



**Centers for Disease Control and Prevention**

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

Develop and Test HIV Prevention Interventions for Black and Hispanic Gay, Bisexual, and  
Other Men Who Have Sex with Men Who Use Substances

RFA-PS-25-113

02/20/2025

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### Overview

#### Participating Organization(s)

Centers for Disease Control and Prevention

#### Components of Participating Organizations

Components of Participating Organizations:

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

#### Notice of Funding Opportunity (NOFO) Title

Develop and Test HIV Prevention Interventions for Black and Hispanic Gay, Bisexual, and Other Men Who Have Sex with Men Who Use Substances

#### Activity Code

U01 – Research Project - Cooperative Agreements

#### Notice of Funding Opportunity Type

New

#### Agency Notice of Funding Opportunity Number

RFA-PS-25-113

#### Assistance Listings Number(s)

93.084

#### Category of Funding Activity

HL - Health

#### NOFO Purpose

The purpose of this Notice of Funding Opportunity (NOFO) is to support pilot research to develop and test behavioral implementation strategies for biomedical interventions (e.g., oral PrEP, condoms) to improve HIV and STI prevention implementation among disproportionately affected populations, especially Black/African American (Black) and Hispanic/Latino (Hispanic)

gay, bisexual, and other men who have sex with men (MSM) without HIV who report substance use (drug or alcohol). The study design and sample size should meet minimum requirements for consideration of the CDC Compendium of Best Evidence (<https://www.cdc.gov/hivpartners/php/compendium/>), and thus may have the potential for future CDC HIV prevention implementation in jurisdictions around the United States. Applicants should have access to research participants in priority jurisdictions outlined in Ending the HIV Epidemic in the United States (EHE), in support of the goals of EHE ([Ending the HIV Epidemic in the US \(EHE\) | EHE Initiative | CDC](#)), the HIV National Strategic Plan for the United States: A Roadmap to End the HIV Epidemic (2021-2025) (<https://www.cdc.gov/nchhstp/media/pdfs/2024/08/hiv-national-strategic-plan-2021-2025.pdf>), and other federal prevention planning efforts.

This NOFO, including funding and eligibility, is not limited based on, and does not discriminate on the basis of race, color, national origin, disability, age, sex (including gender identity, sexual orientation, and pregnancy) or other constitutionally protected statuses.

## Key Dates

### Publication Date:

To receive notification of any changes to RFA-PS-25-113, return to the synopsis page of this announcement at [www.grants.gov](http://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:

01/20/2025

### Application Due Date:

02/20/2025

On-time submission requires that electronic applications be error-free and made available to CDC for processing from the NIH eRA system on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov no later than 11:59 PM U.S. Eastern Time.

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

For more information on accessing or using ASSIST, you can refer to the ASSIST Online Help Site at: <https://era.nih.gov/erahelp/assist>. Additional support is available from the NIH eRA Service desk via <http://grants.nih.gov/support/index.html>.

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

Note: HHS/CDC grant submission procedures do not provide a grace period beyond the application due date time to correct any error or warning notices of noncompliance with

application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

**Scientific Merit Review:**

04/22/2025

**Secondary Review:**

05/22/2025

**Estimated Start Date:**

09/01/2025

**Expiration Date:**

03/21/2025

## Required Application Instructions

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

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

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

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

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

## Executive Summary

- **Purpose:** The purpose of this Notice of Funding Opportunity (NOFO) is to support pilot research to develop and test behavioral implementation strategies for biomedical interventions (e.g., oral PrEP, condoms) to improve HIV and STI prevention implementation among disproportionately affected populations, especially Black/African American (Black) and Hispanic/Latino (Hispanic) gay, bisexual, and other men who have sex with men (MSM) without HIV who report substance use (drug or alcohol). The study design and sample size should meet minimum requirements for consideration of the CDC Compendium of Best Evidence (<https://www.cdc.gov/hivpartners/php/compendium/>) and thus may have the potential for future CDC HIV prevention funding implementation in jurisdictions around the United States. The applicants should have access to research participants in priority jurisdictions outlined in Ending the HIV Epidemic in the United States (EHE), in support of the goals of EHE ([Ending the HIV Epidemic in the US \(EHE\) | EHE Initiative | CDC](#)), the HIV National Strategic Plan for the United States: A Roadmap to End the HIV Epidemic (2021-2025) (<https://www.cdc.gov/nchhstp/media/pdfs/2024/08/hiv-national-strategic-plan-2021-2025.pdf>), and other federal prevention planning efforts. This NOFO, including funding and eligibility, is not limited based on, and does not discriminate on the basis of race,

color, national origin, disability, age, sex (including gender identity, sexual orientation, and pregnancy) or other constitutionally protected statuses.

- **Mechanism of Support:** U01 - Research - Cooperative Agreement
- **Funds Available and Anticipated Number of Awards:** The estimated total funding available, including direct and indirect costs, for the entire three **(3)-year** period of performance is **\$2,850,000**. The number of awards will be **two (2)**. Awards issued under this NOFO are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded, and the number of awards will depend upon the number, quality, duration and cost of the applications received.
- **Budget and Period of Performance:** The estimated total funding (direct and indirect) for the first year (12-month budget period) will be **\$950,000** for the NOFO, with individual awards of **\$475,000** for the first year. The estimated total funding (direct and indirect) for the entire period of performance will be **\$2,850,000**. The period of performance is anticipated to run from **9/01/2025 to 08/31/2028**.
- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. “Application and Submission Information” of this announcement.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III of this announcement are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. CDC does not make awards to individuals directly. Individuals from organizations that are uniquely prepared to examine research relevant to underserved groups as well as individuals with disabilities are always encouraged to apply.
- **Number of PDs/PIs.** There will only be one PD/PI for each application.
- **Number of Applications.** Each institution, identified by a unique entity identifier (UEI) number, may submit up to two (2) applications, with each application focusing on one population as either Black MSM or Hispanic MSM. Each application must clearly specify its focused population.
- **Application Type.** New
- **Application Materials.** See Section IV.1 for application materials.

