

Centers for Disease Control and Prevention

NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION

Demonstration Projects to Research and Evaluate Strategies Aligned with CDC's What Works in Schools Approach

RFA-DP-24-138

03/11/2024

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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 Chronic Disease Prevention and Health Promotion

Notice of Funding Opportunity (NOFO) Title

Demonstration Projects to Research and Evaluate Strategies Aligned with CDC's What Works in Schools Approach

Activity Code

U01

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-DP-24-138

Assistance Listings Number(s)

93.941

Category of Funding Activity

HL - Health

NOFO Purpose

This Notice of Funding Opportunity (NOFO) supports research to implement and evaluate strategies aligned with CDC's What Works in Schools (WWIS) approach for successful implementation in local education agencies and schools serving rural or American Indian and/or Alaska Native (AI/AN) adolescents to address students' health behaviors, experiences, and outcomes, particularly those related to sexual and reproductive health and mental and behavioral health, as well as suicidality, substance use, and experiences of violence. The purpose of the

research is to build the evidence base for innovative, school-based or school-linked strategies that promote the health of youth across multiple health domains while also supporting translation and dissemination of the research findings. Strategies may include programs, policies, or practices that seek to improve sexual and reproductive health as well as improve mental and behavioral health in a manner that also addresses health equity among youth in local education agencies and schools serving rural or AI/AN adolescents. Additionally, strategies may also seek to reduce suicidality, substance use and experiences of violence among school-aged adolescents.

NOFO RFA-DP-24-138 was modified on January 30, 2024. The purpose of this modification was to:

- **Add language back into the NOFO regarding the Population of Focus that was inadvertently deleted when the previous modification was processed.**

NOFO RFA-DP-24-138 was modified on January 12, 2024. The purpose of this modification was to:

- **Update the pre-application teleconference call details:** The pre-application teleconference call will be conducted as a Zoom Webinar. You may join the webinar by link and/or by telephone.
    - The link is https://cdc.zoomgov.com/j/1601547229?pwd=RWtCbkNBd3BsNEc1VzhSYWEzVHFoUT09
    - The passcode is Sz%W3*3*
    - The phone number is +1 669 254 5252
    - The webinar ID is 160 154 7229
    - The telephone passcode is 96042177
- **Update the Scientific/Research Contact email address:** please email your inquiries to researchnofo@cdc.gov

Key Dates

Publication Date:

To receive notification of any changes to RFA-DP-24-138, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.

Letter of Intent Due Date:
02/09/2024
02/09/2024

Application Due Date:
03/11/2024
03/11/2024

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

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

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

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

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

Scientific Merit Review:
05/21/2024
This date is an estimate.

Secondary Review:
06/24/2024
This date is an estimate.

Estimated Start Date:
09/29/2024

Expiration Date:
04/10/2024

Required Application Instructions

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

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

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

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

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

Executive Summary

- **Purpose:** This Notice of Funding Opportunity (NOFO) supports research to implement and evaluate strategies aligned with CDC's What Works in Schools (WWIS) approach for successful implementation in local education agencies and schools serving rural or American Indian and/or Alaska Native (AI/AN) adolescents to address students' health behaviors, experiences, and outcomes, particularly those related to sexual and reproductive health and mental and behavioral health, as well as suicidality, substance use, and experiences of violence. The purpose of the research is to build the evidence base for innovative, school-based or school-linked strategies that promote the health of youth across multiple health domains while also supporting translation and dissemination of the research findings. Strategies may include programs, policies, or practices that seek to improve sexual and reproductive health as well as improve mental and behavioral health in a manner that also addresses health equity among youth in local education agencies and schools serving rural or AI/AN adolescents. Additionally, strategies may also seek to reduce suicidality, substance use and experiences of violence among school-aged adolescents.
- **Mechanism of Support:** U01-Research Project – Cooperative Agreement.
- **Funds Available and Anticipated Number of Awards:** The estimated total funding available, including direct and indirect costs, for the entire five (5)-year project period is **$5,000,000.00.** The number of awards will be **two (2).** Awards issued under this NOFO are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded, and the number of awards will depend upon the number, quality, duration and cost of the applications received.
- **Budget and Project Period:** The estimated total funding (direct and indirect) for the first year (12-month budget period) will be **$1,000,000.00** with individual awards of **$500,000.00** each for two awards. The estimated total funding (direct and indirect) for the entire project period will be **$5,000,000.00**. The project period is anticipated to run from **09/29/2024 to 09/28/2029.**
- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. "Application and Submission Information" of this announcement.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III of this announcement are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.
    - **NOTE:** CDC does not make awards to individuals directly.
- **Number of PDs/PIs.** There will only be one PD/PI for each application.

- **Number of Applications.** Only one application per institution (normally identified by having a unique UEI number) is allowed. Multiple applications from different divisions of the same institution will be returned without further consideration by CDC.
- **Application Type.** New
- **Application Materials.** See Section IV.1 for application materials. Please note that SF424 (R&R) Form H is to be used when completing the application package. Please see https://grants.nih.gov/grants/how-to-apply-application-guide.html

SPECIAL DATE

A pre-application teleconference call will be conducted on **Wednesday, February 7, 2024** to address questions from prospective applicants. The call will begin at **3PM Eastern Time** (ET) and will last approximately one (1) hour. Questions and answers from the discussion will be transcribed and published on Grants.gov under NOFO RFA-DP-24-138 approximately 2-3 weeks after the call.

Participant Access Information:

- Date: Wednesday, February 7, 2024
- Time: 3PM Eastern Time (ET)
- Call Leader: Celeste Sanders, PhD, Scientific Program Official
- Link: https://cdc.zoomgov.com/j/1601547229?pwd=RWtCbkNBd3BsNEc1VzhSYWEzVHFoUT09
    - Passcode: Sz%W3*3*
- Phone Number: +1 669 254 5252
    - Webinar ID: 160 154 7229
    - Telephone passcode: 96042177

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

The CDC's Division of Adolescent and School Health (DASH) seeks to ensure all youth in the U.S. are equipped with the knowledge, skills, and resources they need to be healthy as youth and into adulthood. There is a strong focus on reaching youth through schools and an emphasis on addressing social determinants, through a population-based, integrated approach. CDC/DASH is a unique source of support for HIV, sexually transmitted infection (STI), and pregnancy prevention efforts in the nation's schools, supporting strategies focused on reducing HIV/STIs, and unintended pregnancy along with co-occurring experiences and behaviors such as poor mental health, suicide-related behaviors, substance use, and experiences of violence. CDC/DASH provides funding and technical assistance that enables local education agencies (i.e.,

school districts) to deliver HIV/STI and pregnancy prevention programs that are scientifically sound and grounded in the latest research on effectiveness.

