating Community Health Workers (CHW) and other specialized staff trained in HIV education, advocacy, and health systems navigation into a patient's clinical care team.

Biospecimen Sample Self-collection for Routine ART-related Screenings

An important component of ART uptake and adherence is periodic testing. Types of testing for patients prescribed ART include testing for adequate levels of ART medication in blood samples, CD4 counts, and viral load. For those patients who have limited mobility and/or rely on others

for transportation, each additional clinic appointment can be burdensome. A more patient-centric approach to biospecimen collection includes supplementing telehealth services with new technologies that can bring support to some aspects of adherence and viral suppression to a patient's home (or local community). With advances in biomedical technology, special trips to the provider's clinic can be decreased or eliminated altogether. Instead of needing to travel to the provider's clinic, which in some instances may be far away, patients have the option of home self-collection or, for dried blood spot (DBS) collection and microtainer tubes, referral to other facility-based, mobile or community testing. In addition to reducing time and cost of traveling, other benefits include privacy and collection at the patient's convenience. In some cases, the lack of interaction with the clinical environment may also add to a feeling of anonymity for the patient, which supports medication adherence and retention in care.

Supplemental Service Provision by Community Health Workers (CHWs) and Others

CHWs enhance HIV care teams by working in partnership with case managers, nurses, doctors, social workers, and other service providers to address the medical, social, and economic needs of people living with HIV (PWH). CHWs play an important role in improving the health of clients and their communities and they also influence the program and the clinical setting in which they function. CHWs' unique ability to connect with the community can have an impact on all aspects of the Triple Aim of improving client experience, improving health care, and lowering cost. Table 1 lists common CHW roles as examples of how each role can be performed in one or more stages of the HIV Prevention and Care Continuum.

Table 1. Community Health Worker Role on the HIV Prevention and Care Continuum*

Role		**How the Role is Performed across the HIV Prevention and Care Continuum**
1.	Cultural Mediation Between Individuals, Communities and Health and Social Systems	Support and increase linkage to and retention in care and adherence to treatment by educating clients about treatment and the appropriate use of services
2.	Providing Culturally Appropriate Health Education and Information	Improve adherence to treatment by providing structured educational sessions on topics such as HIV, viral life cycle, treatment, and side effects
3.	Care Coordination, Case Management, and System Navigation	Support retention in care by assisting clients with referrals for transportation, housing, behavioral health treatment, and other support services
4.	Providing Coaching and Social Support	Support retention in care and treatment adherence by providing emotional support to clients
5.	Advocating for Individuals and Communities	Support the entire HIV Care Continuum by serving on Ryan White Planning Councils
6.	Building Individual and Community Capacity	Support retention in care and reduce barriers by collaborating with medical, behavioral health, and social services providers

7.	Providing Direct Service	Support treatment adherence by picking up prescriptions for clients and educating them on the medication and its side effects
8.	Implementing Individual and Community Assessments	Support linkage to and retention in care by working with case managers to assess clients' needs and develop care plans
9.	Conducting Outreach	Support linkage to and retention in care by re-engaging clients lost to follow-up
10.	Participating in Evaluation and Research	Document activities in electronic health records

*Amended from Rosenthal EL, Rush CH, and Allen CG. (2016) Understanding Scope and Competencies. A Contemporary Look at the United States Community Health Workers Field. Progress Report of the Community Health Worker (CHW) Core Consensus Project. Building National Consensus on CHW Core Roles, Skills, and Qualities. Available at: https://chwcentral.org/resources/understanding-scope-and-competencies-a-contemporary-look-at-the-united-states-community-health-worker-field/

Other TeleART Enhancements

Beyond biospecimen sample self-collection and integrating Community Health Workers (CHW) into a patient's clinical care team, this NOFO is seeking any other strategies that may enhance TeleART with MMPRs to sustain or improve clinically stable patients on ART. Other strategies to integrate into a TeleART with MMPRs practice might include, but are not limited to:

- Interactive voice response (IVR) systems to remind patients when it is time to take their medicine or to schedule medical visits and screenings
- Monthly care coordination telephone calls or text messages
- Medication reminder packaging such as weekly pillboxes or multidrug punch cards

From Demonstration to Evidence: Building on Lessons Learned

In 2017, CDC funded *PS17-1710: Telemedicine to Improve HIV Care among Minority Persons Living with HIV in Urban Areas (henceforth referred to as PS17-1710 or "Telemedicine Demo Project")*. The intent of the Telemedicine Demo Project was to create and implement a telemedicine program to reduce barriers associated with decreased retention in HIV care and increase service delivery accessibility and efficiency. Challenges experienced during a demonstration project may be incorporated into research designed to establish evidence of effectiveness for a particular policy, intervention, strategy or set of strategies. With the goal of identifying evidence of effectiveness and cost-effectiveness for TeleART in the US, important lessons learned from the Telemedicine Demo Project have been incorporated into this research NOFO and include:

1. Agency capacity to conduct telehealth services that include multi-month ART prescription refills is critical to program success.
2. Agency capacity to conduct 3rd-party (e.g., Ryan White HAP) billing for reimbursement is vital to implementing program activities.

3. Adequate staffing essential to implementing activities "as intended". Sufficient staffing needed to demonstrate evidence of effectiveness for TeleART include technology assistance for patients (e.g., patient navigator, phone hotline), cost expert(s), and information technologists to assist with adapting electronic health record (EHR) systems to accommodate the research study design (e.g., enabling digital signature solutions for patients needing to sign documents at a telemedicine visit).
4. Obtaining needed data relying on a data collection plan for gathering and managing data on viral loads and the presence of ART in blood samples that are self-collected by participants.
5. Providing continuity of services requiring established guidance, training, and policies regarding how to conduct telehealth appointments, including allotting adequate time to address patient concerns.

Lessons learned from the Telemedicine Demo Project are key features of this research NOFO and should inform the development of competitive proposals by demonstrating sufficient organizational capacity to implement and evaluate proposed telehealth strategies.

Hybrid Effectiveness-Implementation Research on Enhanced TeleART

Whereas the traditional model of diffusion of effective interventions is to first establish intervention efficacy and then evaluate implementation of an effective intervention in real-world settings, this model typically takes a substantial amount of time getting what works to those who need it most. The more expedient way to reach and intervene with persons with HIV for ART adherence and retention in care may be to promote examination of both effectiveness and implementation outcomes within a single study. Such hybrid effectiveness-implementation research designs can bypass the traditional research process that has historically supported a staged, linear approach to evidence-based intervention development.

The goal of the research supported by this NOFO is to: 1) address barriers identified in previous telehealth efforts funded by the CDC's Division of HIV Prevention to increase or maintain retention in HIV care and ART adherence; 2) evaluate the effectiveness of TeleART with multi-month prescription refills to in-person clinical visits; and 3) determine if additional strategies further support medication adherence and retention in HIV care. Proposed strategies should aim to reduce required in-person clinic visits and reallocate staff resources while continuing to provide high-quality medical evaluation, care, and treatment for persons with HIV.

