Centers for Disease Control and Prevention

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

A Bridge to Adherence: Long-Acting Antiretroviral Therapy for People with HIV Released from Prison

RFA-PS-24-042

03/01/2024

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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

A Bridge to Adherence: Long-Acting Antiretroviral Therapy for People with HIV Released from Prison

Activity Code

U01 – Research Project - Cooperative Agreements

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-PS-24-042

Assistance Listings Number(s)

93.084

Category of Funding Activity

HL - Health

NOFO Purpose

This Notice of Funding Opportunity (NOFO) is designed to understand the feasibility and acceptability of providing long-acting injectable antiretroviral therapy (LAI-ART) to incarcerated persons with HIV who are soon to be released from state prison facilities. The ultimate goal is to support the development and implementation of effective, sustainable, replicable LAI-ART programs. People with HIV living in prison facilities are often released to the community lacking support for ongoing HIV care. There is a paucity of programs for this

population demonstrating effectiveness with retention in care and maintaining sustained HIV viral suppression after release. The use of LAI-ART prior to and at the time of release from prison may improve adherence to HIV treatment, retention in care, and maintenance of viral load suppression among persons reentering the community. Applied qualitative and quantitative research resulting from this funding is expected to strengthen adherence to ART and is aligned with the HIV National Strategic Plan (2022-2025) and the Ending the HIV Epidemic in the U.S. (EHE) initiative “Treat” Pillar.

Key Dates

Publication Date:

To receive notification of any changes to RFA-PS-24-042, 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:

02/01/2024

02/01/2024

Application Due Date:

03/01/2024

03/01/2024

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:

05/01/2024

Secondary Review:

06/06/2024

Estimated Start Date:
09/01/2024

Expiration Date:
03/02/2024

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 12 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:** This Notice of Funding Opportunity (NOFO) is designed to understand the feasibility and acceptability of providing long-acting injectable antiretroviral therapy (LAI-ART) to incarcerated persons with HIV who are soon to be released from state prison facilities. The ultimate goal is to support the development and implementation of effective, sustainable, replicable LAI-ART programs. People with HIV living in prison facilities are often released to the community lacking support for ongoing HIV care. There is a paucity of programs for this population demonstrating effectiveness with retention in care and maintaining sustained HIV viral suppression after release. The use of LAI-ART prior to and at the time of release from prison may improve adherence to HIV treatment, retention in care, and maintenance of viral load suppression among persons reentering the community. Applied qualitative and quantitative research resulting from this funding is expected to strengthen adherence to ART and is aligned with the HIV National Strategic Plan (2022-2025) and the Ending the HIV Epidemic in the U.S. (EHE) initiative “Treat” Pillar.
- **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 **$3,000,000**. The number of awards will be **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) will be **$750,000** with individual awards of **$375,000** for the first year. The estimated total funding (direct and indirect) for the entire project period will be **$3,000,000**. The project period is anticipated to run from **09/01/2024 – 08/31/2028**.
- **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) Form 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

Sections 301(a) and 317(k)(2) of the Public Health Service Act; 42 U.S.C. Sections 241(a) and 247b(k)(2).

1. Background and Purpose

Of the 1.5 million persons living in state and federal prisons in the United States, 1.3% are living with HIV — a prevalence more than three times that of the general population. Many persons with HIV (PWH) living in state or federal prisons have access to regular HIV care, treatment, and support. For this reason, rates of HIV continuum of care metrics, such as receipt of antiretroviral therapy (ART) prescription and viral suppression, are often better for PWH while they are living in prison compared to after their release to the community. Negative outcomes like lower ART adherence, subsequent viral rebound, and potential HIV transmission to sexual and substance-using partners during community reentry can be attributed in part to social and structural factors such as HIV- and incarceration-related stigma, substance use relapse, unmet basic needs such as food, transportation and housing, and low levels of social support. Among PWH released from the California state prison system with viral load testing performed 91 days to 1-year post-release, only 11% were virally suppressed.

Each year, approximately 6,500 PWH are released from prison to the community. Previous work among people who have lived in prison has focused on HIV service delivery interventions, such as intensive, community-based transitional case management or individual sessions to increase

awareness and reduce risk of HIV. However, there is a paucity of programs with demonstrated effectiveness at sustaining HIV viral suppression after release. Intervening with PWH prior to release to the community is a critical point of engagement, to provide HIV care and continuity that extends back to the community.

Long-acting injectable ART (LAI-ART) simplifies therapy and may facilitate maintenance of virologic suppression during the transitional time of community reentry. Cabotegravir and rilpivirine injectable formulation (Cabenuva) is now approved as a complete regimen for the treatment of HIV in virally suppressed adults with HIV. Currently, this regimen must be injected every 4 or every 8 weeks. Modeling suggests that LAI-ART may be most cost-effective in individuals with barriers to adherence to daily oral therapy; those released from prisons may encounter such barriers and LAI-ART may be a valuable tool to assist them with maintaining viral suppression post-release.

In areas other than HIV, long-acting injectables have been used successfully at community reentry to overcome barriers to care and adherence. Extended-release naltrexone, a monthly injectable medication for the treatment of opioid use disorder, is currently utilized for people living in prisons and at community reentry. The implementation of injectable naltrexone may have provided a logistic and ethical foundation for the implementation of LAI-ART.

In an effort to address disparities in HIV care continuum metrics for PWH after release to the community, in 2020 CDC published and funded RFA-PS20-2011 “Strategies to Maintain HIV Viral Suppression among State Prison Inmates Released to the Community,” which directs programs to utilize HIV surveillance data to identify people living in correctional facilities with HIV, and to provide enhanced pre-release planning and post-release monitoring of linkage, retention, and viral suppression. Building upon RFA-PS20-2011, the purpose of this NOFO is to support the development and implementation of effective, sustainable and replicable LAI-ART programs for correctional facilities and to understand the feasibility and acceptability of providing LAI-ART to persons with HIV living in prisons who are to be released to the community. Primary outcomes of interest include HIV continuum of care metrics such as timely linkage to and retention in HIV care, adherence to HIV treatment, and suppression of HIV viral load following release from prison. Secondary outcomes of interest include acceptability and feasibility measures collected from surveys or interviews of organization units, consultants, providers, and patients (during and after incarceration, when feasible).

