Centers for Disease Control and Prevention

NATIONAL CENTER FOR INJURY PREVENTION AND CONTROL

Effectiveness Research to Prevent Polysubstance-Impaired Driving

RFA-CE-25-028

12/02/2024

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Overview

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

Components of Participating Organizations:
National Center for Injury Prevention and Control

Notice of Funding Opportunity (NOFO) Title

Effectiveness Research to Prevent Polysubstance-Impaired Driving

Activity Code

Applications for this Notice of Funding Opportunity (NOFO) will be funded using the U01 activity code for a research cooperative agreement.

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-CE-25-028

Assistance Listings Number(s)

93.136

Category of Funding Activity

HL - Health

NOFO Purpose

The Centers for Disease Control and Prevention's (CDC) National Center for Injury Prevention and Control (NCIPC) is soliciting investigator-initiated research to rigorously evaluate and examine effectiveness of strategies, programs, or policies (collectively referred to as "strategies") for preventing polysubstance-impaired driving and associated crashes, nonfatal injuries, or

deaths. Polysubstance-impaired driving means driving while impaired by two or more substances, such as alcohol and opioids or cannabis and alcohol. Comprehensive evaluations of strategies to prevent polysubstance-impaired driving are lacking and urgently needed given the changing landscape of substance use and impaired driving. Additionally, given inequitable impacts on some populations (American Indian and Alaska Native [AIAN] communities, rural populations, etc.), research is needed to examine strategy effectiveness among different populations. This NOFO supports research that can help fill these gaps.

Research may include, but is not limited to, evaluation of the impact of any of the following on preventing polysubstance-impaired driving and related outcomes:

- Evidence-based alcohol-impaired driving strategies that may also prevent polysubstance-impaired driving. Examples include, but are not limited to, screening and brief intervention and alternative transportation or transit programs.
- Strategies that prevent excessive alcohol use, harmful substance use, or substance use disorders that have the capacity to also prevent polysubstance-impaired driving. Examples include, but are not limited to, taxation or pricing policies for alcohol and cannabis, social norming campaigns, and multi-component coalition-based strategies (e.g., Drug Free Communities Programs or similar efforts).

This NOFO encourages examination of strategy effects on polysubstance-impaired driving and associated injuries and deaths among the overall population and disproportionately affected populations.

Key Dates

Publication Date:
To receive notification of any changes to RFA-CE-25-028, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.

Letter of Intent Due Date:
11/01/2024
11/01/2024

While a letter of intent is not mandatory, nor is it binding or a factor in the review of an application, the details it provides help NCIPC staff to plan for the scientific and technical merit peer review process.

Application Due Date:
12/02/2024
12/02/2024

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

Applicants will use a system or platform to submit their applications through Grants.gov and eRA Commons to CDC. ASSIST, an institutional system to system (S2S) solution, or Grants.gov

Workspace are options. ASSIST is a commonly used platform because it provides a validation of all requirements prior to submission and prevents errors.

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

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

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

Scientific Merit Review:
03/18/2025
This date is an estimate.

Secondary Review:
04/22/2025
This date is an estimate.

Estimated Start Date:
09/30/2025

Expiration Date:
02/01/2025

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

This NOFO will support research to rigorously evaluate and examine effectiveness of strategies for preventing polysubstance-impaired driving and associated crashes, nonfatal injuries, or

deaths. Polysubstance-impaired driving means driving while impaired by two or more substances, such as alcohol and opioids or cannabis or alcohol.

Mechanism of Support

The funding mechanism for this NOFO will be a research cooperative agreement (U01).

Funds Available and Anticipated Number of Awards

CDC/NCIPC intends to commit up to $350,000 in FY 2025 to fund one (1) application. Awards issued under this NOFO are contingent upon availability of funds and a sufficient number of meritorious applications.

Budget and Period of Performance

The estimated total funding (direct and indirect) for the first budget period, 9/30/2025 to 9/29/2026, is $350,000. The estimated total funding (direct and indirect) for the entire Period of Performance, 9/30/2025 to 9/29/2028, is $1,050,000.

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. Eligibility Information 1. Eligible Applicants* are eligible to apply.

Eligible Project Directors/Principal Investigators (PDs/PIs)

CDC does not award individuals directly. Individuals possessing the necessary skills, knowledge, and resources to conduct proposed research should collaborate with their institutions to submit a support application. Underrepresented racial and ethnic groups, as well as individuals with disabilities, are especially encouraged to apply.

For applications where the contact PD/PI qualifies as an NIH Early Stage Investigator (ESI), as confirmed through the NIH Investigator Status determination process, and has a commendable peer review score, prioritization may occur during the second level of review (refer to *Section V. Application Review Information 4. Review and Selection Process*).

Regarding the determination of Investigator Status for the contact PD/PI: Before submitting an application, PD/PIs should confirm or update the date of their terminal research degree or the

conclusion of their post-graduate clinical training in their eRA Commons Profile for accurate identification. NIH systems will automatically determine each investigator's status and reflect it in their eRA Commons personal profile. The ESI status for PD/PIs on any R01 or equivalent application will be indicated at submission. Investigators must ensure their status is accurately represented in their profile. If the status is incorrect, they should reach out to the NIH eRA Service Desk.

Number of PDs/PIs

An application may name more than one PD/PI; their names must appear on the face page of the application. However:

- One (1) principal investigator must be designated as the contact PD/PI for all correspondence related to the application.
- All PD/PIs must include their eRA Commons Identification in the Credential Field of the Senior/Key Person Profile Component of the SF-424 (R&R) Application Package.
- Institutions/organizations proposing multiple PDs/PIs must visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF-424 (R&R) Application Guide.