Whereas the primary focus of the research supported by this NOFO is to test the effectiveness of strategies implemented to support TeleART with MMPRs and subsequent retention in HIV care and ART adherence, a secondary focus should be to explore, via a process evaluation and qualitative assessment of a sub-set of patients, providers, and other clinic staff, implementation-related research questions, such as: "Were the strategies implemented as intended?" "What worked or did not work and why?", "What elements need to be adapted for a particular setting or group of people" and "What is needed to support patients, providers, and clinics to realize clinical outcomes?".

Demonstrating maintenance and/or improvement of HIV continuum of care outcomes as a result of this research may support future care and treatment models that reduce more costly interactions with healthcare systems by persons who are effectively maintaining their adherence

to ART, and shift resources to those patients who need more intensive support.

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Health Equity:

CDC supports efforts to improve the health of populations disproportionately affected by infectious diseases by maximizing the health impact of public health services, reducing disease incidence, and advancing health equity.

A health disparity occurs when a health outcome is seen to a greater or lesser extent between populations. Health disparities in infectious diseases are inextricably linked to a complex blend of social determinants that influence which populations are most disproportionately affected by these infections and diseases.

Social determinants are conditions in the places where people live, learn, work, and play that affect a wide range of health and quality-of life-risks and outcomes (https://www.cdc.gov/socialdeterminants/index.htm). These 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 challenges. 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 health disparities are eliminated.

Applicants should use data, including social determinants data, to identify communities within their jurisdictions that are disproportionately affected by infectious diseases and related diseases and conditions, and plan activities to help eliminate health disparities. In collaboration with partners and appropriate sectors of the community, applicants should consider social determinants of health in the development, implementation, and evaluation of specific efforts and use culturally appropriate interventions and strategies that are tailored for the communities for which they are intended.

Healthy People 2030 and other National Strategic Priorities

The research supported by this NOFO should address the "Healthy People 2030" focus area of HIV. Specifically, this research should aim to:

1. Reduce new HIV infections.
2. Increase (and/or maintain) access to care and improve health outcomes for people living with HIV.
3. Reduce HIV-related disparities and health inequities.

The research supported by this NOFO should align with the Ending the HIV Epidemic in the U.S. (EHE) Initiative and CDC DHAP Strategic Plan to: 1) reduce the number of people infected with HIV; 2) increase access to care and optimize health outcomes for people with HIV; and 3) reduce HIV-related disparities.

- Ending the HIV Epidemic in the United States - https://www.hiv.gov/ending-hiv-epidemic
- Secretary's Minority HIV/AIDS Fund (MAI) - https://www.hiv.gov/federal-response/smaif/overview
- CDC Winnable Battles - https://www.cdc.gov/winnablebattles/report/docs/winnable-battles-final-report.pdf
- The United States National HIV/AIDS Strategy and National Strategic Plan (2022-2025) – https://www.hiv.gov/federal-response/national-hiv-aids-strategy/national-hiv-aids-strategy-2022-2025
- HIV/AIDS Care Continuum: https://www.hiv.gov/federal-response/policies-issues/hiv-aids-care-continuum
- National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) Strategic Plan through 2020 – https://www.cdc.gov/nchhstp/strategicpriorities/

Public Health Impact

The research supported by this NOFO should address the DHHS initiative *Ending the HIV Epidemic* in the United States. The research should address one of the four strategies to reduce the number of Americans who are infected with HIV, specifically:

1. Treat the infection rapidly and effectively to achieve sustained viral suppression: Patients will be provided with antiretroviral therapy (ART) and maintained on treatment.

The research supported by this NOFO should address the CDC Winnable Battle – HIV Elimination.

Relevant Work

The research supported by this NOFO should build upon previous and current HIV prevention programs, including:

CDC-RFA PS17-1710: Telemedicine to Improve HIV Care among Minority Persons Living with HIV in Urban Areas – https://www.grants.gov/grantsws/rest/opportunity/att/download/261720

CDC-RFA PS13-1311: Science-Based Translation of Effective Program Strategies (STEPS) to Care – https://www.grants.gov/grantsws/rest/opportunity/att/download/186993

The research supported by this NOFO should complement current and future CDC HIV prevention programs and initiatives to End the HIV Epidemic in the US (www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview).

2. Approach

This hybrid effectiveness-implementation research study (i.e., evaluating an intervention while gathering information on its delivery during the effectiveness trial and/or on its potential for implementation in real world settings) should tailor an existing telehealth program to improve HIV service delivery and maintain retention in care for clinically stable patients with HIV in EHE jurisdictions serving predominantly racial/ethnic minority PWH. The research study is expected to demonstrate the short-term and intermediate outcomes depicted in the logic model (Figure 1). Additionally, this study should identify facilitators and challenges to implementing any proposed enhanced telehealth strategies into routine practice.

Study Design

To accomplish the objectives of this NOFO, the application should describe a plan to assign, via randomization or some other unbiased assignment, clinically stable patients on ART to study conditions that include TeleART with MMPRs. Applications should compare outcomes with a TeleART with MMPRs only condition to any number of telehealth enhancement conditions (see Background for examples) and to a contemporaneous or previous/historical in-person clinical care condition. The study goal should be maintaining ART adherence and retention in care for those currently adherent and improving these outcomes for those not adherent or fully engaged in care.

Participating Clinics and Other Agencies

To recruit participants into the study, applicants who do not have direct access to the study population should partner with any number of local clinics currently providing telehealth

services to persons prescribed ART (for a definition of participating clinics/agencies, please see the "Collaboration/Partnerships" section of this NOFO).

Participating clinics/agencies should implement telehealth appointments for ART monitoring with MMPRs and proposed enhancement strategy or strategies. Participating clinics/agencies should also allow access to providers and clinic staff to conduct quantitative (e.g., surveys) and qualitative assessments (e.g., focus groups, interviews) regarding implementation of the proposed strategies. The application should describe the procurement and distribution of study materials and the hiring and training of study-related staff (e.g., CHWs, patient navigators, staff to conduct qualitative assessments). If biospecimen sample self-collection is proposed, participating clinics/agencies should be responsible for managing the receipt and reporting of sample results collected and provided by patients. The application should describe a plan for coordinating with participating clinics/agencies to abstract patient EHR data (i.e., medication and appointment adherence, viral load suppression, and CD4 counts) at each study data collection time point.