The transition period from incarceration to the community is a particularly critical time for PWH, and ensuring continuity of care and treatment is vital. The intervention proposed—LAI-ART at and prior to time of release—may result in improved retention in care and sustainable viral suppression during the critical transitional time of release. The intervention entails pre-release navigation, counseling for PWH about the use of LAI-ART, and a post-release care plan including linkage to a medical provider in the community to ensure continuity of HIV care. This proposed project will implement and evaluate LAI-ART use among people soon to be released from prisons to the community, and the effects of such use on achievement and maintenance of HIV care continuum metrics. Applied qualitative and quantitative research resulting from this funding is expected to strengthen adherence to ART and is aligned with the HIV National Strategic Plan (2022-2025) and the Ending the HIV Epidemic in the U.S. (EHE) initiative “Treat” Pillar. Findings from this study may strengthen and expand LAI-ART programs and be

used to expand access across the United States and should inform future CDC and partner programming.

Healthy People 2030 and other National Strategic Priorities

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 Objectives

- HIV-1: Reduce the number of new HIV infections
- HIV-3: Reduce the number of new HIV diagnoses
- HIV-5: Increase viral suppression
    - HIV National Strategic Plan (2022-2025) https://www.hiv.gov/federal-response/national-hiv-aids-strategy/national-hiv-aids-strategy-2022-2025/

National Goals

- Goal 1: Prevent new HIV infections
    - 1.3: Expand and improve implementation of effective prevention interventions, including treatment as prevention, pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP) and syringe service programs (SSPs), and develop new options.

- Goal 2: Improve HIV-related health outcomes of people with HIV
    - 2.3: Increase retention in care and adherence to HIV treatment to achieve and maintain long-term viral suppression and provide integrative HIV services for HIV-associated comorbidities, coinfections, and complications, including STIs
    - 2.4: Increase the capacity of the public health, health care delivery systems, and health care workforce to effectively identify, diagnose, and provide holistic care and treatment for people with HIV

- Goal 4: Achieve integrated, coordinated efforts that address the HIV epidemic among all partners and interested parties
    - 4.2: Increase coordination among and sharing of best practices from HIV programs across all levels of government (federal, state, tribal, local, and territorial) and with public and private health care payers, faith-based and community-based organizations, the private sector, academic partners, and the community.
    - 4.4: Foster private-public-community partnerships to identify and scale up best practices and accelerate HIV advances

Ending the HIV Epidemic in the U.S. https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview

- Goal: Reducing new HIV infections by 75% by 2025 and 90% by 2030.

Public Health Impact

To achieve a 90% reduction in new HIV infections by 2030, people with HIV (PWH) will need to be effectively treated with ART rapidly and maintain viral suppression. Increasing the number of PWH that adhere to and maintain viral suppression on ART will help prevent new HIV infections in the United States and further the goals of Ending the HIV Epidemic (EHE) in narrowing HIV-related health disparities. This project may contribute to federal, state, and local community efforts that are aligned with meeting the goals of the EHE Initiative, the National HIV/AIDS Strategy, and the Healthy People 2030 goals and objectives.

The National HIV/AIDS Strategy for the United States 2022-2025 states that there are missed opportunities for HIV diagnosis and linkage to community care after release in the majority of prison systems. This project will examine to what extent LAI-ART can improve HIV clinical outcomes among PWH living in prison nearing release to the community, and will provide critical information on feasibility, sustainability, and acceptability of LAI-ART implementation in state prisons. LAI-ART has the potential to overcome many possible barriers to adherence, thereby decreasing further transmission and incident HIV cases. By identifying how to successfully implement LAI-ART programs in correctional settings with referrals/linkage to care post-release, we can learn how to support and provide individuals with uninterrupted ART during community reentry which can lead to increased and sustained viral suppression, with attendant benefits to the individual, and for HIV treatment as prevention at the community level. The barriers and facilitators identified to LAI-ART use and adherence can be disseminated and leveraged to support implementation of LAI-ART in additional prison settings. Findings from this study may also strengthen and expand LAI-ART programs and inform future CDC and partner programming. From the partnerships built with this NOFO, relationships between health departments and prisons may be strengthened.

Relevant Work
This research NOFO builds upon existing research efforts by the CDC and partners to develop combined HIV interventions for priority populations and scale up their implementations across the United States.

Published programmatic announcements related to Ending the HIV Epidemic in the United States, and the elimination of viral hepatitis in the United States:

- PS20-2011: Strategies to Maintain HIV Viral Suppression Among State Prison Inmates Released to the Community https://www.grants.gov/web/grants/view-opportunity.html?oppId=323273
- PS19-1906: Strategic Partnerships and Planning to Support Ending the HIV Epidemic in the United States: https://www.cdc.gov/hiv/funding/announcements/ps19-1906/index.html
- PS20-2010: Integrated HIV Programs for Health Departments to Support Ending the HIV Epidemic in the United States: https://www.cdc.gov/hiv/funding/announcements/ps20-2010/index.html

NOFO activities will support 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

