Using Real-time Prescription and Insurance Claims Data to Support the HIV Care Continuum
RFA-PS-19-003
Application Due Date: 01/22/2019
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## Part 1. Overview Information

### Participating Organization(s)
Centers for Disease Control

### Components of Participating Organizations
National Center for HIV-AIDS, Viral Hepatitis, STD, and TB Prevention Extramural Research Program Office (NCHHSTP ERPO)

### Notice of Funding Opportunity (NOFO) Title
Using Real-time Prescription and Insurance Claims Data to Support the HIV Care Continuum

### Activity Code
U01 - Research Project - Cooperative Agreement

### Notice of Funding Opportunity Type
New

### Agency Notice of Funding Opportunity Number
RFA-PS-19-003

### Assistance Listings (CFDA) Number(s)
93.941

### Category of Funding Activity:
Health

### NOFO Purpose
The research supported by this Notice of Funding Opportunity (NOFO) is divided into two categories: Category A, Prescription-based Data-to-Care (D2C-Rx) and Category B, Insurance-based Data-to-Care (D2C-I). Applicants may apply for Category A, Category B or both Categories A and B.

The purpose of Category A is to develop, implement and evaluate an “D2C-Rx” model which uses real-time pharmacy claims data to identify persons with HIV who fail to pick up prescribed anti-retroviral (ARV) medications by 30, 60 or 90 days, and to target these individuals for adherence, retention and re-linkage interventions.

The purpose of Category B is to develop, implement and evaluate an “D2C-I” model using medical (diagnosis and procedure) claims and pharmacy claims data to first identify persons with a diagnosis of HIV (via ICD codes) and then to determine, among those persons identified as HIV diagnosed, individuals with no pharmacy claims for ARV medications or no ARV claims for an extended period (minimum > 90 days). For persons with diagnosed HIV who have never been prescribed ARV therapy (ART), the Category B application should propose working with the provider to prescribe ART for the patient (i.e., a prescriber-level intervention). If the patient has been prescribed ARVs, but has not filled ARVs for an extended period (minimum > 90 days), the study should then follow the D2C-Rx (Category A) path of activities. As research studies, appropriate comparison groups should be chosen for each category of activities.

### Key Dates

| Publication Date: | To receive notification of any changes to RFA-PS-19-003, return to the |
synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.

Letter of Intent Due Date: 12/13/2018

Application Due Date: 01/22/2019

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

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

Scientific Merit Review: 03/06/2019

Secondary Review: 03/26/2019

Estimated Start Date: 06/01/2019

Expiration Date: 01/23/2019

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

Required Application Instructions

**ELECTRONIC APPLICATION SUBMISSION VIA ASSIST IS PREFERRED**

It is recommended that applicants use ASSIST for the electronic preparation and submission of applications through Grants.gov to CDC. ASSIST is an alternative method to prepare and submit applications, and provides many features to facilitate the application submission process which improves data quality (e.g., pre-population of organization data, pre-submission validation of business rules, and preview of the application image used for review). Use of the Grants.gov downloadable Adobe application packages and submission process will still be supported.
It is critical that applicants follow the instructions in the SF 424 (R&R) Application Guide except where instructed to do otherwise in this NOFO. Conformance to all requirements (both in the Application Guide and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

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

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

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

**Executive Summary**

- **Purpose:** This NOFO is divided into two categories: Category A, Prescription-based Data-to-Care (D2C-Rx) and Category B, Insurance-based Data-to-Care (D2C-I); applicants may apply for Category A, Category B or both Categories A and B. The purpose of Category A is to develop, implement and evaluate an “D2C-Rx” model which uses real-time pharmacy claims data to identify persons with HIV who fail to pick up prescribed anti-retroviral (ARV) medications by 30, 60 or 90 days, and to target these individuals for adherence, retention and re-linkage interventions. Ultimately, the goal of the study is to demonstrate the feasibility of using pharmacy claims data to identify people who recently stopped filling ARV prescriptions and the effectiveness of an active intervention to re-engage these individuals in HIV medical care (e.g., re-initiate ART, re-link to clinic). The purpose of Category B is to develop, implement and evaluate an “D2C-I” model using medical (diagnosis and procedure) claims and pharmacy claims data to first identify persons with a diagnosis of HIV (via ICD codes) and then to determine, among those persons identified as HIV diagnosed, individuals with no pharmacy claims for ARV medications or no ARV claims for an extended period (minimum >90 days). Ultimately, the goal of the Category B study is to demonstrate the feasibility of using medical and pharmacy claims data to identify people who have never filled ARV prescriptions (or have not filled them for an extended period) and the effectiveness of an active intervention to initiate or re-initiate ART.

- **Mechanism of Support:** U01 – Research Project - Cooperative Agreement. The National Institute of Mental Health (NIMH) of the National Institutes of Health (NIH) will be a collaborator on this NOFO.

- **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 $4,400,000 ($2,200,000 per category). The estimated number of awards is up to two (one per category). 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
The first year (12-month budget period) is $550,000 per category, with individual awards ranging from $450,000 to $550,000 for the first year. The estimated total funding (direct and indirect) for the entire project period is $4,400,000 ($2,200,000 per category). The project period is anticipated to run from 6/1/2019 – 5/31/2023.

- **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.1 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. If applying for both Category A and Category B, a Co-PI for one of the Categories may be listed in the application; however, only one PI may be the primary CDC contact for the entire award (both categories) and this person must be indicated as such in the application.
- **Number of Applications**: Only one application per institution (normally identified by having a unique DUNS number) is allowed.
- **Application Type**: New.
- **Application Materials**: See Section IV.1 for application materials. Please note that Form E is to be used when completing the application package. PLEASE ALSO NOTE: The Research Strategy component of the Research Plan section is limited to 25 pages for Category A and 25 pages for Category B (50 pages for Category A + B).
- **Hearing Impaired**: Telecommunications for the hearing impaired are available at: TTY: 1-888-232-6348

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**Part 2. Full Text**

**Section I. Funding Opportunity Description**

**Statutory Authority**
Public Health Service Act, Section 301(a) [42 U.S.C. 241(a)], as amended;
Public Health Service Act, Section 405(a) [42 U.S.C. 284(b)(2)], as amended; and
Public Health Service Act, Section 464R(a) [42 U.S.C. 285(p)], as amended.

**1. Background and Purpose**

**CATEGORY A**
There are approximately 1.2 million people living with HIV in the United States. In 2014 (the most recent year with complete data available), among persons with diagnosed HIV, 73%
received HIV medical care, 57% were in regular HIV medical care and 58% had reached viral suppression (1,2). The substantial proportion of persons who are not retained in care has important individual and public health implications because approximately 60% of new HIV infections are transmitted from persons diagnosed with HIV who are not fully retained in medical care (3).

Re-engaging out-of-care persons with HIV back into care confers important individual-level health benefits and population-level prevention benefits. Use of HIV surveillance data to identify out-of-care persons is one strategy for identifying and re-engaging out-of-care persons in care and is called Data-to-Care or “D2C” (e.g., https://effectiveinterventions.cdc.gov/en/2018-design/data-to-care/group-1/data-to-care). Data-to-Care uses laboratory reports (i.e., CD4 and HIV viral load test results) received by a health department’s HIV surveillance program as markers of HIV care. The laboratory reports are used to identify individuals who either never linked to care after diagnosis or who did not continue to receive care and to offer these individuals outreach by health departments, providers, or both to assist them with getting into, or back into, HIV care.