Figure 1. Category 1: NOFO Logic Model for Research on Telehealth Strategies to Support Retention and Adherence to Antiretroviral Therapy (TeleART)

Inputs	Illustrative Activities	Outputs	Short-term Outcomes (Year 2)	Intermediate Outcomes (Year 3-4)	Long-term Outcomes
•HIV prevalence surveillance data to identify locations in need of increasing viral suppression & ART adherence, especially among Black/African American (B/AA) or Hispanic/Latino (H/L) persons •If applicable, partnerships with clinics located in EHE priority jurisdictions providing HIV care and Tx to Black cis-gender women, BMSM, HMSM, and/or transgender women •Existing telehealth programs provided by participating clinics/agencies •Engage consultants who are subject matter experts (SMEs) on telemedicine program planning, marketing and implementation	•Hire & train staff •Develop study protocol, including QA •If proposed, develop SOPs for providing linkage & referrals for supportive services to participants in need •If proposed, link & refer participants in need of additional support services (e.g., housing, mental health, etc.) •Purchase materials (e.g., DBS kits) •Identify baseline data on participant-level ART appointment & medication adherence & viral suppression •Track ART adherence (via presence of ART medication in blood samples) & appointment adherence •Assess participant satisfaction with services received •Assess provider/clinic staff satisfaction with implementation of TeleART with MMPR and other proposed strategies	•Staff hired and trained on project activities and target populations; •Materials (e.g., DBS kits) purchased •Study protocol, QA, and M&E plan developed and implemented •Supportive services identified and utilized when needed •Participants recruited and enrolled in study, especially Black cis-gender women, BMSM, HMSM, and/or transgender women •Receipt of samples from participants (e.g., DBS cards, microtainer) •Assessment of participant, provider and staff satisfaction •Determine cost per person receiving each set of services	•Increased # of ART patients served via telemedicine w/ MMPRs •Increased # of ART patients served via one or more additional strategies to support TeleART •Routine submission of deidentified patient outcome data & cost data to CDC	•Stable /improved ART appointment adherence •Stable/ improved ART medication adherence •Stable/ increased viral suppression •Cost comparison & effectiveness of the proposed strategies	•Reduced HIV treatment-related disparities among Black cis-gender women, BMSM, HMSM, and/or transgender women •Reduced costs to maintain or improve ART adherence and retention in care

Note: ART = antiretroviral therapy; MSM = men who have sex with men; BMSM = Black/African American MSM; HMSM = Hispanic/Latino MSM; SMEs = subject matter experts; MMPRs = multi-month prescription refills; CHW = community health worker; SOPs = standard operating procedures; QA = quality assurance; DBS = dried blood spot; M&E = monitoring and evaluation

Research Design Methodology

The application should focus on EHE jurisdictions with high rates of HIV infection among populations disproportionately affected by HIV, particularly Black cis-gender women, and/or Black or Hispanic/Latino MSM, and/or transgender women. Furthermore, the application should provide a detailed description of investigator experience and ability to conduct research on telehealth services and HIV care and treatment among racial/ethnic and sexual minority populations.

The application should propose a research design that compares the effectiveness of the specified

study conditions to each other and compared with in-person clinical visits. If proposing multiple populations (e.g., Black and Hispanic/Latino MSM) the application should include population-specific sub-analyses. The evaluation design should include patient-level baseline data for key study outcomes (i.e., medication and appointment adherence, viral load suppression, and CD4 counts) and follow-up data for these outcomes post-enrollment. Key outcome data should be easily accessible via EHR data abstraction, including data on outcomes with in-person clinical visits that could pre-date telehealth visits as a standard practice. If proposing multiple populations (e.g., Black and Hispanic/Latino MSM) the application should include population-specific sub-analyses.

The research design should meet published standards for interventions with "best-evidence" of efficacy in reaching optimal HIV treatment and prevention outcomes.† These standards from the scientific literature have been summarized and are discussed in greater detail at https://www.cdc.gov/hiv/research/interventionresearch/compendium/ma/criteria.html. The description of the research design and analytic plan should include the following:

- Prospective design;
- Concurrent control group (e.g., patients with available EHR data that are not assigned to one of the study conditions);
- An unbiased assignment (e.g., random assignment) to study groups;
- One baseline and a minimum of one follow-up assessment of the intervention and control groups. At least one follow-up assessment should occur at least 3 months post-enrollment. Follow-up data may be abstracted from electronic medical records (EHR);
- A strategy to retain at least 70 percent of participants at all follow-up assessments in each of the study groups;
- Relevant outcomes (please see NOFO section on "Objectives/Outcomes"); and
- A proposed sample size for each study condition large enough to measure and compare several key outcomes, across strategies, with high precision (i.e., able to detect differences greater than 10 percentage points with an exact statistical test at the 5% significance level and a minimum of 80% power). The sample size calculation should use reasonable expected values for these outcomes, such as values for ART adherence rates within 12 months of enrollment based on most recent clinic adherence rates at time of application. The sample size calculation should also account for participant attrition (e.g., loss-to-follow-up). The actual proportions and attrition rate used in the sample size calculations should be justified based on published studies. The proposed sample size calculation should clearly list the underlying assumptions and describe the statistical methods used.

The application should include a *plan for analysis* that includes the following:

- A comparison of outcomes in groups as originally assigned (i.e., intent-to-treat analyses)
- Use of appropriate cluster-level analyses, if assigned to study groups by cluster or group

Description of Study Activities

The application should propose a project that has two phases: 1) a planning, development and approvals phase; and 2) a study implementation, monitoring and evaluation phase beginning on

or before Budget Year 2 through the end of the project. Applications should include objectives written in the SMART format (e.g., Specific, Measurable, Achievable, Realistic and Time-bound).

The application should provide information to describe the planning and implementation phases, including:

- Description of the current telehealth program, including demographic and clinical data on participating PWH patients for each participating clinic/agency. This description should also incorporate current treatment practices for patients prescribed ART who are seen in the clinic, including frequency of in-person clinic visits, patient flow, and appointment wait times.
- Plan to tailor the current telehealth program to address the requirements of the NOFO, including plan to implement proposed strategies to support telehealth appointments.
- Plan to develop culturally appropriate TeleART marketing materials for people from racial, ethnic, and sexual minority groups (e.g., cis-gender Black women, and/or Black or Hispanic/Latino MSM and/or transgender women). This plan should include a description of the marketing strategy for TeleART to all eligible patients and that subject matter experts (SMEs) will provide input on material development. SMEs might include local HIV care providers, clinic staff, health department staff and other relevant HIV care providers external to clinical settings with various skills and expertise relevant to telehealth, strategies to support telehealth, and minority PWH populations.
- Plan for recruitment and enrollment of patients and staff to be interviewed, including plans for institutional review board (IRB) approval.
- Process for routine abstraction of clinic record data from patients' EHR, with quality assurance and for program evaluation.
- If applicable, a description of procedures to refer participants in any study condition to other essential services as needed, such as housing, mental health, substance use, job training, education.
- Description of the role for Community Health Worker or patient navigator.
- Plan for identifying and addressing the needs of study participants who:
    - fall below the minimum threshold for medication adherence, as determined by the physician
    - request a clinical visit in lieu of a telehealth visit, both short- and long-term
- Plan for engaging staff or consultants for extracting cost data and conducting costs and cost-effectiveness analysis for the intervention(s) versus control conditions.
- Description of research plan that includes implementation-related research questions (e.g., What worked or didn't work and why? What elements need to be adapted and for whom? Is implementation of the proposed strategies into routine care acceptable, feasible and sustainable?).