<table>
<tr><th>Strategies
& Activities</th><th>Short-term
Outcomes</th><th>Intermediate-term Outcomes</th><th>Long-term
Outcomes</th></tr>
<tr><td colspan="4"><u>Logic Model:</u> A Bridge to Adherence: Long-acting Antiretroviral Therapy for People with HIV Released from Prison</td></tr>
<tr><td colspan="3"><u>Strategy 1</u>:
Use HIV surveillance, prison medical records and other available data to identify persons with diagnosed HIV (PWH) living in prison and monitor their HIV care status and clinical outcomes pre- and post-release</td><td rowspan="2"><u>L-T Outcome 1</u>:
Increased viral suppression among PWH released from prison

<u>L-T Outcome 2</u>:
Decreased transmission of HIV from PWH released from prison

<u>L-T Outcome 3</u>:</td></tr>
<tr><td><u>Activity 1.1</u>:
Establish collaboration between state health and corrections departments to use HIV surveillance, corrections, and other data to (1) identify PWH living in prison projected to be released in 2-6 months, so pre-release planning can be conducted; and (2) monitor</td><td><u>S-T Outcome 1.1</u>:
Identification and health monitoring of all PWH living in state prisons and projected to be released to the community within six months</td><td><u>I-T Outcome 1.1.</u>:
Pre-release HIV prevention and care planning provided to all PWH living in state prison and projected to be released within six months

<u>I-T Outcome 1.2</u>:</td></tr>
</table>

their HIV care status and clinical outcomes pre- and post-release		Identification of PWH not linked to HIV medical care within 30 days after release	Reduced HIV infections in the community **<u>L-T Outcome 4</u>:** Improved HIV-related health outcomes for PWH released from prison **<u>L-T Outcome 5</u>:** Reduced HIV-related health disparities and improved health equity **<u>L-T Outcome 6</u>:** Integrated and coordinated programming for LAI-ART
<u>Strategy 2</u>: **Increase LAI-ART understanding and access in prison settings by implementing use pre- and at-release**			
<u>Activity 2.1</u>: Develop and implement a sustainable program of LAI-ART in state prison settings to further understand setting-specific implementation/health outcomes and conduct comparative analyses with current standard of care **<u>Activity 2.2:</u>** Examine acceptability and barriers to implementation of LAI-ART in state prison settings, from both patient and staff/provider perspectives	**<u>S-T Outcome 2.1</u>:** Development of a health care delivery model for implementing LAI-ART for persons being released from prison **<u>S-T Outcome 2.2</u>:** Improved awareness and understanding of LAI-ART by staff, providers, clients, and patients **<u>S-T Outcome 2.3</u>:** Improved local collaborator engagement and mobilization for LAI-ART as HIV treatment **<u>S-T Outcome 2.4:</u>** Development of analyses of the HIV care continuum in patients receiving	**<u>I-T Outcome 2.1</u>:** Improved capacity to provide LAI-ART with increased availability of and access to HIV treatment **<u>I-T Outcome 2.2</u>:** Increased number of PWH on LAI-ART and/or on ART **<u>I-T Outcome 2.3</u>:** Increased knowledge of barriers, challenges, and facilitators to LAI-ART implementation and usage **<u>I-T Outcome 2.4</u>:** Enhanced HIV health outcomes monitoring of patients on LAI-ART	

	LAI-ART, including retention in care, maintenance of viral load suppression, and linkage to care.		
<u>Strategy 3</u>: **Coordinate relationships between prisons, health departments, and other public health partners to facilitate pre-release planning, service continuity after release, and the exchange of post-release clinical data.**			
<u>Activity 3.1:</u> Implement a sustainable program to (1) facilitate continuity of care and sustained HIV viral suppression for each participant released from state prison, and (2) help bridge the prison-to-community transition	**<u>S-T Outcome 3.1</u>:** Coordinated access to HIV medical care & other services to support continuity of care and HIV viral suppression for PWH released from prison **<u>S-T Outcome 3.2</u>:** Improved cross-agency coordination pre-release planning for PWH living in prison projected to be released from state prison within six months	**<u>I-T Outcome 3.1</u>:** Timely linkage to and continuity of HIV medical care and service delivery for PWH released from state prison **<u>I-T Outcome 3.2</u>:** Improved monitoring of retention in HIV medical care and sustained HIV viral load suppression for PWH released from state prison	

CDC is interested in exploring the following topics with LAI-ART:

1. **Feasibility and acceptability of LAI-ART:** Is the administration of monthly or every other month LAI-ART injections for HIV treatment in state prisons for persons soon to be released acceptable, feasible, and sustainable to people living in prisons, clinicians, prison staff, and other members of the care team? What factors affect this acceptability within-prison and post-release, and what challenges exist?
2. **Health outcomes of LAI-ART:** Are there differences in engagement and retention in care, viral suppression, and sustained viral suppression post-release by demographic or clinical characteristics for persons receiving LAI-ART compared to persons on oral

ART? Following release from state prison, do PWH continue to access HIV care and stay on treatment compared with current standard of care in the community?

3. **Cost savings**: What is the estimated cost per PWH, and is it cost-effective to implement utilization of LAI-ART in state prisons for persons soon to be released?

The primary purpose of this NOFO is to develop effective, sustainable, and replicable LAI-ART program models that support the continuity of HIV medical care and viral suppression for PWH released from state prisons into the community. Projects should emphasize identifying PWH, linkage to and retention in HIV medical care, adherence to ART, and HIV viral load suppression before and after community re-entry.

This NOFO supports recipients to develop and conduct a research study to compare an innovative implementation strategy of LAI-ART provision prior to release from prison. State health departments and their proposed contract agencies (e.g., community-based organizations; (CBOs)), if applicable, should partner with their respective department of corrections. The application should describe a study protocol that combines implementation and effectiveness outcomes. Primary outcomes can include HIV continuum of care metrics including linkage to and retention in HIV care, adherence to HIV treatment (self- or provider-reported or pharmacy data), and suppression of HIV viral load following release from prison. Secondary outcomes can include acceptability and feasibility measures collected from surveys or interviews of a convenience sample of prison administrative and clinical organization units, providers, and patients (during and after incarceration, when feasible).