Youth Health Behaviors and Experiences

Many young people engage in sexual risk behaviors which can result in unintended health outcomes. For example, among U.S. high school students surveyed in 2021, 30% had ever had sexual intercourse and 21% had sexual intercourse during the previous 3 months (i.e., currently sexually active). Among currently sexually active students, 48% did not use a condom the last time they had sex. (1) Also, 67% did not use effective hormonal birth control the last time they had sex; and 6% of all high school students had had sex with four or more people during their life. (1) Such sexual risk behaviors place adolescents at risk for HIV, STIs, and unintended and mistimed pregnancy. (1)

Sexual risk behaviors often cluster with risk behaviors and experiences across violence, mental health, suicide, and substance use. (2) These co-occurring health risks also share several protective factors, highlighting opportunities to holistically address adolescent health and well-being across multiple health domains. However, not all youth experience the burden of health risks equally, and disparities exist by individual characteristics, like race and ethnicity, as well as by structural contexts, like geography. In particular, social, structural, and historical factors drive and perpetuate disparities in the health and well-being of youth who live in rural areas and AI/AN youth. (3-5) Research using 2017 and 2019 Youth Risk Behavior Survey data found that AI/AN youth are significantly more likely than White youth to experience sadness and hopelessness, consider suicide, attempt suicide, and experience violence at school. (3) Rural areas have higher rates of poverty and less access to healthcare than urban areas, and rural schools are less likely to provide mental health services, all impacting the health and well-being of youth. (4) Considering documented health disparities, continued research on addressing and supporting the health of rural and AI/AN adolescents is needed.

What Works in Schools (WWIS) Approach

To reduce sexual risk behaviors and related health problems among youth, schools and other youth-serving organizations can help young people develop and maintain attitudes and behaviors which promote their health and well-being—including behaviors which reduce risks for HIV/STIs, unintended pregnancy and related health outcomes and experiences. CDC is nearing conclusion of cooperative agreement, *PS18-1807: Promoting Adolescent Health through School-based HIV Prevention,* with local education agencies (i.e., school districts) and national non-governmental organizations to support efforts to implement the *What Works in Schools* approach in secondary schools designed to reduce HIV/STI, pregnancy, and related health outcomes among youth. (6)

Components of What Works in Schools (WWIS) Approach

The *What Works in Schools (WWIS)* approach combines three programmatic strategies: delivering comprehensive sexual health education, increasing access to youth-friendly health services, and promoting safe and supportive school environments for all youth. (7) Together, these strategies aim to prevent HIV/STI, unintended pregnancy, and related risk behaviors and experiences such as poor mental health, suicide-related behaviors, substance use, and experiences of violence.

The *WWIS* approach includes school-based and school district-wide activities that help strengthen staff capacity, increase student access to programs and services, and engage parents and community partners across all program strategies (i.e., health education, health services, and safe and supportive environments). (7) As part of comprehensive health education, activities focus on implementing instructional programs (i.e., curriculum) which are standards-aligned, culturally responsive and inclusive, and sequential for students in secondary grades. Teachers delivering health education receive professional development to improve their essential knowledge and skills (i.e., instructional competencies) to effectively deliver instruction to all students. The health services strategy includes activities which increase student access to and use of confidential, youth-friendly preventive health services. School districts improve access to health services by implementing activities according to their infrastructure and partnerships which may include referring students to off-site health service providers and providing services on site (e.g., through a school-based health center or wellness clinic). Staff are trained to increase capacity for referring students to on- or off-site health services and integrating skills for accessing health services in comprehensive health education. As part of the safe and supportive environments strategy, activities help foster inclusive school environments where students feel respected by and connected to their peers, teachers, and other adults at school. Activities include implementing Genders and Sexualities Alliance (GSAs) clubs and connecting students to school- or community-based mentoring, service learning, and other positive youth development programming. Professional development for school staff targets effective classroom management and supporting students with lesbian, gay, bisexual, transgender, queer/questioning, and other sexual and gender identities (LGBTQ+). In addition, activities to increase school, parent, and community engagement are integrated throughout each program strategy. For example, schools and school districts can create and maintain school health advisory councils or teams, inclusive of students, staff, parents, and community members, to make recommendations on school health policies, programs, or practices. (7) More details about the WWIS approach is available at https://www.cdc.gov/healthyyouth/whatworks/index.htm. For a detailed program description and logic model, including short, intermediate, and long-term outcomes see https://www.grants.gov/search-results-detail/351244 (available February 1, 2024) and https://www.cdc.gov/healthyyouth/fundedprograms/index.htm.

Evidence for the WWIS Approach and Current Gaps

Evaluation of previous iterations of the WWIS approach show significant effects in reducing the odds of ever having sex, having four or more lifetime sexual partners, being currently sexually active, missing school due to safety concerns, lifetime experience of forced sex, and lifetime and current use of marijuana among students attending schools that were focused on implementing the *WWIS* program compared to students in the same districts in schools that were not the focus of implementing the program.(8) Evaluation among a subgroup of lesbian, gay, and bisexual students found reductions in odds of ever having sex and increased odds of condom use among sexually active youth. (9) Additional dose-response analyses found that incremental implementation of activities under the safe and supportive environments strategy was associated with reductions in odds of ever having sex, having four or more lifetime sexual partners, being currently sexually active, using effective hormonal birth control, dual use of condoms and effective hormonal birth control, lifetime experience of forced sex, missing school due to safety concerns, and lifetime and current marijuana use.(10) Analysis of LGBTQ+-supportive school policies and practices recommended in CDC's *WWIS* approach also found associations between

implementation of supportive practices and increased odds of ever being tested for HIV and reduction in odds of ever having sex, feeling threatened at school, lifetime experience of forced sex, persistent feelings of sadness and hopelessness, and suicide-related behaviors among both LGB and heterosexual students. (11,12)

To date, this evaluation evidence highlights the potential for schools and school districts to positively impact youth health behaviors and experiences by applying the *WWIS* approach, yet gaps remain in understanding program implementation, adaptation, and effectiveness for tailored adolescent groups. Specifically, studies are needed to examine the effectiveness of *WWIS* in schools serving rural adolescents and AI/AN. This NOFO supports studies to implement and evaluate strategies aligned with CDC's *WWIS* approach for successful implementation in school districts and schools serving rural or AI/AN adolescents to address health behaviors, experiences, and outcomes, and supports translation and dissemination of the studies' findings.