## Section I. Funding Opportunity Description

### Statutory Authority

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

### 1. Background and Purpose

Gay, bisexual, and other MSM continue to be disproportionately affected by HIV in the United States, accounting for an estimated 67% of annual incident infections when MSM are estimated to be approximately 4% of the general population ([HIV Diagnoses, Deaths, and Prevalence | HIV Data | CDC](#); [JMIR Public Health and Surveillance - Estimating the Population Sizes of Men](#)

[Who Have Sex With Men in US States and Counties Using Data From the American Community Survey](#)). Further, minority individuals are also disproportionately affected by HIV, with Black persons accounting for 43% of HIV diagnoses (13% of the general population) and Hispanic/Latino persons accounting for 26% of HIV diagnoses (18% of the general population) ([Epidemiology of HIV in the USA: epidemic burden, inequities, contexts, and responses - ScienceDirect](#)).

The CDC Compendium of Evidence-Based Interventions (EBIs) and Best Practices for HIV Interventions is a comprehensive resource that identifies and summarizes effective interventions and strategies for preventing and treating HIV. By compiling research findings and best practices that meet rigorous evidence-based criteria, it aids health departments, community-based organizations, and other collaborators in implementing impactful interventions. The Compendium serves as a guide for entities including CDC-funded programs that seek to adopt proven strategies, ensuring that resources are used effectively to address the epidemic.

Additionally, the Compendium informs program development, funding priorities, and public health policies, while serving as a training resource for providers. By assisting organizations in evaluating and improving their programs through evidence-based approaches, it maximizes the impact of efforts to reduce HIV transmission and enhance health outcomes. Given that Black and Hispanic MSM are especially disproportionately affected by HIV, the goal of this study is to support evaluation research that identifies effective HIV prevention interventions for Black and Hispanic MSM who use substances, with the aim of including these interventions in the Compendium.

CDC has an established history of HIV prevention research on reducing risk for HIV infection among MSM who use substances in the time when condoms were the only available prevention product. Project MIX (CDC IRB Protocol #3985) was a large, randomized control trial of a small-group based intervention focusing on the link between substance use and sexual risk behavior (sometimes in the context of “party-n-play” or “chemsex”) for MSM in Chicago, New York, and San Francisco. This study focused on all substance-using MSM, and not by race/ethnicity.

Although significant intervention effects were not found in this rigorous 3-arm study, several important implications were noted for future research – including methodological considerations for more manageable steps of smaller trials, focused populations, and approaches that can be relatively easy to implement in communities. Others have found it challenging to determine efficacy of behavioral interventions for reducing sexual risk of MSM who use substances, however some also found differential effects of such interventions by race/ethnicity of MSM that suggest a need for tailored approaches for Black and Hispanic men.

A next generation research on this topic was a pilot initiative for testing innovative approaches to increasing sexual protective behavior of methamphetamine-using MSM (RFA-PS-06-007), which included four independent projects. The project found efficacy and promising evidence for the approaches studied, including a text messaging intervention, a couples-based intervention for Black MSM, a single-session motivational interview session, and a modular approach to prevention for out-of-treatment methamphetamine users. The 3-year pilot study model was a successful, relatively “quick win” for determining interventions for further assessment or community implementation.

These interventions were in the time when condoms were the only biomedical device available for HIV prevention, and even then, there was a lack of effective HIV prevention interventions for MSM who use substances. The field is now in need of behavioral interventions for MSM who use substances in the time of PrEP use and adherence, as well as use of doxycycline postexposure prophylaxis for bacterial STI prevention (i.e., Doxy-PEP).

MSM continue to be the most disproportionately affected group among incident and prevalent HIV infections in the United States (U.S.), particularly Black and Hispanic MSM, who are disproportionately affected by HIV as noted above. Substance (drug or alcohol) use has a well-documented association with sexual risk behavior and, more recently, potentially adherence to oral PrEP use. National epidemiologic data lacks representative community estimates for substance use during sexual risk behavior, particularly in an intentional, sexualized substance use context like “party-n-play” or “chemsex”; however, substance use during sex has been a well-established community behavior for decades for many MSM in the U.S. and abroad. This NOFO addresses the lack of effective HIV prevention programs designed for Black or Hispanic MSM who use substances, especially in the time of oral PrEP. At the same time, HIV prevention intervention research often is a long road from concept to implementation.

This NOFO aims to prioritize pilot intervention research that meets the minimum CDC evidence-based criteria for “best evidence.” This research will support recommendations for the CDC Compendium and potential future funding for health departments and community-based organizations in their HIV programs.

### **Healthy People 2030 and other National Strategic Priorities**

This NOFO aims to accelerate evidence-informed decision-making and performance improvements to HIV prevention strategies. Several Healthy People 2030 (HP 2030) <https://odphp.health.gov/healthypeople> objectives are supported through this NOFO:

#### ***Reduce new HIV infections***

- HIV-1 Reduce the number of new HIV diagnoses
- HIV-2 Reduce the number of new HIV infections among adolescents and adults

#### ***Increase HIV testing and prevent HIV risk***

- HIV-13 Increase the proportion of persons living with HIV who know their serostatus
- HIV-17 Increase the proportion of sexually active persons who use condoms

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

- HIV-19 Increase the percentage of persons with newly diagnosed HIV infection linked to HIV medical care (had a routine HIV medical visit) within one month of their HIV diagnosis

### **Public Health Impact**

This NOFO aligns with the Ending the HIV Epidemic (EHE) Initiative and CDC Strategic Plan to (1) reduce the number of new HIV infections; (2) increase access to care and optimize health outcomes for people with HIV; and (3) reduce HIV-related disparities.