Additional Study Activities

For those applications proposing to implement biospecimen sample self-collection, the following descriptions should also be included:

- Description of the proposed options for obtaining biologic specimens for patients enrolled in the study. This should include patients on ART who can provide biospecimens collected at home or other locations, outside of the study clinic. Laboratory tests to be conducted on the biospecimens collected would be based on current clinical practice, and could include testing for sexually transmitted infections, presence of ART medications, HIV viral load, CD4 cell count, and other tests deemed necessary by the clinical provider;
    - If DBS or microtainer collection is provided, the recipient has the option of submitting the DBS cards or microtainer to another testing facility for obtaining test results;
- Plan for fulfilling shipment of biologic sample collection and testing materials to patients.

Study Timeline

Applications should describe the ability to work cooperatively with CDC to obtain Office of Management and Budget (OMB) approval for proposed process and outcomes data collected for inclusion in the OMB Paperwork Reduction Act (PRA) package.

The application should align research activities to the following schedule and timeline:

- Year 1: Develop study design and protocol for study implementation; obtain local IRB approval; develop quality assurance plan, monitoring and evaluation (M&E) plans, data collection systems, OMB materials, referral procedures and study implementation and outcomes tracking and monitoring systems. Develop materials, program design, and systems prior to submission for IRB approval. Initiate the development and purchase of materials and systems for implementation of study activities. Pilot-test all materials and systems. Hire and train staff on study protocol.
- Year 2: Implement study. Following OMB approval, begin collecting and reporting de-identified patient outcomes (from EHR) and cost data.
- Year 3: Continue implementing the study, and reporting patient outcome and cost data.
- Year 4: Interview a subset of patients, providers, and other clinic staff to evaluate facilitators and barriers to implementation. Complete all data transfer from clinics to recipient. Conduct data analyses and prepare reports for dissemination.

† Efficacy Criteria| MA | Compendium | Intervention Research | Research | HIV/AIDS | CDC. Criteria for best evidence can be found here: Medication Adherence Chapter Best Evidence Efficacy Criteria (cdc.gov) and good evidence here: Medication Adherence Chapter Good Evidence Efficacy Criteria (cdc.gov).

Objectives/Outcomes

The work supported by this NOFO should seek to accomplish the following hybrid effectiveness-implementation research objectives:

1. To maintain or improve retention in care and adherence to ART for clinically stable PWH while using enhanced telehealth services.

2. To identify potential facilitators and challenges to implementation and determine feasibility, acceptability, and sustainability of implementing TeleART with multi-month prescription refills, as well as additional strategies supportive of TeleART.

Recipients are expected to demonstrate progress toward achieving the study outcomes listed in the logic model. Indicators for each of the short-term and intermediate outcomes depicted in the logic model are described below.

Short-term Outcomes (Year 2)

- Outcome #1: Increased number of clinically stable ART patients served via telehealth with MMPR
    - Indicator 1a: Number and percent of ART patients attending at least one TeleART appointment quarterly.
    - Indicator 1b: Number and percent of ART patients receiving MMPR for ART quarterly.
- Outcome #2: Stable or improved ART medication adherence
    - Indicator 2a: Presence of ART medication in blood samples of patients on ART tested quarterly or as clinically indicated.
    - Indicator 2b: VL of <200 copies/ml of blood in patients on ART tested quarterly or as clinically indicated.
- Outcome #3: Increased number of clinically stable ART patients served by one or more additional strategies supportive of TeleART with MMPRs.
    - Indicator 3: Number and percent of ART patients receiving one or more additional strategies supportive of TeleART with MMPRs.
- Outcome #4: Routine submission of de-identified EHR and cost data
    - Indicator 4a: Periodic submission of all predetermined EHR and cost data from all clinics to recipient.
    - Indicator 4b. Periodic analysis of all predetermined EHR and cost data.

Intermediate Outcomes (Years 3-4)

- Outcome #5: Stable or improved ART appointment adherence
    - Indicator 5: Number and percentage of patients attending 100% of their scheduled TeleART appointments as clinically indicated.
- Outcome #6: Stable or improved ART medication adherence
    - Indicator 6: Number and percentage of ART patients with study-defined minimum concentration of ART present in blood sample (e.g., TFV-DP ≥1,250 fmol/punch).
- Outcome #7: Stable or increased viral suppression among ART patients
    - Indicator 7: Number and percentage of ART patients with VL of <200 copies/ml of blood as clinically indicated.
- Outcome #8: Cost comparison and effectiveness of the proposed strategies for 12 months.

- Indicator 8a: Estimated unit cost to implement TeleART with MMPRs and each proposed supportive strategy.
- Indicator 8b: Annual total cost and average cost per strategy, participant, and outcome for each strategy.

Target Population

Applications should focus activities on priority populations, with particular emphasis on Black cis-gender women, and/or Black or Hispanic/Latino MSM, and/or transgender women.

Research and implementation activities should be designed so that they are accessible and available to all patients on ART, and especially to racial/ethnic minorities at greatest risk for acquiring HIV, or experiencing greater barriers to viral suppression. Disparities by race, ethnicity, gender identity, sexual orientation, socioeconomic status, disability status, primary language, health literacy, and other relevant dimensions (e.g., tribal communities) should be considered when developing the proposed study and identifying the target population. Proposals should describe services to one or more of the priority groups and all study activities should result in measurable maintenance or improvements among target populations. However, all clinic patients should be included in the implementation study design.

Collaboration/Partnerships

Participating Clinics and Other Agencies
Applicants who do not have direct access to their proposed study population should propose formal partnerships with clinics/agencies able to participate in this study (e.g., referred to in this NOFO as "participating clinics/agencies"). A participating clinic/agency is defined as a local clinic or agency that agrees to partner with the recipient to implement study activities. Participating clinics/agencies should:

- Provide ART treatment for people with HIV, specifically one or more of the following: Black cis-gender women, and/or Black or Hispanic/Latino MSM, and/or transgender women. To reach the intended population, it is recommended that at least 30% of the population of persons served by participating clinics/agencies identify as Black or Hispanic/Latino;
- Primarily serve patients in one of the 48 EHE priority counties, Washington, DC, Puerto Rico, or the seven states with a substantial number of HIV diagnoses in rural areas (Alabama, Arkansas, Kentucky, Mississippi, Missouri, Oklahoma, and South Carolina);
- Have an existing telehealth program/system in place; and
- Use an EHR system.

Memoranda of Agreement or Understanding (MOA/MOU), letters of commitment, or service agreements should be provided to document proposed and current partnerships with participating clinics.

Guidelines for MOU/MOA with Participating Clinics

Applications should demonstrate that there is an MOU/MOA with all participating clinics signifying commitment to engage in the proposed study activities. Each MOU/MOA should be submitted with the application.

The purpose of each MOU/MOA is to set forth the responsibilities of the applicant and the participating clinic/agency relative to the proposed goals of the project. The MOU/MOA should indicate a commitment of participation for the entire four-year project period.