The state department of corrections may be responsible for coordinating a regular (such as monthly) list with upcoming release dates. PWH who have a pending release date within 6 months (but no sooner than 2 months) and are eligible for recruitment into this project should be counseled about LAI-ART risks and benefits. Formative work may be conducted at project sites to assess and identify systems and relationships required for project implementation and completion. This could include assessing policies and procedures that would need to be revised to implement LAI-ART in the participating prisons. These results should be used to design an LAI-ART provision model that can be integrated into current facility practices and may include a model that has buy-in from the health departments, prisons, and community-based organizations, which would be modified as needed before implementation. An advisory board with member representation including formerly incarcerated PWH, prison advocacy community, and other relevant parties may provide input related to the implementation considerations and sensitivities.

Collaborating state prisons must detain people sentenced for at least 12 months in the facility. The study sites should operate within, or be affiliated with, prison and/or clinical facilities that have the infrastructure and staff for navigation of LAI-ART procurement, including issues of cost coverage/reimbursement, and LAI-ART medication initiation and administration. The application should describe collaborative partners (clinics, CBOs, health departments, state department of corrections), current organizational capacity, and the organizational/partners capacity to implement an LAI-ART model. The applicant should also have approval in writing from each participating prison warden or the head of the department of corrections in their respective states.

The application should outline a plan to undertake the project in two phases: (1) a development phase, and (2) an implementation and evaluation phase. The development phase of the project

may include an initial 12-month period to finalize the program strategies and activities (described below), complete a monitoring and evaluation plan, develop protocols, and obtain appropriate approvals. The scope of the project should be outlined in the application, based on contextual considerations, feasibility, and ability to integrate with or leverage existing staff and services. Following completion of the development phase, the implementation phase and analysis may last for the duration of the (4) four-year project period. The applicant is expected to develop study protocol, manual of operations and tools, including refining and detailing the target study enrollment, objectives and outcomes; conduct the study and data analyses; and disseminate aggregated findings with technical assistance from CDC, as warranted.

The applications should include description of qualitative and quantitative research to explore implementation outcomes. The recipients are expected to conduct formative work, use evaluative and iterative strategies to assess LAI-ART readiness in prison settings, and use pilot evaluation data to define and then refine the intervention model. Program evaluation data relevant to pre-implementation standard of care operations and potential post-implementation operations, staffing, and workflow may be assembled. Results from formative and assessment work may be used to design a deployable LAI-ART model in prison settings.

The application should use a qualitative and quantitative research approach that best fits the target population and goals and objectives of the research study. The design should address the following evaluative criteria: the proposed activities are ethical, use appropriate and rigorous methods, and address concept validity, verification, and reliability. The application should describe creating data sharing agreements between the partners and collaborators (which may include state correctional leaders, contractual medical services, health departments, and any subcontractors with prisoner advocacy experience). The collaborating clinics, where PWH are expected to receive care post-release, may utilize their current standards for acquisition of laboratory services and monitoring of treatment for patients who receive ART.

The project may involve training project staff and fielding the study protocol, the intervention implementation, and data collection and review. The application should include a plan to recruit, enroll, and follow PWH who are eligible for LAI-ART. The application should include an approach to recruit, educate, train, or provide interactive assistance to prison administrators, staff, providers, and collaborators. The study protocol and LAI-ART training should be standardized across the proposed prisons, to the extent possible. The application should describe plans for training, roles and responsibilities, and desired competencies of staff. Funding from this NOFO may be used to support department of corrections staff who are engaged in study activities.

The NOFO supports investigator-driven research and invites applicants to design, develop, and conduct data collection to meet the project goals outlined in the Purpose section, and project outcomes outlined in the Logic Model. The recipient will finalize the study instruments and protocols, including human subjects research (Institutional Review Board) protocols.

CDC scientists will provide technical assistance on aspects of study design and data analyses but will not lead or direct data collection activities. The findings from this research may be used by CDC, collaborators, and federal partners to support the development of programs that focus on providing LAI-ART to people soon to be released from prisons.

Applicants may consider a range of study designs, including non-randomized patient-preference designs. The project focuses on enrolling patients who are ART-experienced and virally suppressed on ART (see further eligibility details below). Health outcomes of patients enrolled and opting for LAI-ART can be compared to those of a virally suppressed control group of PWH receiving standard of care daily oral ART being released to community, with matched design or another method of adjustment for age, gender, and race/ethnicity. Implementation outcomes can be based on qualitative and quantitative data and can be compared between LAI-ART and oral standard of care groups, with consideration of RE-AIM framework (www.re-aim.org). Sample sizes may vary, as applicants should attempt to identify and enroll all eligible persons, though the goal of post-release outcomes would be approximately 75 PWH per prison facility.

Patient eligibility for LAI-ART may be determined from medical records maintained in state prison facilities. Included persons should be those living in prison aged 18 years and older, who are currently on oral ART for treatment of HIV with undetectable viral load (HIV-1 RNA less than 50 copies/mL) on a stable ART regimen, with no history of treatment failure, with no known or suspected resistance to either rilpivirine or cabotegravir, and who have a pending release date within 6 months (but no sooner than 2 months).