References

1. Centers for Disease Control and Prevention. Youth Risk Behavior Data Summary and Trends Report. 2023. https://www.cdc.gov/healthyyouth/data/yrbs/pdf/YRBS_Data-Summary-Trends_Report2023_508.pdf
2. Bozzini AB, Bauer A, Maruyama J, Simoes R, Matijasevich A. Factors associated with risk behaviors in adolescence: a systematic review. *Braz J Psychiatry*. Mar-Apr 2021;43(2):210-221. doi:10.1590/1516-4446-2019-0835
3. Jones SE, Satter DE. Implications for Coding Race and Ethnicity for American Indian and Alaska Native High School Students in a National Survey. *J Health Care Poor Underserved*. 2022;33(3):1245-1257. doi:10.1353/hpu.2022.0110
4. Graves JM, Abshire DA, Mackelprang JL, et al. Geographic Disparities in the Availability of Mental Health Services in U.S. Public Schools. *Am J Prev Med*. Jan 2023;64(1):1-8. doi:10.1016/j.amepre.2022.09.003
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6. Centers for Disease Control and Prevention. *PS18-1807 Program Guidance: Guidance for School-based HIV/STD Prevention (Component 2) Recipients of PS18-1807*. Atlanta, GA: U.S. Department of Health and Human Services; 2019. https://www.cdc.gov/healthyyouth/fundedprograms/1807/resources/PS18-1807-GUIDANCE508.pdf
7. Wilkins NJ, Rasberry C, Liddon N, et al. Addressing HIV/Sexually Transmitted Diseases and Pregnancy Prevention Through Schools: An Approach for Strengthening Education, Health Services, and School Environments That Promote Adolescent Sexual Health and Well-Being. *J Adolesc Health*. Apr 2022;70(4):540-549. doi:10.1016/j.jadohealth.2021.05.017
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9. Suarez NA, Cooper AC, Kaczkowski W, Li J, Robin L, Sims VM. Associations of a Multilevel School Health Program and Health Outcomes Among Lesbian, Gay, and

Bisexual Youth. *AIDS Educ Prev*. Oct 2022;34(5):395-412. doi:10.1521/aeap.2022.34.5.395
10. Li J, Timpe Z, Suarez NA, et al. Dosage in Implementation of an Effective School-Based Health Program Impacts Youth Health Risk Behaviors and Experiences. *J Adolesc Health*. Sep 2022;71(3):334-343. doi:10.1016/j.jadohealth.2022.04.009
11. Kaczkowski W, Cooper AC, Li J, Robin L. The Association of LGBTQ-Supportive School Health Policies and Practices with Sexual Health Outcomes. *LGBT Health*. Aug-Sep 2022;9(6):384-392. doi:10.1089/lgbt.2021.0132
12. Kaczkowski W, Li J, Cooper AC, Robin L. Examining the Relationship Between LGBTQ-Supportive School Health Policies and Practices and Psychosocial Health Outcomes of Lesbian, Gay, Bisexual, and Heterosexual Students. *LGBT Health*. Jan 2022;9(1):43-53. doi:10.1089/lgbt.2021.013311

Healthy People 2030 and other National Strategic Priorities

This NOFO supports efforts that align with the following public health priorities:

- **Healthy People 2030** –
    - Social Determinants of Health: education; social and community context; health and health care, neighborhood and built environment.
    - Health topics: adolescent health; LGBT health; educational and community-based programs; schools; health-related quality of life and well-being; HIV; pregnancy; sexually transmitted infections; drug and alcohol use; violence prevention; and mental health.

- **Ending the HIV Epidemic in the U.S. (EHE)** initiative aimed aims to end the HIV epidemic in the United States by 2030. https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview/
- **CDC's Health Impact in 5 Years (HI-5**) initiative includes interventions addressing the social determinants of health, and interventions changing the context. https://www.cdc.gov/policy/hi5/index.html
- **HHS. Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals** addresses supports for LGBTQI+ youth in the nation's schools and educational institutions. https://www.whitehouse.gov/briefing-room/presidential-actions/2022/06/15/executive-order-on-advancing-equality-for-lesbian-gay-bisexual-transgender-queer-and-intersex-individuals/
- **HHS. National Stakeholder Strategy for Achieving Health Equity** provides an overarching roadmap for eliminating health disparities through cooperative and strategic actions. https://www.phdmc.org/agency/programs-services/local-office-on-minority-health/64-achieving-health-equity/file

Public Health Impact

This NOFO will support (1) evaluation of strategies aligned with CDC's *What Works in Schools (WWIS)* approach for successful implementation in local education agencies and schools serving rural or AI/AN adolescents to address health behaviors, experiences, and outcomes, and (2) support translation and dissemination of the studies' findings. Successful implementation may require some adaptation of the current *WWIS* approach. This work will advance the evidence base and build capacity for education agencies in a variety of settings to implement *WWIS*.

Successful research projects will include consistent and meaningful engagement and collaboration with partners such as local education and public health agencies, schools, youth-serving organizations, healthcare providers, youth, parents, families, and community members. Expected impacts include prevention and reduction of risk behaviors related to sexual and reproductive health and behavioral and mental health, as well as suicidality, substance use, and experiences of violence.

Health Equity:

CDC supports efforts to improve the health of populations disproportionately affected by infectious diseases by maximizing the health impact of public health services, reducing disease incidence, and advancing health equity. A health disparity occurs when a health outcome is seen to a greater or lesser extent between populations. Health disparities in infectious diseases are inextricably linked to a complex blend of social determinants that influence which populations are most disproportionately affected by these infections and diseases.

Social determinants are conditions in the places where people live, learn, work, and play that affect a wide range of health and quality-of life-risks and outcomes (https://www.cdc.gov/socialdeterminants/index.htm). These include conditions for early childhood development, education, employment, and work, food security, health services, housing, income, and social exclusion. Health equity is a desirable goal that entails special efforts to improve the health of those who have experienced social or economic challenges. It requires:

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

Applicants should use data, including social determinants data, to identify communities within their jurisdictions that are disproportionately affected by infectious diseases and related diseases and conditions, and plan activities to help eliminate health disparities. In collaboration with partners and appropriate sectors of the community, applicants should consider social determinants of health in the development, implementation, and evaluation of specific efforts and use culturally appropriate interventions and strategies that are tailored for the communities for which they are intended.

Relevant Work

CDC/DASH's current *WWIS* approach is a model reflected in different iterations over two previous program cooperative agreements, PS13-1308 and PS18-1807.

- **CDC-FOA-PS13-1308,** Promoting Adolescent Health Through School-Based HIV/STD Prevention and School-Based Surveillance (https://www.cdc.gov/healthyyouth/fundedprograms/1308/pdf/rfa-1308.pdf)
    - Kaczkowski, W., Cooper, A.C., Li, J., & Robin, L. (2022) The association of LGBTQ-supportive school health policies and practices with sexual health outcomes. *LGBT Health*; 9(6), 384-392. https://doi.org/10.1089/lgbt.2021.0132
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psychosocial health outcomes of lesbian, gay, bisexual, and heterosexual students. *LGBT Health*, *9*(1), 43-53. https://doi.org/10.1089/lgbt.2021.0133
    - Li, J., Timpe, Z., Suarez, N. A., Phillips, E., Kaczkowski, W., Cooper, A. C., Dittus, P. J., Robin, L., Barrios, L. C., & Ethier, K. A. (2022). Dosage in implementation of an effective school-based health program impacts youth health risk behaviors and experiences. *Journal of Adolescent Health*, *71*(3), 334-343. https://doi.org/10.1016/j.jadohealth.2022.04.009
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- **CDC-RFA-PS18-1807,** Promoting Adolescent Health through School-Based HIV Prevention (https://www.cdc.gov/healthyyouth/about/nofo.htm)
    - Centers for Disease Control and Prevention. PS18-1807 program guidance: Guidance for school-based HIV/STD prevention (Component 2) recipients of PS18-1807. Atlanta, GA: U.S. Department of Health and Human Services; 2019. https://www.cdc.gov/healthyyouth/fundedprograms/1807/resources/PS18-1807-GUIDANCE508.pdf
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2. Approach

Research studies supported by this NOFO are expected (1) to implement and evaluate strategies aligned with CDC's *What Works in Schools (WWIS)* approach for successful implementation in local education agencies and schools serving rural or AI/AN adolescents to address health behaviors, experiences, and outcomes, and (2) to support translation and dissemination of the studies' findings. All research activities should focus on communities who are experiencing high levels of health disparities or health inequities. Applicants are expected to consider the underlying social and structural conditions (e.g., Social Determinants of Health) that contribute to, drive, or perpetuate health disparities or inequities. For more information visit https://www.cdc.gov/chronicdisease/healthequity/health-equity-science.html.

