Centers for Disease Control and Prevention

NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION

Effectiveness of Telehealth-Based Programs to Detect Glaucoma Among High-Risk Populations in Community Health Settings

RFA-DP-24-081

02/05/2024

Table of Contents

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

Effectiveness of Telehealth-Based Programs to Detect Glaucoma Among High-Risk Populations in Community Health Settings

Activity Code

U 01 Cooperative Agreement

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-DP-24-081

Assistance Listings Number(s)

93.068

Category of Funding Activity

HL - Health

NOFO Purpose

The purpose of this NOFO is to support comparative effectiveness trials to investigate the feasibility, effectiveness, and cost-effectiveness of telehealth-based interventions to detect and manage glaucoma among high-risk populations. This NOFO aims to support the study of replicable and scalable interventions that use real-world, payer-provider reimbursement structures within community-based, health care delivery settings in various regions of the United States. Outcomes should be relevant to clinical practice, public health, community

implementation, and policy. This NOFO also supports the cost-effectiveness analyses of proposed interventions. The resulting data will assist policymakers, clinicians, and patients make informed decisions to reduce the burden of glaucoma and improve the quality of life for millions of people.

This NOFO will be accomplished through two components, Component A: Comparative effectiveness trials among high-risk populations within community-based settings, and Component B: a coordinating center to provide scientific and logistical support to Component A studies.

Key Dates

Publication Date:

To receive notification of any changes to RFA-DP-24-081, 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:
01/15/2024
January 15, 2024

Application Due Date:
02/05/2024
February 5, 2024

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

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

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

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

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

Scientific Merit Review:
03/19/2024

Secondary Review:

05/24/2024

Estimated Start Date:
09/30/2024

Expiration Date:
03/08/2024

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: The purpose of this NOFO is to support comparative effectiveness trials to investigate the feasibility, effectiveness, and cost-effectiveness of telehealth-based interventions to detect and manage glaucoma among high-risk populations. This NOFO aims to support the study of replicable and scalable interventions that use real-world, payer-provider reimbursement structures within community-based, health care delivery settings in various regions of the United States. Outcomes should be relevant to clinical practice, public health, community implementation, and policy. This NOFO also supports the cost-effectiveness analysis of proposed interventions. The resulting data will assist policymakers, clinicians, and patients make informed decisions to reduce the burden of glaucoma and improve the quality of life for millions of people.

This NOFO will be accomplished through two components, Component A: Comparative effectiveness trials among high-risk populations within community-based settings, and Component B: a coordinating center to provide scientific and logistical support to Component A studies.

Mechanism of Support: Cooperative Agreement

Funds Available and Anticipated Number of Awards: The amount available for the five-year period of performance, September 30, 2024 to September 29, 2029, is $15,000,000 for both components. Awards issued under this NOFO are contingent upon availability of funds and a sufficient number of meritorious applications. The total amount awarded and the number of awards will depend upon the number, quality, and budgets of the applications received.

Budget and Period of Performance: The estimated total funding (direct and indirect) for the first budget period, September 30, 2024 - September 29, 2025, is $3,000,000.

Number of Applications: Only one application per institution is allowed, as indicated by a unique entity identifier (UEI) at the time of submission. An organization may apply for Component A or Component B, not both.

Application Type: NEW

Special Date(s): A pre-application informational webinar will be held tentatively on December 19, 2023 at 2 pm. Details and any changes will be posted on Grants.gov.

Section I. Funding Opportunity Description

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

1. Background and Purpose

The purpose of this NOFO is to support comparative effectiveness trials to investigate the feasibility, effectiveness, and cost-effectiveness of telehealth-based interventions to detect and manage glaucoma among high-risk populations. This NOFO aims to support the study of replicable and scalable interventions that use real-world, payer-provider reimbursement structures within community-based, health care delivery settings in various regions of the United States. Outcomes should be relevant to clinical practice, public health, community implementation, and policy. The resulting data will assist policymakers, clinicians, and patients make informed decisions to reduce the burden of glaucoma and improve the quality of life for millions of people.

The interventions under study to detect and manage glaucoma are likely to detect other ocular conditions (e.g., age-related macular degeneration, cataract, diabetic retinopathy, uncorrected refractive error). These may form part of the study and its outcomes; however, the primary focus should be to detect and manage glaucoma. The purpose of this NOFO is also to support cost-effectiveness analyses of proposed interventions in a real-world setting as well as to improve vision-related quality of life.