- Ending the HIV Epidemic: A Plan for America - <https://www.hiv.gov/ending-hiv-epidemic>
- Secretary’s Minority HIV/AIDS Fund (MAI) - <https://www.hiv.gov/federal-response/smaif/overview>

- The United States National HIV/AIDS Strategy and National Strategic Plan (2021-2025) [HIV National Strategic Plan for the United States: A Roadmap to End the HIV Epidemic \(2021-2025\)](#)
- HIV/AIDS Care Continuum: <https://www.hiv.gov/federal-response/policies-issues/hiv-aids-care-continuum>

## Relevant Work

This NOFO builds upon previous and current HIV prevention research programs, including:

- RFA-PA-02-136: Reducing sexual risk for HIV transmission in substance-using MSM
- RFA-PS-06-007: Reducing sexual risk behavior of methamphetamine-using MSM

## 2. Approach

This NOFO supports investigator-driven research and invites applicants to design, develop, direct, and conduct data collection to achieve the project outcomes outlined in the NOFO, with the understanding that the CDC will provide technical assistance and consultation as needed. The research proposed in the application should aim to meet the minimum criteria for CDC's best evidence-based study standards, with the goal of recommendation and community implementation (see CDC HIV Compendium of Best Practices; <https://www.cdc.gov/hivpartners/php/compendium/>).

**NOTE: As noted above (see Background section), Black and Hispanic MSM are disproportionately affected by HIV. Each application must clearly specify in the Specific Aim section of the application the focused population as either:**

- **Black MSM, or**
- **Hispanic MSM.**

Given that Black and Hispanic MSM are especially disproportionately affected by HIV, applications should focus on either Black or Hispanic MSM who reported recent substance use (drug or alcohol) during condomless and PrEPless anal sex with a non-primary male partner. Applications will need to demonstrate cultural competence through community engagement and access to and experience with enrolling and retaining Black or Hispanic MSM who use substances in research.

Research should be conducted in, and participants should be recruited from one or more of the EHE jurisdictions: <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/jurisdictions/phase-one>. In support to the Ending the HIV Epidemic (EHE) strategy, the CDC Compendium highlights published interventions that have undergone rigorous evaluation and are recognized as effective in the field. The research proposed in this application should aim to meet the minimum criteria for CDC's best evidence-based study standards, with the ultimate goal of recommendation and community implementation. The minimum criteria for best evidence include:

- A prospective study with random allocation of participants to a minimum of two comparison arms (e.g., intervention arm and control arm).
- Common and concurrent assessment of study arms with a minimum of baseline, immediate intervention post-test, and 3-month follow-up measurement points.

- Minimum 60% retention at follow-up assessment for each study arm, with a resultant sample size of at least n=40 per study arm for outcome analysis.

Applications should describe the design and development of research strategies to conduct an independent pilot intervention for HIV prevention focusing on either Black or Hispanic MSM who use substances. Results from the pilot study will be used to develop and test the efficacy of enhancements to oral PrEP use/adherence and condom use interventions to increase sexual protective behavior. Formative (e.g., qualitative) research will be implemented by each recipient to further develop the intervention's approach and materials needed to successfully implement the quantitative study trial, including evidence of understanding psychosocial and behavioral complexities in HIV prevention. The research design will need to meet or exceed minimum required criteria for determination of CDC best-evidence interventions, known as evidence-based interventions or EBIs, for post-study evaluation. The proposal should include data collection and analysis methods that are appropriate and rigorous to qualitative and quantitative research approaches. In addition to the best-evidence criteria applications should also propose a minimum enrollment of n=75 per arm at enrollment (n=150 for a 2-arm design). The intervention should consider and address potential scalability among the key population if it is found to be efficacious.

CDC best evidence criteria is essential for study design and implementation. Efficacious pilot projects will be well situated for evaluation review by CDC EBI staff for official recognition and inclusion in the CDC Compendium of best evidence interventions. This will allow for CDC funded agencies and community-based organizations (CBOs) to implement the program throughout the United States in the future by using CDC HIV prevention funding. This is a unique aspect of the project, balancing between broader scientific requirements of randomized control trials (RCTs) and more practical criteria for Compendium evidence-based interventions (EBIs) and CDC programs (see CDC HIV Compendium of Best Practices : <https://www.cdc.gov/hivpartners/php/compendium/>).

### **Objectives/Outcomes**

The primary study objective is to develop and pilot test HIV prevention interventions for Black and Hispanic MSM, with one recipient focusing on Black and one focusing on Hispanic MSM populations who use substances. Each recipient will conduct formative (e.g., qualitative) research and quantitative outcome research for their intervention. The study design and outcomes are intended to meet minimum criteria for CDC Best Practices Compendium "best evidence" inclusion if found to be efficacious.

Outcomes of interest are recent use of oral PrEP and condoms, and PrEP and condom awareness, knowledge, motivations, and acceptance, including condomless/PrEPless anal sex overall and substance use during condomless/PrEPless anal sex.

### **Population of Focus**

Research participants should be recruited in one or more of the EHE jurisdictions <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/jurisdictions/phase-one>. The sample size is based on what is required for CDC best-evidence criteria (EBIs listed online in the CDC Compendium), for efficiency in potential implementation of programs following outcome analyses and CDC best-evidence intervention determination.

The intent of this NOFO is to address drug use and alcohol use as it relates to HIV and STI prevention among Black and Hispanic gay, bisexual, and other MSM. This could include alcohol abuse (e.g., binge-drinking) as well as drug use.

### **Collaboration/Partnerships**

Applicants are encouraged to partner with HIV prevention community organizations and/or health departments in intervention development, testing, and overall study implementation, and to link study participants to HIV prevention and medical care services as needed. Collaborators should demonstrate cultural competence for the intended key population of the study.

### **Evaluation/Performance Measurement**

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

The NOFO supports research and invites recipients to design, develop, and conduct data collection to meet the project goals outlined in the Purpose section. Outcomes of interest are recent use of oral PrEP and condoms, and PrEP and condom awareness, knowledge, motivations, and acceptance, including condomless/PrEPless anal sex overall and substance use during condomless/PrEPless anal sex.

### **Translation Plan**

Key findings will be shared locally through community and health department partners in the designated geographical area of the study. Outcome analyses will be written up for conference abstracts and peer-reviewed journal articles and presented widely for the scientific and programmatic communities.