Each MOU/MOA should include:

- An effective date range that aligns with all four (4) years the NOFO.
- Commitment of the participating clinic to work with the recipient and other collaborative partners to address project requirements, including the designation of a HIV program lead dedicated to the implementation of required activities.
- Acknowledgment that the clinic or agency meets each of the criteria stated in the NOFO for participating clinics/agencies.
- Overview of the participating clinic or agency's plan and the estimated budget for implementing required study activities, including: 1) workforce development, 2) infrastructure development, 3) HIV prevention and treatment service delivery, and 4) evaluation and quality improvement.
- Confirmation that the participating clinic/agency can coordinate and receive reimbursement for telehealth visits, including for patients with health coverage through the Ryan White program.
- Confirmation that the clinic or agency's participation in the project will not result in a reduction of the level or quality of primary care services currently provided to patients served by the clinic.
- Agreement that the recipient will engage clinic/agency representatives in relevant study-related meetings and processes, where appropriate, and that the clinic/agency will participate accordingly.
- Commitment of the recipient to work with the clinic and other collaborative partners to address project requirements, including the designation of a point of contact among the study team dedicated to the implementation of study activities.
- Commitment of the clinic/agency to either participate in, or assist recipient with, required data reporting and evaluation activities, including EHR data abstraction.
- Signatures for both parties by authorized representatives and Principal Investigators.

Evaluation/Performance Measurement

The application should include measurable goals and aims based on a four (4)-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.

Evaluation and performance measurement help demonstrate achievement of proposed program

outcomes; build a stronger evidence base for specific program strategies; clarify applicability of the evidence base to different populations, settings, and contexts; and drive continuous program improvement. Proposed evaluation and performance measurement can also determine if program strategies are scalable and effective at reaching target populations.

Applications should provide an evaluation and performance measurement plan that is consistent with their work plan and the evaluation and performance measurement strategy. The application should describe evaluation activities.

The strategy for monitoring and evaluating programs and recipients' performance should include several activities, spanning both process monitoring and evaluation, and monitoring of outcomes, and will be consistent with the logic model and approach previously presented.

The application should provide the following information to describe the proposed evaluation design:

- Description of experience and ability to develop a rigorous, prospective research design to evaluate the effectiveness of each strategy.
- Process for collecting baseline information on patient clinic record demographics, HIV treatment history, and HIV risk category (e.g., MSM).
- Process for consenting and collecting interview data from a group of patients, providers, and other staff. This should occur approximately 2 months after completing program participation and after 12 months follow-up for patients, and at end of the implementation research study for providers and other staff. The purpose is to assess patient and provider satisfaction, barriers and facilitators to strategy implementation, and other feasibility, acceptability, and sustainability measures.
- Plans for abstracting necessary data to evaluate appointment and medication adherence from EHR data.
- Description of an evaluation design that allows for ongoing comparison of the study conditions, and each condition compared to in-person clinic visits. Historic clinic data and patient-level data at baseline can be used for comparison. The research design should allow for a limited number of specific modifications to materials or strategies within a pre-determined scope that does not change the core elements of the strategies being evaluated.
- Description and justification of the proposed study design, including sample size, power, and effect size, as described in the Research Design Methodology section of this NOFO.
- Description of the proposed process evaluation plan that includes assessments of implementation-related research questions, as described in the Research Design Methodology section of this NOFO.
- Description of the proposed data management plan detailing data access, data sources, data collection methods, and sharing of the data during and at the completion of research study.
- Description of a quality assurance plan. The quality assurance (QA) plan to be developed during the first year should include a thorough written description of all project activities
- Description of the recruitment and retention of clinically stable ART patients.
- Description of plan for replacement of patients in study arms, if needed.

Translation Plan

When relevant to the goals of the research project, the application should describe how the findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. The proposed translation plan 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.

At the conclusion of the project, the recipient should provide a final report with details on background, literature review, methods, data analysis, results, and discussion. The final report should also include a translation plan on how the recipient will disseminate the model program to other health care providers nationally. Additional data and results may be submitted as appendices to the report. Other dissemination products may include the development of conference presentations and peer-reviewed publications. The dissemination of final outcome products may include the development of conference presentations and peer-reviewed publications and may be subject to CDC clearance.

3. Funding Strategy

N/A

Section II. Award Information

Funding Instrument Type:
CA (Cooperative Agreement)
A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

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

Estimated Total Funding:
$3,600,000

Estimated Total Annual Budget Period Funding, including direct and indirect costs:

Year 1: $900,000 ($350,000 to $450,000 per award)
Year 2: $900,000 ($350,000 to $450,000 per award)
Year 3: $900,000 ($350,000 to $450,000 per award)
Year 4: $900,000 ($350,000 to $450,000 per award)

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

indirect costs: $900,000

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

Anticipated Number of Awards:
2
Awards issued under this NOFO are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Award Ceiling:
$450,000
Per Budget Period

Award Floor:
$350,000
Per Budget Period

Total Period of Performance Length:
4 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 (https://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.
If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR Part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:
00 (State governments)

01 (County governments)

02 (City or township governments)

04 (Special district governments)

05 (Independent school districts)

06 (Public and State controlled institutions of higher education)

07 (Native American tribal governments (Federally recognized))

08 (Public housing authorities/Indian housing authorities)

11 (Native American tribal organizations (other than Federally recognized tribal governments))

12 (Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education)

13 (Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education)

20 (Private institutions of higher education)

22 (For profit organizations other than small businesses)

23 (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 an applicant requests a funding amount greater than the ceiling for the first budget period as indicated in Section II. of this NOFO, HHS/CDC will consider the application non-responsive and it will not enter into the review process. HHS/CDC will notify the applicant that the application did not meet the submission requirements.

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 Unique Entity Identifier (UEI) number in order to begin each of the following registrations.

PLEASE NOTE: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission. The UEI replaced the Data Universal Numbering System (DUNS) and is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and Grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: NCAGE Tool / Products / NCS Help Center (nato.int).
- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, SAM.gov.
- 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 Senior/Key Personnel (including Program Directors/Principal Investigators (PD/PIs) must also work with their institutional officials to register with the eRA Commons or ensure their existing Principal 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 an 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 Unique Entity Identifier (UEI) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The UEI number is a twelve-digit number assigned by SAM.gov. An AOR should be consulted to determine the appropriate number. If the organization does not have a UEI number, an AOR should register through SAM.gov. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a UEI number.

Additionally, 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.gov 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 SAM.gov and the SAM.gov Knowledge Base.

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 UEI 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 NOFO 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 entity identifier [UEI] number) is allowed.

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants will use a system or platform to submit their applications through Grants.gov and eRA Commons to CDC. ASSIST, an institutional system to system (S2S) solution, or Grants.gov Workspace are options. ASSIST is a commonly used platform because, unlike other platforms, it provides a validation of all requirements prior to submission and prevents errors.

To use ASSIST, applicants must visit https://public.era.nih.gov 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: http://grants.nih.gov/support/index.html

- Email: commons@od.nih.gov
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552.
  Hours: Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding Federal holidays.

2. Content and Form of Application Submission

Applicants must use FORMS-G application packages for due dates on or before January 24, 2023 and must use FORMS-H application packages for due dates on or after January 25, 2023.