Number of Applications

Organizations eligible to apply may submit multiple applications to this NOFO, as long as each is scientifically distinct. However, institutions may only submit one application per contact PD/PI. Only one application for each contact PD/PI will receive funding under this announcement. If multiple applications from the same contact PD/PI are submitted, only the most recent one, based on the time and date stamp at www.grants.gov, will be considered for review. It is the applicant's responsibility to withdraw any duplicate applications before the review date.

Institutions that submit applications proposing essentially the same research to two or more CDC NOFOs will not receive funding for more than one.

Application Type

NEW

Special Date(s)

A pre-application webinar call will be conducted on October 16, 2024 to address questions from prospective applicants regarding NOFO RFA-CE-25-028. The call will begin at 2:00pm Eastern Standard Time (EST) and end at 2:50pm Eastern Standard Time (EST), or sooner if all questions are addressed. Questions and answers from the discussion will be included in an amended NOFO approximately 3 weeks after the call.

Participant Access Information

- Call Date: October 16, 2024
- Call Start Time: 2:00pm Eastern Standard Time (EST)
- Call End Time: 2:50pm Eastern Standard Time (EST)
- Call Leader: Emiko Petrosky, MD, MPH, Scientific Program Official
- Webinar Link: https://cdc.zoomgov.com/j/1619698650?pwd=bkZRcU9ZQmhSbksxWnZqaVl3VVNaQT09
- Webinar ID: 161 969 8650
- Passcode: 9+s5.!b?
- Call-In Numbers:
    - +1 669 254 5252 US (San Jose)
    - +1 646 828 7666 US (New York)
    - +1 646 964 1167 US (US Spanish Line)
    - +1 415 449 4000 US (US Spanish Line)
    - +1 551 285 1373 US (New Jersey)
    - +1 669 216 1590 US (San Jose)
- Dial-In Passcode: 12693189

Application Materials

See *Section IV.1* for application materials.

Hearing Impaired

Telecommunications for the hearing impaired are available at: TTY: 1-888-232-6348.

Section I. Funding Opportunity Description

Statutory Authority
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 Health Service Act, as amended.

1. Background and Purpose

Substance use and polysubstance use are prevalent behaviors in the United States that are associated with numerous public health problems and harms. According to the 2022 National Survey on Drug Use and Health, approximately 137 million people reported alcohol use; 42 million people reported marijuana (hereafter referred to as cannabis) use; 41 million people reported any prescription tranquilizer or sedative use; and 74 million people reported any opioid use in the month prior to the survey. Among people who drank alcohol in the past month, 11% combined cannabis and alcohol the last time they drank [1]. Recent surveillance also indicates

that more than 80% of individuals reporting opioid misuse also reported misuse of other drugs, and among those who used heroin, 36% used methamphetamine [2].

A notable harm associated with substance use and polysubstance use is transportation-related crashes and associated nonfatal and fatal injury. Alcohol and other drugs have impairing effects on the skills needed for safe driving [3,4], and the prevalence of substance- and polysubstance-related impairment while driving is substantial. In 2022, 23 million people aged 21 years and older self-reported driving under the influence of alcohol or illegal drugs in the year prior to the survey, with 11 million reporting driving under the influence of cannabis and 2 million reporting driving under the influence of other illegal drugs including cocaine, heroin, hallucinogens, inhalants, or methamphetamine [1]. In addition to self-report data, several recent reports have examined drug presence among drivers in biological samples [5-7]. In a recent National Transportation Safety Board (NTSB) report on drivers arrested for impaired driving who were tested at the Orange County, California Laboratory from August 2018 to July 2020, 28% of drivers arrested for impaired driving were positive for both alcohol and one other potentially impairing substance (e.g., cannabis, stimulants, inhalants). More drivers were positive for alcohol and cannabis (14%) than cannabis only (5%) [6]. Moreover, a recent National Highway Traffic Safety Administration (NHTSA) report examined data from September 2019 to July 2021 of drivers killed in crashes and found that of the 555 fatally injured drivers, 12% were positive for alcohol and cannabis [7].

Alcohol-impaired driving-related crashes are consistently associated with one third of traffic crashes (i.e., crashes occurring on public trafficways, like roads or highways). In 2022, more than 13,000 lives were lost in impaired driving-related crashes [8]. Previous research demonstrates that driving while polysubstance-impaired is a road safety and public health issue of particular concern [1,3,4,6,7, 8], given evidence demonstrating the effects of drugs on driving performance [3,4], the high prevalence of self-reported driving under the influence of drugs, and evidence of combined alcohol and drug positivity in the driving population. Additionally, several evolving safety concerns underscore the need for urgent understanding and implementation of effective strategies to prevent polysubstance-impaired driving. These safety concerns include the decrease in perceived risks of cannabis use and continuing high levels of opioid use and overdose [9-12]. Comprehensive evaluations of strategies to prevent polysubstance-impaired driving are lacking.