Final outcome analysis will determine the efficacy of each pilot behavioral intervention and whether they meet the CDC Compendium criteria for best evidence. If found efficacious while meeting those criteria, a successful intervention will be officially listed in the CDC Compendium as an evidence-based intervention endorsed for community implementation through health departments and CBOs. To apply study findings, it is critical to disseminate these findings to communities through written and oral presentations. The implementation of these prevention findings by community prevention programs would result in improved HIV prevention for communities of MSM.

## **3. Funding Strategy**

N/A

## **Section II. Award Information**

### **Funding Instrument Type:**

CA (Cooperative Agreement)

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

**Application Types Allowed:**

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

**Estimated Total Funding:**

\$2,850,000

**Estimated Total Annual Budget Period Funding for the NOFO is:**

Year 1: \$950,000 (\$475,000 per award)

Year 2: \$950,000 (\$475,000 per award)

Year 3: \$950,000 (\$475,000 per award)

**Anticipated Number of Awards:**

2

**Estimated total funding available for the first year (first 12 months), including direct and indirect costs:** \$950,000 (\$475,000 per award)

**Estimated total funding available for the entire period of performance, including direct and indirect costs:** \$2,850,000 (\$1,425,000 per award)

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

**Award Ceiling:**

\$475,000

Per Budget Period

**Award Floor:**

\$350,000

Per Budget Period

**Total Period of Performance Length:**

3 year(s)

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

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

If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR Part 75, currently in

effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

## **Section III. Eligibility Information**

### **1. Eligible Applicants**

Eligibility Category:

00 (State governments)

01 (County governments)

02 (City or township governments)

04 (Special district governments)

05 (Independent school districts)

06 (Public and State controlled institutions of higher education)

07 (Native American tribal governments (Federally recognized))

08 (Public housing authorities/Indian housing authorities)

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

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

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

20 (Private institutions of higher education)

22 (For profit organizations other than small businesses)

Additional Eligibility Category:

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

Hispanic-serving Institutions

Historically Black Colleges and Universities (HBCUs)

Tribally Controlled Colleges and Universities (TCCUs)

Alaska Native and Native Hawaiian Serving Institutions

Nonprofits (Other than Institutions of Higher Education):

Nonprofits (Other than Institutions of Higher Education)

Governments:

Eligible Agencies of the Federal Government

U.S. Territory or Possession

Other:

## Faith-based or Community-based Organizations

### Regional Organizations

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

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

## 2. Foreign Organizations

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

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

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

## 3. Additional Information on Eligibility

N/A

## 4. Justification for Less than Maximum Competition

N/A

## 5. Responsiveness

If an application requests a funding amount greater than the ceiling of \$475,000 for the first budget period and the total of \$1,425,000 for the entire period of performance as indicated in Section II. of this NOFO, CDC may consider the application non-responsive.

An application that does not specify the focused population **in the Specific Aim section** is deemed to be non-responsive.

Non-responsive applications will not enter into the review process. CDC will notify the applicants that their applications did not meet the submission requirements.

## 6. Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Unique Entity Identifier (UEI) number in order to begin each of the following registrations.

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

(Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: [NCAGE Tool / Products / NCS Help Center \(nato.int\)](#).

System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, [SAM.gov](#).

[Grants.gov](#)

[eRA Commons](#)

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

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

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

All applicant organizations **must obtain** a Unique Entity Identifier (UEI) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The UEI number is a twelve-digit number assigned by SAM.gov. An AOR should be consulted to determine the appropriate number. If the organization does not have a UEI number, an AOR should register through SAM.gov. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a UEI number.

Additionally, organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is

made, until a final financial report is submitted or the final payment is received, whichever is later.

SAM.gov is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at [SAM.gov](https://www.sam.gov) and the [SAM.gov Knowledge Base](#).

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

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

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. CDC does not make awards to individuals directly. Individuals from organizations that are uniquely prepared to examine research relevant to underserved groups as well as individuals with disabilities are always encouraged to apply.

## **9. Cost Sharing**

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

## **10. Number of Applications**

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

Each institution, identified by a unique entity identifier (UEI) number, may submit up to two (2) applications, with each application focusing on one population as either Black MSM or Hispanic MSM. Each application must clearly specify its focused population.

# **Section IV. Application and Submission Information**

## **1. Address to Request Application Package**

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

To use ASSIST, applicants must visit <https://public.era.nih.gov> where you can login using your eRA Commons credentials, and enter the Notice of Funding Opportunity Number to initiate the application, and begin the application preparation process.

If you experience problems accessing or using ASSIST, you can refer to the ASSIST Online Help Site at: <https://era.nih.gov/erahelp/assist>. Additional support is available from the NIH eRA Service desk via: <http://grants.nih.gov/support/index.html>

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

## 2. Content and Form of Application Submission

Application guides for FORMS-H application packages are posted to the [How to Apply - Application Guide](#) page.

It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide [How to Apply - Application Guide](#) except where instructed in this Notice of Funding Opportunity to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review. The package associated with this NOFO includes all applicable mandatory and optional forms. Please note that some forms marked optional in the application package are required for submission of applications for this NOFO. Follow the instructions in the SF-424 [Application Guide](#) to ensure you complete all appropriate “optional” components.

When using ASSIST, all mandatory forms will appear as separate tabs at the top of the Application Information screen; applicants may add optional forms available for the NOFO by selecting the Add Optional Form button in the left navigation panel.

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

**Letters of Support** from partners or other organizations should be placed in the PHS 398 Research Plan "Other Research Plan Section" of the application under "9. Letters of Support".

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

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

### **Mandatory**

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

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

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

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

### **3. Letter of Intent**

Due Date for Letter Of Intent 01/20/2025

A Letter of Intent is requested as the information that it contains allows CDC staff to better plan and line up proper review panels for applications.