Background

Glaucoma is one of the leading causes of irreversible blindness in the United States. About 3 million Americans have the disease, and this is expected to increase to 7.3 million by 2050 (1). Currently, 50% of those who have glaucoma are unaware of their condition; if current methods to reach and care for patients remain in use, there will be about 3.5 million Americans with undiagnosed glaucoma in 2050 (1-2).

The prevalence and risk factors for glaucoma are well-documented. Compared to non-Hispanic Whites, the prevalence of glaucoma is substantially higher among Black, Hispanics/Latino, and Asian individuals (2-4). Prevalence increases with age among all ethnic groups. Risk factors for glaucoma include race (Black, Asian), ethnicity (Hispanic) and age, as well as a family history of glaucoma and diagnosis of diabetes (5).

Treatments to slow the progression of glaucoma and avoid vision loss are available, therefore timely examination and follow-up are recommended for people at high risk for glaucoma (4). However, national and state data suggest that only about half of people at high risk for serious vision loss have visited an eye doctor in the past 12 months. Despite the preferred practice

patterns of eye care professional communities and Medicare's glaucoma screening benefit for high-risk patients, access to glaucoma care among vulnerable populations falls short of recommendations (5-6). The Medicare benefit is underutilized among "high-risk patients," defined by Medicare as those with a family history of glaucoma, those with diabetes, Black adults over age 50, and Hispanic adults over age 65 (7).

In the past decade, technology has advanced, and innovative tools such as telemedicine have enhanced glaucoma screening and early diagnosis, especially in underserved populations and rural settings. Peer-reviewed studies demonstrate the potential of such tools to reach large populations of vulnerable individuals cost-effectively (8-11).

In 2016, the National Academies of Sciences, Engineering, and Medicine published the landmark report *Making Eye Health a Population Health Imperative: Vision for Tomorrow*, defining vision and eye health problems as a growing public health concern for the nation. The report recommended an agenda that includes efforts to focus on innovative models of care to improve access to appropriate diagnosis and follow-up treatment, and to address eye care disparities (12).

The Agency for Healthcare Research and Quality, Effective Health Care Program sponsored a comparative effectiveness review of glaucoma screening published in 2012 (13). This and a subsequent 2013 and a 2022 statement by the US Preventive Services Task Force conclude that the current evidence is insufficient to assess the balance of benefits and harms of screening for primary open-angle glaucoma in the general adult population, noting: "This recommendation applies to adults who do not have vision symptoms and are seen in a primary care setting" (14). However, given the known risk factors for glaucoma, the American Academy of Ophthalmology, in its *Primary Open Angle Glaucoma Preferred Practice Pattern*, citing several studies, concluded that "Screening may be more useful and cost-effective when it is targeted at populations at high risk for glaucoma" (15). These expert recommendations and evidence of the effectiveness of treatment, as well as new potential screening tests, justify further evaluation of the comparative effectiveness of different real-world approaches to detecting and managing glaucoma among high-risk populations (16).

The Centers for Disease Control and Prevention/Vision Health Initiative has been engaged in numerous community-based studies over the past 12 years — conducted in geographically diverse settings — demonstrating that targeted screening in high-risk populations has a high sensitivity for identifying those with both early and later stages of glaucoma (5-7). In 2012, CDC's Vision Health Initiative demonstrated that reaching people at high risk for glaucoma by either a mobile eye health program or telemedicine program provided useful information for wider implementation in public health clinics and optometry clinics located in retail outlets. These glaucoma screening programs in underserved communities have identified glaucoma and glaucoma suspect cases at much higher rates than within the general population.

The current project, Screening and Interventions for Glaucoma and Eye Health through Telemedicine (SIGHT) Studies, taking place in Michigan, New York City, and Alabama (SIGHTSTUDIES.org), is detecting higher rates of glaucoma among high-risk populations than are found in the general population. These studies are operating in a variety of settings including federally qualified health centers, community health centers, and primary care locations in rural areas. These studies find that interventions are improving glaucoma and other major eye diseases detection and management among groups at high-risk (9).

