Division of Overdose Prevention

Notice of Funding Opportunity

Application due December 2, 2024

Rigorous Evaluation of Primary and Secondary Overdose Prevention Activities Among Populations Disproportionately Affected by Overdose

Opportunity number: RFA-CE-25-149

Contents

Before you begin

If you believe you are a good candidate for this funding opportunity, secure your SAM.gov and Grants.gov registrations now. If you are already registered, make sure your registrations are active and up-to-date.

SAM.gov registration (this can take several weeks)

You must have an active account with SAM.gov. This includes having a Unique Entity Identifier (UEI).

See Step 2: Get Ready to Apply

Grants.gov registration (this can take several days)

You must have an active Grants.gov registration. Doing so requires a Login.gov registration as well.

See Step 2: Get Ready to Apply

Apply by December 2, 2024

Applications are due by 11:59 p.m. Eastern Time on December 2, 2024.

To help you find what you need, this NOFO uses internal links. In Adobe Reader, you can go back to where you were by pressing Alt + Left Arrow (Windows) or Command + Left Arrow (Mac) on your keyboard.

Step 1: Review the Opportunity

In this step

Basic information

Centers for Disease Control and Prevention

National Center for Injury Prevention and Control

Division of Overdose Prevention

Rigorously evaluate overdose prevention activities.

Summary

This NOFO funds research focused on people experiencing disproportionate burden of drug overdose, those who are at greater risk of exposure to drug use, or those experiencing adverse drug use outcomes related to social determinants of health.

Your research should rigorously evaluate either primary or secondary prevention strategies for reducing rates of nonfatal overdose, fatal overdose, and/or substance use disorders involving federally illegal drugs or misuse of prescription medications, drug use, or initiation of drug use, particularly among youth.

Funding details

Instrument type: Cooperative Agreement

Application type: New

Expected total program funding over the performance period: Up to $24,500,000

Expected total program funding per budget period: Up to $4,900,000

Expected number of awards: Up to 7

Maximum Funding per budget period: $700,000

Expected average award amount per budget period: $700,000

We plan to offer two funding options for this Notice of Funding Opportunity. You may submit a research proposal under either **Funding Option A** or **Funding Option B**.

Have questions? See Contacts and Support.

Key facts

Opportunity name: Rigorous Evaluation of Primary and Secondary Overdose Prevention Activities Among Populations Disproportionately Affected by Overdose

Opportunity number: RFA-CE-25-149

Activity code: U01

Funding activity category: HL — Health

Federal assistance listing: 93.136

Key dates

Application deadline: December 2, 2024

Optional letter of intent deadline: November 4, 2024

Informational call: October 10, 2024, at 2 p.m. ET

Expected scientific review date: March 25, 2025

Expected secondary review date: May 7, 2025

Expected award date: August 29, 2025

Expected start date: September 30, 2025

Expiration date: March 7, 2025

Funding option A

Funding option A will support research projects that support implementation and rigorous evaluation of prevention activities.

These projects will be funded up to **$350,000** per 12-month budget period for up to **3 years**.

The period of performance is expected to be September 30, 2025, to September 29, 2028, for three-year awards.

Funding option B

Funding option B will support research projects that support development, implementation, and rigorous evaluation of prevention activities.

These projects will be funded up to **$700,000** per 12-month budget period for up to **5 years**.

The period of performance is expected to be September 30, 2025, to September 29, 2030, for five-year awards.

You must clearly indicate in the abstract whether your research proposal falls under:

- **Funding option A:** Implement and rigorously evaluate strategies (3-year award)
- **Funding option B:** Develop, implement, and rigorously evaluate strategies (5-year award)

The number of awards is subject to available funds and program priorities.

Number of applications

You may submit more than one application if each application is scientifically distinct.

However, applicant institutions can submit only one grant application with the same principal investigator in response to this NOFO. Only one application per principal investigator will be reviewed or funded under this announcement, regardless of funding option selected.

If two or more applications from the same PI are received, the only application that will be submitted for review will be the last application received based on the document's time and date stamp in Grants.gov

Additionally, applicant institutions submitting applications with essentially the same proposed research to two or more CDC NOFOs will not be funded under more than one NOFO.

You must ensure that duplicate applications are withdrawn prior to the application review date.

Eligibility

Eligible applicants

Only the following types of organizations may apply. State, territorial, local, and tribal government organizations may also opt to select a bona fide agent to apply on their behalf:

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

Bona fide agents must submit documentation that demonstrates their arrangement with the eligible applicant. See other attachments.

Other required responsiveness factors

The following additional factors must be addressed in your application to qualify for funding under this NOFO. Please see also Initial Review.

- **The proposed research should rigorously evaluate either primary or secondary prevention strategies, on reducing rates of at least two required outcomes from this list: nonfatal overdose, fatal overdose, substance use disorders involving federally illegal drugs or misuse of prescription medications, drug use, or initiation of drug use, particularly in youth.** Applications that do not propose to develop,

implement, and rigorously evaluate or implement, and rigorously evaluate strategies that (1) prevent adverse outcomes related to drug use among those not yet engaged in it (i.e., primary prevention) or (2) reduce adverse outcomes among those already engaged in drug use by linking them to and retaining them in care (i.e., secondary prevention), as evidenced in the Research Strategy section of the application's research plan, will be considered nonresponsive and will not be forwarded for peer review.

- **The proposed research should not focus on measures of alcohol use disorder only, alcohol use only, tobacco use disorder only, or tobacco use only.** Applications that do not propose to measure federally illegal drugs or prescription medications, or substance use disorders not involving federally illegal drugs or misuse of prescription medications as a required outcome will be considered nonresponsive and will not be forwarded for peer review.
- **The proposed research must employ rigorous evaluation designs (i.e., experimental, quasi-experimental) that include a control/comparison group.** Applications that do not include a control/comparison group or do not propose an experimental or quasi-experimental design, as evidenced in the Research Strategy section of the application's research plan will be considered nonresponsive and will not be forwarded for peer review.
- **The proposed research must not focus on law enforcement strategies without inclusion of a strong public health component, as a primary research aim.** Applications that propose to focus on law enforcement strategies without a public health component or focus, as evidenced in the Research Strategy section of the application's research plan, will be considered nonresponsive and will not be forwarded for peer review.
- **The proposed research must focus on human subjects.** Applications proposing research using non-human species, as evidenced in the Research Strategy section of the application's research plan, will be considered nonresponsive and will not be forwarded for peer review.
- **The proposed budget for each fiscal year must be less than or equal to the budget ceiling outlined in the Funding Details section.** Applications that exceed the budget in any year will be considered nonresponsive and will not be forwarded for peer review.
- **Applicants must include required documentation that meets the following PD or PI/Co-PI requirements:**
    - The SF-424 Biographical Sketch for the PD, PI or Co-Investigator(s) must include documentation of expertise in substance use, substance use disorders, or overdose that is reflected in the

application's research strategy section. The knowledge, experience, and expertise necessary to conduct this research and achieve proposed objectives must be documented with either of the following:

- At least one first-authored, peer-reviewed publication as defined by the NIH National Library of Medicine in the relevant area of substance use, substance use disorders, or overdose
- By serving as a PD, PI, or co-PI on a research grant in substance use, substance use disorders, or overdose
- Experience requirements may be demonstrated through the combined experiences of a PI and Co-PI (if applicable). The citation of the relevant publication(s) or research experience must be clearly identified (by bold text or highlight) in the appropriate SF 424 Biographical Sketch.
- Applications that do not include documentation to meet this PI/co-PI requirement will be considered nonresponsive and will not be forwarded for peer review.