Given CDC's emphasis on primary prevention, the purpose of this NOFO is to further research on upstream strategies that can prevent polysubstance-impaired driving. Potential strategies of interest could include:

- Evidence-based strategies previously employed to prevent alcohol-impaired driving, including screening and brief intervention and alternative transportation or transit programs [13]. Primary prevention strategies proven effective for preventing alcohol-impaired driving might or might not also be effective at preventing polysubstance-impaired driving [13].
- Strategies that prevent excessive alcohol use, harmful drug/substance use, or substance use disorders that may also prevent polysubstance-impaired driving. Examples include, but are not limited to, taxation or pricing policies on alcohol and/or cannabis, social norming campaigns, and multi-component coalition-based strategies (e.g., Drug Free Communities Programs or similar efforts). Given the complexity of the polysubstance use

landscape and the multitude of efforts focused on reducing excessive alcohol use, harmful drug/substance use, or substance use disorders, understanding the extent to which these evidence-based strategies for substance use outcomes also reduce crashes and related nonfatal and fatal transportation injury outcomes is warranted.

Equity considerations are critical when implementing and evaluating any public health approach, including impaired driving-related strategies. Some populations have higher risk for crashes and deaths involving impaired driving. For example, AIAN individuals have the highest alcohol-impaired driving death rates among all racial and ethnic groups in the United States, and rural populations have higher alcohol-impaired driving death rates than urban populations [14-15]. This NOFO encourages examination of strategy effects on overall populations and populations disproportionately affected by crashes and related injuries and deaths.

Purpose
See detailed *NOFO Purpose* section.

References

1. Substance Abuse and Mental Health Services Administration. 2022 NSDUH Detailed Tables, Center for Behavioral Health Statistics and Quality; Nov 2023. Available at: https://www.samhsa.gov/data/report/2022-nsduh-detailed-tables.
2. Bobashev GV, Warren LK. National polydrug use patterns among people who misuse prescription opioids and people who use heroin. Results from the National Household Survey on Drug Use and Health. *Drug and Alcohol Dependence*. 2022;238(1). doi: 10.1016/j.drugalcdep.2022.109553
3. Hartman RL, Huestis MA. Cannabis effects on driving skills. *Clin Chem.* 2013;59(3):478–492. doi:10.1373/clinchem.2012.194381
4. Hels T, Lyckegaard A, Simonsen KW, Steentoft A, Bernhoft IM. Risk of severe driver injury by driving with psychoactive substances. *Acc Analysis & Prev*. 2013;59:346-56.
5. Berning A, Smith RC, Drexler M, Wochinger K. Drug testing and traffic safety: What you need to know (Report No. DOT HS 813 264)). Washington, DC: U.S. Department of Transportation, National Highway Traffic Safety Administration (NHTSA); 2022. Available at: https://rosap.ntl.bts.gov/view/dot/60969
6. National Transportation Safety Board. Alcohol, other drug, and multiple drug use among drivers (ntsb.gov), Safety Research Report SRR-22-02, National Transportation Safety Board: Washington, DC; 2022.
7. Thomas FD, Darrah J, Graham L, Berning A, Blomberg R, Finstad K, Griggs C, Crandall M, Schulman C, Kozar R, Lai J, Mohr N, Chenoweth J, Cunningham K, Babu K, Dorfman J, Van Heukelom J, Ehsani J, Fell J, Whitehill J, Brown T, Moore C. Alcohol and drug prevalence among seriously or fatally injured road users (Report No. DOT HS 813 399). Washington, DC: U.S. Department of Transportation, National Highway Traffic Safety Administration (NHTSA), Office of Behavioral Safety Research; 2022.
8. National Center for Statistics and Analysis. Alcohol-impaired driving: 2022 data (Traffic Safety Facts. Report No. DOT HS 813578), National Highway Traffic Safety

Administration: Washington, DC; 2024. Available at: https://crashstats.nhtsa.dot.gov/Api/Public/ViewPublication/813578
9. Insurance Institute for Highway Safety. Marijuana laws. Insurance Institute for Highway Safety, Highway Loss Data Institute; 2024. https://www.iihs.org/topics/alcohol-and-drugs/marijuana-laws-table
10. Terry-McElrath YM, O'Malley PM, Patrick ME, Miech RA. Risk is still relevant: Time-varying associations between perceived risk and marijuana use among US 12th grade students from 1991 to 2016. *Addictive Behaviors* 2017;74:13-19.
11. Han BH, Funk-White M, Ko R, Al-Rousan T, Palamar JJ. Decreasing perceived risk associated with regular cannabis use among older adults in the United States from 2015 to 2019. *Journal of the American Geriatrics Society* 2021;69(9):2591-7.
12. Kariisa M, Davis NL, Kumar S, Seth P, Mattson CL, Chowdhury F, Jones CM. Vital Signs: Drug Overdose Deaths, by Selected Sociodemographic and Social Determinants of Health Characteristics — 25 States and the District of Columbia, 2019–2020. *MMWR* 2022;71(29):940-7.
13. Kirley BB, Robison KL, Goodwin AH, Harmon KJ, O Brien NP, West A, Harrell SS, Thomas L, Brookshire K. Countermeasures that work: A highway safety countermeasure guide for state highway safety offices, 11th Edition, National Highway Traffic Safety Administration. Wa Report No. DOT HS 813 490; 2023.
14. National Highway Traffic Safety Administration. Fatality and Injury Reporting System Tool (FIRST). Washington, DC: U.S. Department of Transportation, National Highway Traffic Safety Administration, National Center for Statistics and Analysis. Available at https://cdan.dot.gov/query. Accessed July 2024.
15. National Highway Traffic Safety Administration (NHTSA). Rural/urban comparison of motor vehicle traffic fatalities (Traffic Safety Facts. Report No. DOT HS 813488). Washington, DC: U.S. Department of Transportation, National Highway Traffic Safety Administration, National Center for Statistics and Analysis; 2024.