Enrollment of participants could occur for up to 24 months. Patients eligible for LAI-ART who are interested in LAI-ART and interested in participating in the study should undergo a study informed consent process and be offered the choice between continuing their oral agent or administration of LAI-ART. Consistent with HHS clinical guidance, each consented participant should receive at least two LAI-ART injections prior to release; one to ascertain tolerability and monitor for adverse reactions, and one within 14 days of release to serve as a bridge until their first HIV care provider appointment post-release. Applications should describe plans to collaborate with participating prisons, community providers and relevant CBOs to implement current standard of care linkage to community HIV services and provision of LAI-ART to ensure pre-release planning for PWH soon to be released. These efforts would include coordinating medical, behavioral health, and social services for those released from state prison to the community, as these are influential for appropriate continuum of care. The prisons should have long-standing relationships with local community service agencies and care providers that allow for in-person or virtual meetings between the agency staff and the PWH approximately 30 days prior to their release from custody. The community service agency should currently provide case management services that include linkage to community-provided services, such as health care, job training, housing, and mental health support. Through these partnerships, there is a goal of providing, and possibly strengthening, pre-release HIV prevention and care planning for PWH living in state prison and projected to be released within six months. Following linkage to community care, LAI-ART could be continued or a transition to oral ART could occur, depending on availability from health care providers and individual circumstances or preferences. To help bridge the prison-to-community transition, innovative approaches to support post-release linkage to care and retention are encouraged.

Health department HIV surveillance data, state department of corrections data, and data from other available sources (i.e., data-to-care methods or collaborating clinics) can be used to gather outcomes data for all released PWH for a minimum of 12 months after their release from prison. Applications should clearly outline data sources access, storage, transfer and security, as well as funding and capacity needs for collaborating governmental and non-government partners. Applicants may consider surveys/interviews of PWH pre-release, at-release, and post-release

(e.g., at 2,4, and 12 months) to gather data on patient and care team experiences with LAI-ART and perceived benefits, barriers, and challenges with the LAI-ART treatment modality. An assessment of why eligible participants chose to start LAI-ART or not could also be included. Clinical outcomes can also be compared with previously published HIV care continuum data among PWH released from that prison or with historic data provided by the site/state jurisdiction.

Objectives/Outcomes

The overall research objectives are to:

1. Implement an LAI-ART program for PWH in prisons who are scheduled for release to the community within the next two to six months;
2. Analyze LAI-ART clinical outcomes including linkage to and retention in HIV care, adherence to HIV treatment, and suppression of HIV viral load (primary outcomes) for 12 months post-release;
3. Analyze acceptability, feasibility, and cost of implementing pre-release LAI-ART injections (secondary outcomes).

A complete list of outcomes and associated indicators should be finalized in the first 6-months post award and can include technical assistance provided by CDC staff. Study research variables, outcomes, and tools **could include** (but are not limited to):

Research Variable Assessed	Study Sample(s)	Data Collection Tool(s)
Health Outcomes (Linkage to HIV medical care, retention in care, achieving and maintaining viral suppression)	Patients	Electronic Health Record in prison and community providers / Surveillance Data from health department
Implementation Process Measures (Strategies, adaptation, barriers, facilitators)	Facility and collaborator staff, consultants, clinicians	Survey, Interview
Implementation Context and Outcomes (Acceptability, feasibility, adherence, and sustainability)	Prison facility and collaborator staff, consultants, clinicians, and patients (during and after incarceration, when feasible).	Survey, Interview
Cost (labor and non-labor)	Staff/Location Setting	Cost Questionnaires

Implementation outcomes:

- Feasibility and acceptability of LAI-ART by patients, prison staff, administrators, and clinicians.
    - Assessed through surveys and interviews with physicians, staff, nurses, administrators, and PWH

    - Assessed through record review of PWH who are offered and accept study enrollment

- RE-AIM framework-based measures of sustainability (maintenance) and scalability (reach), which can include post-release partners that support continuity of services.
- Fidelity assessment (in addition to above):
    - Adherence to clinically recommended spacing between injection 1 and 2 (injection date and frequency)
    - Discontinuation rate

- Assessment of reasons why eligible participants chose to participate in LAI-ART or remain on oral standard of care.
- Assessment of barriers and facilitators to implementation of LAI-ART by survey of patients, providers, prison administrators/staff:
    - Insurance and payment structure
    - Clinic workflow
    - Privacy and workflow
    - Flexibility with appointment scheduling
    - Security issues
    - Fear, trust, stigma, personal preferences

Health outcomes:

- Care Continuum
    - Linkage to HIV care post-release: first clinic appointment kept within 30, 60 or 90 days

- Retention in HIV care (defined as 2 clinical and/or tele-health visits at least 3 months apart within 12 months OR as 2 HIV-related laboratory measures at least 3 months apart within 12 months) post-release
- Adherence to ART (i.e., injection date, self-report, prescription refill history)
- Missed date of injection data
    - Days from missed appointment to injection
    - Days from initial due date for injection to date received
    - Adverse events
    - Viral suppression at 2- and 4-months post-release
    - Maintenance of viral suppression(HIV VL<50 copies/mL) at 12 months post-release
    - Sustained, or durable viral suppression (defined as two consecutive suppressed HIV viral load results at least 3 months apart within 12 months or longer)

Cost outcomes:

- Cost data and savings to assess cost-effectiveness of intervention and associated adherence (i.e., based on disease state, maintenance of viral suppression, health improvement for PWH, and prevention of new infections achieved with LAI-ART compared to oral ART standard of care)

Target Population

The target population for this project are all persons living in state prison with HIV ≥ 18 years old who have a pending release date to the community within 2- 6 months and are clinically eligible to start LAI-ART, as per current U.S. clinical practice. Populations can include but are not limited to American Indian or Alaska Native, Asian, Black/African American, Native Hawaiian or Other Pacific Islanders, White, Hispanic/Latino, Migrant populations, Women, Older people (65+), Lesbian, Gay, Bisexual, and Transgender (LGBT) populations, and/or persons who inject drugs.

Collaboration/Partnerships

Local Jurisdiction

Application should describe plans to establish and maintain working partnerships with other CDC recipients in the jurisdiction (e.g., city and county health departments; directly-funded CBOs; and the state health department), as needed, and should communicate, collaborate, and coordinate with them to ensure effective delivery of HIV prevention activities consistent with CDC standards and guidance.