Eligible project directors and principal investigators

We invite anyone who has the educational background, skills, knowledge, and resources necessary to carry out the proposed research as a project director or principal investigator (PD/PI) to work with their organization or institution to apply for support.

We encourage people from underrepresented groups to apply, such as people from underrepresented racial, ethnic, sexual orientation and gender identity groups, and those with disabilities.

Please refer to PI criteria in the "Investigators" section of Scored Criteria.

Cost sharing and matching funds

This program has no cost-sharing or matching funds requirement. We will not consider cost-sharing fund contributions during your application review.

However, if you choose to submit voluntary cost-sharing funds in your application, and we fund the award, we will require you to report on these funds.

Program description

Background and purpose

In 2022, drug overdose deaths surpassed 100,000.[1] Death rates increased among both sexes, all adults above age 25, and all races and Hispanic-origin groups except non-Hispanic Asian people. Rates of overdose deaths in 2022 varied among demographic groups, and percentage increases varied from 2021 to 2022, suggesting disproportionate burden of fatal overdose across groups.[2] The intersection of demographic characteristics is also important: data from 25 states and the District of Columbia showed that overdose death rates were higher in counties with higher income inequality ratios, and disparities were starker for Black and Hispanic people.[3]

Exposure to drug use and other adverse outcomes of drug use vary. For example, adverse family conditions and certain social network characteristics (such as lack of social support or a peer network that uses substances) are associated with initiation of substance use, and the influence of these experiences may be modified by characteristics such as age, race, socioeconomic status, and sex.[4] [5] Community characteristics such as neighborhood disadvantage, unemployment rates, and witnessing high-risk events such as arrests correlate with initiation of drug use.[6] [7]

Similarly, access to substance use treatment is unequal across population groups. For example, data from 25 states show that among overdose decedents in 2019 and 2020, Black, Hispanic, and American Indian/Alaskan native persons had the lowest proportions of documented evidence of substance use treatment.[8] Community characteristics such as ease of access to drugs are associated with returning to drug use.[9]

Research suggests that some people may have a greater risk for exposure to drug use. These people include children and young adults growing up in a home where adults were negatively impacted by substance use[10] [11] and children with adverse childhood experiences more broadly.[12] Additionally, children with behavioral disorders such as conduct disorder may be more likely to engage in risky substance use later in life.[13] [14] A bidirectional association between chronic pain and substance use[15] potentially places people in pain at higher risk of adverse outcomes related to drug use, and pain is the most frequently reported reason for prescription pain reliever misuse.[16] Groups that have been economically or socially marginalized can also be at greater risk for substance use and related harms in relation to

racism and discrimination[17] or witnessing community violence.[18] **Primary prevention strategies among these groups that reduce exposure to drug use and enhance buffers against drug use and adverse outcomes are needed.**

Research suggests that some people may be at greater risk compared to other groups for drug overdose or for adverse drug use outcomes related to social determinants of health and experiences and conditions that occur after drug use and impede access to treatment and recovery. People who are not treated for overdoses in emergency departments or other medical facilities may not be linked to harm reduction services or evidence-based care.[19] [20] [21] Parents with substance use disorder may not seek care due to fear of child removal or the inability to reside with their children during treatment. [22] [23] Those who have been recently incarcerated are at greater risk of overdose post-release and can benefit from strategies that serve them once they re-enter the community.[24] [25] People who inject drugs may be deterred from accessing treatment potentially because of stigma[26] and may need access to specialists who address medical consequences specific to injection drug use.[27] Some pregnant persons may be less likely to be screened for substance use disorder,[28] also potentially from stigma,[29] and many who need treatment do not receive it[30] despite increased admissions.[31]

People with both mental health conditions and substance use disorders report lower percentages of treatment for their conditions than do people who report only one of these diagnoses.[32] They also face negative outcomes including returning to use[33] [34] and may benefit from integrated treatment.[35] Persons experiencing homelessness often lack health care because basic needs like food and shelter come first[36] and untreated substance use disorders may be common. Treatment services may be limited at clinics that serve persons experiencing homelessness.[37] **Secondary prevention strategies to identify and effectively link these groups to and retain them in evidenced-based care are needed.**

The Centers for Disease Control and Prevention's (CDC) National Center for Injury Prevention and Control (NCIPC) solicits investigator-initiated research on overdose prevention strategies. **This research should focus on people experiencing a disproportionate burden of drug overdose, those who are at greater risk of exposure to drug use, or those experiencing adverse drug use outcomes related to social determinants of health.**

Funding can be used to develop, implement, and rigorously evaluate strategies to prevent drug-related adverse outcomes among those not yet

engaged in drug use (primary prevention), or reduce adverse outcomes among those already engaged in drug use by linking them to and retaining them in care (secondary prevention).

Healthy People 2030

This research addresses the Healthy People 2030 focus areas of Substance Use and Injury Prevention. Specifically, this NOFO supports the following Healthy People Substance Use (SU) areas:

- **SU-01:** Increase the proportion of people with a substance use disorder who got treatment in the past year
- **SU-03:** Reduce drug overdose deaths
- **SU-07:** Reduce the proportion of adults reporting use of any illicit drugs during the past 30 days
- **SU-15:** Reduce the proportion of people with illicit drug use disorder in the past year.

This research also supports the Healthy People Injury Prevention (IVP) area of IVP-20: Reduce overdose deaths involving opioids, and IVP-03: Reduce unintentional injury deaths.

Public health impact

The proposed research is expected to expand the evidence base for primary and secondary prevention of drug-use outcomes, identified as required outcomes in the Approach section. It will focus on people most at risk for exposure to drugs and most affected by drug overdose or adverse outcomes related to drug use.

Related work

This work addresses the following focus areas in the strategic plan for NCIPC's Division of Overdose Prevention:

- Increase rigorous evaluation, applied research, and opportunities for linking and retaining persons with disproportionate risk for overdose and adverse outcomes related to substance use to harm reduction services, evidence-based treatment, and recovery support services.
- Identify and address shared risk and protective factors associated with substance use initiation and misuse and other comorbidities across the prevention continuum, including mental health and well-being.

This proposal also aligns with the current research priorities of the Division of Overdose Prevention.

This project addresses the following research priority:

- Develop and evaluate innovative prevention strategies designed to prevent overdose, including among those at greatest risk.

This works complements the following programmatic efforts from the Division of Overdose Prevention:

- CDC funded 66 jurisdictions as part of its Overdose Data to Action Program, a cooperative agreement that began in September 2019. The program focuses on the complex and changing nature of the overdose epidemic, including stimulant overdoses, and highlights the need for an interdisciplinary, comprehensive, and cohesive public health approach to preventing overdoses. In 2023, CDC released two new funding opportunities, one for states (Overdose Data to Action in States) and one for localities and territories (Overdose Data to Action: Limiting Overdose through Collaborative Actions in Localities), to help ensure broad resources and support to respond to the evolving overdose crisis. Both awards support five-year cooperative agreements to expand and strengthen overdose surveillance and prevention efforts to reduce fatal and nonfatal overdoses involving opioids, stimulants, or polysubstance use. A total of 90 jurisdictions were funded.
- In partnership with the Office of National Drug Control Policy (ONDCP), CDC supports more than 750 community coalitions across the country to prevent and reduce substance use among youth through its Drug-Free Communities Support Program.