Healthy People 2030 and other National Strategic Priorities

The proposed research aligns with NCIPC's approach to injury prevention, described in: https://www.cdc.gov/injury-violence-prevention/programs/research-priorities.html?CDC_AAref_Val=https://www.cdc.gov/injury/researchpriorities/index.html. This research supports the specific motor vehicle injury prevention research priorities, described in: https://www.cdc.gov/injury/pdfs/researchpriorities/NCIPC_Research-Priorities_Transportation_Safe.pdf.

This research addresses the Healthy People 2030 focus areas of injury and violence prevention as described in: https://health.gov/healthypeople. Specifically, this NOFO supports the Healthy People 2030 Injury and Violence Prevention (IVP) areas of:

- IVP-1 Reduce fatal injuries
- IVP-2 Reduce emergency department visits for nonfatal injuries
- IVP-3 Reduce unintentional injury deaths
- IVP-4 Reduce emergency department visits for nonfatal unintentional injuries
- IVP-6 Reduce deaths from motor vehicle crashes
- SU-11 Reduce the proportion of motor vehicle crash deaths that involve a drunk driver

Public Health Impact
The goal of this funding is to identify strategies most effective at preventing polysubstance-impaired driving and associated deaths and injuries. Increasing our understanding of this public health problem could inform prevention efforts at both the federal and state levels. State departments of health and transportation could use the results of this research to inform the prioritization of safe driving strategies that could reduce polysubstance-impaired driving deaths and injuries. Given the high rates of impaired driving-related crashes among some populations (AIAN individuals, rural populations, etc.), the proposed project could examine potential strategy effects on polysubstance-impaired driving and associated injuries and deaths among disproportionately affected populations as well as aggregate population-level effects.

Relevant Work
For more than 30 years, NCIPC has been the nation's leading public health authority on injury and violence prevention. CDC's approach involves focusing on data, science, and action to address public health problems and keep people safe, healthy, and productive.

Relevant work conducted by the Injury Center includes:

- Barry V, Schumacher A, Sauber-Schatz E. Alcohol-impaired driving among adults—USA, 2014–2018. *Inj Prev*. 2022;28(3):211–217. doi:10.1136/injuryprev-2021-044382
- Shults RA, Shaw KM, Yellman MA, Jones SE. Does geographic location matter for transportation risk behaviors among U.S. public high school students?. *J Transp Health*. 2021;22:101134. doi:10.1016/j.jth.2021.101134
- Jones JM, Shults RA, Robinson B, Komatsu KK, Sauber-Schatz EK. Marijuana and alcohol use among injured drivers evaluated at level I trauma centers in Arizona, 2008–2014. *Drug Alcohol Depend*. 2019;204:107539. doi:10.1016/j.drugalcdep.2019.06.041
- Shults RA, Jones JM, Komatsu KK, Sauber-Schatz EK. Alcohol and marijuana use among young injured drivers in Arizona, 2008–2014. *Traffic Inj Prev*. 2019;20(1):9–14. doi:10.1080/15389588.2018.1527032

2. Approach

For NOFO RFA-CE-25-028, applicants should rigorously evaluate and examine effectiveness of strategies to prevent polysubstance-impaired driving and associated crashes, nonfatal injuries, or deaths. Polysubstance-impaired driving means driving while impaired by two or more substances, such as alcohol and opioids. Applicants should propose rigorous evaluation designs. Rigorous evaluation designs use experimental (i.e., randomization) and quasi-experimental methods (e.g., matched comparison groups, propensity score matching, instrumental variables, regression point displacement, regression discontinuity, time series). Data analytic plans should be appropriate to the prevention strategy, research design, hypotheses, data collection measures, and period of performance. Investigators should anticipate, evaluate, and address threats to the internal and external validity of the specified research design.

Given challenges with estimating and examining polysubstance-impaired driving-related outcomes (e.g., lack of testing and documentation on some death records), applicants should clearly state and justify how they will obtain valid estimates of polysubstance-impaired driving-related outcomes. Regardless of the design, using multiple data sources is encouraged to improve the validity and reliability of outcomes selected and measured. Examples of potential primary outcome measures and data sources include, but are not limited to:

- Motor vehicle crash data
- Emergency medical services data
- Emergency department records
- Police reports
- Hospital records
- Vital Statistics (death certificate data)
- Roadside testing data
- Self-reported survey data
- Other toxicology or drug test data

Investigators who propose using existing data should:

- Articulate plans for securing data use agreements
- Broadly describe data cleaning and standardization protocols
- Discuss methods for use, evaluation, and validation of results

Applicants should detail the prevention strategy implementation and evaluation design feasibility, including but not limited to, demonstrating expertise with data sources and methods described in the proposal. Details should include access to data and the research team.

Objectives/Outcomes

Investigators will conduct effectiveness research to identify strategies that can prevent polysubstance-impaired driving. Polysubstance-impaired driving means driving while impaired by two or more substances. Examples include: alcohol and cannabis; alcohol and opioids (prescription or illegal); cannabis and opioids (prescription or illegal); alcohol and other drugs; or alcohol and cannabis and opioids (prescription or illegal). Applicants must clearly define and justify how they are measuring polysubstance impairment and fully describe the strategies studied.

Research questions might include:

- What is the impact of innovative strategies on the prevention of polysubstance-impaired driving crashes, injuries, and deaths?
- What is the effectiveness of strategies shown to prevent alcohol-impaired driving to also prevent polysubstance-impaired driving and related crash, injury, and death outcomes?
- Are positive and negative impacts of the strategy constant across groups? What are the health equity implications of any differences?