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

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

The letter of intent should be emailed to:  
Seraphine Pitt Barnes, PhD, MPH, CHES  
Extramural Research Program Office  
Office of the Associate Director of Science

National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention  
Centers for Disease Control and Prevention  
U.S. Department of Health and Human Services  
Telephone: 770-488-6115  
Email: [SPittBarnes@cdc.gov](mailto:SPittBarnes@cdc.gov)

#### 4. Required and Optional Components

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

#### 5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of components. Not all components of the Research Plan apply to all Notices of Funding Opportunities (NOFOs). Specifically, some of the following components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guide at [How to Apply - Application Guide](#) for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Notice of Funding Opportunity Description).

Follow the page limits stated in the SF 424 unless otherwise specified in the NOFO. As applicable to and specified in the NOFO, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

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

## 12. Authentication of Key Biological and/or Chemical Resources

## 13. Appendix

All instructions in the SF424 (R&R) Application Guide at [How to Apply - Application Guide](#) must be followed along with any additional instructions provided in the NOFO.

Applicants that plan to collect public health data must submit a Data Management Plan (DMP) in the Other Plan(s) section of the PHS 398 Research Plan Component of the application. A DMP is required for each collection of public health data proposed. Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds.

The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include:

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;
- Mechanisms for 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);
- A statement (required) of any limitations you may encounter with sharing data collected or generated under this award with CDC (such as legal, regulatory, policy, or technical concerns);
- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified (this section should address archiving and preservation of identifiable and deidentified data).

The AR-25 outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

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

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

<https://www.cdc.gov/nccdphp/dch/media/files/Data-Management-Plan-template.docx>

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

Application guides for FORMS-H application packages are posted to the [How to Apply - Application Guide](#) page.

**Letters of Support** from partner companies or organizations should be placed in the PHS 398 Research Plan "Other Research Plan Section" of the application under "9. Letters of Support".

## 6. Appendix

Do not use the appendix to circumvent page limits. A maximum of 10 PDF documents are allowed in the appendix. Additionally, up to 3 publications may be included that are not publicly

available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

**PLEASE NOTE:** If applications go beyond the page limit designated for a given section, excess pages will be removed from the application prior to peer review and may negatively affect the application's scoring.

## 7. Page Limitations

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

## 8. Format for Attachments

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

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

Application guides for FORMS-H application packages are posted to the [How to Apply - Application Guide](#) page.

**PLEASE NOTE:** If applications go beyond the page limit designated for a given section, excess pages will be removed from the application prior to peer review and may negatively affect the application's scoring.

## 9. Submission Dates & Times

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

ASSIST is a commonly used platform because it provides a validation of all requirements prior to submission. If ASSIST detects errors, then the applicant must correct errors before their application can be submitted. Applicants should view their applications in ASSIST after submission to ensure accurate and successful submission through Grants.gov. If the submission is not successful and post-submission errors are found, then those errors must be corrected and the application must be resubmitted in ASSIST.

Applicants are able to access, view, and track the status of their applications in the eRA Commons.

Information on the submission process is provided in the SF-424 (R&R) Application Guidance and ASSIST User Guide at [https://era.nih.gov/files/ASSIST\\_user\\_guide.pdf](https://era.nih.gov/files/ASSIST_user_guide.pdf).

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

Applicants who encounter problems when submitting their applications must attempt to resolve them by contacting the NIH eRA Service desk at:

Toll-free: 1-866-504-9552; Phone: 301-402-7469

<http://grants.nih.gov/support/index.html>

Hours: Mon-Fri, 7 a.m. to 8 p.m. Eastern Time (closed on Federal holidays)

Problems with Grants.gov can be resolved by contacting the Grants.gov Contact Center at:

Toll-free: 1-800-518-4726

<https://www.grants.gov/support>  
[support@grants.gov](mailto:support@grants.gov)

Hours: 24 hours a day, 7 days a week; closed on Federal holidays

It is important that applicants complete the application submission process well in advance of the due date time.

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

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

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

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

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

- a. If the deadline has passed, he/she should email the Grants Management contact listed in the Agency Contacts section of this announcement explaining why the submission failed.

b. If there is time before the deadline, correct the problem(s) and resubmit as soon as possible.

Due Date for Applications 02/20/2025

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

## **10. Funding Restrictions**

### **Expanded Authority:**

For more information on expanded authority and pre-award costs, go to <https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf> and speak to your GMS.

All HHS/CDC awards are subject to the federal regulations, in 45 CFR Part 75, terms and conditions, and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.

### **Public Health Data:**

CDC requires that mechanisms for, and cost of, public health data sharing be included in grants, cooperative agreements, and contracts. The cost of sharing or archiving public health data may also be included as part of the total budget requested for first-time or continuation awards.

### **Data Management Plan:**

Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Other Plan(s) section of the PHS 398 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, but not limited to, any statutory limitations prohibiting data sharing, privacy and confidentiality considerations, embargo issues).

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.

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

### **Human Subjects:**

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

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

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

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

**Additional Funding Restrictions:**

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

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

3) Funds relating to the conduct of research involving human subjects will be restricted until the appropriate assurances and Institutional Review Board (IRB) approvals are in place. Copies of all current local IRB approval letters and local IRB approved protocols (and CDC IRB approval letters, if applicable) will be required to lift restrictions. Please see Section IV.2 of this NOFO, "Content and Form of Application Submission" for guidance on single IRB (sIRB) Plan content.

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

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

6) On September 24, 2014, the Federal government issued a policy for the oversight of life sciences "Dual Use Research of Concern" (DURC) and required this policy to be implemented by September 24, 2015. This policy applies to all New and Renewal awards issued on

applications submitted on or after September 24, 2015, and to all non-competing continuation awards issued on or after that date. CDC recipient institutions and their investigators conducting life sciences research subject to the Policy have a number of responsibilities that they must fulfill. Institutions should reference the policy, available at <http://www.phe.gov/s3/dualuse>, for a comprehensive listing of those requirements. Non-compliance with this Policy may result in suspension, limitation, or termination of US Government (USG) funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

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

## **11. Intergovernmental Review**

This NOFO is not subject to executive order 12372, Intergovernmental Review of Federal Programs. No action is needed.