The following publications from Division of Overdose Prevention authors have been recently released:

Increased Risk of Exposure

- Harper CR, Li J, Sheats K, et al. Witnessing Community Violence, Gun Carrying, and Associations with Substance Use and Suicide Risk Among High School Students — Youth Risk Behavior Survey, United States, 2021. MMWR Suppl 2023;72(Suppl-1):22–28. DOI: http://dx.doi.org/10.15585/mmwr.su7201a3
- Rikard, SM, Strahan, AE, Schmit, KM, Guy, GP Jr. Chronic Pain Among Adults — United States, 2019–2021. MMWR Morb Mortal Wkly Rep 2023;72:379–385. DOI: http://dx.doi.org/10.15585/mmwr.mm7215a1
- Stokes EK, Pickens CM, Wilt G, Liu S, David F. County-level social vulnerability and nonfatal drug overdose emergency department visits and hospitalizations, January 2018-December 2020. Drug Alcohol

Depend. 2023 Jun 1;247:109889. DOIO: https://doi.org/10.1016/j.drugalcdep.2023.109889. Epub 2023 Apr 23. PMID: 37148633.

- Jiang X, Govoni TD, Illg Z, Connolly S, et al. Sources of nonmedically used prescription psychotherapeutic drugs using real-world data from adolescents and adults assessed for substance use treatment–2014-2022. *Research in Social and Administrative Pharmacy.* 2023. DOI: https://doi.org/10.1016/j.sapharm.2023.10.014

Increased Risk of Adverse Outcomes Related to Social Determinants of Health

- Terranella A, Guy G, Strahan A, Mikosz C. Out-of-Pocket Costs and Payer Types for Buprenorphine Among US Youth Aged 12 to 19 Years. JAMA Pediatrics. 2023;177(10):1096–1098. DOI: 10.1001/jamapediatrics.2023.2376
- Kariisa M, Davis NL, Kumar S, et al. Vital Signs: Drug Overdose Deaths, by Selected Sociodemographic and Social Determinants of Health Characteristics — 25 States and the District of Columbia, 2019–2020. MMWR Morb Mortal Wkly Rep. ePub: 19 July 2022. DOI: http://dx.doi.org/10.15585/mmwr.mm7129e2

Secondary Prevention

- Worthington, N, Gilliam, T, Mital, S. First Responder Assertive Linkage Programs: A Scoping Review of Interventions to Improve Linkage to Care for People Who Use Drugs. Journal of Public Health Management and Practice. 28(Supplement 6):S302-S310, November/December 2022. DOI: https://doi.org/10.1097/phh.0000000000001611
- Joshi S, Rivera BD, Cerdá M, et al. One-Year Association of Drug Possession Law Change With Fatal Drug Overdose in Oregon and Washington. *JAMA Psychiatry. 2023;80(12):1277–1283.* DOI: 10.1001/jamapsychiatry.2023.3416

Approach

Strategy focus: Primary or secondary prevention

There are two applicable funding options for this research:

- **Funding option A:** Implement and rigorously evaluate strategies (3-year award)
- **Funding option B:** Develop, implement, and rigorously evaluate strategies (5-year award)

You must rigorously evaluate primary or secondary prevention strategies for drug use outcomes. For this NOFO, drug use is defined as use of federally illegal drugs (e.g., heroin, cocaine, methamphetamine, psilocybin, cannabis) or misuse of prescription medications (i.e., use in any way not directed by a doctor, including use of someone else's prescription; use in greater amounts, more often, or longer than recommended; or use in any other way not directed by a doctor). "Drug use outcomes" include measures such as overdose (nonfatal and/or fatal), substance use disorders, drug use, and initiation of drug use, particularly in youth.

For this NOFO, primary prevention strategies are for **people not yet engaged in drug use** who are at greater risk of exposure to drug use or experiencing adverse drug use outcomes related to social determinants of health (e.g., children of families with intergenerational drug use as well as those with mental health conditions or behavioral disorders, people with chronic pain, children and adults who have experienced trauma, people experiencing poverty or violence in their neighborhoods, or lack of economic opportunity) on reducing rates of at least two required outcomes (See Objectives and Outcomes).

For this NOFO, secondary prevention strategies should include linkage to and retention in care for **people already engaged in drug use** who are experiencing disproportionate burden of drug overdose or who are at greater risk of experiencing adverse drug use outcomes related to social determinants of health, like people who experience nonfatal overdoses and do not receive care at an emergency department, persons leaving incarceration, persons who inject drugs, parents who may fear child removal, pregnant persons, people with co-occurring mental health conditions and substance use disorders involving federally illegal drugs or misuse of prescription medications, and people experiencing homelessness on reducing rates of at least two required outcomes (See Objectives and Outcomes).

Care is defined as evidence-based treatment for opioid use disorder (OUD) (i.e., buprenorphine, methadone, naltrexone) alone or in combination with behavioral health strategies (such as counseling, motivational interviewing, cognitive behavioral therapy). While currently there are no FDA-approved medications to treat stimulant use disorder, there are evidence-based behavioral health strategies (i.e., motivational interviewing, contingency management, community reinforcement approach, and cognitive behavioral therapy).

Objectives and outcomes

This section includes outcomes you are expected to report progress on and achieve within the period of performance if you receive funding.

Your research should rigorously evaluate either primary or secondary prevention strategies for reducing rates or counts of at least **two required outcomes from this list:**

- Nonfatal overdose
- Fatal overdose
- Substance use disorders involving federally illegal drugs or misuse of prescription medications
- Drug use
- Initiation of drug use, particularly in youth

Measurement of your two selected required outcomes should include rates and/or counts. Additionally, you are encouraged to include the following under your required outcomes (where applicable):

- Drug(s) involved in nonfatal overdose
- Drug(s) involved in fatal overdose
- The specific type(s) of drugs involved in substance use disorders
- Current drug use
- Frequency of drug use
- Types of drug(s) use
- Route(s) of drug administration
- Age of initiation of drug use
- Types of drug(s) used at initiation

Note: Measures of alcohol use disorder only, alcohol use only, tobacco use disorder only, or tobacco use only are not applicable under this NOFO.

The measurement of optional outcomes, though not required, can also be included. Secondary outcomes can include correlates of drug use or overdose morbidity and mortality, or variables that impact the association between those outcomes and the strategy (e.g., potential mediators or moderators). This could include but is not limited to social determinants of health, substance use disorder treatment initiation, changes to behaviors related to drug use, other potential mediators of the association between the strategy and the outcome, and moderators of the association between the strategy

and the outcomes. These should also be incorporated into the Theory of Change section.