Secondary questions could also include those on understanding strategy implementation, such as:

- What are barriers and facilitators to polysubstance-impaired driving strategies?
- How can strategy implementation occur on a large scale or in specific populations/locations/settings?
- What are the costs of strategy implementation and any associated cost effectiveness?

Recommended outcomes of interest include motor vehicle crashes associated with polysubstance-impaired driving and resulting injuries and deaths. However, measuring these recommended outcomes of impaired driving is very difficult. Therefore, research may propose outcomes which do not directly measure polysubstance-impaired driving or its consequences as

long as the outcomes measured can be sufficiently linked to polysubstance-impaired driving (e.g., self-reported polysubstance-impaired driving behavior). For research proposing an outcome that is not directly measuring polysubstance-impaired driving, motor vehicle crash, injury or death, applicants should clearly describe how the outcomes are sufficiently linked to polysubstance-impaired driving or outcomes. Data for outcome measurement may include, but are not limited to crash records, emergency department records, roadside substance testing, toxicology data, or self-report survey data. Applicants are encouraged to examine strategy effectiveness in at least one disproportionately affected population (race, ethnicity, rurality, etc.). It is critical that the selection of a disproportionately affected population is made using high quality, accessible and up-to-date data, with a defensible rationale to show how the group selected meets criteria related to high burden and/or rates of morbidity and mortality.

Population of Focus

This research should focus on users of public roads affected by polysubstance-impaired driving. This includes, but is not limited to:

- drivers
- passengers
- pedestrians
- bicyclists
- other road users
- Groups who have high risk for impaired driving and related crashes, injuries, and deaths (AIAN individuals, people living in rural communities, etc.).

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.

Collaboration/Partnerships

For all applications, it is anticipated that the applicant organization and the principal investigator (PI) will provide the necessary scientific and technical leadership to carry out the proposed research for the duration of the project. The Research Strategy section of the application, along with the SF-424 Research and Related Budget, should reflect the organization's leadership and engagement for the full period of performance. The applicant organization must not act merely as a "pass through" to fund another entity to conduct most of the research or to provide the essential groups at higher risk for scientific or technical leadership needed to complete the project.

NCIPC acknowledges the significance of community conditions and community-centered research in completing the proposed work. Applicants are highly encouraged to involve communities meaningfully, including state and local health departments, local government agencies, businesses, and community organizations, in research development, conduct, and dissemination of findings. This includes forming robust partnerships with community members who have lived experience to inform the strategy evaluation design.

Collaborations between the applicant institution and external entities may be necessary or

beneficial to complete the proposed work. The application must distinctly outline the roles and responsibilities of each partner. This includes proof of the applicant's access to the intended data sources and study populations, as well as all necessary partnerships to carry out the proposed project.

The Research Strategy section should clearly describe the roles and responsibilities of each research team member and participating organization. It should detail how the collaboration will enable the applicant to carry out the proposed work. The section must delineate the nature and scope of the partnership, including the duties of the Principal Investigator(s) and partner entities, the current working relationship, research plans, the level of involvement from both the applicant institution and the partner, the partner's work scope, and how the partnership will facilitate the execution and continuity of the proposed evaluation. Additionally, the Research Strategy must comprehensively outline all data sources and the established partnerships that will ensure data availability for all intended analyses within the period of performance.

Each partnering entity's roles and responsibilities must be validated with a signed Data Sharing Agreement, Letter of Support (LOS), or Memorandum of Understanding (MOU). These documents must detail the partner's commitment to resources, time, and personnel for the proposed research. Applications lacking a signed Data Sharing Agreement, Letter of Support, or Memorandum of Understanding from each partner may not be recommended for funding (refer to *Section V. Application Review Information, 4. Review and Selection Process*). Applicants are responsible for clearly outlining each partner's contributions to the proposed research in the Research Strategy and confirming each partner's intent and capabilities with a signed agreement.

This NOFO aims for diversity among applicant institutions, research investigators, and partnering organizations to ensure research experiences and outcomes benefit all segments of the population and social ecology. 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 may be considered during the second level of review (see *Section V. Application Review Information, 4. Review and Selection Process*). Applicants may indicate this in the Research Strategy of their application.

This NOFO supports the involvement of early-stage investigators on the SF-424 Senior/Key Personnel research team to foster experience and expertise in injury prevention research. Applications must show that the research team possesses the required skills and experience to guarantee the quality and timely execution of the proposed activities. Involvement of students and emerging researchers is recommended. Those intending to integrate training and mentorship into their research should outline their strategies for recruiting, educating, and overseeing trainees/mentees, as well as ensuring the continuous quality of their scientific outputs.

Evaluation/Performance Measurement

Applicants must evaluate and document performance during each stage of the research process. This could include partnership development, study development, outcome measurement, data collection, and data analysis. The application should clearly describe relevant performance

measures for each stage of the research project. Comparison of actual progress to the performance measures should document whether the research is progressing appropriately and in a timely manner. This comparison should also document whether the research activities are of high scientific quality.

Translation Plan
The application should clearly describe the potential for widespread dissemination, implementation, and sustainability of the proposed research. Investigators should collaborate with CDC investigators to develop a plan for next steps for the research findings. The plan should describe how dissemination of the results will achieve the greatest impact. Investigators must propose how to translate research findings into actionable recommendations.

Grant recipients may be required to attend one reverse site visit per year in Atlanta with CDC/NCIPC staff during the period of performance 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 the application's travel budget submitted in response to this NOFO.