This NOFO will support studies aimed at implementing and evaluating strategies aligned with *WWIS* approach, including adaptations addressing sexual and reproductive health and mental and behavioral health, in local education agencies and schools serving one of the following populations (**Choose only one**):

1. Rural adolescents

2. AI/AN adolescents

Please note: applicants must indicate the chosen population on the Specific Aims page of their application.

Applicants who select to implement and evaluate strategies aligned with the *WWIS* approach for schools serving rural adolescents are expected to work *primarily* in school districts and schools not included within an urban area. Additional guidance from HRSA and the Federal Office of Rural Health can be found at: https://www.hrsa.gov/rural-health/about-us/what-is-rural .

Applicants who choose to implement and evaluate strategies aligned with the *WWIS* approach for schools serving AI/AN adolescents are expected to work with school districts and schools serving a significant population of AI/AN adolescents. These school districts and schools may be located in urban, suburban, rural, and/or tribal communities. Applicants proposing to work with school districts and schools within tribal settings or communities are expected to demonstrate approval and support or a tribal resolution for the proposed project from a currently elected tribal leader(s).

Studies are expected to employ a quasi-experimental design (i.e., use of comparison group(s)) and use implementation science frameworks, theories, principles, and methods. Studies should use equity-based frameworks, measures, and methodologies intended to address the needs of adolescents excluded or marginalized (e.g., youth in rural communities, AI/AN youth, youth in tribal or native communities, youth of color, youth with LGBTQ+ identities) in their design, implementation, and evaluation approach. Studies may also include Indigenous Knowledge methods and approaches. Indigenous Knowledge is a body of observations, oral and written knowledge, innovations, practices, and beliefs developed by Tribes and Indigenous Peoples through interaction and experience with the environment, and related practices". Strategies may not yet be rigorously evaluated and are considered innovative and community-based, including a variety of activities (e.g., traditional, healing, and spiritual practices such as ceremonies and rituals, talking circles, and drumming; wellness practices such as learning and speaking a traditional language, engaging in traditional practices, and developing connectedness through community and family activities). Studies are strongly encouraged to incorporate voices, perspectives, and input from program recipients (e.g., school staff, students), implementers (e.g., district and school staff), and partners (e.g., community organizations or healthcare providers) about contexts, priorities, and needs when determining necessary adaptations to evaluate WWIS-aligned strategies.

Studies may use a combination of existing data and newly collected data to answer select research questions, including various methods (e.g., surveys, focus groups, interviews, classroom observations) to gather information from program recipients (e.g., school staff, students), implementers (e.g., district and school staff), and partners (e.g., community organizations or healthcare providers). Applications should include a plan to get approval for any research with human subjects through their affiliated Institutional Review Board for the Protection of Human Subjects. Studies should include reaching students within one or more school districts in sufficient numbers to provide statistical power for measuring changes in student health behaviors and experiences as a result of the implemented approach strategies. A detailed list of student-level health behaviors and experiences of interest is included in the table below and aligns with CDC's priority health domains.

Applicants should include plans to provide technical assistance to their partnering local education agencies (i.e., school districts) to support implementation of strategies aligned with CDC's *WWIS* approach in each project. Applications should specify how to translate project findings and develop tools and resources to guide and support *WWIS*-related technical assistance for education agencies and other youth-serving organizations working to address the health of youth in equitable and sustainable ways. Lastly, an annual budget allocation for financial support to the partnering local education agencies is recommended. This financial support is to help local education agencies address challenges or barriers limiting their participation in this NOFO, including but not limited to staffing limitations and budget constraints.

Student health outcomes of interest aligned with CDC's *What Works in Schools* (*WWIS*) priority domains and protective factors

Priority Domain	**Student health behaviors and experiences of interest**
Sexual and reproductive health	• Ever had sexual intercourse • Number of sexual partners • Currently sexually active • Condom use at last sexual intercourse • Effective hormonal contraceptive use • Condom and effective hormonal contraceptive use (dual method use) • STI testing • HIV testing
Behavioral and mental health, including suicide-related behaviors	• Persistent feelings of sadness or hopelessness • Poor mental health • Seriously considering attempting suicide • Made a suicide plan • Attempted suicide • Injured in a suicide attempt
Substance use	• Alcohol use • Marijuana use • Electronic vapor product use • Use of select illicit drugs • Prescription opioids misuse
Violence	• Threatened or injured with a weapon at school • Not attending school due to safety concerns • Electronically bullied • Bullied at school

	• Forced to have sex • Experienced sexual or dating violence
Protective Factors	• School connectedness • Parental monitoring a. What adaptations to the current CDC *WWIS* approach are needed to implement *WWIS* with schools serving rural or AI/AN adolescents?

Applications should describe a plan to address the following high-level evaluation questions about strategies aligned with the *WWIS* approach in schools serving rural and AI/AN adolescents:

a. To what extent does CDC's *WWIS* approach affect students' health behaviors, experiences, and outcomes in schools serving rural and AI/AN adolescents?
b. To what extent does CDC's *WWIS* approach affect staff's (including staff in schools, community-based organizations, and community healthcare providers) capacity and experiences with program implementation in schools serving rural or AI/AN adolescents?
c. What barriers and facilitators exist when implementing CDC's *WWIS* approach with schools serving rural or AI/AN adolescents?
d. How can CDC's *WWIS* approach be implemented more equitably (e.g., in settings where financial and human resources are low, or where cultural or social norms affect health behaviors)?
e. How can evidence-based strategies aligned with CDC's *WWIS* approach under investigation be scaled up to broader regions or populations?
f. What research supports/activities are necessary for successful implementation? Are they replicable?

Applications should describe plans to accomplish the following activities:

Activity 1. Engage partners to build capacity for program adaptation and implementation of *WWIS*-aligned strategies**.**

1. Build and maintain relationships with one or more school districts, their schools, and relevant partners to support implementation and evaluation of the *WWIS*-aligned strategies.
2. Communicate information about research project activities to intended audiences and partners using a variety of channels.