In the current D2C model, there is a delay in the identification of out-of-care persons due to the time interval between recommended monitoring tests (i.e., every 3 to 6 months) and the subsequent reporting of these tests to surveillance. Thus, the current D2C model identifies persons already out of care rather than identifying persons at risk for dropping out of care; the current model cannot intervene in the short time interval between the start of a gap in care (typically 6 months from the last visit) and the point at which a person is declared out of care. More real-time data are required to identify persons at risk of dropping out of care and to intervene prior to a gap in care, or loss to care.

Pharmacy prescription refill (claims) data are a source to identify HIV-infected persons who have stopped filling antiretroviral (ARV) medications and who are at risk for becoming out of care. Patients may elect to fill prescriptions at one of many pharmacies that accept their insurance plan. Within one pharmacy network, prescriptions can be tracked across partnered pharmacies (e.g., chain drug stores). However, if a patient switches pharmacies (to another chain or independent pharmacy), the prior refill history remains with the first pharmacy. Pharmacy claims are adjudicated for an insurance company by a third-party claims processor or a pharmacy-benefit management (PBM) company. All pharmacy claims that are billed to an insurance company for an individual patient can be tracked through the PBM, regardless of where a patient filled the prescription. Three large PBMs manage pharmacy benefits for approximately 85% of all people with prescription benefits. Because most ARVs are prescribed as a 30-day supply of medication, data from PBMs and other like sources can be used to identify persons who are not filling their medications on a monthly basis. Tracking ARV refill data, therefore, can be a more real-time indicator of poor adherence and can act as a harbinger of potential poor retention in care. Using real-time pharmacy claims data to identify persons who fail to fill ARV prescriptions, and to intervene, could have a significant impact on adherence, viral suppression and potentially on retention in care.

The purpose of the Category A study is to develop, implement and evaluate a Prescription-based Data to Care (D2C-Rx) model using real-time pharmacy data to identify persons who fail to pick up prescribed ARV medications by 30, 60 or 90 days, and target these individuals for progressive adherence and retention interventions. The application should propose a low level, first line adherence intervention (e.g., contact patient by phone) for persons who fail to fill prescribed ARVs by 30 days. Persons who are identified as being 60 days late would receive second line
adherence and retention interventions at project clinics (those which prescribed the ARVs) and/or filling pharmacies. Persons who are identified as being 90 days late would receive a third line intervention where the health department uses Disease Intervention Specialists, or similar personnel, and their current D2C process to locate the individuals and re-link the persons to the prescribing clinic. Additional patient navigation services may also be offered.

As a research project, the application should describe comparison groups for people living with HIV who are 30 days, 60 days and 90 days late filling ARV prescriptions (e.g., the application may describe a process where persons are randomized to receive the intervention versus standard of care, or the comparison group is selected from a contemporary group identified through the pharmacy claims dataset, or more than one control group).

References:


CATEGORY B

ART has been recommended for all persons with HIV since 2012 (1). However, an estimated 19% of people with diagnosed HIV who are in care are not receiving ART (e.g., not prescribed or stopped taking ART, fallen out of care with no remaining prescriptions, etc.) (2). Without ART, few will reach viral suppression. Insurance claims data, which include diagnosis, pharmacy, procedure and office visit claims, can be used to identify people living with HIV and to identify persons with HIV who have no ARV claims (either because they have never been prescribed ART or because they have not filled an ARV prescription for an extended period of time).

The purpose of the Category B study is to develop, implement and evaluate an Insurance-based D2C (D2C-I) model using medical (diagnosis and procedure) claims and pharmacy claims data to first identify persons with a diagnosis of HIV (via ICD codes) and then to determine, among those persons identified as HIV diagnosed, individuals with no pharmacy claims for ARV medications or no ARV claims for an extended period (minimum > 90 days). The Category B application should propose working with providers to determine if persons identified as HIV diagnosed with no ARV claims have ever been prescribed ARVs; for individuals never prescribed ARVs, the application should propose working with providers to prescribe ART (i.e., a prescriber-level intervention). Persons identified as HIV diagnosed who have been prescribed ARVs but who have failed to fill ARVs for an extended period (minimum > 90 days) would receive interventions similar to the second line or third line interventions in Category A. As a research study, the application should describe an appropriate comparison group for the
prescriber-level intervention.

References:


Health Equity:

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

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

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

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

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

Programs should use data, including social determinants data, to identify communities within their jurisdiction that are disproportionately affected by HIV, viral hepatitis, STDs and TB and related diseases and conditions, and plan activities to help eliminate health disparities. In collaboration with partners and appropriate sectors of the community, programs should consider social determinants of health in the development, implementation, and evaluation of program specific efforts and use culturally appropriate interventions that are tailored for the communities for which they are intended.
Healthy People 2020 and other National Strategic Priorities

This NOFO addresses the Healthy People 2020 (http://www.healthypeople.gov) priority area of HIV and supports the following Healthy People 2020 objectives:

- HIV-2: Reduce number of new HIV infections among adolescents and adults
- HIV–3: Reduce the rate of HIV transmission among adolescents and adults
- HIV–4: Reduce new AIDS cases among adolescents and adults
- HIV-22: (Developmental) Increase the proportion of persons with an HIV diagnosis in medical care with a viral load <200 copies/mL at the last test during the 12-month measurement period

This NOFO also supports the following national goals and objectives (https://files.hiv.gov/s3fs-public/nhas-update.pdf):

- Goal 1, Step 1.B: Expand efforts to prevent HIV infection using a combination of effective, evidence-based approaches
- Goal 1, Step 1.B.4: Expand prevention with persons living with HIV
- Goal 2, Step 2.A.2: Ensure linkage to HIV medical care and improve retention in care for people living with HIV

Also related to the National HIV/AIDS Strategy, this study supports the HIV Care Continuum Initiative, which calls for coordinated action to increase the number of people living with HIV in the United States who have achieved the treatment goal of controlling the HIV virus. For more information, please see http://aids.gov/federal-resources/policies/care-continuum/.

Public Health Impact

Insurance claims data, including pharmacy and medical diagnosis claims, are a source to identify HIV-infected persons who have stopped filling ARV prescriptions. Data and interventions based on pharmacy refills through insurance claims have yet to be fully employed as a strategy for monitoring adherence behavior prior to the occurrence of a gap in care or loss to care. ARV refill data have the potential to be a real-time indicator of poor adherence, thereby providing earlier opportunities to intervene (on non-adherent persons) and subsequently to improve adherence to ART, viral suppression and retention in care. In addition, use of both medical and pharmacy claims data to identify persons with HIV who have never been prescribed ARVs and initiating these individuals on ART has the potential to increase viral suppression and decrease onward HIV transmission.

Relevant Work

This NOFO is informed by current Data-to-Care models where health departments have demonstrated success in using HIV surveillance data to identify persons with HIV who are out-of-care and re-engaging these individuals in care. Successful Data-to-Care models have been implemented in both local and state health departments and in healthcare systems. More information about the current Data-to-Care model can be found at: https://effectiveinterventions.cdc.gov/en/2018-design/data-to-care/group-1/data-to-care.
2. Approach

Applicants may apply for Category A, Category B or both Categories A and B. The Project Team for Category A or B projects should be composed of the grantees and other partners, including local or state health department. The applicant may suggest additional members for the Project Team. The Project Team will have substantial involvement in the development and evaluation of the Data-to-Care model(s). Examples of core activities and outcomes for Category A and Category B projects are outlined below.

**CATEGORY A**

Specific activities for Category A projects can be broadly categorized into three areas: 1) develop the Prescription-based Data-to-Care model (D2C-Rx) and study procedures; 2) implement the study; and 3) evaluate project outcomes and disseminate results.