## **12. Other Submission Requirements and Information**

### **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."

### **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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11144)).

**Important reminders:**

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

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

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

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

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

- [http://grants.nih.gov/grants/ElectronicReceipt/avoiding\\_errors.htm](http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm)
- [http://grants.nih.gov/grants/ElectronicReceipt/submit\\_app.htm](http://grants.nih.gov/grants/ElectronicReceipt/submit_app.htm)
- [https://era.nih.gov/files/ASSIST\\_user\\_guide.pdf](https://era.nih.gov/files/ASSIST_user_guide.pdf)
- <http://era.nih.gov/erahelp/ASSIST/>

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

## **Section V. Application Review Information**

### **1. Criteria**

Only the review criteria described below will be considered in the review process. As part of the CDC mission (<https://www.cdc.gov/about/divisions-offices/index.html>), 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 public health be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

- Does the proposed research align with populations of Black or Hispanic MSM who use substances disproportionately affected by HIV?
- Does the application adequately demonstrate an understanding of the psychosocial and behavioral complexities of Black or Hispanic MSM who use substances (e.g., stigma, substance abuse and addiction)?
- Does the proposed research have the potential to be scalable and reach a large portion of the population who experience risk for HIV?

#### **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?

- Is there evidence that the investigators and staff have experience working with the focused population of study participants?
- Does the PI have experience serving as lead investigator of an HIV prevention research award?
- Does the application demonstrate experience working with populations that use or abuse drugs and alcohol?
- Do the investigators have experience with research activities (e.g., recruitment, enrollment, retention) focusing on Black or Hispanic MSM?
- Do the investigators have experience with designing and implementing culturally competent HIV prevention interventions for Black or Hispanic MSM?
- Do the investigators have experience developing and testing HIV prevention interventions through an RCT design?

- Do the investigators have experience working in HIV prevention collaborative partnerships within their proposed research community?

### **Innovation**

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

- Is the proposed research innovative with reasonable potential for concrete application to Ending the HIV Epidemic efforts by the CDC and its partners?
- Does the application propose a novel approach to HIV prevention for Black or Hispanic MSM who use substances that is culturally competent and potentially impactful?
- Is this approach scalable to other populations outside of study sites?
- Does the proposed research study have the potential to increase efficiency or lead to cost savings at a broader population-level?

### **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 research project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed?

If the project involves human subjects and/or 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?

If applicable, how will populations with health disparities be considered and addressed in the design and implementation of the proposed research activities?

- Is the proposed research in a designated EHE jurisdiction?
- Does the application focus on developing and testing a prevention intervention for their focused population of either Black or Hispanic MSM who use substances?
- Does the application meet EBI criteria, for example, by including enrollment of a minimum 75 MSM in each arm of a minimum 2-arm RCT design?
- Is the study plan feasible for sampling, recruiting, enrolling, and retaining study participants from the proposed population in a culturally appropriate manner?
- Are the study design and plans for the development of data collection instruments culturally appropriate for the population of focus?
- Does the application include community engagement and formative work that will be used to inform the intervention?

- Does the study plan show evidence of establishing a partnership with at least one community organization to consult on all aspects of conducting the study and to link participants with prevention and medical services as needed?
- Does the study plan include a plan to measure efficacy or effectiveness? Are the measures of effectiveness objective and quantitative? Does the study plan measure the intended outcome?
- Does the application consider the scalability and sustainability of the proposed research, if an intervention is proposed?
- Are plans for dissemination of the project and translation of results stated, including potential ways that the project results might inform programmatic activities by the state and local health departments for Ending the HIV Epidemic?
- Does the application focus research on participants in priority EHE jurisdictions? Please refer to the following link for further information on disproportionately affected areas: <https://www.cdc.gov/hiv/statistics/overview/geographicdistribution.html>
- Does the application propose data collection and analysis methods that are appropriate and rigorous to qualitative and quantitative research approaches?
- Does the application adequately address recruitment and enrollment of appropriate numbers of Black or Hispanic MSM?

### **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?

To what extent will findings be disseminated to communities and populations of focus in an appropriate and accessible manner?

- Does the application include Memoranda of Understanding (MOU) from partnering agencies that identify participant sampling, outreach, and enrollment?
- Does the application describe how the sites were selected? Does the application provide a sound justification (i.e., need) for including the proposed sites?
- Does the planned location for the study have access to an adequate number of persons in the proposed focused population to meet minimum Compendium criteria?
- Does the application demonstrate access to qualified personnel with realistic and sufficient percentage time commitments relative to each phase of the study timeline?
- Does the study plan demonstrate baseline epidemiologic, behavioral, clinical, administrative, and management experience needed to conduct the proposed research?
- Does the application provide a description of duties, percentage time commitments, and responsibilities of project personnel including clear lines of authority and supervisory capacity over the behavioral, administrative, data management, and statistical aspects of the research?

## 2. Additional Review Criteria

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

### Protections for Human Subjects

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

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

### Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research (<https://www.cdc.gov/women/research/index.htm>) and the policy on the Inclusion of Persons Under 21 in Research (<https://www.cdc.gov/grants/additional-requirements/ar-28.html>).

### Vertebrate Animals

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

### Biohazards

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

### Dual Use Research of Concern

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

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

### **3. Additional Review Considerations**

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

#### **Applications from Foreign Organizations**

N/A

#### **Resource Sharing Plan(s)**

Reviewers will comment on whether the Resource Sharing Plan(s) (e.g. [Sharing Model Organisms](#)) or the rationale for not sharing the resources, is reasonable.

#### **Budget and Period of Support**

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain budget preparation guidance for completing a detailed justified budget on the CDC website, at the following Internet address: <https://www.cdc.gov/grants/applying/application-resources.html>. Following this guidance will also facilitate the review and approval of the budget request of applications selected for award.