Activity 2. Collaborate with partners to design and conduct evaluation research that aligns with one of the identified research priorities for this NOFO.

1. Identify a project timeline that includes all research activities to be achieved during the 5-year period of performance for this NOFO. The timeline should include but is not limited to (1) school/school district recruitment, research protocol and instrument development, implementation, data collection and analysis, (2) dissemination of research project findings, tools, and lessons learned to community, public health and education

practitioners, and academic audiences, and (3) translation of research findings and lessons learned. The timeline should be updated at least semi-annually to note any modifications to the plan.

2. Engage partnering school districts, schools, and relevant partners in all aspects of the research process including designing and conducting the project, implementing *WWIS*-aligned strategies, managing and analyzing data, and disseminating findings. These include but are not limited to partners that can: (a) support implementation, (b) deliver the intervention and (c) translate research findings for sustainability and scale-up beyond the project period.
3. Apply equity-based frameworks, measures, and methods intended to address the needs of adolescents excluded or marginalized (e.g., youth in rural settings, AI/AN youth, youth of color, youth with LGBTQ+ identities) in all aspects of the research process.
4. Secure all research approvals, including human subjects research determination, and if needed, Paperwork Reduction Act approval from the Office of Management and Budget (OMB).
5. Develop an evaluation report that includes how and why *WWIS*-aligned strategies were adapted, barriers and facilitators to implementation, and data documenting effectiveness of strategies and changes in outcomes of interest.

Activity 3. Develop and disseminate research findings and products.

1. Develop and annually update a plan to disseminate research findings and key implementation support materials for use by project partners and the public. Dissemination activities should include publishing and presenting project findings through peer-reviewed channels (e.g., journal articles, conference/meeting presentations). Activities should reach a diverse range of audiences using a variety of strategies and channels.
2. Annually, implement activities to disseminate key implementation support materials and research findings.
    - Any products and materials created under a cooperative agreement from this NOFO must be available and accessible at no additional expense to CDC and the research partners.

Activity 4. Conduct activities to support translation of research findings to improve practice of *WWIS*-aligned strategies.

1. Develop and annually update a plan to translate research findings and key implementation support materials for use by project partners and the public. Considerations for using implementation science and research translation frameworks (e.g., Knowledge into Action Framework) should be made when developing and implementing the Translation Plan. The plan should also identify appropriate audiences, strategies, and communication channels to translate project findings. Translation products may include summaries of key findings and data visualization for project partners, as well as lessons learned and success stories to be shared with the broader public.
2. Implement the translation plan.

Activity 5. Routinely communicate with selected research partners, organizations, agencies and the CDC on an ongoing basis.

1. Attend at least one (1) meeting in Atlanta within the first six (6) months of the cooperative agreement to discuss research project and plan for all activities for the year.
2. Communicate with partner agencies/organizations participating in the research project and the CDC on the progress of project activities and implementation through phone, e-mail, and other methods of communication on a regular basis.

Objectives/Outcomes

Short-Term Outcomes (STO):

- STO1. Increase program implementation and evaluation data collection/compilation among NOFO partners (e.g., collaborating local education agencies and schools).
- STO2. Increase understanding of strategies aligned with CDC's *WWIS* approach among NOFO partners.

Intermediate-Term Outcomes (IO):

- IO1. Increase implementation and adoption of evidence-based school strategies aligned with CDC's *WWIS* approach.
- IO2. Expand the evidence base on the effectiveness of strategies aligned with CDC's *WWIS* approach.
- IO3. Increase student or staff receipt of or exposure to strategies aligned to CDC's *WWIS*.

Long-Term Outcomes (LTO):

- LTO1. Reduce disparities in health behaviors, outcomes, and experiences among youth in schools serving rural and AI/AN adolescents.
- LTO2. Improve health outcomes among youth, specifically to include, but not be limited to:
    - Decreased sexual risk behavior
    - Improved mental health
    - Decreased violence-related behaviors and experiences
    - Decreased substance use
    - Increased protective behaviors and factors

Population of Focus

This NOFO has a specific focus on reaching rural or AI/AN adolescents. This NOFO addresses the public health needs of the rural or AI/AN adolescents in population groups that exhibit disproportionately high prevalence of health risk behaviors and experiences which are amenable to prevention intervention, such as the following populations and communities:

- Populations experiencing health disparities due to race, ethnicity, gender identity or expression, sexual orientation, rural geography, tribal affiliation or community attachment, socioeconomic status, disability status, primary language, health literacy, and other relevant dimensions.
- Communities disadvantaged by social and structural determinants of health that create health inequities.

In the Research Plan, applicants should clearly identify the population and communities they will address and describe the health disparities and health inequities they experience and how the

proposed research can benefit the identified population of focus and communities. Furthermore, as outlined in the objectives of this NOFO, the applicant should clearly identify whether they will be working with local education agencies serving rural or serving AI/AN adolescents.

Collaboration/Partnerships

It is anticipated that research supported under this NOFO will involve collaboration with both CDC and external partners (e.g., education and public health agencies, youth-serving organizations, healthcare providers, individuals, community members, governmental, non-governmental and private sector partners) on projects for the purpose of implementing and evaluating strategies aligned with CDC's *What Works in Schools* (*WWIS*) approach for successful implementation in local education agencies and schools serving rural or AI/AN adolescents to address students' health behaviors, experiences, and outcomes, and supporting translation and dissemination of the studies' findings. At a minimum, applicants will be expected to show evidence of their ability to work with one or more school districts to conduct the proposed research projects. The research plan should include reaching students within one or more districts in sufficient numbers to provide statistical power for measuring changes in student health behaviors and experiences as a result of the implemented program strategies.

It is also expected that collaboration among recipient staff and external partners on research will result in shared decision-making, resource sharing, and the creation of key implementation support materials and translation products. School and community engagement is fundamental to both the success and relevance of the research and activities supported by this cooperative agreement.

Evaluation/Performance Measurement

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

Applicants can use evaluation findings to ensure continuous program quality improvement, help create an evidence base for strategies aligned with CDC's *WWIS* approach and assess which strategies are adaptable and scalable for reaching rural or AI/AN adolescents over time. In the evaluation plan, draft performance measurements will monitor the extent to which planned activities are completed successfully, show the alignment of strategies aligned with CDC's *WWIS* approach with desired student health behaviors and outcomes in schools serving rural or AI/AN adolescents, and demonstrate the achievement of research outcomes. Applicants are expected to detail how they will (1) track the implementation of strategies aligned with *WWIS* approach and (2) demonstrate progress made in achieving project objectives. Regarding proposed performance measurements to capture effectiveness, measures should be:

1. Objective
2. Quantitative and standardized
3. Reflective of selected program outcomes (e.g., student health behaviors and outcomes)
4. Meaningful measures of change over time (e.g., increase or decrease)
5. Clear in specifying the unit of measurements (e.g., number or percentage of)

Applicants should describe process measures to track progress in implementing strategies aligned with the *WWIS* approach with schools serving rural or AI/AN adolescents, and outcome measures will determine progress in achieving the period of performance (5-year) outcomes. The program will work with recipients to determine which process and outcome measures are most appropriate for them and included in their final evaluation plan.