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:
$1,050,000
Anticipated Number of Awards:
1
Awards issued under this NOFO are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Award Ceiling:
$350,000
Per Budget Period

Award Floor:

$0
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)

23 (Small businesses)

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

99 (Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility")

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)

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

See *Section III. Eligibility Information.*

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

Applicants are responsible for ensuring their application complies with all the responsiveness criteria outlined in this section. Applications failing to meet these criteria will be deemed nonresponsive and will not proceed to peer review. The proposed research objectives in the applicant's abstract must align with the objectives of this announcement, as detailed in Section I, "Objectives/Outcomes."

- The proposed budget for each fiscal year must be less than or equal to the budget ceiling of $350,000 as outlined in *Section II: Award Information*. **Applications that exceed the budget in any year will be considered nonresponsive and will not be forwarded for peer review.**
- Applicants must include a SF-424 Biographical Sketch for the PI or Co-Investigator(s) that documents expertise in motor vehicle injury prevention, specifically impaired driving. The knowledge, experience, and expertise necessary to conduct this research and achieve proposed objectives must document experience of at least one first-authored, peer-reviewed publication as defined by the NIH National Library of Medicine in the relevant area of motor vehicle injury prevention, specifically impaired driving, OR by serving as a principal investigator on a research grant in motor vehicle injury prevention, specifically impaired driving prevention. Experience requirements may be demonstrated through the combined experiences of a Principal and Co-Principal Investigator (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 non-responsive and will not be forwarded for peer review.**
- Applicants must propose to evaluate the effectiveness of a strategy, program, or policy to prevent driving while impaired by two or more substances in the Research Strategy section of the Research Plan. **Applications that do not propose to evaluate the effectiveness of a strategy to prevent driving while impaired by two or more substances, as evidenced in the Research Strategy section of the Research Plan, will be considered nonresponsive and will not be forwarded for peer review.**

6. Required Registrations

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

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

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

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

Grants.gov

eRA Commons

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

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

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

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

Additionally, organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later.

SAM.gov is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at SAM.gov and the SAM.gov Knowledge Base.

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

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

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 undeserved groups, including sexual orientation and gender identity minorities 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.

Eligible organizations may submit multiple applications to this NOFO, provided each is scientifically distinct. To prevent duplication, project titles must be unique. However, institutions may only submit one application per contact PD/PI. Only one application for each contact PD/PI will be considered for funding under this announcement. If multiple applications from the same contact PD/PI are submitted, only the most recent one, based on the time and date stamp in www.grants.gov, will be reviewed. Applicants must withdraw any duplicate applications before the review date.

Furthermore, institutions that submit applications proposing essentially the same research to multiple CDC NOFOs will not receive funding for more than one NOFO.

Section IV. Application and Submission Information

1. Address to Request Application Package

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

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

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

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

2. Content and Form of Application Submission

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.

3. Letter of Intent

Due Date for Letter Of Intent 11/01/2024

11/01/2024
While a letter of intent is not mandatory, nor is it binding or part of the subsequent application review, it does help NCIPC staff in preparing for the peer review of scientific and technical merit. By the date specified in *Part 1. Overview Information*, interested applicants are encouraged to submit a letter of intent containing the following details:

- Descriptive title of the proposed research
- The objective(s) the application will address
- A brief description (one to two paragraphs) of the proposed research, including its objectives
- Contact information of the Principal Investigator/Project Director (name, address, and telephone number)
- Names of all other Senior/Key Personnel
- Names of all participating institutions
- The number and title of this funding opportunity

The letter of intent should be sent electronically to:
Carlisha Gentles, PharmD, BCPS, CDCES

Scientific Review Official
National Center for Injury Prevention and Control (NCIPC)
Email: ncipc-peer-review@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.

Applicants should develop and include, as part of the application's Resource Sharing Plan section of the PHS 398 Research Plan Component, a data management plan that meets the requirements of AR-25 using their own template. Award recipients funded under this NOFO will be required to use NCIPC's Data Management Plan Template, OMB NO: 0920-1301 to make revisions to the DMP as required during the award's period of performance.

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.

The three 'not publicly available' publications will count towards the 10 PDF documents allowed in the appendix. The five appendices described below for the Research Plan supporting materials will also count towards the 10 PDF documents allowed in the appendix. The total number of pages in the appendix may not exceed 25 pages.

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.

9. Submission Dates & Times

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

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

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

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

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

Applicants who encounter problems when submitting their applications must attempt to resolve them by contacting the NIH eRA Service desk at:
Toll-free: 1-866-504-9552; Phone: 301-402-7469
http://grants.nih.gov/support/index.html
Hours: Mon-Fri, 7 a.m. to 8 p.m. Eastern Time (closed on Federal holidays)

Problems with Grants.gov can be resolved by contacting the Grants.gov Contact Center at:
Toll-free: 1-800-518-4726
https://www.grants.gov/support
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 12/02/2024

12/02/2024
Electronically submitted applications must be submitted no later than 11:59 p.m., ET, on the listed application due date.

10. Funding Restrictions

Expanded Authority:

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

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

Public Health Data:

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

Data Management Plan:

Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the 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.

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).

Important reminders:

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

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

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

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

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

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

- http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm
- http://grants.nih.gov/grants/ElectronicReceipt/submit_app.htm
- https://era.nih.gov/files/ASSIST_user_guide.pdf
- http://era.nih.gov/erahelp/ASSIST/

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

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the CDC mission (https://www.cdc.gov/about/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?