To maximize public health impact and acknowledging the low prevalence of glaucoma in the general population, CDC intends to fund studies that include an intervention group and control group with an acceptable standard of care within real-world, payer-provider structures. SIGHT studies have demonstrated that well-funded demonstration projects increase detection of glaucoma in resource-poor settings; however, there is a knowledge gap in the applicability of these study findings to real world settings in which detection and management of eye disease is governed by existing reimbursement structures.

Many people with glaucoma are likely to have other eye diseases. Since eye diseases and vision impairment affect large numbers of people, especially older-age and disadvantaged populations, an intervention design that can identify other eye diseases and general vision impairment is desired. Community-based detection and management programs with standard, measurable outcomes have the capacity to improve quality of vision, eye health, and quality of life for millions of people every year.

References:

1. Vajaranant TS, Wu S, Torres M, Varma R. The changing face of primary open-angle glaucoma in the United States: demographic and geographic changes from 2011 to 2050. AJO, 2012 Apr;154(2):303-314
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3. Tielsch JM, Sommer A, Katz J, et al. Racial variations in the prevalence of primary open-angle glaucoma. The Baltimore Eye Survey. JAMA 1991;266:369–74.
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9. Kolomeyer NN, Katz LJ, Hark LA, et al. Lessons learned from 2 large community-based glaucoma screening studies. J Glaucoma. 2021;30:875–877.
10. Hark L, Waisbourd M, Myers JS. Improving access to eye care among persons at high-risk of glaucoma in Philadelphia: design and methodology: the Philadelphia Glaucoma Detection and Treatment Project. Ophthalmic Epidemiol. 2016;23:122–130.
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12. National Academies of Sciences, Engineering, and Medicine, Health and Medicine Division, Board on Population Health and Public Health Practice. *Committee on Public Health Approaches to Reduce Vision Impairment and Promote Eye Health*. National Academies Press (US); 2016.
13. Ervin, A. M., Boland, M. V., Myrowitz, E. H., Prince, J., Hawkins, B., Vollenweider, D., ... & Robinson, K. A. (2012). Screening for glaucoma: comparative effectiveness.

14. US Preventive Services Task Force. Mangione CM, Barry MJ, et al. Screening for primary open-angle glaucoma: US Preventive Services Task Force Recommendation Statement. JAMA. 2022;327:1992–1997.
15. American Academy of Ophthalmology Glaucoma Panel. Preferred Practice Pattern® Guidelines. Primary Open Angle Glaucoma. San Francisco, CA: American Academy of Ophthalmology; 2010.
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Healthy People 2030 and other National Strategic Priorities

This NOFO supports these three topics outlined in Healthy People 2030, a national disease prevention initiative that identifies opportunities to improve the health of all Americans.

Objective V-02 calls to "Increase the proportions of adults who have had a comprehensive eye exam in the last two years" to improve early detection and timely treatment of eye conditions leading to vision impairment.

Objective V-05 specifically calls for the reduction of vision impairment due to glaucoma, "Reduce visual impairment due to glaucoma"

Objective V-R01 calls to "Increase access to comprehensive vision services in community health centers." "This objective currently has research status, meaning it is a high-priority public health issue that doesn't yet have evidence-based interventions developed to address it. It may or may not have reliable baseline data available. If both baseline data and evidence-based interventions become available, this objective may become a core Healthy People 2030 objective."

Other National Public Health Priorities and Strategies

- This NOFO supports a CDC/Division of Diabetes Translation objective to promote health equity by reducing disparities that affect vision loss and eye diseases.
- The National Academies of Sciences, Engineering, and Medicine calls for transforming vision impairments from common to rare, and eliminating correctable and avoidable vision impairments in the U.S. by 2030. The NASEM Board on Population Health and Public Health Practice has called on CDC to develop a comprehensive surveillance system for eye and vision health coupled with a common research agenda and coordinated research and demonstration grant programs that target eye conditions and diseases that contribute the greatest public health burden to provide evidence of effective policies, practices, and interventions (8).

Public Health Impact

Fifty percent of people with glaucoma do not know they have it (2), and many people are not familiar with the disease and its potential to cause severe vision impairment and blindness. Additionally, there is a lack of access to eye care for those at high-risk for glaucoma in the United States, making office visits and medications necessary to diagnose, treat, and monitor glaucoma out-of-reach for many populations.