As an example, process and outcomes measures may include:

Process measures

- List of local education agencies (and their associated agencies or organizations) considered for participation in research projects.
- Number of local education agency staff trained on strategies aligned with CDC's *WWIS* approach.
- Number of proposed research staff who have completed research-related trainings and certificates (e.g., Human Research Protection Training).
- Completion of fully developed research protocol and instruments to support implementation of each project.
- Completion of a fully developed and up-to-date research dissemination and translation plan for each project.

Outcome measures

- Number of research partnerships (e.g., with schools, health service providers) developed and maintained to support project activities.
- Number of manuscripts for peer-reviewed publication.
- # of presentation materials (e.g., PowerPoint slides, handouts, speaker's notes) related to research activities.
- Percent of schools in partnering local education agencies that implemented strategies aligned with the *WWIS* approach.
- Number of school or school district policies and practices that support student access to strategies aligned with the *WWIS* approach.
- Number students who received or were exposed to strategies aligned with the *WWIS* approach.
- Number of staff (including staff in schools, community-based organizations, and community health providers) with increased capacity for implementing strategies aligned with the *WWIS* approach.
- Percent of students reporting risk and protective health behaviors and experiences before and after exposure to strategies aligned with the *WWIS* approach.
- Percent of students from subpopulations of interest (e.g., rural youth, AI/AN youth, racial and ethnic minority youth, youth who identify as LGBTQ+) reporting health risk behaviors and experiences of interest before and after exposure to strategies aligned with the *WWIS* approach.
- Percent of students reporting protective factors (e.g., school connectedness) before and after exposure to strategies aligned with the *WWIS* approach and associated with health outcomes.

- Percent of students from subpopulations of interest (e.g., rural youth, AI/AN youth, racial and ethnic minority youth, youth who identify as LGBTQ+) reporting protective factors (e.g., school connectedness) before and after exposure to strategies aligned with the *WWIS* approach.

CDC will use the information collected from recipients' performance reports to document project status, progress, and completion. Conference calls (frequency to be determined) between CDC and recipients will include project updates, discussion of technical assistance needs, and challenges around and solutions for completing research and implementation activities.

Translation Plan
Applications should include a dissemination and translation plan for each project's results. This plan should meet the dissemination and translation needs of the selected research partners and education agencies or organizations participating in the project. At a minimum, the plan should outline all proposed reports, manuscripts or presentations, and implementation support materials which highlight project findings.

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:
$5,000,000
Estimated total funding available for first year (first 12 months), including direct and indirect costs: $1,000,000.00

***Estimated total funding available for entire project period, including direct and indirect costs: $**5,000,0000.00

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

Throughout the project period, CDC's commitment to continuation of awards will be conditional on 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.

Anticipated Number of Awards:

2
Awards issued under this NOFO are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Award Ceiling:
$500,000
Per Budget Period

Award Floor:
$350,000
Per Budget Period

Total Period of Performance Length:
5 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

Governments:

Eligible Agencies of the Federal Government

U.S. Territory or Possession

Other:

Faith-based or Community-based Organizations

Regional Organizations

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

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

2. Foreign Organizations

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

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

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

3. Additional Information on Eligibility

N/A

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

It is the applicant's responsibility to ensure that the application meets all responsiveness criteria listed in this section. Applications that do not meet all of the following responsiveness criteria will be considered nonresponsive and will not be forwarded for peer review.

1. The application meets all of the requirements outlined in the NOFO.
    a. Please refer to Section I. Funding Opportunity Description and Section III. Eligibility Information.
2. The application includes at least one (1) letter of support from a local education agency that serves rural or AI/AN adolescents. This letter of support must indicate that the applicant will have access to the focal population.
    a. Letters of Support should be placed in the PHS 398 Research Plan "Other Research Plan Section" of the application under "9. Letters of Support". Additionally, applicants focusing on schools serving AI/AN adolescents associated with tribal communities must provide an official letter from a currently elected tribal leader or a tribal resolution to demonstrate support from the Tribe.

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.

Number of Applications Allowed:

- **Only one application per institution (normally identified by having a unique entity identifier [UEI]) is allowed. Multiple applications from different divisions of the same institution will be returned without further consideration by CDC**

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.

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

Please note: If requesting indirect costs in the budget based on a federally negotiated rate, a copy of the indirect cost rate agreement is required. Include a copy of the current negotiated federal indirect cost rate agreement or cost allocation plan approval letter in the R&R Budget Form as part of the Budget Justification attachment.

Letters of Support from partners or other organizations should be placed in the PHS 398 Research Plan "Other Research Plan Section" of the application under "9. Letters of Support". Letters of Support are required for applications engaging partners outside of the application institution. Applicants should provide Letters of Support from local education agencies or schools they plan to partner with throughout the duration of the funding period. Additionally, applicants focusing on schools serving AI/AN adolescents associated with tribal communities must provide an official letter from a currently elected tribal leader or a tribal resolution to demonstrate support from the Tribe, where appropriate.

3. Letter of Intent

Due Date for Letter Of Intent 02/09/2024

02/09/2024
Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information it contains allows CDC staff to plan the review. By the date listed above and in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

Name of the Institution
Descriptive title of proposed research

Name, address, and telephone number of the PD(s)/PI(s)
Names of other key personnel

Participating institutions

Place the number and title of this funding opportunity in the subject line.

The letter should be emailed to:
Celeste Sanders, PhD
Scientific Program Official
Email: researchnofo@cdc.gov

4. Required and Optional Components

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

5. PHS 398 Research Plan Component

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

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

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

Other Research Plan Sections

5. **Vertebrate Animals**
6. **Select Agent Research**
7. **Multiple PD/PI Leadership Plan.**
8. **Consortium/Contractual Arrangements**
9. **Letters of Support**

10. **Resource Sharing Plan(s)**
11. **Authentication of Key Biological and/or Chemical Resources**
12. **Appendix**

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

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

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

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;
- Mechanisms for 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).

CDC OMB approved templates may be used (e.g. NCCDPHP template https://www.cdc.gov/chronicdisease/pdf/nofo/DMP-Template-508.docx)

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

Application guides for FORMS-H application packages are posted to the How to Apply - Application Guide page.

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

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

This NOFO will support studies aimed at implementing and evaluating strategies aligned with *WWIS* approach, including adaptations addressing sexual and reproductive health and mental and

behavioral health, in local education agencies and schools serving one of the following populations (**Choose only one**):

1. Rural adolescents
2. AI/AN adolescents

Please note: applicants must indicate the chosen population on the Specific Aims page of their application.

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.

7. Page Limitations

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

8. Format for Attachments

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

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

Application guides for FORMS-H application packages are posted to the How to Apply - Application Guide page.