The project model includes: 1) a real-time pharmacy claims data source; 2) involvement of project clinics and/or pharmacies; and 3) participation by a health department and disease intervention specialists, or similar personnel.

Expected core activities and outcomes for Category A projects are outlined below:

A pharmacy claims data source is used to identify persons who have not picked up prescribed anti-retroviral drugs (ARVs) by 30, 60 and 90 days. For persons who failed to pick up prescribed ARVs by 30 days, a first line intervention is conducted. The first line intervention should be a low intensity intervention and can be an intervention conducted by a pharmacy benefits manager (PBM) or insurer, filling pharmacy, or other intervention. For persons who failed to pick up prescribed ARVs by 60 days, a second line intervention is conducted. The second line intervention is conducted at project clinics and/or filling pharmacies. The second line intervention is conducted at a sufficient number of prescribing clinics and/or filling pharmacies to enroll a minimum of 350 persons in the intervention group. Lastly, the partnering health department is informed of persons who failed to pick up prescribed ARVs by 90 days, and conducts a third line intervention, which uses disease intervention specialists (or similar personnel) and their existing D2C process to locate these individuals and then re-link them to the prescribing clinic and provide follow-up. The health department may implement additional strategies to locate the person, such as determining if the person is deceased (via vital statistics), moved out of the jurisdiction, is incarcerated, or changed providers/insurers (e.g., HIV surveillance records with CD4 or viral load ordered from a different provider). As a research study, appropriate comparison groups of persons with HIV are chosen. The grantee also conducts a cost-effectiveness analysis.

It is expected that data will be collected throughout the implementation phase of the project to determine project outcomes. First year activities include study planning and obtaining Institutional Review Board (IRB) and Office of Management and Budget (OMB) approvals. Second and third year activities focus on study implementation. Fourth year activities include an analysis of project outcomes and the dissemination of results.
Figure 1: Sample schematic of Prescription-based Data-to-Care (D2C-Rx) model

This 4-year project should include the following activities:

1) Develop model and study procedures

- Develop procedures for using real-time pharmacy claims data from pharmacy benefit manager (PBM), insurer(s) or other source(s) to identify persons with HIV who failed to pick up prescribed ARVs by 30, 60 and 90 days.
- Develop procedures, first, second, and third line interventions for persons who failed to pick up prescribed ARVs.
  - An example of a low intensity first line intervention is contacting the patient to remind them to pick up the prescribed ARV.
  - Examples of evidence-based or evidence-informed adherence and retention interventions for the second line intervention are available at: https://www.cdc.gov/hiv/research/interventionresearch/compendium/index.html
  - It is suggested that the third line intervention be modified from the health department’s existing D2C process. Development of a process to inform prescribing clinics of patients who fail to pick up prescribed ARVs by 90 days (for both project clinics and non-project clinics), a re-linkage process to prescribing clinic, and follow-up procedures is encouraged
- Determine procedure(s) for selecting comparison groups of persons with HIV (e.g., randomized to intervention or standard of care, contemporary group from the pharmacy
claims dataset, numbers of controls per line of intervention, matched versus unmatched).
- Develop procedures for conducting a cost-effectiveness study.

2) Implement study

- Operationalize process, conduct first line intervention, and choose controls.
- Partner with project clinics and/or pharmacies to implement second line intervention.
  - Grantees should collaborate with a sufficient number of clinics and/or pharmacies to achieve a minimum of 350 people in the intervention group.
- Using the pharmacy claims data, develop a list of persons who failed to pick up prescribed ARVs by 60 (and 90) days, choose controls, conduct second line intervention (minimum of 350 people in the intervention group), and conduct third line interventions for those who are subsequently a total of 90 days late. There should be a minimum of 350 controls for the second line intervention. The number of controls for the third line intervention should be large enough so that a comparison is adequately powered.
- Obtain ethical approval(s), including project IRB approval, and assist project clinic and/or pharmacy sites and health department to obtain local IRB approval, if required.
- Ensure grantee and partners implement study procedures in a manner compliant with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), HIPAA regulations, and all other applicable laws that govern the use, disclosure and transmission of individually identifiable information.
- Finalize the service model.
- Conduct a cost-effectiveness analysis.

3) Evaluate study outcomes and disseminate results

- Collect, manage and clean study data.
  - Ensure that all required project data elements are collected, including baseline data.
  - Conduct process and outcome monitoring of the project sites and provide project progress reports of specified outcomes to CDC on a quarterly (at minimum) basis.
  - Provide CDC with cleaned, analytic datasets of the required data elements, quarterly (at minimum).
- Develop analysis plans and analyze study data to determine project outcomes, including a cost-effectiveness analysis.
- Form a Publication Committee composed of one representative from the grantee organization, one from each of the other partner organizations, and one from the partnering health department to determine rules for authorship of publications, abstracts, presentations and select target journals.
- Disseminate results.

**CATEGORY B**

Specific activities for Category B projects can be broadly categorized into three areas: 1) develop the Insurance-based Data-to-Care model (D2C-I) and study procedures; 2) implement the study;
and 3) evaluate project outcomes and disseminate results.

The project model includes: 1) a medical (diagnosis and procedure) claims and real-time pharmacy claims data source; 2) involvement of project clinics and/or pharmacies; and 3) participation by a health department and disease intervention specialists, or similar personnel.

Expected core activities and outcomes for Category B projects are outlined below:

A medical diagnosis claims data source is used to identify persons with a diagnosis of HIV (e.g., via ICD codes). Once persons with a diagnosis of HIV are identified, a pharmacy claims data source is reviewed to determine if these individuals have ever had pharmacy claims for ARVs. A list of persons with a diagnosis of HIV and no pharmacy claims for ARV medications, or no ARV claims for an extended period (minimum > 90 days), is then created. The grantee then works with clinic providers to determine if each patient is a patient of the provider(s), the patient is truly HIV infected, and if the patient has ever been prescribed ARVs. If an HIV diagnosis is confirmed, and the patient has never been prescribed ARVs, the grantee works with the provider to prescribe ART for the patient (i.e., a prescriber-level intervention is initiated). An appropriate comparison group for the provider-level intervention is chosen. If the patient has been prescribed ARVs (i.e., the reason there are no ARV claims for the patient is not because the patient has never been prescribed ARVs, but because the patient has never filled ARV prescriptions, or has not filled ARVs in an extended period), then the grantee implements interventions similar to the Category A second and third line interventions.

**Figure 2: Sample schematic of Insurance-based Data-to-Care (D2C-I) model**

This 4-year project should include the following activities:

1) Develop model and study procedures
• Develop procedures for using medical claims data to identify persons with a diagnosis of HIV (e.g., via ICD codes).
• Develop procedures for using real-time pharmacy claims data to identify persons with a diagnosis of HIV who have no ARV claims or no ARV claims in an extended period (minimum >90 days).
• Develop procedures to contact clinic providers and adjudicate lists of patients initially identified as diagnosed with HIV (i.e., determine if truly HIV diagnosed) and if ever been prescribed ART.
• Develop procedures and a prescriber-level intervention aimed at supporting prescribers to initiate ART for patients never prescribed ARVs.
• For persons prescribed ARVs, but who have failed to fill ARVs for an extended period (minimum > 90 days), develop relevant D2C-Rx procedures as outlined for Category A projects in the “Develop model and study procedures” section above.
• Determine comparison groups and procedures for selecting controls for the prescriber-level intervention.
• Develop procedures to collect data for a cost-effectiveness analysis.