Research design

For this NOFO, rigorous evaluation designs must include a control/ comparison group and are defined as either:

- Experimental (i.e., randomized controlled trials)
- Quasi-experimental (e.g., comparative interrupted time series design, difference-in-differences, instrumental variable methods, regression discontinuity, regression point displacement, stepped wedge, designs using propensity-score matching, designs involving matched comparison groups)

Theory of change

You should provide a theory of change that clearly links how the strategy is expected to influence at least two required outcomes. The theory of change should include, as appropriate, process or implementation measures. Additionally, risk and protective factors for overdose at multiple levels of the social ecology may serve as mediators of the association between the strategy and the outcomes as well as factors that may function as moderators of the association between the strategy and the outcomes should be identified (Baron and Kenney, 1986). Including such variables can help us understand how implementation and contextual factors affect achieving the strategy's intended outcomes. Additionally, you are encouraged to include the following: implementation measures such as barriers and facilitators; the extent to which the strategy was implemented as planned; and acceptability of the population impacted by the strategy. These elements can contribute to understanding the strategy's differential impacts and potential scalability.

Specifically, the theory of change should describe:

- The strategy focus (i.e., primary or secondary)
- How the strategy is suited or tailored to serve the selected population
- How the strategy could affect rates or counts of at least two required outcomes

Data collection, acquisition, and analysis

You must identify and describe appropriate data sources and provide evidence of your ability to acquire and/or collect data of sufficient quantity and quality within the period of performance. Your application should clearly describe and justify the proposed sampling methods, sample size, power

estimates, and data collection methods for the required outcome(s), at a minimum, and subgroup analyses. You must specify the timeline for data acquisition (requests for extant data and or primary data collection). Numerous data sources can be used for the outcome data, including emergency department data, emergency medical services data, electronic health records, mortality data (e.g., vital statistics or medical examiner/ coroner report data), survey data, and/or other sources of data. Appropriate data sources will vary by the proposed research approach and outcome measures.

Focus populations

For this NOFO, people experiencing disproportionate burden of drug overdose, those who are at greater risk of exposure to drug use, or those experiencing adverse drug use outcomes related to social determinants of health should be selected and identified using at least one of the following:

- Meta-analyses or systematic reviews that indicate disproportionate burden of overdose and/or are at greater risk of exposure to drug use or experiencing adverse drug use outcomes related to social determinants of health.
- Multiple observational studies from U.S. settings that indicate disproportionate burden of overdose and/or greater risk of exposure to drug use or experiencing adverse drug use outcomes related to social determinants of health.
- Formative research showing disproportionate burden of overdose or greater risk of exposure to drug use or experiencing adverse drug use outcomes related to social determinants of health.

Equal opportunities

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.

Health disparities

The goal of health equity is for everyone to have a fair and just opportunity to attain their highest level of health. Health disparities are often caused by social determinants that influence which people are most disproportionately affected by health conditions.

A health disparity is a difference in health burdens between groups of people with differing social determinants of health.

Social determinants of health are conditions in the environments where people are born, live, learn, work, play, worship, and age. These determinants affect a wide range of health, functioning, and quality-of-life outcomes and risks.

For more information on people experiencing a disproportionate burden of drug overdose, please see Overdose Prevention Research Priorities 2022 (cdc.gov). Adverse drug use outcomes related to social determinants of health include lack of access to evidence-based substance use disorder treatment and other resources that can support recovery.

Collaborations and partnerships

We expect that for all applications, your organization and contact PD/PI will provide the scientific and technical leadership necessary to conduct the proposed research throughout the entire period of performance. We expect that the proposed research work plan described in the Research Strategy section of the application and the SF-424 Research and Related Budget will demonstrate your organization's leadership and involvement throughout the entirety of the period of performance. Your organization cannot serve as a "pass through" to fund another entity to conduct the majority of the research or provide the scientific or technical leadership necessary to complete the proposed research project.

NCIPC recognizes the importance of community conditions and community-centered research to complete the proposed work. We strongly encourage you to seek and include the meaningful involvement of communities, including state and/or local health departments, local governmental agencies and/or businesses, and community-based organizations in all phases of the research, translation, and dissemination of research results. This may include strong partnerships with community members with lived experience who participate in all phases of the research (e.g., developing study methods, collecting data, interpreting results, and disseminating findings).

Partnerships between the applicant institution and outside entities may be necessary or advantageous to complete the proposed work. Your application must clearly describe each partnering entity's roles and responsibilities. This includes demonstrating your access to planned data sources and study populations, and all partnerships necessary to complete the project.

The Research Strategy section of the application is expected to clearly describe the roles and responsibilities of each research team member individually and each participating entity. This includes describing how the partnership will allow you to complete the proposed work. The Research

Strategy section must describe the nature and extent of the proposed partnership, including:

- The roles and responsibilities of the Project Director(s)/Principal Investigator(s) and of the outside entities or partner agencies.
- The existing working relationship.
- The nature and extent of the involvement to be provided by the applicant institution and outside entity for the proposed research.
- The outside entity's scope of work.
- How the partnership will ensure implementation and sustainability of the proposed evaluation.

The Research Strategy section must describe all data sources and the partnerships that are in place to ensure data access for all proposed analyses are completed within the period of performance.

Each partnering entity's roles and responsibilities must be substantiated with a signed Data Sharing Agreement, Letter or Support (LOS), or Memorandum of Understanding (MOU), and be included in your application's LOS section. The Data Sharing Agreement, LOS, or MOU must describe the partner's resources, time, and personnel commitments to the proposed research. Applications that do not include a signed Data Sharing Agreement, LOS, or MOU from each partnering entity may not be recommended for funding.

Translation plan

You should describe the potential for widespread use of your research results and the potential to translate the results with and for community partners. You should also include plans to document relevant strategy implementation methods and lessons learned to facilitate future replication in another research or non-research setting if the strategy is effective. These plans may include but are not limited to identifying the core components of the strategy and documenting lessons learned from the study that might inform decisions about future adaptation or modification for other settings or populations.

Your application should describe the strategy's scalability as part of the translation plan. Research findings should be disseminated through publications, including articles in peer reviewed scientific journals, and "Research Briefs" for diverse audiences (e.g., policy makers, public health programs, community groups), as well as presentations at professional conferences and in institutional and community-based venues.

The PD/PI should describe how the findings may be used to address key drivers of health inequities (e.g., through focusing on disproportionately affected people). The description should include consideration of structural inequalities.[38]

Cooperative agreement recipients will be required to attend one reverse site visit per year in Atlanta with CDC/NCIPC staff during the performance period to review their progress and findings and to discuss opportunities for widespread dissemination of their research achievements and lessons learned. Travel costs for attending this meeting must be included in your travel budget submitted in response to this NOFO.

Funding policies and limitations

General guidance

- Your budget is arranged in eight categories: salaries and wages, fringe benefits, consultant costs, equipment, supplies, travel, other, and contractual.
- You may use funds only for reasonable program purposes consistent with the award, its terms and conditions, and federal laws and regulations that apply to the award. Questions about this determination should be posed to the grants management specialist.
- Generally, you may not use funds to purchase furniture or equipment. Clearly identify and justify any such proposed spending in the budget.

Unallowable costs

You may not use funds for:

- Clinical care except as allowed by law.
- Pre-award costs unless CDC gives you prior written approval.
- Other than for normal and recognized executive-legislative relationships:
  - Publicity or propaganda purposes, including preparing, distributing, or using any material designed to support or defeat the enactment of legislation before any legislative body.
  - The salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before any legislative body.