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

9. Submission Dates & Times

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

ASSIST is a commonly used platform because it provides a validation of all requirements prior to submission. If ASSIST detects errors, then the applicant must correct errors before their

application can be submitted. Applicants should view their applications in ASSIST after submission to ensure accurate and successful submission through Grants.gov. If the submission is not successful and post-submission errors are found, then those errors must be corrected and the application must be resubmitted in ASSIST.

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

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

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

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

Problems with Grants.gov can be resolved by contacting the Grants.gov Contact Center at:
Toll-free: 1-800-518-4726
https://www.grants.gov/web/grants/support.html
support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

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

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

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

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

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

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

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

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

Due Date for Applications 03/11/2024

03/11/2024
Electronically submitted applications must be submitted no later than 11:59 p.m., ET, on the listed application due date.

10. Funding Restrictions

Expanded Authority:

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

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

Public Health Data:

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

Data Management Plan:

Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Resource Sharing Plan(s) section of the PHS398 Research Plan Component of the application.

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

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

Human Subjects:

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

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

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

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

11. Intergovernmental Review

You will need to submit application information for intergovernmental review under Executive Order 12372. Under this order, states may design their own processes for obtaining, reviewing, and commenting on some applications. Some states have this process and others don't.

To find out your state's approach, see the list of state single points of contact. If you find a contact on the list for your state, contact them as soon as you can to learn their process. If you do not find a contact for your state, you don't need to do anything further. This requirement never applies to American Indian and Alaska Native tribes or tribal organizations.

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."

Please note: If requesting indirect costs in the budget based on a federally negotiated rate, a copy of the indirect cost rate agreement is required. Include a copy of the current negotiated federal indirect cost rate agreement or cost allocation plan approval letter in the R&R Budget Form as part of the Budget Justification attachment.

Application Submission

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

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

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

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

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

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

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

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

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

- http://era.nih.gov/erahelp/ASSIST/

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

Section V. Application Review Information

1. Criteria

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

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

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

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

- Does the application demonstrate how the proposed research project can contribute evidence about policies, practices, or programs aligned with all strategies of the *WWIS* approach, including replication or adaptation of implementation with schools serving rural or AI/AN adolescents?

Investigator(s)
Are the PD/PIs, collaborators, and other researchers well suited to the project? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

- Does the research team have experience conducting research in school settings and collecting outcome data from students and staff in schools?
- Does the research team have experience and capacity to effectively work with schools serving rural or AI/AN adolescents (e.g., describes demographic characteristics of populations served in prior research/evaluation)?

- Does the research team demonstrate capacity and willingness to engage in the requirements of the cooperative agreement, including cultural adaptations of interventions, adherence to and needed adaptation of evaluation methods for cultural integrity, data sharing across schools serving rural and AI/AN adolescents, and provision of program data with CDC and other recipients?
- For applications focusing on schools serving AI/AN adolescents: does the research team describe the nature of their relationship with AI/AN populations and their history (including number of years) serving or working with these groups?

Innovation

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

- Does the application expand current research on effective or innovative school health policies, practices, programs, or strategies aligned with CDC's *WWIS* approach?
- Does the application propose use of implementation science and health equity-related theoretical concepts, approaches and methods, or adaptation of policies, practices, programs, or strategies aligned with CDC's *WWIS* approach?
- In collaboration with partners and appropriate sectors of the community, does the application use culturally appropriate interventions and strategies that are tailored for the communities for which they are intended?
- Does the application show considerations for using implementation science and research translation frameworks (e.g., Knowledge into Action Framework) in the development and implementation of the Translation Plan?
- Does the plan also include identifying appropriate audiences, strategies, and communication channels to translate project findings.

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?

- Does the application timeline include a reasonable 5-year timeline that covers (1) school/school district recruitment, research protocol and instrument development, implementation, data collection and analysis, (2) dissemination of research project findings, tools, and lessons learned to community, public health and education practitioners, and academic audiences, and (3) translation of research findings and lessons learned?
- For applications focusing on schools serving AI/AN adolescents: Does the application include documentation of Tribal approval, where appropriate? Applicants may reference the following resource when planning approvals: https://nativedata.npaihb.org/ .
- For applications focusing on schools serving AI/AN adolescents: Does the application detail plans to secure Tribal IRB (or equivalent as determined by the tribe) approval, where appropriate?
- Does the application employ a quasi-experimental design (i.e., use of comparison group(s)) and use implementation science frameworks, theories, principles, and methods?
- Does the application use equity-based frameworks, measures, and methodologies intended to address the needs of adolescents excluded or marginalized (e.g., youth in rural communities, AI/AN youth, youth of color, youth with LGBTQ+ identities) in their design, implementation, and evaluation approach?
- Does the application use a combination of existing data and newly collected data and various methods (e.g., surveys, focus groups, interviews, classroom observations) to gather information from program recipients (e.g., school staff, students), implementers (e.g., district and school staff), and partners (e.g., health service providers)?
- Does the application include plans to include sufficient numbers of students to provide statistical power for measuring changes in student health behaviors and experiences as a result of the implemented strategies aligned with WWIS approach?
- Does the application describe how the *WWIS* approach can be adapted for successful implementation in schools that serve either (1) rural adolescents, or (2) American Indian or Alaska Native (AI/AN) adolescents?
- Does the application adequately describe plans to achieve the purpose and outcomes of the cooperative agreement, including using a design that will allow for assessment of changes in student health behaviors, experiences, and outcomes?
- Does the application reference evidence for the focal population's capacity-building and quality improvement needs?
- Does the application demonstrate understanding of the capacity-building and quality improvement needs for the focal population?
- Does the application describe the translation of project findings to develop tools and resources to guide and support *WWIS*-related technical assistance for education agencies and other youth-serving organizations?

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?

- Is the allocation of resources to help partnering education agencies address potential barriers to participation in this research (e.g., staffing limitations and budget constraints) adequate?

2. Additional Review Criteria

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

Protections for Human Subjects

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

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

If your proposed research involves the use of human data and/or biological specimens, you must provide a justification for your claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

Inclusion of Women, Minorities, and Children

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

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following four points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable

restraining devices; and 4) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (https://grants.nih.gov/grants/olaw/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)
HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: https://www.cdc.gov/grants/additional-requirements/ar-25.html

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

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

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

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

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;
- Mechanisms for 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 de-identified data).

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

CDC OMB approved templates may be used (e.g. NCCDPHP template https://www.cdc.gov/chronicdisease/pdf/nofo/DMP-Template-508.docx

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

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

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

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

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

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

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

4. Review and Selection Process

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

- Will 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.
- Selection to ensure diversity in population of focus

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 grantee’s business official.

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

2. CDC Administrative Requirements

Overview of Terms and Conditions of Award and Requirements for Specific Types of Grants

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

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. Grantees (foreign and domestic) receiving CDC funding on or after September 24, 2015 are subject to this policy. Research funded by CDC, involving the agents or toxins named in the policy, must be reviewed to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. This review must be completed by an Institutional Review Entity (IRE) identified by the funded institution.