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

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

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

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

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

## 4. Review and Selection Process

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

As part of the scientific peer review, all applications:

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

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

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

The NOFO intends to make two awards, one for each of the two focused populations (Black MSM or Hispanic MSM). If there are no qualified applications for a particular focused population, then two awards will be made for one focused population with geographic diversity among EHE jurisdictions.

### **Review of risk posed by applicants.**

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

In accordance with 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM 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 review of risk may impact award eligibility.

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

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

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

## **5. Anticipated Announcement and Award Dates**

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

## **Section VI. Award Administration Information**

### **1. Award Notices**

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

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

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the Grants Management Officer is the authorizing document and will be sent via email to the recipient'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.** See [CDC General Terms and Conditions](#).

If you receive an award, you must follow all applicable nondiscrimination laws. You agree to this when you register in [SAM.gov](#). You must also submit an Assurance of Compliance ([HHS-690](#)). To learn more, see the [HHS Office for Civil Rights website](#).

### ***Generally applicable ARs:***

[\*AR-1: Human Subjects Requirements\*](#)

[\*AR-2: Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research\*](#)

[\*AR-3: Animal Subjects Requirements\*](#)

[\*AR-7: Executive Order 12372, Intergovernmental Review of Federal Programs\*](#)

[\*AR-9: Paperwork Reduction Act Requirements\*](#)

[\*AR-10: Smoke-Free Workplace Requirements\*](#)

[\*AR-11: Healthy People 2030\*](#)

[\*AR-12: Lobbying Restrictions\*](#)

[\*AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities\*](#)

[\*AR-14: Accounting System Requirements\*](#)

[\*AR-16: Security Clearance Requirement\*](#)

[\*AR-17: Peer and Technical Reviews of Final Reports of Health Studies – ATSDR\*](#)

[\*AR-21: Small, Minority, And Women-owned Business\*](#)

[\*AR-22: Research Integrity\*](#)

[\*AR-24: Health Insurance Portability and Accountability Act Requirements\*](#)

[\*AR-25: Data Management and Access\*](#)

[\*AR-26: National Historic Preservation Act of 1966\*](#)

[\*AR-28: Inclusion of Persons Under the Age of 21 in Research\*](#)

[\*AR-29: Compliance with EO13513, “Federal Leadership on Reducing Text Messaging while Driving”, October 1, 2009\*](#)

[\*AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973\*](#)

[\*AR-31: Research Definition\*](#)

[\*AR-32: Appropriations Act, General Provisions\*](#)

[AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern](#)

[AR-37: Prohibition on certain telecommunications and video surveillance services or equipment for all awards issued on or after August 13, 2020](#)

**ARs applicable to HIV/AIDS Awards:**

[AR-4: HIV/AIDS Confidentiality Provisions](#)

[AR-6: Patient Care](#)

### 3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

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

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

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

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

**Copyright Interests Provision:** This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Applicants may

include reasonable publication costs and costs associated with submission, curation, management of data, and special handling instructions as allowable expenses in all research budgets. 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 without any embargo or delay after publication. Also at the time of submission, Recipient and/or Recipient's submitting author must also post the manuscript through PMC without any embargo or delay after publication. The recipient must obtain prior approval from the CDC for any exception to this provision.

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

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

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

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

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

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

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

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

The AR-25 <https://www.cdc.gov/grants/additional-requirements/ar-25.html> outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

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

#### 4. Cooperative Agreement Terms and Conditions

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

the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and HHS/CDC as defined below.

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

- Defining the scope, methods, and data collection design.
- Disseminating findings by presenting at national or international meetings and publishing research findings in peer-reviewed scientific literature.
- Participating in regular conference calls with CDC project officer(s).
- Collaborating in the development of human subject research protocols and additional documents for IRB review by all cooperating institutions participating in the project and for OMB review, if needed.
- Developing study protocols for CDC Project Determination and review, and potential data sharing. Complying with the responsibilities for the Extramural Investigators as described in the Policy on Public Health Research and Non-research Data Management and Access <https://www.cdc.gov/grants/additionalrequirements/ar-25.html>
- Ensuring the protection of human subjects through ethical review of all protocols involving human subjects at the local institution and at CDC and obtaining the appropriate Institutional Review Board approvals for all institutions or individuals engaged in the conduct of the research project.
- Working with CDC scientists to obtain OMB-PRA approvals, as needed.
- PUBLICATIONS/PRESENTATIONS: Publications, journal articles, presentations, etc. produced under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate, for example: “This publication (journal article, etc.) was supported by the Cooperative Agreement Number above from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention”. In addition, the PI/PD must provide to CDC Program abstracts or manuscripts prior to any publication related to this funding. The recipient will not seek to publish or present results or findings from this project without prior clearance and approval from CDC.
- Complying with the responsibilities for the PI as described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) <http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf>.
- 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.
- Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.

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

- Providing technical assistance in the development of the design and conduct of the research.

- Assistance in the analysis of research information and the presentation and publication of research findings, as warranted.
- Conducting site visits to ensure that research sites are appropriate, collaborations outlined in application are effective, the focused population is actively involved in the research activities, and investigators are adhering to the research protocol.
- Assisting the PI, as needed, in complying with the Investigator responsibilities described in the Policy on Public Health Research and Non-research Data Management and Access <https://www.cdc.gov/grants/additionalrequirements/ar-25.html>
- Preparing the paperwork necessary for submission of research protocols to the CDC Institutional Review Board for review, as needed.
- Obtaining Office of Management and Budget approval per the Paperwork Reduction Act, if necessary.
- Assisting the PI, as needed, in complying with the PI responsibilities described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) <http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf>

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

- Named in the Notice of Award as the Program Official to provide overall scientific and programmatic stewardship of the award.
- Serve as the primary point of contact for official pre-award activities and for all award-related activities, including an annual review of the recipients' performance as part of the request for continuation application.
- Make recommendations on requests for changes in scope, objectives, and/or budgets that deviate from the approved peer-reviewed application.
- Carry out continuous review of all activities to ensure objectives are being met.
- Attend committee meetings and participate in conference calls for the purposes of assessing overall progress, and for program evaluation purposes.
- Monitor performance against approved project objectives.