2) Implement the study

• Using the medical and pharmacy claims data, develop list of persons who have a diagnosis of HIV and no ARV claims, collaborate with clinic providers to adjudicate the list (i.e., determine if truly HIV diagnosed), and determine if person was ever prescribed ARVs. Applicant should plan to identify a minimum of 350 people with confirmed HIV diagnosis who have never been prescribed ART.
• Implement a prescriber-level intervention aimed at supporting prescribers to initiate ART for patients never prescribed ARVs and choose appropriate comparison group (minimum of 350 controls).
• For persons identified as having been prescribed ARVs, but have not filled ARVs for an extended period (minimum > 90 days), implement relevant D2C-Rx procedures as outlined for Category A in the “Implement study” section above.
• Obtain ethical approval(s), including project IRB approval(s), and assist project clinic and/or pharmacy sites and health department in obtaining local IRB approval, if required.
• Ensure grantee and partners implement study procedures in a manner compliant with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), HIPAA regulations, and all other applicable laws that govern the use, disclosure and transmission of individually identifiable information.
• Finalize the service model.
• Conduct a cost-effectiveness analysis.

3) Evaluate study outcomes and disseminate results

• Collect, manage and clean study data.
  o Ensure that all required project data elements are collected, including baseline data.
  o Conduct process and outcome monitoring of the project sites and provide project progress reports of specified outcomes to CDC on a quarterly (at minimum) basis.
- Provide CDC with cleaned, analytic datasets of the required data elements, quarterly (at minimum).
- Develop analysis plans and analyze study data to determine project outcomes, including a cost-effectiveness analysis.
- Form a Publication Committee composed of one representative from the grantee organization, one from each of the other partner organizations, and one from the partnering health department to determine rules for authorship of publications, abstracts, presentations and select target journals.
- Disseminate results.

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

CATEGORY A
Research objectives for the Prescription-based Data-to-Care (D2C-Rx) model (Category A):

1. Develop and implement a model to use real-time pharmacy claims data to: a) identify persons with HIV who fail to fill prescribed ARVs within 90 days and b) target these individuals for adherence and retention interventions.
2. Implement progressive adherence and retention interventions (including health department field services investigations) to increase the number of persons with HIV who fail to fill prescribed ARVs within 90 days who: a) re-initiate ART; b) are adherent to ARV medication therapy; c) are persistent on ARV medication therapy; d) achieve HIV viral suppression; and e) remain in HIV medical care.

Scientific knowledge to be achieved by the Prescription-based Data-to-Care (D2C-Rx) model (Category A):

1. Determine the important components and feasibility of using real-time pharmacy claims data to identify persons with HIV who have recently failed to fill prescribed ARVs.
2. Determine the extent to which a clinic and/or pharmacy and health department intervention can successfully re-engage persons in HIV medical care (e.g., re-initiate ART, re-link to clinic).
3. Measure the cost-effectiveness of this intervention in terms of adherence to therapy and viral suppression.

Primary Outcomes:

1. Service model leads to re-initiation of ART (Re-initiation of ART is defined as a person filling ARV prescriptions after lapse in filling. Potential data source: pharmacy claims dataset.)
2. Service model leads to improved adherence to ART (Adherence is defined as a Proportion of Days Covered (PDC) of ≥ 90%. Potential data source: pharmacy claims dataset.)
3. Service model leads to improved persistence to ART (Persistence is defined as the time
from the prescription fill until the patient has a gap in therapy. Potential data source: pharmacy claims dataset.)

Secondary Outcomes:

1. Service model leads to improved viral suppression (Viral suppression is defined as an HIV viral load < 200 copies/mL at most recent test in the measurement period. Sustained viral suppression may also be measured. Potential data sources: project clinic records, health department records.)
2. Service model leads to improved retention in HIV care (Retention in care is defined as at least two CD4 or HIV viral load tests at least three months apart in a 12-month measurement period or as at least one medical visit in each 6-month period of a 12-month measurement period with a minimum of 60 days between medical visits. Potential data sources: project clinic records, health department records, medical claims data)

CATEGORY B

Research objectives for the Insurance-based Data-to-Care (D2C-I) model (Category B):

1. Develop and implement a model to use insurance claims data, including real-time pharmacy claims and medical diagnosis claims, to identify persons with HIV who have never been prescribed ART or who have failed to fill prescribed ARVs for an extended period (minimum >90 days) and to target these individuals for ARV initiation, adherence and retention interventions.
2. Implement ARV initiation, adherence and retention interventions (including health department field services investigations) to increase the number of persons with HIV who: a) initiate ART (for those never prescribed ARVs); b) re-initiate ART (for those who have not filled ARVs for a minimum of >90 days); c) are adherent to ARV medication therapy; d) are persistent on ARV medication therapy; e) achieve HIV viral suppression; and f) remain in HIV medical care.

Scientific knowledge to be achieved by the Insurance-based Data-to-Care (D2C-I) model (Category B):

1. Describe the important components and feasibility of using medical diagnosis and pharmacy claims data to identify persons with HIV who have never been prescribed ARVs or who have failed to fill prescribed ARVs in an extended period (minimum > 90 days).
2. Determine the extent to which a prescriber-level intervention can be used to successfully initiate ART for persons never prescribed ARVs.
3. Measure the cost-effectiveness of this intervention in terms of adherence to therapy and viral suppression.

Primary Outcomes:

1. Service model leads to initiation of ART for those never prescribed ARVs. (Initiation of ART defined as a person [who was never prescribed ARVs] filling an initial ARV
prescription. Potential data source: pharmacy claims dataset.)
2. Service model leads to re-initiation of ART (Re-initiation of ART defined as a person filling ARV prescriptions after lapse in filling. Potential data source: pharmacy claims dataset.)
3. Service model leads to improved adherence to ART (Adherence defined as a Proportion of Days Covered (PDC) of ≥ 90%. Potential data source: pharmacy claims dataset.)
4. Service model leads to improved persistence to ART (Persistence defined as the time from the prescription fill until the patient has a gap in therapy. Data source: pharmacy claims dataset.)

Secondary Outcomes:

1. Service model leads to improved viral suppression (Viral suppression defined as a HIV viral load < 200 copies/mL at most recent test in the measurement period. Sustained viral suppression may also be measured. Potential data sources: project clinic records, health department records.).
2. Service model leads to improved retention in HIV care (Retention in care defined as at least two CD4 or HIV viral load tests at least three months apart in a 12-month measurement period or as at least one medical visit in each 6-month period of a 12-month measurement period with a minimum of 60 days between medical visits. Potential data sources: project clinic records, health department records, medical claims data).

Target Population
Category A: Persons with HIV who are prescribed ART.
Category B: Persons with HIV who were never prescribed ARVs or have not filled ARVs for an extended period.

Collaboration/Partnerships
For both Category A and Category B studies, the application should propose working collaboratively with other project partners to develop or implement the study (studies). These partners include the project clinics and/or pharmacies, the health department and, potentially, the source of the pharmacy or medical claims data.

The application should describe collaborations with a sufficient number of clinics to achieve an adequate study sample size (e.g., large HIV clinics in the jurisdiction) and with a diversity of clinic types (e.g., Ryan White-funded, academic-affiliated, health maintenance organization, private, or veterans administration clinics). These project clinics should also serve a patient population whose sociodemographics (e.g., race/ethnicity, gender, and socioeconomic status) are representative of people living with HIV in their jurisdiction. Applications should include a description of how the project clinics will be selected, including a description of the minimum criteria to participate (e.g., provide HIV care to a minimum number of patients).