- What is the public health impact of the research on understanding how to prevent motor vehicle crash injury related to polysubstance-impaired driving?
- What is the impact of the research on public health at the local or state level (depending on the reach of the project)? What is the impact on public health in the US and among populations disproportionately affected by polysubstance-impaired driving in the US?
- Will the work be influential? Influential means that it will lead others to investigate the problem, open new areas of research, or change the scientific approach or public health practice. How will this improve and be of value to public health?
- If successful, to what extent will research results have the potential to be scalable and reach a large portion of the people who have elevated risk for polysubstance-impaired driving and associated crashes, nonfatal injury, and death?

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?

- Has the proposed research team collaborated in the past?
- Have previous research results provided high quality outputs and improved public health practice and population health?
- To what extent does the PI/Co-I team demonstrate extensive expertise and research experience in the areas of motor vehicle injury prevention, impaired driving, and related outcome measurement?
- To what extent does the PI/Co-I team demonstrate extensive expertise and experience with the proposed data sources, methods, and analysis?

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?

- To what extent does the proposed research include innovative prevention strategies and rigorous methods to evaluate the prevention of polysubstance-impaired driving and associated injuries and deaths?
- Is the proposed research innovative and yet offer reasonable potential for meeting the Purpose and Research Objectives of this NOFO?
- To what extent does the application propose how to translate research findings into actionable recommendations?

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?

- To what extent does the proposed research seek to identify effective strategies to prevent polysubstance-impaired driving and associated injuries and deaths?
- To what extent does the applicant adequately demonstrate the strength of their evaluation approach in assessing polysubstance-impaired driving and associated injuries and deaths?
- For research proposing an outcome not directly measuring polysubstance-impaired driving or its consequences, to what extent can the proposed outcomes be sufficiently linked to polysubstance-impaired driving or its consequences?
- To what extent does the research plan include a rigorous design and evaluate threats to internal and external validity?
- To what extent does the research plan describe the research questions, study design, hypotheses, key outcomes, data access, proposed analytic strategy, and estimated sample size and power for proposed hypotheses?
- To what extent does the applicant plan to examine strategy effectiveness in at least one disproportionately affected population (race, ethnicity, rurality, etc.)?
- To what extent does the research plan describe analyzing outcomes by key measures of equity (race, ethnicity, rurality, etc.)?
- To what extent does the applicant provide evidence of the feasibility of the research design?
- To what extent does the applicant seek to understand facilitators and barriers of strategy implementation?
- Does the applicant describe how the results from the research will be disseminated and used?

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 project use critical partnerships or collaborations? If so, to what extent does the application include well-defined working relationships between the research institution and all partners?
- Does the application clearly describe the involvement and scope of work of the partners and their willingness to commit to ensuring the successful implementation of the study? Does this include providing or facilitating access to relevant study participants, implementation, or outcome data within the proposed period of performance?
- To what extent are the relationships and activities of the partnerships described in the Research Strategy documented by a signed Data Sharing Agreement, Letter of Support, or Memorandum of Understanding that delineates the intent and capabilities of each partnership?

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/VAChecklist.pdf).

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

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

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

3. Additional Review Considerations

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

Applications from Foreign Organizations
N/A

Resource Sharing Plan(s)
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.
- Consideration for meritorious applications that contribute to differing strategies or interventions in proposed research to address NCIPC’s research priorities.
- Consideration for meritorious applications that contribute to a diverse mix of approaches in proposed research to prevent polysubstance impaired driving as evidenced by the Research Strategy section of the application's research plan.

- Consideration for meritorious applications that contribute to a geographic balance of proposed projects, as evidenced by the congressional district of the applicant organization, to broaden the distribution of awards.
- 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 for research to better address inequities in risk for polysubstance-impaired driving and strategies that address social and structural conditions that contribute to inequities in risk for polysubstance-impaired driving, as evidenced by the Research Strategy section of the application's research plan.
- 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.

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

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.

Specific requirements that apply to this NOFO are the following:

AR-1: Human Subjects Requirements
AR-2: Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR-3: Animal Subjects Requirements
AR-9: Paperwork Reduction Act Requirements
AR-10: Smoke-Free Workplace Requirements
AR-11: Healthy People 2030
AR-12: Lobbying Restrictions
AR-14: Accounting System Requirements
AR-16: Security Clearance Requirement
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 surveillance services or equipment for all awards issued on or after August 13, 2020.

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

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

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

Additional CDC Award Requirements

The following Additional Requirements, some of which emphasize and expand upon those above, will be required for all recipients funded under this NOFO.

Additional Requirement – 12: Lobbying Restrictions – Award recipients are prohibited from using CDC/HHS funds to engage in any lobbying activity. Restrictions on lobbying activities specifically apply to lobbying related to any proposed, pending, or future Federal, state, or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing.

All award recipients under this NOFO will be required to complete pre-registration of the research project(s) using publicly available platforms or ClinicalTrials.gov as applicable, consistent with the National Science Foundation's open science principles. The platform for intended pre-registration should be described in the Research Plan at the time of application.

All award recipients under this NOFO will be required to make data publicly available within 30 months of completing data collection, this includes making source code available to the public, and ensuring open access to research publications consistent with the National Science Foundation's open science principle.

The CDC will follow established implementation schedules and procedures for making grant awards under this NOFO in accordance with HHS and CDC Policy for Grant Program Administration and CDC Policy for Peer Review of Research and Scientific Programs to ensure that these awards support ideologically and politically unbiased research projects.

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

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

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

Plain Writing Act: The Plain Writing Act of 2010, Public Law 111-274, was signed into law on October 13, 2010. The law requires that federal agencies use "clear Government communication that the public can understand and use" and requires the federal government to write all new

publications, forms, and publicly distributed documents in a "clear, concise, well-organized" manner. For more information on this law, go to: https://www.plainlanguage.gov/.