See Anti-Lobbying Restrictions for CDC Recipients.

Indirect costs

Indirect costs are those for a common or joint purpose across more than one project and that cannot be easily separated by project. Learn more at 45 CFR 75.414, Indirect Costs and CDC Budget Preparation Guidelines.

To charge indirect costs you can select one of two methods:

Method 1 – Approved rate. You currently have an indirect cost rate approved by your cognizant federal agency.

Justification: Provide a summary of the rate. Enclose a copy of the current approved rate agreement in the Attachments.

Method 2 – *De minimis* rate. Per 45 CFR 75.414(f), if you have never received a negotiated indirect cost rate, you may elect to charge a *de minimis* rate. If you are awaiting approval of an indirect cost proposal, you may also use the *de minimis* rate. If you choose this method, costs included in the indirect cost pool must not be charged as direct costs.

This rate is 10% of modified total direct costs (MTDC). See 45 CFR 75.2 for the definition of MTDC. You can use this rate indefinitely.

Other indirect cost policies

As described in 45 CFR 75.403(d) and 45 CFR 75.414, you must consistently charge items as either indirect or direct costs and may not double charge.

- Indirect costs may 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. The indirect cost rate is fixed at eight percent of modified total direct costs.
- 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, you must attach a copy of the indirect cost rate agreement. See other attachments form.

Expanded authority

For more information on expanded authority and pre-award costs, see the HHS Grants Policy Statement and speak to the grants management contact.

Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.

Public health data

We require that awards include mechanisms for, and the costs of, public health data sharing. You may also include the reasonable cost of sharing or archiving public health data as part of the total budget requested for first-time or continuation awards. For more information, please see Additional Requirement – 25 | Grants | CDC.

Human subjects

We will restrict funds related to conducting research involving human subjects until the appropriate assurances and Institutional Review Board (IRB) approvals are in place. To lift the restrictions, we will require copies of all current local IRB approval letters, local IRB-approved protocols, and CDC IRB approval letters, when applicable.

If the proposed research project involves more than one institution and will be conducted in the United States, we expect you to:

- Use a single Institutional Review Board (sIRB) to conduct the required ethical review.
- Include a single IRB plan in your research plan and PHS Human Subjects and Clinical Trials Information form, unless review by a sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy or you provide a compelling justification based on ethical or human subject protection issues or other well-justified reasons.

Do not duplicate information in the Research Plan form and the PHS Human Subjects and Clinical Trials Information form. In your research plan, discuss the overall strategy, methodology, and analyses of your proposed research. Use the PHS Human Subjects and Clinical Trials Information form to provide detailed information for human subjects studies and clinical trials.

We will review and approve exceptions in accordance with 45 CFR part 46 and, as applicable, 21 CFR part 50 and 21 CFR part 56 and Public Health Service Act (PHSA) section 301(d) (42 USC 241(d)), or we may place a restriction on the award. a restriction on the award.

For more information, please consult the scientific and research contact listed for this NOFO.

Statutory authority

Awards are made under the authorization of Section 301 (a) [42 U.S.C. 241(a)] of the Public Health Service Act, and section 391 (a) [42 U.S.C. 280 b(a)] of the Public Service Health Act, as amended.

Step 2:
Get Ready to Apply

In this step

Get registered

While you can review the requirements and get started on developing your application before your registrations are complete, you must be registered in both SAM.gov and Grants.gov to apply.

SAM.gov

You must have an active account with SAM.gov. This includes having a Unique Entity Identifier (UEI). SAM.gov registration can take several weeks. Begin that process today.

To register, go to SAM.gov Entity Registration and select **Get Started**. From the same page, you can also select the Entity Registration Checklist for the information you will need to register.

Grants.gov

You must also have an active account with Grants.gov. You can see step-by step instructions at the Grants.gov Quick Start Guide for Applicants.

Need help? See Contacts and Support.

eRA Commons

You must register in eRA Commons. Your senior and key personnel must also register and affiliate their accounts with your organization's account.

Register at least 4 weeks before the application deadline.

Find the application package

The application package has all the forms you need to apply. You can find it online. Go to Grants Search at Grants.gov or eRA ASSIST and search for opportunity number RFA-CE-25-149.

If you can't use Grants.gov to download application materials or have other technical difficulties, including issues with application submission, contact Grants.gov for help.

To get updates on changes to this NOFO, select **Subscribe** from the View Grant Opportunity page for this NOFO on Grants.gov.

Help applying

For help on the application process and tips for preparing your application see How to Apply on our website and the Research Instructions for NIH and Other PHS Agencies.

If any instructions differ from those in this NOFO, follow the instructions in this NOFO.

For other questions, see Contacts and Support.

Join the informational call

Get more information about this opportunity.

Thursday, October 10, 2024
2 to 2:50 p.m. ET

Join by video

Join the webinar in Zoom
Zoom passcode: *PERT8Nu

Join by phone

Phone numbers

- +1 646 828 7666 US (New York)
- +1 646 964 1167 US (US Spanish Line)
- +1 669 254 5252 US (San Jose)
- +1 551 285 1373 US (New Jersey)
- +1 415 449 4000 US (US Spanish Line)
- +1 669 216 1590 US (San Jose

Meeting ID: 160 634 8153

Passcode: 9005 2173

Step 3:
Prepare Your Application

In this step

Application contents and format

You must follow the Research Instructions in the How to Apply: Application Guide unless this NOFO says otherwise. We strictly enforce these requirements. If you do not follow them, we may delay or not accept your application for review. We encourage you to submit your application in advance of deadlines.

Application components

You must follow the instructions for each of the following components in the Research Instructions. We also provide NOFO-specific guidance for some forms in this section. All the components you need are listed in the following checklist.

Form	Required for
☐ PHS 398 Research Plan form	All applications.
☐ SF424 (R&R)	All applications.
☐ PHS 398 Cover Page Supplement Form	All applications.
☐ SF424(R&R) Other Project Information	All applications.
☐ SF424(R&R) Project/Performance Site Locations	All applications.
☐ SF424(R&R) Senior/Key Person Profile	All applications.
☐ R&R Budget Form	All applications.
☐ R&R Subaward Budget Attachments Form	If your application proposes subawards.
☐ PHS Human Subjects and Clinical Trials Information	All applications.
☐ PHS Assignment Request Form	Optional.
Other Attachments Form	All applications.
☐ Duplication of efforts	If applicable.
☐ Bona fide agents documentation	If applicable.

PHS 398 Research Plan form

You will use the PHS 398 Research Plan form to complete your research plan. You will upload each of the following parts listed in the appropriate section of the form as a separate attachment. Not all parts may be required for your application. We provide guidance here and in the Application Guide.

Follow all instructions beginning on page 82 of the Research Instructions. Added instructions are also noted here.

Introduction

This section only applies to resubmission or revision applications. Do not include this section if you are submitting a new or renewal application.