Letters of Support
The application should include Letters of Support from each project clinic that will collaborate in the study. The Letters of Support should include estimates of the total number of HIV-infected patients that receive care at each clinic. Project clinics are expected to maintain a timely (within
Funding

Publications. Health, Medicine), Public Translation persistence models developed?) data key monitor applicants on plan, project.

If the applicant is other than a health department, the application should include a Letter of Support from the proposed partner health department. The Letter of Support should include the health department staff that will be responsible for health department program activities and the number of Disease Intervention Specialists (or similar personnel) that will be assigned to the project. The application should also include Letters of Support from the proposed project clinics and/or pharmacies.

If the applicant intends to partner with a PBM, insurer or other source of pharmacy claims data (i.e., make the PBM, insurer or other organization with the pharmacy claims data part of the Project Team), the application should include a Letter of Support from the organization. If the applicant intends to use consultants to assist with project activities, the application should include Letters of Support from the proposed consultant(s).

Evaluation/Performance Measurement

The application should include measurable goals and aims based on a five (5)-year research project period. The application should include specific, measurable, achievable, realistic and time-phased (SMART) project objectives for each activity described in the application’s project plan, and describe the development and implementation of project performance measures based on specific programmatic objectives.

Applicants should develop a timeline to achieve study-related milestones and develop metrics to monitor the study’s performance and progress. The performance monitoring plan should include key evaluation questions for both processes (e.g., were procedures for using pharmacy claims data to identify persons with HIV who failed to pick up prescribed ARVs by 30, 60 and 90 days developed?) and outcomes (e.g., did persons who failed to pick up prescribed ARVs by 30, 60, and 90 days receive first, second and third line interventions?), process and outcome measures, potential data sources, and reporting frequency.

Outcome and process monitoring should be used to demonstrate the effectiveness of the D2C models in increasing project outcomes (e.g., initiation/re-initiation of ART, adherence and persistence to ART, HIV viral suppression, and retention in HIV care).

Translation Plan

Potential targeted audiences include professional public health associations (e.g., American Public Health Association), professional HIV organizations (e.g., American Academy of HIV Medicine), pharmacy associations (e.g., American Pharmacist Association) as well as public health, medical, and pharmacy practitioners. Results should be submitted for presentation at local, regional or national conferences and for publication in peer-reviewed journals or other publications.

Section II. Award Information

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

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

**Estimated Total Funding:** $4,400,000

**Estimated funds available for each year:**
Year 1: $1,100,000 ($550,000 per category)
Year 2: $1,100,000 ($550,000 per category)
Year 3: $1,100,000 ($550,000 per category)
Year 4: $1,100,000 ($550,000 per category)

** Estimated total funding available for the first year, including direct and indirect costs:** $1,100,000 ($550,000 per category).

**Estimated total funding available for the entire four year project period, including direct and indirect costs:** $4,400,000 ($2,200,000 per category).

**Anticipated Number of Awards:** 2
Up to one award per category.

The ceiling and floor amounts below are for the first budget period only and reflect an application that applies for both Category A and B. The ceiling for an application that only applies for one Category (A or B) would be $550,000 and the floor would be $0.

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

**Award Ceiling:** $1,100,000 Per Budget Period
**Award Floor:** $0 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
will apply to the applications submitted and awards made in response to this NOFO.

Section III. Eligibility Information

1. Eligible Applicants

<table>
<thead>
<tr>
<th>Eligibility Category:</th>
<th>State governments</th>
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<tbody>
<tr>
<td></td>
<td>County governments</td>
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<td></td>
<td>City or township governments</td>
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<td></td>
<td>Special district governments</td>
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<td></td>
<td>Independent school districts</td>
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<td></td>
<td>Public and State controlled institutions of higher education</td>
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<td></td>
<td>Native American tribal governments (Federally recognized)</td>
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<td>Public housing authorities/Indian housing authorities</td>
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<td></td>
<td>Native American tribal organizations (other than Federally recognized tribal governments)</td>
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<td></td>
<td>Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education</td>
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<tr>
<td></td>
<td>Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education</td>
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<tr>
<td></td>
<td>Private institutions of higher education</td>
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<td></td>
<td>For profit organizations other than small businesses</td>
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<td></td>
<td>Small businesses</td>
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<td></td>
<td>Others (see text field entitled &quot;Additional Information on Eligibility&quot; for clarification)</td>
</tr>
</tbody>
</table>

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://dap.dau.mil/acquipedia/Pages/ArticleDetails.aspx?aid=5e3079b8-44f2-43df-a0e7-9f379e8c48ed

2. Foreign Organizations
Foreign Organizations are not eligible to apply.

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

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

3. Special Eligibility Requirements
N/A
4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

N/A

6. Required Registrations

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

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https://eportal.nsdp.nato.int/AC135Public/Docs/US%20Instructions%20for%20NSPA%20NCAGE.pdf
- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, https://www.sam.gov/portal/SAM/.
- Grants.gov
- eRA Commons

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

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

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

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

If an award is granted, the recipient organization must notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the recipient organization.

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

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

9. Cost Sharing

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

10. Number of Applications

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

Only one application per institution (normally identified by having a unique DUNS number) is allowed.

Section IV. Application and Submission Information

1. Address to Request Application Package
In order to use ASSIST, applicants must visit https://public.era.nih.gov/assist where you can login using your eRA Commons credentials, and enter the Notice of Funding Opportunity Number to initiate the application, and begin the application preparation process. If you experience problems accessing or using ASSIST, you can refer to the ASSIST Online Help Site at: https://era.nih.gov/erahelp/assist. Additional support is available from the NIH eRA Service desk via:
  · E-mail: http://grants.nih.gov/support/index.html
  · Phone: 301-402-7469 or (toll-free) 1-866-504-9552. The NIH eRA Service desk is available Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding federal holidays.

2. Content and Form of Application Submission

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

Special Instructions:

Clearly indicate in the application if you are applying for only Category A, only Category B, or both Categories A and B.

For applicants applying for both Categories A and B

Even if you are applying for both Categories A and B, you will submit only one application. However, each section of the application must be clearly marked as to whether it applies to only Category A, only Category B, or both Categories A and B.

Project Summary/Abstract

Please provide a separate Project Summary/Abstract for each Category for which you are applying (Category A or Category B). The Project Summary/Abstract for each Category should be a stand-alone section that describes the research that will be conducted for the specified Category. Use subheadings (Category A, Category B) to identify whether the Project Summary/Abstract is for Category A or Category B.

Specific Aims

Please provide separate Specific Aims for each Category for which you are applying (Category A or Category B). Use subheadings (Category A, Category B) to identify whether the Specific Aims are for Category A or Category B.
**Research Strategy**

There should be a separate Research Strategy component for each Category for which you are applying (Category A or Category B – these should be separate, even if both categories are being submitted). The Research Strategy component of the Research Plan section of the application should be a stand-alone section for each Category that describes the research that will be conducted for the specified Category. Please note that Categories A and B will be reviewed and scored separately. Again, please be sure that each Research Strategy component is clearly marked as to whether it is for Category A or Category B.

For this NOFO, the “Research Strategy” section for each Category is limited to 25 pages (Category A projects = 25 pages, Category B projects = 25 pages, Category A + B projects = 50 pages).

**Supporting Information for the Research Strategy**

The following sections are not part of the Research Strategy and not part of the page limit for the Research Strategy component but should be included in the application: human subjects, references, letters of support, and detailed budgets.