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

Copyright Interests Provision: This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. 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 the 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 recipients is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC's 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 reside with the recipients for the project as a whole, although specific tasks and activities may be shared among the recipients and HHS/CDC as defined below.

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

- Complying with the responsibilities for the Extramural Investigators as described in the Policy on Public Health Research and Non-research Data Management and Access https://www.cdc.gov/grants/additional-requirements/ar-25.html
- Designing and conducting research to address the described research objectives of this cooperative agreement.
- Undertaking any data collection solely to meet the applicant’s research needs. Retaining custody of and exercising 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.
- Partnering effectively with any outside entities expected to participate in the proposed research. Such partnerships should be well-defined and documented by letters of support or Memoranda of Understanding detailing the nature and extent of involvement.
- Establishing goals and objectives that are realistic, measurable, and time-oriented for all phases of the project.
- Developing a research protocol involving human subjects for Institutional Review Board (IRB) review and approval by all cooperating institutions participating in the research project, including CDC if applicable.
- Assuring that IRB approvals are current for research involving human subjects for all participating sites.
- Considering suggestions from CDC on the design and implementation of research and the analysis, interpretation, and dissemination of study findings.
- Developing, designing, and piloting research protocols and instruments; recruiting participants; and conducting appropriate data management procedures.
- Analyzing data and disseminating findings in peer-reviewed journals and presentations at scientific conferences and other meetings.

- Requesting consultation and technical assistance from CDC, as needed. Considering suggestions from CDC on the design and implementation of research and the analysis, interpretation, and dissemination of study findings.
- Collaborating with CDC in translating and disseminating research findings.
- Participating in an initial kick-off meeting with CDC by phone or in Atlanta.
- Participating in one reverse site visit with CDC in Atlanta on an annual basis to review the project's progress with CDC scientists and staff.
- Developing and implementing a plan for sharing research resources and data with other collaborating partners, the agency, the public, and scientific community. The PI is responsible for developing and updating a data management plan that identifies the level of data access and plans for data sharing.

CDC staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below. CDC staff will work collaboratively with the PIs/PDs, as described below:

- 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 https://www.cdc.gov/grants/additional-requirements/ar-25.html
- 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.
- 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 SPO will be named in the award notice.

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.

The recipient agrees that upon award, their application and the summary of reviewers' comments will be shared with the CDC staff, who will provide support as described above. Recipient organization will retain custody of and have primary rights to the information, data, and software developed under this award.

5. Reporting

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

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

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

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

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

A. Submission of Reports

The Recipient Organization must submit:

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) 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:

Technical Review and Summary Statement Response Requirements

Recipients will be required to electronically submit a response to the peer reviewers' comments and/or concerns, as documented in the Summary Statement, within 30 days of the notification of their initial award. Recipients will also be required to electronically submit a 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. Annual Report Requirements Recipients will be required to electronically submit an Annual Report within 90 to 120 days before the end of the current budget period. The Annual Report should include:

- A description of the completion status of each Specific Aim and/or research objective or milestone for the budget period.
- A complete list of the publications planned or completed to date - including status (e.g., published [include reference], in review, under development).
- A description of any changes made in the use of human subjects or IRB approval status.
- A description of any changes made in the Data Management Plan. Award recipients funded under this NOFO will be required to use NCIPC's Data Management Plan Template, OMB NO: 0920-1301 to make revisions to the DMP as required during the award’s period of performance.

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. Organizations not yet registered can go to https://commons.era.nih.gov/commons/ for instructions. It generally takes several days to complete this registration process. This registration is independent of Grants.gov and may be done at any time.

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

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

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

Scientific/Research Contact

Emiko Petrosky, MD, MPH
National Center for Injury Prevention and Control (NCIPC)

Email: ncipc_erpo@cdc.gov

Peer Review Contact
Carlisha Gentles, PharmD, BCPS, CDCES

Scientific Review Official
National Center for Injury Prevention and Control (NCIPC)
Email: ncipc-peer-review@cdc.gov

Financial/Grant Management Contact(s)
Angie Willard
Grants Management Officer
CDC Office of Grants Services
Email: aen4@cdc.gov

Section VIII. Other Information

Other CDC Notices of Funding Opportunities can be found at www.grants.gov.

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

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

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

Successful recipients may be permitted expanded authorities in the administration of this award as provided for in the Code of Federal Regulations, Title 2, Subtitle A, Chapter II, Part 200, Subpart D, §200.308(d)(4). Specific authorities granted will be detailed in the official Notice of Award document.

Application Submission Process
Applications must be successfully submitted and complete all validation actions prior to 11:59 PM U.S. Eastern Time of the application due date for this NOFO. Applicants are encouraged to submit the application in ASSIST three (3) business days before the stated due date to provide sufficient time to correct any errors. If post-submission errors are identified during the validation process, the errors must be corrected and the application must be re-submitted in ASSIST prior to 11:59 PM U.S. Eastern Time of the application due date. 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.

Applicants who encounter problems when submitting their applications must attempt to resolve them by contacting the NIH eRA Service desk and the Grants.gov Contact Center. See Section IV. Application and Submission Information, 9 Submission Dates & Times for contact information.

General Information
All applications submitted for this NOFO must be responsive to the specific requirements and objectives of this NOFO and must be submitted as a new application through www.grants.gov.

All applicants are advised to carefully review the responsiveness requirements and instructions on how applicants must document responsiveness in *Section III. Eligibility Information 5. Responsiveness* of this NOFO.