Research plan section

The parts for this section include:

Parts	Required for	Page limit
Specific aims	All applications.	1
Research strategy	All applications.	12

Other research plan section

The parts for this section include:

Parts	Required for	Page limit
Multiple PI/PD leadership plan	If you designate multiple PD/PIs (on the R.240 - R&R Senior/Key Person Profile (Expanded) Form).	None
Consortium and contractual arrangements	If you include any consortiums or contracts in your budget.	None
Letters of support	If applicable	None
Resource sharing plans	All applications.	None

Data management

If you plan to collect public health data, you must submit a Data Management Plan (DMP) in the Other Plans section of your PHS 398 Research Plan. We require a DMP for each collection of public health data you propose. If you contend that the public health data you collect or create are not appropriate for release, you must justify that contention in the DMP submitted with your application. You can find a sample template on our website.

For all public health data you plan to collect as part of this NOFO, please describe:

- The data you plan to collect and their available sources.
- The feasibility of collecting appropriate evaluation and performance data.
- A data management plan (DMP) that includes:
  - The data you will collect or generate.
  - Who can access data and how you will protect it.
  - Standards that ensure released data have documentation that describes collection methods, what the data represent, and data limitations.
  - Archival and long-term data preservation plans.
  - How you will update the DMP as new information is available over the life of the project. You will provide updates to the DMP in annual reports.
- Other relevant data information, such as performance measures you propose.

For more information about CDC's policy on the DMP, and for a definition of "public health data" and other key information, read the Data Management and Access Requirement.

Appendix

We allow only limited appendix materials. Follow all instructions for the appendix in the Research Instructions.

Do not use the appendix to circumvent page limits. You may attach up to 10 PDF documents in the appendix. Additionally, up to 3 publications may be included that are not publicly available.

Budget form

To develop your budget, read CDC's Budget Preparation Guidelines.

Be sure to follow the guidance in funding policies and limitations.

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

Other attachments form

You will provide the following attachments by uploading them to the Other Attachments form.

Duplication of efforts

You must provide this attachment only if you have submitted a similar request for a grant, cooperative agreement, or contract to another funding source in the same fiscal year and it may result in any of the following types of overlap:

Programmatic

- They are substantially the same project, or
- A specific objective and the project design for accomplishing it are the same or closely related.

Budgetary

- You request duplicate or equivalent budget items that already are provided by another source or requested in the other submission.

Commitment

- Given all current and potential funding sources, an individual's time commitment exceeds 100 percent, which is not allowed.

We will discuss the overlap with you and resolve the issue before award.

File name: Report on overlap

Bona fide agents documentation

A bona fide agent is an organization identified as eligible to submit an application on behalf of another organization. If applying as a bona fide agent of a state, territorial, tribal, or local government, you must attach a legal, binding agreement from the government as documentation of your status as their agent.

File name: Bona fide agent

Indirect cost agreement

If you include indirect costs in your budget using an approved rate, include either a copy of your:

- Current agreement approved by your cognizant agency for indirect costs.
- Cost allocation plan approval letter.

If you use the *de minimis* rate, you do not need to submit this attachment.

File name: Indirect cost agreement

Step 4: Learn About Review and Award

In this step

Application review

Initial review

We review each application to make sure it meets responsiveness requirements. These are the basic requirements you must meet to move forward in the competition.

The proposed research is expected to expand the evidence base for primary and secondary prevention of drug use outcomes, making it essential that proposed approaches meet the criteria for outcome measures and research designs.

For both funding options, we won't consider an application that:

- Is from an organization that doesn't meet eligibility criteria. See requirements in Eligibility.
- Is submitted after the deadline.
- Does not meet the responsiveness criteria.

Additionally, we will not review any pages that exceed the page limit.

Scientific merit review

We use a two-level merit review process. The first level of merit review is carried out by non-federal scientists who have expertise in relevant scientific disciplines and research areas. The second level of review is performed by the NCIPC Board of Scientific Counselors.

First level of merit review

Reviewers will consider each of the following review criteria to determine 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 is not innovative may be essential to advance a field.

The reviewers use the following criteria.

Overall impact (1 to 9 scale)

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the

research fields involved. They consider the following review criteria, including the additional review criteria as applicable for each project proposed.

We average the overall impact scores from all eligible reviewers for a given application (calculated to one decimal point) and multiply by 10 to determine the final overall impact score. The overall impact score ranges from 10 to 90.

Scored criteria

Reviewers will evaluate the five individual criteria (significance, investigators, innovation, approach, and environment) and consider the strengths and weaknesses within each criterion. The impact score for the application is not intended to be an average of criterion.

Significance

- Does the project address an important problem or a critical barrier to progress in the field?
- If the project aims are achieved, how will scientific knowledge, technical capability, or public health be improved?
- If successfully completed, how will the proposed activities advance current knowledge (i.e., create new knowledge) of the effectiveness of primary and secondary prevention strategies to impact required outcomes and build the evidence base of effective strategies?

Investigators

- 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?
- 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?
- To what extent do the PI and/or Co-I and other members of the research team have prior experience and knowledge in conducting rigorous evaluations of strategies consistent with that proposed in the evaluation (i.e., experimental or quasi-experimental research designs with a control/comparison group)?
- To what extent is there evidence of past collaboration between the proposed research team and external partners to support the success of the proposed research?

Innovation

- Does the application challenge and seek to shift current research or clinical practice paradigms by using 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 in a broad sense?
- Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
- Is the Theory of Change explicitly identified and explained in the application, including details on the strategy implementation?
- Is the proposed evaluation of at least two required outcomes well-supported by the Theory of Change?
- To what extent does the application balance innovation with an approach likely to provide relevant results within the 3-year or 5-year period of performance?

Approach

- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the project's specific aims?
- Are potential problems, alternative strategies, and benchmarks for success presented?
- If the project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed?
- Since the project involves human subjects or clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities, all sexes and genders, and children, justified in terms of the scientific goals and research strategy proposed?
- If applicable, how will the design and implementation of the proposed research activities consider and address populations with health disparities?
- How well does the applicant provide justification that the proposed design and data analysis plans are appropriate for evaluating the strategy's impacts?
- How well does the application describe the selection of populations and communities experiencing disproportionate burden of overdose or groups that are at greater risk of exposure to drug use or experiencing adverse drug-use outcomes related to social determinants of health?

- To what extent does the Research Strategy describe selection of the population using one or more of the three criteria outlined in the approach section:
  - Meta-analyses or systematic reviews that indicate disproportionate burden of overdose and/or are at greater risk of exposure to drug use or experiencing adverse drug use outcomes related to social determinants of health.
  - Multiple observational studies from U.S. settings that indicate disproportionate burden of overdose and/or greater risk of exposure to drug use or experiencing adverse drug use outcomes related to social determinants of health.
  - Formative research showing disproportionate burden of overdose or greater risk of exposure to drug use or experiencing adverse drug use outcomes related to social determinants of health.
- To what extent does the strategy selected for evaluation have sufficient theoretical support to suggest it may be effective in reducing required outcomes among the selected population?
- To what extent does the applicant justify how the strategy is suited or tailored to serve the selected population with which it is intended to intervene?
- Does the applicant demonstrate the ability to access or collect and analyze the necessary data for the evaluation of the selected strategy? Are these data appropriate for documenting the effects of the strategy and likely to show the expected changes in the time available?
- To what extent are proposed process or implementation characteristics described and will the data collected facilitate understanding of the impact to outcomes after implementation, in particular, acceptability by the population?
- Does the application's proposed study, including sampling and retention strategies assure sample retention and adequate statistical power to test the proposed hypotheses and produce meaningful results over time, including for any subpopulations being studied?
- To what extent does the design address threats to validity and the ability to identify the key components?
- How well does the Research Strategy section of the application describe the roles and responsibilities of each partner involved in collecting data and/or evaluating effectiveness?
- To what extent does the Research Strategy describe the strategy scalability as part of the translation plan?