## 5. Reporting

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

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

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

that continued funding is in the best interest of the Federal government.

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

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients:

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

#### **A. Submission of Reports**

The Recipient Organization must submit:

**Annual Performance Report (APR)/RPPR** is due 120 days before the end of the current budget period, or the date identified in the guidance that CDC distributes. The RPPR form (<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.

**Annual Federal Financial Report (FFR) SF-425** ([Reporting | Grants | CDC](#)) is required and must be submitted to the Payment Management System accessed through the FFR navigation link in eRA Commons or directly through PMS **within 90 days after the budget period ends**.

**Closeout Reports: a final progress report**, invention statement, equipment/inventory report, and the **Final FFR (SF-425)** are required **120 days after the end of the period of performance**.

#### **B. Content of Reports**

1. Annual Performance Report (APR)/RPPR: The recipient's continuation application/progress report should include:
  - Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the RPPR form in eRA Commons (<https://grants.nih.gov/grants/rppr/index.htm>). Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.

- Research Aims: list each research aim/project
  - a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned
  - b) Leadership/Partnership: list project collaborations and describe the role of external partners.
- Translation of Research (1 page maximum). When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that were translated into public health policy or practice and how the findings have been or may be adopted in public health settings. Or, if they cannot be applied yet, this section should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. Questions to consider in preparing this section include:
  - How will the scientific findings be translated into public health practice or inform public health policy?
  - How will the project improve or effect the translation of research findings into public health practice or inform policy?
  - How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs or practices?
  - How will the findings advance or guide future research efforts or related activities?
- Public Health Relevance and Impact (1 page maximum). This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques, inform policy, or use of technology in public health. Questions to consider in preparing this section include:
  - How will this project lead to improvements in public health?
  - How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
  - How will the findings, results, or recommendations contribute to documented or projected reductions in morbidity, mortality, injury, disability, or disease?
- Current Budget Period Financial Progress: Status of obligation of current budget period funds and an estimate of unobligated funds projected provided on an estimated FFR.
- New Budget Period Proposal:

- Detailed operational plan for continuing activities in the upcoming budget period, including updated Measures of Effectiveness for evaluating progress during the upcoming budget period. Report listed by Research Aim/Project.
- Project Timeline: Include planned milestones for the upcoming year (be specific and provide deadlines).
- New Budget Period Budget: Detailed line-item budget and budget justification for the new budget period. Use the CDC budget guideline format.
- Publications/Presentations: Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate "Not applicable: No publications or presentations have been made."
- IRB Approval Certification: Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.
- Update of Data Management Plan: The DMP is considered a living document that will require updates throughout the lifecycle of the project. Investigators should include any updates to the project's data collection such as changes to initial data collection plan, challenges with data collection, and recent data collected. Applicants should update their DMP to reflect progress or issues with planned data collection and submit as required for each reporting period.
- Additional Reporting Requirements:

**2. Annual Federal Financial Reporting** The Annual Federal Financial Report (FFR) SF-425 is required and must be submitted through the Payment Management System (PMS) within 90 days after the end of the budget period. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The Final FFR (SF-425) must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the Final FFR expenditure data and the Payment Management System's (PMS) cash transaction data.

Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information.

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

Recipients must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, recipients must submit a Final FFR (SF-425), final progress report, and Final Invention Statement and Certification within 120 days after the end of the period of performance. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

Organizations may verify their current registration status by running the “List of Commons Registered Organizations” query found at: [https://era.nih.gov/registration\\_accounts.cfm](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](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 recipient's final report should include:

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

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

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

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

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

## **6. Termination**

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

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

- (1) By the HHS awarding agency or pass-through entity, if the non-Federal entity fails to comply with the terms and conditions of the award;
- (2) By the HHS awarding agency or pass-through entity for cause;
- (3) By the HHS awarding agency or pass-through entity with the consent of the non-Federal entity, in which case the two parties must agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated; or
- (4) By the non-Federal entity upon sending to the HHS awarding agency or pass-through entity written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the HHS awarding agency or pass-through entity determines in the case of partial termination that the reduced or modified portion of the Federal award or subaward will not accomplish the purposes for which the Federal award was made, the HHS awarding agency or pass-through entity may terminate the Federal award in its entirety.

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

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

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

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

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

3) Terms: For purposes of this clause:

“Commodity” means any material, article, supplies, goods, or equipment;

“Foreign government” includes any foreign government entity;

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

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

5) Contents of Reports: The reports must contain:

a. recipient name;

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

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

d. reporting period;

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

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

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

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

## Section VII. Agency Contacts

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

### **Application Submission Contacts**

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading or navigating forms)

Contact Center Phone: 800-518-4726

<https://www.grants.gov/support>

Email: [support@grants.gov](mailto: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

<https://www.era.nih.gov/need-help>

Email: [commons@od.nih.gov](mailto:commons@od.nih.gov)

Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time; closed on Federal holidays

### **Agency Contacts:**

#### **Scientific/Research Contact**

Jocelyn Patterson Mosley, 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

Telephone: 404-639-6437

Email: [JPatterson@cdc.gov](mailto:JPatterson@cdc.gov)

#### **Peer Review Contact**

Seraphine Pitt Barnes, PhD, MPH, CHES

Extramural Research Program Office

Office of the Associate Director of Science

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

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

Telephone: 770-488-6115

Email: [SPittBarnes@cdc.gov](mailto:SPittBarnes@cdc.gov)

#### **Financial/Grants Management Contact**

Manal Ali

Office of Grants Services

Office of Financial Resources

Office of the Chief Operating Officer

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

Telephone: 770-488-2706

Email: [hfo8@cdc.gov](mailto:hfo8@cdc.gov)

## **Section VIII. Other Information**

Other CDC Notices of Funding Opportunities can be found at [www.grants.gov](http://www.grants.gov).

All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

### **Authority and Regulations**

Awards are made under the authorization of Sections of the Public Health Service Act as amended and under the Code of Federal Regulations.

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