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

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

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

Data Management Plan(s) CDC requires that all new collections of public health data include a Data Management Plan (DMP). For purposes of this announcement, "public health data" means

digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation.

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

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

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

4. Cooperative Agreement Terms and Conditions

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Part 75, and other HHS, PHS, and CDC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial CDC programmatic involvement with the recipients is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; CDC Project Officers are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the 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 PI(s) will have the primary responsibility for:

- Complying with the Investigator responsibilities described in the Policy on Public Health Research and Nonresearch Data Management and Access https://www.cdc.gov/grants/additional-requirements/ar-25.html
- Ensuring the protection of human subjects through ethical review of all protocols involving human subjects at the local institution and at CDC and obtaining the appropriate Institutional Review Board approvals for all institutions or individuals engaged in the conduct of the research project.
- Working with CDC scientists to obtain OMB-PRA approvals, as needed.
- Ensuring that publications, journal articles, presentations, etc. produced under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate, for example: "This publication (journal article, etc.) was supported by the Cooperative Agreement Number above from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention". In addition, the PI must provide to CDC Program abstracts or manuscripts prior to any publication related to this funding. The recipient will not seek to publish or present results or findings from this project without prior clearance and approval from CDC.
- Complying with the responsibilities for the PI as described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf).

CDC staff will have substantial programmatic involvement that is beyond the normal post-award oversight and stewardship responsibilities and functions, as described below:

- Assisting the PI, as needed, in complying with the Investigator responsibilities described in the Policy on Public Health Research and Nonresearch Data Management and Access, https://www.cdc.gov/grants/additional-requirements/ar-25.html
- Preparing the paperwork necessary for submission of research protocols to the CDC Institutional Review Board for review, as needed.
- Obtaining Office of Management and Budget approval per the Paperwork Reduction Act, if necessary.
- Assisting the PI, as needed, in complying with the PI responsibilities described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf
- Collaborating with recipients in overall project planning and development, including development and selection of data collection instruments and protocols, and data abstraction forms.
- Reviewing and approving the recipients' proposed staffing plan and proposed subcontracts.
- Providing guidance on selection of local education agency inclusion criteria.
- As needed, assisting in developing supporting materials to guide *WWIS* adaption and implementation.
- Assisting in development of data analysis plans, analysis, and interpretation of data analysis, both quantitative and qualitative.

- Monitoring and evaluating the accomplishments of the project. This will be accomplished through periodic site visits, telephone calls, and review of technical reports and interim data analyses.
- Providing technical assistance to local education agency partners as needed or required.

Please note: recipients will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.

Areas of Joint Responsibility include:

- Collaborating in the development of human subject research protocols and additional documents for IRB review by all cooperating institutions participating in the project and for OMB review, if needed.
- Attending quarterly calls for project progress updates and for CDC to provide guidance to the grantee

Additionally, a Scientific Program Official in the NCCDPHP's Extramural Research Program Operations and Services (ERPOS) will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice. Normal scientific and programmatic stewardship includes:

- Providing overall scientific and programmatic stewardship of the award.
- Serving as the primary point of contact for official pre-award activities and for all award-related activities, including an annual review of the grantee's performance as part of the continuation application.
- Making recommendations on requests for changes in scope, objectives, and or budgets that deviate from the approved peer-reviewed application.
- Attending committee meetings and participate in conference calls for the purposes of assessing overall progress and for program evaluation purposes.
- Ongoing monitoring performance against approved project objectives.
- Ensuring compliance with applicable policy requirements as well as the terms and conditions of the 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:

1. **Yearly Non-Competing Grant Progress Report** is due 90 to 120 days before the end of the current budget period. The RPPR form (https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf) is to be completed on the eRA Commons website. The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.
2. **Annual Federal Financial Report (FFR) SF 425 (**Reporting | Grants | CDC) is required and must be submitted to the Payment Management System accessed through the FFR navigation link in eRA Commons or directly through PMS **within 90 days after the budget period ends.**
3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **120 days after the end of the period of performance.**

B. Content of Reports

1. Yearly Non-Competing Grant Progress Report: The grantee's continuation application/progress should include:
    - Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the RPPR form in eRA Commons (https://grants.nih.gov/grants/rppr/index.htm). Detailed narrative report for the

current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.

- Research Aims: list each research aim/project

a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned

b) Leadership/Partnership: list project collaborations and describe the role of external partners.

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

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

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

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

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

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

- Publications/Presentations: Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate "Not applicable: No publications or presentations have been made."

- IRB Approval Certification: Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.

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

- Additional Reporting Requirements:

N/A

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

Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to

submit a letter explaining the reason and date by which the Grants Officer will receive the information.

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

Recipients must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, recipients must submit a final FFR, final progress report, and Final Invention Statement and Certification within 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 grantee's final report should include:

- Research Aim/Project Overview: The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.
- Translation of Research Findings: The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the Period of Performance. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.
- Public Health Relevance and Impact: This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI

should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.

- Publications; Presentations; Media Coverage: Include information regarding all publications, presentations or media coverage resulting from this CDC-funded activity. Please include any additional dissemination efforts that did or will result from the project.
- Final Data Management Plan: Applicants must include an updated final Data Management Plan that describes the data collected, the location of where the data is stored (example: a repository), accessibility restrictions (if applicable), and the plans for long term preservation of the data.

6. Termination

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

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

(1) By the HHS awarding agency or pass-through entity, if the non-Federal entity fails to comply with the terms and conditions of the award;

(2) By the HHS awarding agency or pass-through entity for cause;

(3) By the HHS awarding agency or pass-through entity with the consent of the non-Federal entity, in which case the two parties must agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated; or

(4) By the non-Federal entity upon sending to the HHS awarding agency or pass-through entity written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the HHS awarding agency or pass-through entity determines in the case of partial termination that the reduced or modified portion of the Federal award or subaward will not accomplish the purposes for which the Federal award was made, the HHS awarding agency or pass-through entity may terminate the Federal award in its entirety.

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

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

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

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

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

3) Terms: For purposes of this clause:

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

“Foreign government” includes any foreign government entity;

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

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

5) Contents of Reports: The reports must contain:

a. recipient name;

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

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

d. reporting period;

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

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

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

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

Section VII. Agency Contacts

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

Application Submission Contacts

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading or navigating forms)
Contact Center Phone: 800-518-4726
Email: support@grants.gov

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

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

Scientific/Research Contact
Celeste Sanders, PhD
Scientific Program Official, Extramural Research Program Operations & Services
National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)
Telephone: (770) 488-2536
Email: researchnofo@cdc.gov

Peer Review Contact
Katie Barrett, PhD
Scientific Review Official, Extramural Research Program Operations & Services
National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)
Telephone: (404) 718-7664
Email: ohi6@cdc.gov

Grants Management Contact
Angie Willard
Grants Management Officer, Team Lead
Office of Grants Services
Telephone: (770) 488-2863
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.

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.