Application guides for FORMS-G and FORMS-H application packages are posted to the How to Apply - Application Guide page.

It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide How

to Apply - Application Guide 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.

Please use the form and instructions for SF424 (R&R) FORMS-H for this application.

Please note: 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.

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".

Please note: Follow the instructions in this NOFO for including a **Data Management Plan** in the **Resource Sharing Plan section of the PHS 398 Research Plan Component** of your application.

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

Mandatory

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

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

Optional

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

3. Letter of Intent

Due Date for Letter Of Intent 02/17/2023

02/17/2023

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

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

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

The letter of intent should be sent to:
Gregory Anderson, MPH, MS
Extramural Research Program Office

Office of the Associate Director of Science
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road, MS US8-1
Atlanta, GA 30329
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 at How to Apply - Application Guide 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 at How to Apply - Application Guide 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).

CDC OMB approved templates may be used (e.g. NCCDPHP template https://www.cdc.gov/chronicdisease/pdf/nofo/DMP-Template-508.docx)

Other examples of DMPs may be found here: USGS, http://www.usgs.gov//products/data-and-tools/data-management/data-management-plans

Applicants must use FORMS-G application packages for due dates on or before January 24, 2023 and must use FORMS-H application packages for due dates on or after January 25, 2023.

Application guides for FORMS-G and FORMS-H application packages are posted to the How to Apply - Application Guide page.

Please use the form and instructions for SF424 (R&R) FORMS-H for this 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".

Please note: Follow the instructions in this NOFO for including a **Data Management Plan** in the **Resource Sharing Plan section of the PHS 398 Research Plan Component** of your application.

Please note: According to the Additional Requirement-25 (AR-25)(https://www.cdc.gov/grants/additional-requirements/ar-25.html), investigators who plan to collect public health data must submit a Data Management Plan (DMP) in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application as follows. The DMP must describe how investigators will make data readily available. Investigators who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds. A Data Management Plan (DMP) is required for each collection of public health data proposed. The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include **the following five elements**:

- A description of the data to be collected or generated in the proposed project.
- Standards to be used for the collected or generated data.
- Mechanisms for, or limitations to, providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights - this section should address access to identifiable and de-identified data).
- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use.
- 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).

Examples of DMPs may be found here: USGS, http://www.usgs.gov//products/data-and-tools/data-management/data-management-plans

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 publicly 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 of this NOFO, excess pages will be removed from the application prior to peer review and may

negatively affect the application's scoring.

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 20 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 50 pages for all appendices. Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

8. Format for Attachments

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

CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide at .How to Apply - Application Guide.

Applicants must use FORMS-G application packages for due date on or before January 24, 2023 and must use FORMS-H application packages for due dates on or after January 25, 2023.

Application guides for FORMS-G and FORMS-H application packages are posted to the How to Apply - Application Guide page.

Please use the form and instructions for SF424 (R&R) FORMS-H for this application.

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. Applicants will use a platform or system to submit applications.

ASSIST is a commonly used platform because it provides a validation of all requirements prior to submission. If ASSIST detects errors, then the applicant must correct errors before their application can be submitted. Applicants should view their applications 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 must be 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 03/17/2023

03/17/2023
Electronically submitted applications must be submitted no later than 11:59 p.m., ET, on the listed application due date.

10. 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, in 45 CFR Part 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.

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

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 (45 CFR 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) Applications submitted under this notice of funding opportunity must not include activities that overlap with simultaneously funded research under other awards (no scientific, budgetary or percent effort overlap allowed).

2) **Please note:** Certain grants or recipients are not eligible for expanded authorities. In addition, one or more expanded authority may be overridden by a special term or condition of the award. The Notice of Award (NoA) will indicate the applicability of expanded authorities by reference to the HHS Grants Policy Statement or through specific terms and conditions of the award. Therefore, recipients must review the NoA to determine whether and to what extent they are, or are not, permitted to use expanded authorities.

3) 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. Please see Section IV.2 of this NOFO, "Content and Form of Application Submission" for guidance on single IRB (sIRB) Plan content.

4) 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.

5) 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).

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

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

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

11. 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. 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 UEI.

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.

Please also note: 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.

Application Submission

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

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

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

Important reminders:

All Senior/Key Personnel (including any Program Directors/Principal Investigators (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.

It is also important to note that for multi-project applications, this requirement also applies to the individual components of the application and not to just the Overall component.

The applicant organization must ensure that the UEI 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?

- What is the potential or actual impact of the proposed research on HIV prevention and treatment as a public health issue in the US?
- If successful, how will the research results influence or change current public health practices that target adherence to, and retention in, HIV prevention, care, and treatment?
- How well does the proposal address models of telehealth for ART?

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

- Does the application provide a detailed description of the investigators' experience and ability to successfully conduct research on delivery of HIV treatment (ART) among racial/ethnic and sexual minority populations?
- Does the application provide a detailed description of the investigators' experience and ability to successfully recruit, enroll and deliver HIV treatment (ART) programs for racial/ethnic and sexual minority populations (directly or in collaboration with partner agencies)?

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 applicant's proposed approach seek to substantially build upon existing telehealth models of prevention and treatment?
- Do the proposed telehealth models have the potential to be sustainable beyond the period of performance?
- Does the project have the potential to increase access to prevention and care for persons at greatest risk of acquiring and transmitting HIV infection?
- Is the program likely to result in reducing barriers to services?

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?

- Are the proposed study locations in EHE jurisdictions with high rates of HIV infection, particularly populations disproportionately affected by the HIV epidemic?
- Does the application provide a sufficient detailed description of a current telehealth program being implemented at each participating clinic, including client demographics (e.g., race, gender, HIV risk transmission category) and clinical outcomes (e.g., VL, CD4 count)?
- Does the application provide a sufficient description of the plan to tailor the current telemedicine program to address the requirements of the NOFO?
- Does the application provide a sound plan for conducting a qualitative assessment of a subset of participating patients and staff?
- Does the application describe a sound plan and process for identifying and addressing participants who:
    - fall below the minimum threshold for medication adherence?
    - request a clinical visit in lieu of a telemedicine visit, both short- and long-term?
- If applicable, does the application package include Memoranda of Agreement or Understanding (MOA/MOU) for each clinic/agency proposed as a partner? Did each MOU/MOA include details outlined in the Collaborations/Partnerships section of the NOFO?
- Does the application propose an appropriate evaluation design that includes staffing for cost analyses?

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?

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/additional-requirements/ar-1.html).

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

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

Vertebrate Animals
The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following four points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 4) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (https://grants.nih.gov/grants/olaw/VAChecklist.pdf).

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

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

For more information about this Policy and other policies regarding dual use research of concern, visit the U.S. Government Science, Safety, Security (S3) website

at: http://www.phe.gov/s3/dualuse. Tools and guidance for assessing DURC potential may be found at: http://www.phe.gov/s3/dualuse/Pages/companion-guide.aspx.