By testing the comparative effectiveness of interventions in this study to clinical standards of care, the public health community will gain knowledge about the feasibility (clinical, patient quality-of-life improvement, and cost-effectiveness) of real-world implementation. Community-

based detection and management programs with standard, measurable outcomes have the capacity to improve quality of vision, eye health, and quality of life for millions of people every year. The resulting interventions will have sufficient rigor and fidelity to be replicated and scaled-up in communities across the nation. The results of this research will generate information that will assist patients, policymakers, and clinicians make informed decisions about glaucoma and vision health.

Relevant Work

CDC has been engaged in coordinated research and demonstration grant programs that target glaucoma detection and management to provide evidence of effective policies, practices, and interventions since 2012 (CDC-RFA-DP12-1207; CDC-RFA-DP14-002, SIGHT Studies CDC-RFA-DP19-004).

CDC's Vision Health Initiative and NORC at the University of Chicago partnered to develop the National Vision and Eye Health Surveillance System. VEHSS leverages new and existing data sources to help health professionals, researchers, policymakers, and patients understand the scope of vision loss, eye disorders, and eye care services. It reports the prevalence of glaucoma, use of eye health services, and eye health disparities in treatments and outcomes nationally and at the state level whenever available.

2. Approach

This NOFO will be accomplished through two components, Component A: Comparative effectiveness trials among high-risk populations, and Component B: A coordinating center to provide logistics and scientific support to the funded research studies under Component A. Applicants may apply for either Component A or Component B. Applications from one institution for both components will not be accepted.

Strategies and Activities

Component A: Comparative effectiveness trials in high-risk populations

- Test the real-world efficacy of the intervention compared to usual care that is well-described and justified. The proposed study should have an intervention and a control arm, and should be conducted in a real-world setting(s) (e.g., Federally Qualified Health Centers).
- Fully leverage existing community settings, such as retail, clinical infrastructure, and payer-provider structures.
- Study settings should be in geographic locations in the United States with high proportions of people living at or below the federal poverty level, in communities that are predominantly comprised of minority groups, and among communities that are less likely to access eye care services.
- Demonstrate how the methods to perform glaucoma detection in a real-world setting can generate evidence for detecting other eye diseases, functional vision loss, and vision impairment.
- Conduct an economic analysis of the costs and benefits of the proposed intervention, cost-per-case detected, and cost-effectiveness of the intervention vs. usual care. An economic analysis should account for existing reimbursement structures for detection and management of glaucoma.

Component B: Coordinating Center

The coordinating center will play a critical role in facilitating collaboration between Component A recipients, which will independently implement their interventions. The Component B recipient will serve as a logistical and organizing hub, accelerating information exchange between the studies and with stakeholders. It will provide a strong organizational foundation and accommodate the needs of Component A recipients.

Strategies and activities include:

- Collaborate with Component A recipients to develop common, standardized protocols that will enable the comparison of outcomes across Component A studies, including the cost-effectiveness assessment. Assist recipients to refine their study designs.
- Establish the infrastructure and implement processes to support collaboration. Organize, facilitate, and develop the governance for a steering committee (and work groups); ensure it has primary responsibility for developing common study protocols, indicators, manuals, and reporting standards.
- Maintain study-wide timeline management. Coordinate logistics for study meetings including planning agendas, securing facilities for face-to-face meetings, and preparing minutes.
- Facilitate the exchange of abstracts, manuscripts, presentations, fact sheets, and other scientific materials and drafts among the recipients and CDC. Facilitate the development of guidelines for presentations at scientific meetings, and for writing and publishing materials about the findings.
- Develop and maintain a study website with internal and external access.

Objectives/Outcomes

Outcomes should be relevant to clinical practice, public health, community implementation, providers, and policy.

This NOFO is expected to include the following outcomes from Component A:

- An innovative, telehealth-based intervention for detection and management of glaucoma among high-risk population(s) in one or more real-world setting(s).
- A protocol that uses or modifies the intervention to detect other eye diseases and vision impairment.
- Outcome measures that identify and assess reductions in health disparities.
- A description of the prevalence of glaucoma, glaucoma suspect, vision impairment, and other potentially blinding eye diseases among the study population.
- Patient-centered outcome measures such as vision-related quality of life, patient satisfaction, functional status, adherence to follow-up, and if possible, improved vision.
- An assessment of participant retention strategies.
- A cost-effectiveness analysis of the proposed intervention, accounting for existing payer-provider reimbursement structures.
- Sufficient evidence of the cost benefit of glaucoma detection compared to "usual care."
- Transition of the intervention to a program in the community.