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?
- Will the project benefit from unique features of the scientific environment, participant populations, or collaborative arrangements?
- To what extent will findings be disseminated to communities and populations of focus in an appropriate and accessible manner?
- If the application involves collaborations or partnerships, to what extent does the Research Strategy provide evidence of collaboration or partnership throughout the application?
- Does the applicant describe the duties, percentage-of-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?
- To what extent does the applicant provide evidence of access to and support from systems and organizations in which the strategies are being implemented (e.g., health systems, criminal justice settings, community settings)?
- How much is each entity's involvement sufficient and appropriate for the successful completion of the project, including strategy implementation and data access for evaluation?
- How much does the Research Strategy describe the working relationships between the applicant institution and all partner organizations?
- To what extent are the partnership relationships and activities described in the Research Strategy documented by a signed Data Sharing Agreement, Letters of Support, or Memorandum of Understanding that clearly delineates the intent and capabilities of each partnership?
- To what extent does the described scientific environment reflect the necessary staffing, collaboration, and support to evaluate the effects of the proposed strategy on primary overdose-related outcomes?

Additional review criteria

When applicable to a proposed project, reviewers will evaluate the following additional items and consider them when assigning an impact score but will not give separate scores for these items.

Protections of 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, and, as applicable, 21 CFR part 50 and 21 CFR part 56 and Public Health Service Act (PHSA) section 301(d) (42 USC 241(d)), the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation using the following five review criteria: and 21 CFR part 56 and Public Health Service Act (PHSA) section 301(d) (42 USC 241(d)), the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation using the following five review criteria:

- Risk to subjects
- Adequacy of protection against risks
- Potential benefits to the subjects and others
- Importance of the knowledge to be gained
- 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:

- The justification for the exemption
- Human subject involvement and characteristics
- Sources of materials

For additional information on review of the Human Subjects section, please refer to Additional Requirements AR-1 Human Subjects.

If your proposed research involves the use of human data or biological specimens, you must justify your claim that no human subjects are involved in your PHS 398 Research Plan.

Inclusion of women, minorities, and children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities, all genders, and children. For additional information, read:

- Inclusion of Women and Racial and Ethnic Minorities in Research
- Inclusion of Persons Under 21 in Research

Vertebrate animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following four points:

- Proposed use of the animals, and species, strains, ages, sex, and numbers to be used.
- Justifications for the use of animals and for the appropriateness of the species and numbers proposed.
- 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, or comfortable restraining devices.
- 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, see the Checklist for Applicants and Reviewers: Vertebrate Animals.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel 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 U.S. Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern, and, if so, whether the applicant has identified a Dual Use of Concern Review Entity (DURC-IRE) to assess the project for DURC potential and develop mitigation strategies if needed.

For more information, read:

- U.S. Government Science, Safety, Security (S3) website
- Institutional Policy Companion Guide and Resources

Additional review considerations

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

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.

Resource sharing plan

Reviewers will comment on whether the Resource Sharing Plan (for example, Sharing Model Organisms) or the rationale for not sharing the resources is reasonable.

After the merit review of your application is complete, the PD/PI will be able to access their Summary Statement in eRA Commons.

Second level of merit review

After the first level of merit review, we refer applications to a second level of review where they are evaluated based on programmatic importance/value of the applications relative to program priorities, program relevance, research portfolio balance, geographic considerations, budgetary considerations, or other criteria stated in the notice of funding opportunity.

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.
- Consideration for meritorious applications that contribute to a diverse mix of approaches in proposed research to rigorously evaluate primary and secondary overdose prevention activities among populations disproportionately affected by overdose as evidenced by the Research Strategy section of the application's research plan.
- Consideration for applicant organizations from or conducting research in collaboration or partnership with institutions that have a demonstrated record of or historical commitment to serving underrepresented students, including racial and ethnic minorities, individuals from disadvantaged backgrounds and individuals with disabilities. Applicants may indicate this in the Research Strategy section of their application.
- Consideration of research conducted in collaboration/ partnership with the community, as evidenced by the Letters of Support section of the

application. This may include state and/or local health departments, local governmental agencies and/or businesses, and community-based organizations.

- Consideration for applications including signed Data Sharing Agreements, Letters of Support, or Memorandum of Understanding for each partnership described in the Research Strategy section of the application clearly describing the support to be provided to conduct the proposed research.
- Consideration for applications in which the contact Eligible PD/PI meets NIH Early Stage Investigator (ESI) status, as verified by the NIH Determination of Investigator Status process.

Risk review

Before making an award, we review the risk that you will not prudently manage federal funds. As part of that review, we need to make sure you've handled any past federal awards well and demonstrated sound business practices. We use SAM.gov Responsibility / Qualification to check this history for all awards likely to be over $250,000. We also check Exclusions.

You can comment on your organization's information in SAM.gov. We'll consider your comments before making a decision about your level of risk.

We may ask for additional information prior to award based on the results of the risk review.

If we find a significant risk, we may choose not to fund your application or to place specific conditions on the award.

For more details, see 45 CFR 75.205.

Selection process

When making funding decisions, we consider:

- Scientific merit review results. The results of the first and second level reviews are key in making decisions but are not the only factor.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- Geographic balance of proposed projects to broaden distribution of the awards.

We may:

- Fund application out of the rank order developed in merit review to increase geographical balance of proposed projects as evidenced by the congressional district of the applicant organization, to broaden the distribution of awards.
- Fund applications in whole or in part.
- Fund applications at a lower amount than requested.
- Decide not to allow a prime recipient to subaward if they may not be able to monitor and manage subrecipients properly.
- Choose to fund no applications under this NOFO.

Our ability to make awards depends on available appropriations.

Award notices

If we are considering your application for funding, we will request "just-in-time" information from you as described in the HHS Grants Policy Statement.

If you are successful, we will email a Notice of Award (NoA) to your authorized official.

We will email you or write you a letter if your application is disqualified or unsuccessful.

The NoA is the only official award document. The NoA tells you about the amount of the award, important dates, and the terms and conditions you need to follow. Until you receive the NoA, you don't have permission to start work.

Once you draw down funds, you have accepted all terms and conditions of the award.

If you want to know more about NoA contents, go to Understanding Your Notice of Award at CDC's website.

Step 5:
Submit Your Application

In this step

Application submission and deadlines

See Find the Application Package to make sure you have everything you need.

You must obtain a UEI number associated with your organization's physical location. Some organizations may have multiple UEI numbers. Use the UEI number associated with the location of the organization receiving the federal funds.

Make sure you are current with SAM.gov and UEI requirements before applying for the award. See Get Registered.

You will have to maintain your registration throughout the life of any award.

Deadlines

Optional letter of intent

Due on November 4, 2024.

Application

Due on December 2, 2024, at 11:59 p.m. ET.

Grants.gov creates a date and time record when it receives the application. If you submit the same application more than once, we will accept the last on-time submission.