**Human Subjects**

Provide a separate human subjects section for each Category for which the applicant is applying. Clearly mark each section. Use subheadings (Category A, Category B) to identify each human subjects section. Place the human subjects Targeted/Planned Enrollment Tables for each Category in the Targeted/Planned Enrollment Table section of the application. Clearly mark each table as belonging to Category A or Category B.

**References**

Place all of the references in the Bibliography & References Cited section of the application. Use subheadings (Category A, Category B) to identify which references belong to which component of the application.

**Letters of Support**

Place all letters of support in the Letters of Support section of the application. Use subheadings (Category A, Category B) to identify which letters belong to which component of the application.

**Budget Pages**

Applications are expected to contain a separate detailed budget for each year, for each Category, for which you are applying (Category A, Category B).

If applying for both Category A and Category B, the detailed budget for Category B should be listed as a subaward on the SF424(R&R) form [R&R Subaward Budget Attachment(s) Form]. The application is expected to include a separate detailed budget for each year of support for each Category for which you are applying (Category A and Category B).

Each subaward budget for each year should be clearly titled (e.g., Category B budget year 1, Category B budget year 2, etc).

For each budget, the project roles listed in the budget component should be consistent with
those used in the Senior/Key Person component.

A separate budget justification narrative is expected to be submitted with each budget (Category A, Category B) for each year of support requested. Use subheadings (Category A, Category B) to identify each budget justification.

In conjunction with the SF424(R&R) components, CDC grant applicants should also complete and submit additional components titled “PHS398.” Note: the PHS398 should include assurances and certifications, and additional data required by the agency for a complete application. Whereas these are not identical to the PHS398 application form pages, the PHS398 reference is used to distinguish these additional data requirements from the data collected in the SF424(R&R) components. A complete application will include SF424(R&R) and PHS398 components.

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

**Mandatory**

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

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

**Optional**

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

### 3. Letter of Intent

**Due Date for Letter of Intent: 12/13/2018**

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 better plan the review.

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

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

The letter of intent should be sent to:
Gregory Anderson, MPH, MS
Extramural Research Program Office
Office of the Associate Director of Science
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road, MS E-60
Atlanta, GA 30333
Telephone: 404-718-8833
Fax: 404-718-8822
Email: GAnderson@cdc.gov

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

5. PHS 398 Research Plan Component
The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of components. Not all components of the Research Plan apply to all Notices of Funding Opportunities (NOFOs). Specifically, some of the following components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/generalforms-e.pdf and https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Notice of Funding Opportunity Description).
Follow the page limits stated in the SF 424 unless otherwise specified in the NOFO. As applicable to and specified in the NOFO, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

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

4. **Progress Report Publication List** (for Continuation ONLY)

Other Research Plan Sections

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

All instructions in the SF424 (R&R) Application Guide [https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf) and here: [https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf](https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf) 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:

- Descriptions of the data to be produced in the proposed project
- How access will be provided to the data (including provisions for protection of privacy, confidentiality, security, intellectual property, or other rights)
- Use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use
- Plans for archival and long-term preservation of the data, or explaining why long-term preservation and access cannot be justified


**Please Note:** According to the Additional Requirement-25 (AR-25) ([https://www.cdc.gov/grants/s/additionalrequirements/ar-25.html](https://www.cdc.gov/grants/s/additionalrequirements/ar-25.html)), 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 as follows:

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

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

6. Appendix

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

7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 25 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 50 pages for all appendices.

8. Format for Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff. Applicants should ensure that all attachments are uploaded to the system. **CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide** [https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf) and here: [https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf](https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf).

9. Submission Dates & Times

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

Applicants are able to access, view, and track the status of their applications in the eRA Commons. Information on the submission process is provided in the SF-424 (R&R) Application Guidance and ASSIST User Guide at [https://era.nih.gov/files/ASSIST_user_guide.pdf](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](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](https://www.grants.gov/web/grants/support.html)

Support@grants.gov

Hours: 24 hours a day, 7 days a week (closed on federal holidays)

If the applicant encounters problems that prevent the ability to submit an application which cannot be resolved by Grants.gov or NIH eRA Service Desks, then applicants must contact CDC Technical Information Management Section (TIMS) at 770-488-2700; ogstims@cdc.gov for guidance at least 3 calendar days before the deadline date. Therefore, 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", 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 and ogstims@cdc.gov explaining why the submission failed.
   b. If there is time before the deadline, correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: 01/22/2019

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

10. Intergovernmental Review (E.O. 12372)
Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order 12372 (http://www.archives.gov/federal-register/codification/executive-order/12372.html). This order sets up a system for state and local review of proposed federal assistance applications. You should contact your state single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your state’s process. Click on the following link to get the current SPOC list: https://www.whitehouse.gov/wp-content/uploads/2017/11/Intergovernmental_Review__SPOC_01_2018_OFFM.pdf.

11. Funding Restrictions
All HHS/CDC awards are subject to the federal regulations, 45 CFR 75, terms and conditions, and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.
In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability (https://www.cdc.gov/grants/additionalrequirements/ar-35.html).
For more information on expanded authority and pre-award costs, go to: https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.
CDC requires that mechanisms for, and cost of, public health data sharing be included in grants, cooperative agreements, and contracts. The cost of sharing or archiving public health data may also be included as part of the total budget requested for first-time or continuation awards. Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or
collecting public health data and must be included in the Resource Sharing Plan(s) section of the PHS398 Research Plan Component of the application.

Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds (for example, privacy and confidentiality considerations, embargo issues).

Recipients who fail to release public health data in a timely fashion will be subject to procedures normally used to address lack of compliance (for example, reduction in funding, restriction of funds, or award termination) consistent with 45 CFR 74.62 or other authorities as appropriate. For further information, please see: https://www.cdc.gov/grants/additionalrequirements/ar-25.html for revised AR-25.

Additional Funding Restrictions:

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

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

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

4. On September 24, 2014, the Federal government issued a policy for the oversight of life sciences “Dual Use Research of Concern” (DURC) and required this policy to be implemented by September 24, 2015. This policy applies to all New and Renewal awards issued on applications submitted on or after September 24, 2015, and to all non-competing continuation awards issued on or after that date. CDC grantee institutions and their investigators conducting life sciences research subject to the Policy have a number of responsibilities that they must fulfill. Institutions should reference the policy, available at http://www.phe.gov/s3/dualuse, for a comprehensive listing of those requirements. Non-compliance with this Policy may result in suspension, limitation, or termination of United States Government (USG) funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

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

Risk Assessment Questionnaire Requirement

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

CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-1132 annually. This questionnaire, which is located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, along with supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. If your organization has completed CDC’s Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization representative to include the original submission date, organization’s EIN and DUNS.

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

Duplication of Efforts

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

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

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

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

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

**Important reminders:**
All PD/PIs must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to CDC.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization’s profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.

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

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

**Section V. Application Review Information**

### 1. Criteria

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

**Overall Impact**

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

**Scored Review Criteria**

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

#### Significance

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

All of the questions above for **Significance** apply to both CATEGORY A and B.

#### 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?

All of the questions above and below for **Investigators** apply to both CATEGORY A and B.

- Do the investigators or the proposed partnered health department personnel have experience with implementation of the current Data-to-Care (D2C) public health strategy that uses HIV surveillance data (i.e., CD4 and HIV viral load test results reported to the health department) to identify HIV-diagnosed individuals not in care
and to re-engage these individuals in care?

- Do the investigators have experience conducting HIV adherence and retention in care interventions?
- Do the investigators have the appropriate training and skills to conduct this study?
- Do the investigators demonstrate the epidemiologic, behavioral, clinical, administrative, and management experience needed to conduct this proposed study?