Strategic Partners

Applicants should establish, build, and maintain collaborative relationships with organizations that currently provide services to PWH released from prisons and will support implementation of the proposed LAI-ART intervention. Strategic partnerships must include state departments of corrections and affiliated prisons, and might also include the following types of organizations 1) parole agencies, and other state and relevant local government agencies; (2) CBOs and other agencies providing case management, service navigation and social services (e.g., housing support, job training); (3) medical facilities including federally qualified health centers (FQHCs), Ryan White HIV/AIDS Program treatment clinics, Veteran Administration facilities, LGBT health centers, STD clinics, hospitals, and specialty clinics; (4) substance use and mental health treatment centers; (5) other relevant federal agencies (e.g., the Health Resources and Services Administration [HRSA], the Centers for Medicaid and Medicare Services [CMS], and the Substance Abuse and Mental Health Services Administration [SAMHSA]; and (6) community advocates; community members; and other stakeholders that may have a vested interest in promoting health through HIV prevention, care, and treatment. Expectations for these collaborations include the development of data sharing processes and agreements to identify gaps, track client outcomes and facilitate evaluation of program effectiveness. In particular, Ryan White HIV/AIDS Program grant recipients across Part A (local jurisdictions), Part B (state health departments), Part C and Part D (community-based clinics and organizations) could be important partners in this program. Ryan White HIV/AIDS Program grant recipients have flexibility to provide core medical and support services in state prisons, on a transitional basis, if those services are not required to be provided by the prison (See HRSA HIV/AIDS Bureau Policy Clarification Notice 18-02 The Use of Ryan White HIV/AIDS Program Funds for Core Medical Services and Support Services for People Living with HIV Who Are Incarcerated and Justice Involved).

Clinical Care Partners

The application should describe plans to collaborate with clinics expected to provide HIV treatment to PWH post-release, health departments for surveillance, and department of

corrections for pre-release lists of eligible participants. Applications should describe operation of, or capability to, provide LAI-ART administration. The application should describe experience of effective collaboration with clinical providers.

Application should demonstrate the establishment of memoranda of understanding and data sharing and use agreements, as appropriate, to ensure LAI-ART program-related data are collected per protocol and available for harmonized cross-site analyses.

The application should propose formal partnerships with clinics that are eligible to participate in this study (referred to in this NOFO as "participating clinics"). A participating clinic is defined as a clinic that agrees to partner with the applicant to implement study activities. A participating clinic is deemed eligible if it:

- Provides ART treatment for people with HIV that are living in and/or released from state prisons.
- Agrees to: a) engage in the primary recruitment strategy, b) allow the award applicant access to patients, providers, and clinic staff to conduct quantitative and qualitative assessments of health outcomes and perceived challenges, barriers, and facilitators of LAI-ART anticipated and/or experienced, and c) provide space for interviews.
- Is not otherwise engaged in current, planned, or anticipated research activities that may hinder implementation of this project.

Guidelines for a MOU/MOA with State Health Departments, State Department of Corrections, and Participating Clinics

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

Applications should include an MOU/MOA with a participating clinical site and data contributors signifying a commitment to engage in the proposed study activities. All 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 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 or letter of support should include:

- An effective date range that aligns with all 4 years of the NOFO.
- Acknowledgment that the clinic meets each of the participating clinic eligibility criteria stated in the NOFO.
- A description of the activities the clinic, department of corrections, and/or state health department will provide.
- An overview of the participating clinic health department or department of corrections plan and the estimated budget for implementing required study activities.
- Agreement that the applicant will engage clinic representatives in relevant study-related meetings and processes and that the clinic will participate accordingly.

- Commitment of the applicant 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, department of corrections, and/or health department to either participate in, or assist applicant with, required data reporting and evaluation activities, including EMR data abstraction and HIV surveillance data.
- Signatures for both parties by authorized representatives.

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 project plan and describe the development and implementation of project performance measures based on specific programmatic objectives.

The evaluation plan should align with the stated purpose and outcomes described in the NOFO. Applicants should develop an implementation plan that includes a timeline to achieve study milestones and a staffing, recruitment, and enrollment plan.

The applicant should also collect and summarize background data on all participating health departments, potential clinics, and prison settings (including their location, HIV prevalence in the facility, and HIV care and treatment continuum outcomes among PWH in that area). In addition, agency background data should include services provided and the number of PWH clients served, including demographics and HIV care continuum outcomes.

The application should describe an evaluation plan which may include the following components:

- Non-discriminatory recruitment and enrollment of eligible PWH by sex, age, and race/ethnicity
- Clear collaborator roles and relationships
- Orientation and training on administering LAI-ART for participating prison clinical staff
- Tailoring of an intervention to local context and participating sites
- Integration of LAI-ART into prison facility routine HIV treatment for soon-to-be-released PWH
- Qualitative/quantitative assessment of provider/staff knowledge, attitudes, and beliefs about LAI-ART and feasibility/acceptability of LAI-ART from the provider/setting/systems perspective
- Qualitative/quantitative assessment of patient knowledge, attitudes, and beliefs about LAI-ART and feasibility/acceptability of LAI-ART
- Quantitative assessment of implementation, service, and patient objectives/outcomes outlined in this NOFO
- Post-study qualitative/quantitative assessment of prison health care provider and patient experiences with LAI-ART use
- Identification of barriers/facilitators to LAI-ART initiation and continued use
- Cost of the LAI-ART intervention at each site/location, including identifying resources, labor and non-labor costs

LAI-ART related patient evaluation measures (to the extent feasible):

- Completion of participant surveys with specification of the timepoints during the study to ascertain social determinants of health, attitudes around LAI-ART, and adherence to LAI-ART
- Number of patients virally suppressed and durably virally suppressed (defined as two consecutive suppressed HIV viral load results at least 3 months apart within 12 months or longer)
- Number linked to care
- Number retained in treatment with LAI-ART
- Number retained in treatment with ART (not LAI-ART)
- Number retained in care
- Number experienced side effects and documentation of side effects
- Number continued on LAI-ART following release from prison; subsequent missed/delayed injections and missed/delayed appointments

The application evaluation plan should also describe the inclusion of relevant protocols, including human subjects research (IRB) protocol development and approval. The evaluation plan should also include a quality assurance plan that ensures that the educational materials provided to patients and staff are accurate and up-to-date and that survey, focus group, and interview protocols are culturally appropriate and tailored for people with HIV.