The grants management officer may extend an application due date based on emergency situations such as documented natural disasters or a verifiable widespread disruption of electric or mail service.

Submission methods

To prepare your application for submission, you have three choices:

- Directly in Grants.gov using Workspace.
- Using eRA ASSIST, which connects to Grants.gov.
- Using a different system-to-system interface of your choice that connects to Grants.gov.

See Contacts and Support if you need help.

Grants.gov

For instructions on how to prepare and submit in Grants.gov, see the Quick Start Guide for Applicants. Make sure that your application passes the Grants.gov validation checks or we may not get it. Do not encrypt, zip, or password protect any files.

eRA ASSIST

The Application Submission System and Interface for Submission Tracking (ASSIST) helps you to prepare your application, submit it through Grants.gov, and track it.

You must have an eRA Commons ID to use this system. The system will prompt your signing official to enter the Grants.gov Authorized Organizational Representative (AOR) credentials to submit the application.

For instructions, see Using ASSIST and Submit the Application on our website.

Other submissions

Optional letter of intent

We ask that you let us know if you plan to apply for this opportunity. We do this to plan for the number of reviewers we will need to evaluate applications. You do not have to submit a letter of intent to apply.

Email the notice to Dr. Carlisha Gentles at ncipc-peer-review@cdc.gov.

In your email, include:

- The funding opportunity number and title
- Your organization's name and address
- A contact name, phone number, and email address
- The descriptive title of your proposed research
- Names of your project director or principal investigator and other key personnel
- Participating institutions

See the deadline for notices of intent.

Mandatory disclosure

You must submit any information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. See Mandatory Disclosures, 45 CFR 75.113.

Send written disclosures to CDC at aen4@cdc.gov **and** to the Office of Inspector General at grantdisclosures@oig.hhs.gov.

Step 6: Learn What Happens After Award

In this step

Post-award requirements and administration

We adopt by reference all materials included in the links within this NOFO.

Administrative and national policy requirements

There are important rules you need to read and know if you get an award. You must follow:

- All terms and conditions in the Notice of Award. The NoA includes the requirements of this NOFO.
- The rules listed 45 CFR part 75, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards.
- The HHS Grants Policy Statement (GPS). This document has policies relevant to your award. If there are any exceptions to the GPS, they'll be listed in your Notice of Award.
- All federal statutes and regulations relevant to federal financial assistance, including the cited authority in this award, the funding authority used for this award, and those provisions in the HHS Administrative and National Policy Requirements.
- 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.
- The following CDC's Additional Requirements (AR) apply to this NOFO's awards: 1, 2, 3, 8, 9, 10, 11, 12, 14, 25, 16, 21, 22, 23, 24, 25, 26, 28, 29, 30, 31, 32, 33, 34, 36, and 37.

Reporting

If you are successful, you will have to submit financial and performance reports. These include:

Report	Description	When
Annual Performance Report (Research Performance Progress Report)	• Serves as yearly continuation application. • Includes performance measures, successes, challenges. • Updates research plan. • How CDC could help overcome challenges. • Includes budget for the next 12-month budget period. • Complete list of the publications planned or completed to date - including status (e.g., published [include reference], in review, under development). • Description of any changes made in the use of human subjects or IRB approval status. • Includes how data are collected and used (Data Management Plan).	120 days prior to the end of the budget period, or the date identified in guidance that CDC distributes
Federal Financial Report	• Includes funds authorized and disbursed during the budget period. • Indicates exact balance of unobligated funds and other financial information.	90 days after the end of each budget period
Final Performance Report	• Includes information similar to the Annual Performance Report.	120 days after the end of the period of performance
Final Financial Report	• Includes information in Federal Financial Report.	120 days after the end of the period of performance
Response to Technical Review	• Response to any progress concerns or areas for improvement noted on their annual Technical Review within the time period specified in the annual award continuation notice.	Annually specified in annual award continuation notice

To learn more about these reporting requirements, see Reporting on the CDC website.

CDC award monitoring

Monitoring activities include:

- Routine and ongoing communication between CDC and recipients.
- Site visits.
- Recipient reporting, including work plans, performance reporting, and financial reporting.

We expect to include the following in post-award monitoring:

- Tracking recipient progress in achieving the outcomes.
- Ensuring the adequacy of your systems to hold information and generate data reports.
- Creating an environment that fosters integrity in performance and results.

We may also include the following activities:

- Ensuring that work plans are feasible based on the budget.
- Ensuring that work plans are consistent with award intent.
- Ensuring that you are performing at a level to achieve outcomes on time.
- Working with you to adjust your work plan based on outcome achievement, evaluation results, and changing budgets.
- Monitoring programmatic and financial performance measures to ensure satisfactory performance levels.
- Other activities that assist CDC staff to identify, notify, and manage risk, including high-risk recipients.

CDC's role

- Assist 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.
- Provide suggestions for refining research protocols (e.g., for sampling, recruitment, assessment, and data management).
- Participate in the analysis, interpretation, and dissemination of study findings (may include co-authorship of peer-reviewed manuscripts and scientific presentations). CDC will not initiate or direct data collection, own or manage the data, require the use of a specific methodological

approach, or disseminate findings as part of an official CDC report. Monitoring and evaluating the scientific and operational accomplishments of the project through conference calls, site visits, and review of technical reports. Provide ongoing suggestions as needed to ensure project success.

- Collaborate with the grant recipient to ensure human subjects assurances are in place as needed.
- As necessary, collaborate in the development or amendment of a research protocol involving human subjects for Institutional Review Board (IRB) review by all collaborating institutions, including CDC if applicable.
- Obtain IRB approvals as required by CDC when CDC is engaged in research involving human subjects. If applicable, the CDC IRB will review the protocol initially and on an annual basis until the project is complete.
- Monitor and evaluate the scientific and operational accomplishments of the project through conference calls, site visits, and review of technical reports.
- Provide ongoing suggestions as needed to ensure project success.
- The agency Scientific Program Official (SPO) and CIO program director will be responsible for the normal scientific and programmatic stewardship of the award. The award notice will name the SPO.

Areas of Joint Responsibility include:

- The grant recipient and CDC will agree upon and establish a schedule for regular phone calls to discuss ongoing research project progress.

Nondiscrimination and assurance

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 Laws and Regulations Enforced by the HHS Office for Civil Rights.

Contacts and Support

In this step

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Grants.gov

Grants.gov provides 24/7 support. You can call 1-800-518-4726 or email support@grants.gov. Hold on to your ticket number.

SAM.gov

If you need help, you can call 866-606-8220 or live chat with the Federal Service Desk.

eRA Commons

Contact the eRA Commons Help Desk for questions regarding eRA Commons registration, tracking application status, and post submission issues. The Help Desk is open Monday through Friday from 7 a.m. to 8 p.m. ET.

You can call toll free at 301-402-7469 or 866-504-9552 or TTY 301-451-5939.

Email to commons@od.nih.gov.

Reference websites

- U.S. Department of Health and Human Services (HHS)
- Grants Dictionary of Terms
- CDC Grants: How to Apply
- Research Instructions
- CDC Grants: Already Have a CDC Grant?
- Grants.gov Accessibility Information
- Code of Federal Regulations (CFR)
- United States Code (U.S.C.)
- Bayh-Dole Regulations

Endnotes

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