### 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?

All of the questions above for **Innovation** apply to both CATEGORY A and B.

### 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?

All of the questions above for **Approach** apply to both CATEGORY A and B.

#### CATEGORY A and B

- To what extent does the application describe a detailed plan to develop the model and study procedures? Does the plan include timelines for completion of each activity and milestones for accomplishing tasks? Are the plans feasible?
- To what extent does the application describe a detailed plan to implement the study? Does the plan include timelines for completion of each activity and milestones for accomplishing tasks? Are the plans feasible?
- To what extent does the application describe a detailed plan to evaluate study outcomes and disseminate results? Does the plan include timelines for completion of each activity and milestones for accomplishing tasks? Are the plans feasible?
- Does the application describe a detailed plan to collect baseline data (e.g., adherence, viral suppression pre-intervention)?
- Does the application describe plans to conduct a cost-effectiveness analysis?
- Does the application describe how data will be shared between project partners (e.g., insurer/PBM [if applicable], health department, project clinics)?
- Does the application propose to use evidence-based interventions or strategies in the
research plan?
• Does the application describe a plan on how outcome and process monitoring will be performed throughout the project period?
• Does the application describe a plan to clean and submit study data on a quarterly basis?

CATEGORY A ONLY

• Does the application clearly describe the comparison groups and suggested procedures for selecting the controls for the first, second and third line interventions?
• Does the application describe the proposed evidence-based/evidence-informed second line intervention?

CATEGORY B ONLY

• Does the application clearly describe the proposed prescriber-level intervention?
• Does the application clearly describe the comparison groups for the prescriber-level interventions?
• Does the application clearly describe the comparison groups and suggested procedures for selecting the controls for those persons identified as prescribed ARVs but failing to fill for an extended period [> 90 days] who will receive second and third line interventions similar to Category A?
• Does the application propose to use evidence-based interventions or strategies in the research plan?
• Does the application describe the proposed evidence-based/evidence-informed second line intervention (for those persons identified as prescribed ARVs but failing to fill in an extended period [> 90 days] who will receive second and third line interventions similar to Category A?)

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?

All of the questions above for Environment apply to both CATEGORY A and B.

CATEGORY A and B

• Does the application include all necessary Letters of Support? E.g., if the applicant plans to partner with a Pharmacy Benefits Manager or other pharmacy claims data organization (i.e., make the PBM, insurer or other organization with the pharmacy claims data part of the Project Team), does the application include a Letter of Support from the partnered source, proposed project clinic and/or pharmacies? If the applicant is other than a health department, does the application include a Letter of Support from the proposed partnered health department?
• Does the Letter of Support from the project clinics include estimates of the total number of HIV-infected patients that receive care at their clinic, estimates of how many existing
patients become disengaged from care per year and language that data can be shared with the health department, for this project, or that approval to share data with the health department is anticipated?

- If the applicant is other than a health department, does the Letter of Support from the health department include the health department staff that will be responsible for health department program activities and the number of Disease Intervention Specialists (or similar personnel) that will be assigned to the project?

**CATEGORY A ONLY**

- Does the application describe how the project clinics and/or pharmacies were selected?
- Are the collaborating clinics representative of the types of HIV medical care clinics in the study jurisdiction (e.g., Ryan White-funded, academic-affiliated, private)?
- Do the project clinics have sufficient numbers of patients to enroll a minimum of 350 persons into the second line intervention?

**CATEGORY B ONLY**

- Does the application describe how the project clinics and/or pharmacies were selected (for second line intervention)?
- Are the collaborating clinics representative of the types of HIV medical care clinics in the study jurisdiction (e.g., Ryan White-funded, academic-affiliated, private)?
- Do the project clinics have sufficient numbers of patients to enroll a minimum of 350 persons (for those persons identified as prescribed ARVs but failing to fill in an extended period [ > 90 days] who will receive second and third line interventions similar to Category A)?

**2. Additional Review Criteria**

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

**Protections for Human Subjects**

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

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements ([https://www.cdc.gov/grants/additionalrequirements/ar-1.html](https://www.cdc.gov/grants/additionalrequirements/ar-1.html)).
If your proposed research involves the use of human data and/or biological specimens, you must provide a justification for your claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

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

**Vertebrate Animals**
The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (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.

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

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

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

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

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

• Type of data to be produced in the proposed project;
• Mechanisms for providing access to and sharing of the data (including provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights);
• 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.

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

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

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

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

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

4. Review and Selection Process
Applications will be evaluated for scientific and technical merit by an appropriate peer review group, in accordance with CDC peer review policy and procedures, using the stated review criteria.

As part of the scientific peer review, all applications:

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

- Will receive a written critique.

Applications will be assigned to the appropriate HHS/CDC Center, Institute, or Office.

Applications will compete for available funds with all other recommended applications submitted in response to this NOFO. Following initial peer review, recommended applications will receive a second level of review. The following will be considered in making funding decisions:

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

Applications for each category will be reviewed separately according to the review criteria for Category A and for Category B. Applicants who apply for both categories may be funded for Category A or Category B or for both Category A and Category B. If funding is only available to support one category, scientifically meritorious applications in Category A will be given preference over scientifically meritorious applications in Category B.
Review of risk posed by applicants.
Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.

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

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

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

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

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

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

Section VI. Award Administration Information

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

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

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

2. CDC Administrative Requirements

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

Specific requirements that apply to this NOFO are the following:

AR-1: Human Subjects Requirements
AR-2: Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR-3: Animal Subjects Requirements
AR-5: HIV Program Review Panel Requirements
AR-6: Patient Care
AR-7: Executive Order 12372 Review
AR-9: Paperwork Reduction Act Requirements
AR-10: Smoke-Free Workplace Requirements
AR-11: Healthy People 2020
AR-12: Lobbying Restrictions
AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities
AR-14: Accounting System Requirements
AR-15: Proof of Non-profit Status
AR-16: Security Clearance Requirement
AR-21: Small, Minority, And Women-owned Business
AR-22: Research Integrity
AR-23: Compliance with 45 C.F.R. Part 87
AR-25: Policy on Public Health Research and Non-research Data Management and Access
AR-26: National Historic Preservation Act of 1966
AR-28: Inclusion of Persons Under the Age of 21 in Research
AR-29: Compliance with EO13513, “Federal Leadership on Reducing Text Messaging while Driving”, October 1, 2009
AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973
AR 31 - Distinguishing Public Health Research and Public Health Nonresearch
AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern
AR-34: Language Access for Persons with Limited English Proficiency
AR-36: ; Certificates of Confidentiality

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

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

3. Additional Policy Requirements
The following are additional policy requirements relevant to this NOFO:
HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items and Printing Publications This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on
Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy apply to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website at: https://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html.

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

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

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

**Copyright Interests Provision** This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC’s Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient’s submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient’s submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.