3. Additional Review Considerations

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

Applications from Foreign Organizations

N/A

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/additional-requirements/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.

CDC OMB approved templates may be used (e.g. NCCDPHP template

https://www.cdc.gov/chronicdisease/pdf/nofo/DMP-Template-508.docx

Other examples of DMPs may be found here USGS, http://www.usgs.gov//products/data-and-tools/data-management/data-management-plans

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/application-resources.html

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

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

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

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

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

4. Review and Selection Process

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

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

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

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

Review of risk posed by applicants.
Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.

In accordance with 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 45 CFR Part 75, subpart F, 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 UEI, 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).

PLEASE NOTE: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission. The UEI is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and Grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

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/

Specific requirements that apply to this NOFO are the following:

Generally applicable ARs:
AR-1: Human Subjects Requirements
AR-2: Inclusion of Women and Racial and Ethnic Minorities in Research
AR-3: Animal Subjects Requirements
AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements
AR-11: Healthy People 2020
AR-12: Lobbying Restrictions
AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities
AR-14: Accounting System Requirements
AR-16: Security Clearance Requirement
AR-21: Small, Minority, And Women-owned Business
AR-22: Research Integrity
AR-23: Compliance with 45 C.F.R. Part 87
AR-24: Health Insurance Portability and Accountability Act Requirements
AR-25: Data Management and Access
AR-26: National Historic Preservation Act of 1966
AR-28: Inclusion of Persons Under the Age of 21 in Research
AR-29: Compliance with EO13513, "Federal Leadership on Reducing Text Messaging while Driving", October 1, 2009
AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973
AR 31 - Distinguishing Public Health Research and Public Health Nonresearch
AR 32 – FY 2012 Enacted General Provisions
AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern
AR-36: Certificates of Confidentiality
AR-37: Prohibition on certain telecommunications and surveillance services or equipment for all awards issued on or after August 13, 2020.

ARs applicable to HIV/AIDS Awards:
AR-4: HIV/AIDS Confidentiality Provisions
AR-5: HIV Program Review Panel Requirements
AR-6: Patient Care

Organization Specific ARs:
AR-8: Public Health System Reporting Requirements
AR-15: Proof of Non-profit Status
AR-23: Compliance with 45 C.F.R. Part 87

The full text of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, 45 CFR 75, can be found at: https://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75

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

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS will be required to complete an HHS Assurance of Compliance form (HHS 690) in

which you agree, as a condition of receiving the grant, to administer your programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, age, sex and disability, and agreeing to comply with federal conscience laws, where applicable. This includes ensuring that entities take meaningful steps to provide meaningful access to persons with limited English proficiency; and ensuring effective communication with persons with disabilities. Where applicable, Title XI and Section 1557 prohibit discrimination on the basis of sexual orientation, and gender identity. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider- obligations/index.html and https://www.hhs.gov/civil-rights/for- individuals/nondiscrimination/index.html.

- For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.
- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

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 applies 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: https://www.plainlanguage.gov/.

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 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: https://www.cdc.gov/grants/additional-requirements/ar-25.html
- 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-supported 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 recipient 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.

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: https://www.cdc.gov/grants/additional-requirements/ar-25.html
- 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

Areas of Joint Responsibility include:

- Collaborating in the development of human subject research protocols and additional documents for IRB review by all cooperating institutions participating in the project and for OMB review, if needed.
- For applications that are successfully funded under this NOFO, the recipient agrees that upon award, the application, and the summary of reviewers' comments for the application, may be shared with the CDC staff who will provide technical assistance, as described above. The recipient organization will retain custody of and have primary rights to the information, data, and software developed under this award, subject to U.S. Government rights of access and consistent with current HHS/CDC grant regulations and policies.

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

- Named in the Notice of Award as the Program Official to provide overall scientific and programmatic stewardship of the award.
- Serve as the primary point of contact for official pre-award activities and for all 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.
- Monitor performance against approved project objectives.

5. Reporting

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

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

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

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.

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

A. Submission of Reports

The Recipient Organization must submit:

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 (**Reporting | Grants | CDC) is required and must be submitted to the Payment Management System accessed through the FFR navigation link in eRA Commons or directly through PMS **within 90 days after 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 contribute 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 budget period. 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.

Additional resources on the Payment Management System (PMS) can be found at https://pms.psc.gov.

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 period of performance. 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).

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

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

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

- Research Aim/Project Overview: The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.
- Translation of Research Findings: The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the Period of Performance. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.
- Public Health Relevance and Impact: This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.
- Publications; Presentations; Media Coverage: Include information regarding all publications, presentations or media coverage resulting from this CDC-funded activity. Please include any additional dissemination efforts that did or will result from the project.
- Final Data Management Plan: Applicants must include an updated final Data Management Plan that describes the data collected, the location of where the data is stored (example: a repository), accessibility restrictions (if applicable), and the plans for long term preservation of the data.

6. Termination

CDC may impose other enforcement actions in accordance with 45 CFR 75.371- Remedies for Noncompliance, as appropriate.

The Federal award may be terminated in whole or in part as follows:

(1) By the HHS awarding agency or pass-through entity, if the non-Federal entity fails to comply with the terms and conditions of the award;

(2) By the HHS awarding agency or pass-through entity for cause;

(3) By the HHS awarding agency or pass-through entity with the consent of the non-Federal entity, in which case the two parties must agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated; or

(4) By the non-Federal entity upon sending to the HHS awarding agency or pass-through entity written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the HHS awarding agency or pass-through entity determines in the case of partial termination that the reduced or modified portion of the Federal award or subaward will not accomplish the purposes for which the Federal

award was made, the HHS awarding agency or pass-through entity may terminate the Federal award in its entirety.

7. Reporting of Foreign Taxes (International/Foreign projects only)

A. Valued Added Tax (VAT) and Customs Duties – Customs and import duties, consular fees, customs surtax, valued added taxes, and other related charges are hereby authorized as an allowable cost for costs incurred for non-host governmental entities operating where no applicable tax exemption exists. This waiver does not apply to countries where a bilateral agreement (or similar legal document) is already in place providing applicable tax exemptions and it is not applicable to Ministries of Health. Successful applicants will receive information on VAT requirements via their Notice of Award.

B. The U.S. Department of State requires that agencies collect and report information on the amount of taxes assessed, reimbursed and not reimbursed by a foreign government against commodities financed with funds appropriated by the U.S. Department of State, Foreign Operations and Related Programs Appropriations Act (SFOAA) ("United States foreign assistance funds"). Outlined below are the specifics of this requirement:

1) Annual Report: The recipient must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 – September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the recipient did not pay any taxes during the reporting period.]

2) Quarterly Report: The recipient must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.

3) Terms: For purposes of this clause:

"Commodity" means any material, article, supplies, goods, or equipment;

"Foreign government" includes any foreign government entity;

"Foreign taxes" means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.

4) Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in which you are carrying out the activities associated with this cooperative agreement. In countries where there is no CDC office, send reports to VATreporting@cdc.gov.