Translation Plan

The strategies to decrease barriers to care following release from incarceration, provide linkage to HIV care, and increase treatment opportunities for LAI-ART should be evaluated to identify best practices for LAI-ART implementation in prison settings in an era of multiple ART options and delivery models. These best practices may be incorporated in CDC guidelines and support materials and may also serve as the basis for future implementation studies that aim to scale-up and expand the use of LAI-ART. CDC and the recipient may collaborate to disseminate key findings at national or international meetings and in peer-review journals, in addition to sharing findings with the department of corrections, state health departments, and Bureau of Prisons, as warranted.

Questions to consider in preparing this section of the application include:

- How will successful activities of this implementation research be identified?
- How will successful activities be incorporated into routine clinical practice and shared with prison medical services?
- How will this work guide scale-up of LAI-ART use and delivery models in the United States?
- How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs, community/non-clinic site, or practices?
- How will findings advance or guide future research efforts or related activities?

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:
$3,000,000
Estimated total funding available for the first year (first 12 months), including direct and indirect costs: $750,000

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

Estimated Total Annual Budget Period Funding:

Year 1: $750,000 for two (2) awards, $375,000 each award

Year 2: $750,000 for two (2) awards, $375,000 each award

Year 3: $750,000 for two (2) awards, $375,000 each award

Year 4: $750,000 for two (2) awards, $375,000 each award

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:
$375,000
Per Budget Period

Award Floor:
$285,000
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)

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

Additional Eligibility Category:

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

Hispanic-serving Institutions

Historically Black Colleges and Universities (HBCUs)

Tribally Controlled Colleges and Universities (TCCUs)

Alaska Native and Native Hawaiian Serving Institutions

Nonprofits (Other than Institutions of Higher Education):

Nonprofits (Other than Institutions of Higher Education)

Governments:

Eligible Agencies of the Federal Government

U.S. Territory or Possession

Other:

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

It is the applicant’s responsibility to ensure that the application meets all responsiveness criteria listed in this section. Applications that do not meet all of the following Responsiveness criteria

will be considered nonresponsive and will not be forwarded for peer review. The following criteria are required for responsiveness:

Memorandum of Understanding/Agreement (MOU/MOA) or Letter of Support (LOS)

MOU/MOA or LOS is required from participating sites and data contributors and included in the application, in the Letter of Support section.

Applicants must have approval in writing from each participating prison warden or the head of the department of corrections in their respective states. Applications without MOU/MOA or LOS when applicable will be deemed as non-responsive and will not enter into the review process. CDC will notify the applicant that the application did not meet the submission requirement.

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 (1) application per institution (normally identified by having a unique entity identifier [UEI]) 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 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 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.

Letters of Support (including MOU/MOA) 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: 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.

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 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.

Please provide a separate budget for each partner in addition to the total budget for all.

Please use the form and instructions on SF 424 (R&R) FORMS-H for applications due on or after January 25, 2023.

3. Letter of Intent

Due Date for Letter Of Intent 02/01/2024

02/01/2024
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:
Seraphine Pitt Barnes, PhD, MPH, CHES
Extramural Research Program Office
Office of the Associate Director of Science
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
Telephone: 770-488-6115
Email: SPittBarnes@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 applications due on or after January 25, 2023.

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.

N/A

7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 12 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 25 pages for all appendices. Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

8. Format for Attachments

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

CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide 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 applications due on or after January 25, 2023.

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 03/01/2024

03/01/2024
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 USG funding, or loss of future US Government (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/additionalrequirements/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. Documents uploaded for the Risk Questionnaire are not counted towards the page limit in Appendices.

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?

- Does the work have potential to result in a LAI-ART delivery model that increases LAI-ART use among PWH in prisons and/or soon to be released from prison?
- Does the application describe how the work will help to understand determinants of a successful implementation of LAI-ART in prison settings?
- Does the application use local epidemiologic and other relevant program or clinical data to demonstrate the need for improved implementation strategies to facilitate better outcomes for populations that may benefit from this research?
- Does the application propose a set of project activities that are methodologically strong, and yet realistic to accomplish, such that they will contribute significantly to HIV treatment implementation research in the United States?

- If successful, do the research results have the potential to be scalable and reach a large portion of populations at risk of ART non-adherence or PWH interested in LAI-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 demonstrate that the investigators have the skills necessary to conduct research resulting in a LAI-ART delivery model that increases LAI-ART use among PWH in prisons and/or are soon to be released?
- Does the application demonstrate that the investigators have the potential to conduct work to help understand determinants of a successful implementation of LAI-ART in prison settings?
- Does the application demonstrate that the investigators have the capacity to perform work that could provide information for further integration of LAI-ART in ART treatment services in the United States for prison populations?
- Does the application demonstrate that the investigators are capable of carrying out a set of project activities methodologically strong, and yet realistic to accomplish, such that the activities will contribute significantly to HIV treatment implementation research in the United States?
- Does the application demonstrate that the investigators have the experience necessary to conduct research that has the potential to be scalable and reach a large portion of prison populations at risk of ART non-adherence or PWH interested in LAI-ART?