The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the
CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

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

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

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

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

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

**Data Management Plan(s)**

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

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

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

4. Cooperative Agreement Terms and Conditions

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

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

• Obtaining real-time pharmacy claims (Category A and Category B) and medical claims (Category B) datasets.
• Establishing necessary agreements with the project clinic and/or pharmacy project sites and health department (e.g., Memorandum of Understanding, financial agreements [i.e., contracts] and clinic and/or pharmacy project sites work plans) and making necessary arrangements for clinic and/or pharmacy site and health department participation.
• Establishing data sharing agreements between project partners, as necessary.
• Developing data management systems to collect information necessary for the project.
• Ensuring grantee and partners implement study procedures in a manner compliant with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), HIPAA regulations, and all other applicable laws that govern the use, disclosure and transmission of individually identifiable information.
• Establishing procedures to maintain the rights and privacy of all patients evaluated in this study.
• Hosting CDC project officer(s) for site visits.
• Complying with the responsibilities for the Extramural Investigators as described in the Policy on Public Health Research and Non-research Data Management and Access.
• Ensuring the protection of human subjects through ethical review of all protocols involving human subjects at the local institution and 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.
• Disseminating study results at national or international meetings and publishing research findings in peer-reviewed scientific literature.
• PUBLICATIONS/PRESENTATIONS: Publications, journal articles, presentations, etc. produced under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate, for example: “This publication (journal article, etc.) was supported by the Cooperative Agreement Number above from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention”. In addition, the PI/PD must provide to CDC Program abstracts or manuscripts prior to any publication related to this funding. The grantee will not seek to publish or present results or findings from this project without prior clearance and approval from CDC.
• Grantees 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.

All of the following apply to both Category A and Category B projects:

• Providing technical assistance in the design and conduct of the research.
• Assisting in development of study related materials (e.g., data collection forms, consent forms).
• Facilitating the development of a research protocol for CDC IRB review, if CDC is engaged in the research.
• Assisting, as needed, in designing a data management system.
• Facilitating storage of aggregate data with participating recipients, as needed.
• Assisting in data analysis.
• Conducting site visits to ensure investigators are conforming to research protocols.
• Working with the grantee(s) to finalize a program performance monitoring plan.
• Reviewing program outcome and process data to monitor program performance.
• Assisting the PI, as needed, in complying with the Investigator responsibilities described in the Policy on Public Health Research and Non-research Data Management and Access.
• Preparing the paperwork necessary for submission of research protocols to the CDC Institutional Review Board for review, as needed.
• Obtaining Office of Management and Budget approval per the Paperwork Reduction Act, if necessary.
• Assisting the PI, as needed, in complying with the PI responsibilities described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC): http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf

NIMH Responsibilities:

• Reviewing study clearance documents (e.g., Research Determination, Information Collection Review, Institutional Review Board package).

CDC/NIMH Joint Responsibilities:

• Providing guidance in the scientific development of the study protocol(s).
• Assisting the grantee(s) with the dissemination of study results at national or international meetings and with publishing research findings in peer-reviewed scientific literature, as warranted.

Areas of Joint Grantee/CDC/NIMH Responsibility include:

• Studies will be developed by the grantee(s) with technical assistance from the Project Team. The Project Team may be composed of the grantee, CDC, NIMH and others as deemed appropriate by the grantee(s).
• 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 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 on official award-related activities including an annual review of the grantee’s performance as part of the request for continuation application;
• Make recommendations on requests for changes in scope, objectives, and or budgets that deviate from the approved peer-reviewed application;
• Carry out continuous review of all activities to ensure objectives are being met;
• Attend committee meetings and participate in conference calls for the purposes of assessing overall progress, and for program evaluation purposes; and
• Monitor performance against approved project objectives.

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

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

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

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.
Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients:
1) Information on executive compensation when not already reported through the SAM Registration; and
2) Similar information on all sub-awards/ subcontracts/ consortiaums 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.

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

1. **Yearly Non-Competing Grant Progress Report**, is due 90 to 120 days before the end of the current budget period. The RPPR form ([https://grants.nih.gov/grants/rppr/index.htm;](https://grants.nih.gov/grants/rppr/index.htm) [https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf](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.


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](https://grants.nih.gov/grants/rppr/index.htm)). Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.
   - Research Aims: list each research aim/project

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

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

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

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

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

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

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

Publications/Presentations: Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate “Not applicable: No publications or presentations have been made."
• IRB Approval Certification: Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.

• Update of Data Management Plan: The DMP is considered a living document that will require updates throughout the lifecycle of the project. Investigators should include any updates to the project’s data collection such as changes to initial data collection plan, challenges with data collection, and recent data collected. Applicants should update their DMP to reflect progress or issues with planned data collection and submit as required for each reporting period.

• Additional Reporting Requirements:

N/A

Additional information regarding the use of eRA Commons may be found at the following website:


2. Annual Federal Financial Reporting The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through eRA Commons within 90 days after the end of the calendar quarter in which the budget period ends. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data. Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information. The due date for final FFRs will continue to be 90 days after the Period of Performance end date.

Recipients must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, recipients must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

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

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

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

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

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

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

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

- Public Health Relevance and Impact: This section should address improvements in 
public health as measured by documented or anticipated outcomes from the project. The 
PI should consider how the findings of the project related beyond the immediate study to 
improved practices, prevention or intervention techniques, or informed policy, 
technology or systems improvements in public health.
• Publications; Presentations; Media Coverage: Include information regarding all publications, presentations or media coverage resulting from this CDC funded activity. Please include any additional dissemination efforts that did or will result from the project.

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

Section VII. Agency Contacts

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

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

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

CDC Technical Information Management Section (TIMS)
Telephone 770-488-2700
Email: ogstims@cdc.gov
Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Standard Time

Scientific/Research Contact
Paul Smutz, PhD
Extramural Research Program Office
Office of the Associate Director for Science
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
Section VIII. Other Information
Frequently Asked Questions

1. **Question:** Do I have to apply to both Categories A and B?
   
   **Answer:** Applicants may apply for only Category A, only Category B or both Categories A and B.

2. **Question:** If I apply to both Categories A and B, do I need to submit one application or two separate applications?

   **Answer:** Submit one application. This application should contain the required information for both Categories A and B. Clearly identify which sections of the application belong to Category A and which sections of the application belong to Category B.

3. **Question:** Will my application be reviewed as a whole or will Categories A and B be reviewed separately?

   **Answer:** Categories A and B will be reviewed and scored separately.

4. **Question:** If I apply to both Categories A and B, will I receive funding for both categories?

   **Answer:** Not necessarily. Funding decisions for Categories A and B will be made independently. Applicants who apply for both categories may be funded for Category A only or for Category B only or for both Category A and Category B.

5. **Question:** If I apply to both Categories A and B, does the Principal Investigator have to be the same for both Categories A and B?

   **Answer:** No. The PI for Category A can be different from the PI for Category B. However, only one PI may be the primary CDC contact for the entire award (both Categories) and this person should be indicated as the contact PI in the application.

6. **Question:** How do I organize my application if I am applying to both Categories A and B?

   **Answer:** If you are applying to both Categories A and B, you will submit only one application. However, each section of the application should be clearly marked as to whether it applies to only Category A, only Category B, or both Categories A and B. This includes the Project Summary/Abstract, the Specific Aims, the Research Strategy, the Human Subject section, the References, the Letters of Support, and the Budgets.
7. **Question:** How do I separate my budgets if I am applying to both Categories A and B?

**Answer:** Applications should contain a separate detailed budget for each year for each Category to which the applicant is applying (Category A, Category B). If applying for both Category A and Category B, the detailed budget for Category B should be listed as a subaward on the SF424 R&R application form (R&R Subaward Budget Attachment(s) Form). The application should include a separate detailed budget for each year of support requested for each Category to which the applicant is applying (Category A and Category B). Each subaward budget should be clearly titled (e.g., Category B budget year 1, Category B budget year 2, etc). For each budget, the project roles listed in the budget component should be consistent with those used in the Senior/Key Person section of the application. A separate budget justification narrative should be submitted with each budget (Category A and Category B) for each year of support requested.