5) Contents of Reports: The reports must contain:

a. recipient name;

b. contact name with phone, fax, and e-mail;

c. agreement number(s) if reporting by agreement(s);

d. reporting period;

e. amount of foreign taxes assessed by each foreign government;

f. amount of any foreign taxes reimbursed by each foreign government;

g. amount of foreign taxes unreimbursed by each foreign government.

6) Subagreements. The recipient must include this reporting requirement in all applicable subgrants and other subagreements.

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 of Science
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road, MS US8-1
Atlanta, GA 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 of Science
National Center for HIV, Viral Hepatitis, STD and TB Prevention
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Atlanta, GA 30329
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Email: GAnderson@cdc.gov

Financial/Grants Management Contact
Sharon Cassell
Office of Financial Services/Office of Grants Services
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road, MS TV-2
Atlanta, GA 30329
Telephone: 770-488-2703
Email: SCassell@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 of Federal Regulations.

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

NOFO-specific Glossary and Acronyms

Antiretroviral Therapy (ART): Any HIV treatment that uses a combination of two or more drugs. A healthcare provider may choose to prescribe a combination of three or more drugs to improve the treatment's chance of success.

Appointment Adherence: The ratio of number of medical visits a patient attended by the number of medical visits scheduled in a given time period.

ART Adherence: A patient's ability to follow a treatment plan, take medications at prescribed times and frequencies, and follow restrictions regarding food and other medications.

Biospecimen Sample Self-collection: A natural specimen such as blood, urine, oral fluid, or other tissue that is collected by the patient without assistance from another person.

Cis-gender: Denoting or relating to a person whose sense of personal identity and gender corresponds with their birth sex.

Community Health Worker (CHW): Staff who primarily work in underserved communities and are a resource to help advance goals of improved care coordination, health equity, and population health. CHWs assist individuals and communities by working in a broad range of capacities that include care coordination, case management, health coaching, health education, health assessment and screening, resource linking, medication management, remote care, patient follow-up, and social and literacy support. Other names for CHWs include health advocates, lay health educators, community outreach workers, health coaches, and patient navigators. CHW training and educational requirements vary across states, cities, employers, and employment sectors, but CHWs typically have a high school diploma with on-the-job training.

Cost-effectiveness Analysis (CEA): A type of economic analysis where both the cost and the outcome (impact, result, effect, benefit, health gain, etc.) of an intervention or strategy are evaluated and then expressed in the form of a cost-effectiveness ratio. The numerator of the cost-effectiveness (CE) ratio represents the cost of the intervention or strategy associated with one unit of "outcome". The denominator is the unit of outcome. It can be expressed using many types of measures including years of life gained, quality-adjusted life years gained (QALYs), new diagnoses, infections averted, and deaths averted.

Differentiated Service Delivery (DSD): A recommended approach to service delivery that simplifies and/or adapts HIV prevention and treatment services to more effectively and efficiently serve the needs of people living with and at risk of acquiring HIV while reducing unnecessary burdens on the healthcare system.

Dried Blood Spot (DBS) Cards: A card on which one or more drops of blood are collected, dried, packaged and sent to a laboratory for analyses.

Ending the HIV Epidemic in the U.S. (EHE): A bold plan announced in 2019 that aims to end the HIV epidemic in the United States by 2030. Agencies across the U.S. Department of Health and Human Services (HHS) developed an operational plan to pursue that goal accompanied by a request for additional resources that were provided by Congress.

Evaluation (Program Evaluation): The systematic collection of information about the activities, characteristics, and outcomes of programs (which may include interventions, policies, and specific projects) to make judgments about that program, improve program effectiveness, and/or inform decisions about future program development.

Evaluation Plan: A written document describing the overall approach that will be used to guide an evaluation, including why the evaluation is being conducted, how the findings will likely be used, and the design and data collection sources and methods. The plan specifies what will be done, how it will be done, who will do it, and when it will be done. The NOFO evaluation plan is used to describe how activities will be implemented appropriately and how outcomes will be achieved.

Health Equity: Striving for the highest possible standard of health for all people and giving special attention to the needs of those at greatest risk of poor health, based on social conditions.

Implementation Science: The scientific study of methods and strategies that facilitate the uptake of evidence-based practice and research into regular use by practitioners and policymakers.

IRB: An Institutional Review Board is a committee within an agency, university or organization that has been formally designated to review research involving human subjects.

Logic Model: A visual representation showing the sequence of related events connecting the activities of a program with the programs' desired outcomes and results.

Medication Adherence: A pre-determined concentration of medication (e.g., tenofovir diphosphate (TFV-DP), ≥1,250 fmol/punch) in a patient's blood sample.

Memoranda of Agreement or Understanding (MOA/MOU): Document that describes a bilateral or multilateral agreement between parties expressing a convergence of will between the parties, indicating an intended common line of action. It is often used in cases where the parties either do not imply a legal commitment or cannot create a legally enforceable agreement.

Microtainer Tubes: A small tube with a screw cap that allows the collection of skin punctured capillary blood collection.

Multi-month Prescription Refills (MMPRs): The recommended practice of allowing people who are stable on their HIV treatment (e.g., ART) to collect enough medication to cover three or six months – therefore minimizing unnecessary visits to healthcare facilities. Also known as multi-month scripting (MMS)**.**

Office of Management and Budget (OMB): Oversees the performance of federal agencies and administers the federal budget.

Paperwork Reduction Act (PRA): The Paperwork Reduction Act (PRA) of 1995 requires that agencies obtain Office of Management and Budget (OMB) approval before requesting most types of information from the public. "Information collections" include forms, interviews, and record keeping, to name a few categories.

Patient Navigator: Patient Navigators work one-on-one with patients to encourage continued commitment and adherence to medical treatment, access to social services, improved communication, and prompt re-engagement in care.

Patient Portal: A secure online website that gives patients convenient, 24-hour access to personal health information from anywhere with an Internet connection. Using a secure username and password, patients can view health information such as recent doctor visits, lab results, request prescription refills, and view educational materials. A patient portal can save a patient time, help them communicate with their doctor, and support care between visits.

Quality Assurance (QA): Planned, step-by-step activities that let one know that implementation is being carried out correctly, results are accurate, and mistakes are found and corrected to avoid

adverse outcomes. Quality assurance is an ongoing set of activities that help to ensure that the results provided are as accurate and reliable as possible.

Retained in care: The percentage of persons with diagnosed HIV who had two or more CD4 or viral load tests performed at least three months apart.

TeleART: A convenient method that allows a patient prescribed an antiretroviral therapy (ART) to virtually connect, using a personal electronic device, to their medical provider in lieu of in-person medical or clinic visits without having to leave their home or community. Patients can see, hear, and speak to a provider to discuss their ART medical care by phone and/or video chat.

Telehealth: The use of electronic information and telecommunication technologies to provide care when the patient and the medical provider are not in the same place at the same time.

Workforce Development: Employment initiatives offered by agencies and government offices that help create, sustain, and retain a viable workforce. The objective of workforce development is to create economic prosperity for individuals, businesses, and communities.