Innovation

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

- Does the application clearly describe the proposed research questions and any innovation that the results may lead to?
- Do the proposed partnerships provide opportunities for innovation? Particularly as it relates to innovative and feasible settings for LAI-ART administration.
- Does the application describe innovative approaches to support post-release linkage to medical care and retention?
- Does the application outline a plan to evaluate acceptability, feasibility and efficiency to assess potential cost savings?
- Does the application include timelines with measurable goals and aims based on a four (4)-year research project period?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed?

If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

- Does the application demonstrate partnership with health departments, prisons, and outpatient clinics, pharmacies, CBOs, and other agencies for surveillance, administration of LAI-ART, and linkage to care post-release?
- Is the approach presented in the research plan consistent with the implementation research logic model?
- Does the application describe strategies and capacities for payment and patient navigation for initiation of LAI-ART?
- Does the application describe a 2-phase process that includes strategies to conduct formative work and use evaluative and iterative strategies to assess for study readiness and address any ethical considerations?
- Does the application describe an approach to recruit, train, educate, and provide interactive assistance to prison staff, providers, and collaborators?
- Does the application describe strategies to support clinicians?
- Does the application describe strategies for best methods to collect data among persons living prisons?
- Are strategies outlined in the application consistent with HHS clinical guidance, each participant receiving LAI-ART injections prior to release; one to ascertain tolerability and monitor for adverse reactions, and one within 14 days of release to serve as a bridge until their first HIV care provider appointment post-release?
- Does the application include appropriate MOUs/MOAs describing plans to collaborate with participating prisons, community providers, and relevant CBOs to implement linkage to community HIV services and pre-release planning, that outline data sources access as well as funding and capacity needs for collaborating governmental and non-government partners?
- Does the application describe change infrastructure strategies, to integrate LAI-ART interventions into workflow processes?
- Does the application describe a plan to collect and manage the relevant study data elements, including surveillance data, medical records data; and a process to obtain data sharing agreements from all collaborators (which may include state correctional leaders, contractual medical services, health departments, and any subcontractors with prisoner advocacy experience)?

- Does the application describe a relevant infrastructure to use HIV surveillance and other data systems and processes for supporting efficient implementation of data to care?
- Are outputs identified and are measures/metrics to assess implementation outcomes included?
- Does the application describe published, evidence-based ART adherence, linkage, retention, and follow up tools that will be used to accomplish the study goals?
- Does the application describe an approach for longitudinal monitoring of patients and appropriate plans for analyzing linkage, retention, adherence, and suppression outcomes at least 12 months post-release?

Environment

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

- Does the application propose recruiting participants from state prison facilities and detained for at least 12 months? Federal prisons and jails that serve as prisons or state facilities housing prisoners less than 12-months are not the intended environment.
- Does the application describe tailoring of an intervention to local context and including the integration of LAI-ART into prison facility routine?
- Does the application demonstrate institutional and facility support, and other resources necessary for the project activities proposed? For example, does the applicant have approval from each participating warden or the head of the department of corrections in their respective states?
- Does the application use critical partnerships or collaborations to maximize the potential for success in study implementation and translation into practice?
- Does the application support key collaborator involvement throughout the research process?
- Does the application describe plans to conduct the study at prison sites experiencing issues with adherence to ART and sustained viral suppression?
- Does the application demonstrate a proven track record of collaborations with health department, clinical, community and other partners related to health of PWH in prison settings?
- Does the application describe plans for establishing collaborations with health departments, departments of corrections, community healthcare providers, and other proposed partners?
- Does the application include MOU letters of collaboration from proposed partners that reflect their role and capacity to participate in the research project?

2. Additional Review Criteria

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

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

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements (https://www.cdc.gov/grants/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/women/research/index.htm) 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/VASchecklist.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 budget preparation guidance for completing a detailed justified budget on the CDC website, at the following Internet address: https://www.cdc.gov/grants/applying/application-resources.html. Following this guidance will also facilitate the review and approval of the budget request of applications selected for award.

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.

N/A

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

If you receive an award, you must follow all applicable nondiscrimination laws. You agree to

this when you register in SAM.gov. You must also submit an Assurance of Compliance (HHS-690). To learn more, see the HHS Office for Civil Rights website.

Generally applicable ARs:

AR-1: Human Subjects Requirements

AR-2: Requirements for 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 2030

AR-12: Lobbying Restrictions

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

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

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

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

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: 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: Research Definition

AR-32: Appropriations Act, 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

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

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

Employee Whistleblower Rights and Protections Employee Whistleblower Rights and Protections: All recipients of an award under this NOFO will be subject to a term and condition that applies the requirements set out in 41 U.S.C. § 4712, "Enhancement of contractor protection from reprisal for disclosure of certain information" and 48 Code of Federal Regulations (CFR) section 3.9 to the award, which includes a requirement that recipients and subrecipients inform employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. § 4712. For more information see: https://oig.hhs.gov/fraud/whistleblower/.

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

- Developing and finalizing the study instruments and protocols, including human subjects research (Institutional Review Board) protocols.
- Collaborating, coordinating and communicating with other CDC recipients ensure effective delivery of HIV prevention activities consistent with CDC standards and guidance.
- Collaborating with CDC to disseminate key findings at national or international meetings and in peer-review journals, in addition to sharing findings with the department of corrections, state health departments, and Bureau of Prisons, as warranted.
- 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/additionalrequirements/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 support project must bear an acknowledgment and disclaimer, as appropriate, for example: "This publication (journal article, etc.) was supported by the Cooperative Agreement Number above from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention". In addition, the PI/PD must provide to CDC Program abstracts or manuscripts prior to any publication related to this funding. The 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/additionalrequirements/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

Agency Contacts:

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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.

Sections 301(a) and 317(k)(2) of the Public Health Service Act; 42 U.S.C. Sections 241(a) and 247b(k)(2).