- A blueprint for future scaling and replication of the intervention to decrease disparities in glaucoma care and minimize glaucoma-related vision impairment beyond the study setting.

This NOFO is expected to include the following outcomes from Component B:

- Standardized measurements that will enable comparison of outcomes across Component A studies.
- Timely logistical and scientific communications via a study website with both internal-only access and external pages.
- An effective steering committee that produces collaborative protocols and guidelines.

Target Population

The study population is people in the US at high-risk for and disproportionally affected by glaucoma, including people 65 and older, those with a family history of glaucoma, those with diabetes, non-Hispanic Black and Hispanic adults aged 50 and older, and/or those living in poverty and lacking access, resources, and/or education regarding vision and eye health. Included among this population are those affected by disparities such as, but not limited to, race, ethnicity, gender, geography, and socioeconomic status.

Collaboration/Partnerships

Collaborations and strategic partnerships are crucial to implement program strategies and sustain outcomes. They allow for more efficient use of existing resources and exchange of information between experts working in various areas of public health and other sectors. Applicants are encouraged to form and expand existing community partnerships to maximize the capacity of their intervention, as well as to possibly transition the intervention to community vision care services once the study is complete.

Suggested partners include health care systems, retail vision services, non-profit organizations, community organizations, and professional organizations.

Evaluation/Performance Measurement

Applicants should propose a rigorous evaluation framework for key milestones that establishes high-priority process and outcome measures for activities/strategies. Evaluation efforts should include measurable outputs; short-term, intermediate, and long-term outcomes and their indicators; and a strategy for using the results to improve the study.

Recipients will have six months to finalize the performance measures and plan. The evaluation plan may be updated throughout the period of performance. Recipients are expected to continuously implement the evaluation plan to measure and track the process (e.g., implementation, quality, and reach) and incorporate rapid feedback provided by CDC. Recipients' performance milestones related to the NOFO activities in the annual RPPR work plan allows CDC to monitor the recipients’ activities and their achievement of the project goals, objectives, and activities.

For Component A, this plan must include methods to:

- identify, track, and report qualitative and quantitative indicators.
- identify and assess reductions in health disparities.
- access data and continuously monitor data quality.

- engage community partners to achieve the outcome of eventual transition of the program into the community/community health systems.
- develop measures for replicating and scaling-up in communities/public health systems.

For component B, this plan must include measurements of quality related to facilitating a multi-site, collaborative environment; execution of communication and information exchange; and documenting, tracking, and coordinating steering committee activities.

Translation Plan
Applicants for Components A and B are expected to outline a translation and dissemination plan to guide future efforts to expand and implement glaucoma screening and management programs in real-world settings that include other eye diseases and vision loss detection. Award recipients are expected to collaborate and submit a full translation and dissemination plan to CDC within six months. The plan should include how the information will be shared with key stakeholders, including public health practitioners, academic researchers, governmental agencies, patient advocacy groups, eye care providers, insurance providers, the target population, and the public at large.

The plan should include a variety of approaches for sharing research findings and how it measures audience impact (e.g., website, webinars, podcasts, media relations, reports, fact sheets, and electronic manuals), as well as materials to guide replication and expansion of interventions.

Recipients are expected to communicate the findings throughout the study to the larger scientific and public health communities in peer-reviewed journals presentations at professional meetings and conferences. Topics should include recruitment strategies, analysis of provider-payer structures applicable to the intervention, methods, protocol, measurements, and scalability. Translations should define setting, partners, scope, economic considerations (e.g., engagement of payers, upfront costs, and financial benefits to provider organization), and outcome measures. Materials should be finished products during the fifth year of the period-of-performance.

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:
$15,000,000

The estimated total funding (direct and indirect) for the entire five-year period of performance, September 30, 2024 to September 29, 2029, is $15,000,000 to fund up to 5 awards in two components. CDC will award one applicant for Component B, a coordinating center. The remaining awards will be for Component A.

Applicants may apply for either Component A or Component B. Applications from one institution applying for both components will not be accepted.

Anticipated Number of Awards:
5
The estimated total funding (direct and indirect costs) for the first budget period is **$3,000,000.**

Component A:

Number of Awards: four (4)

Estimated Funding: $2,750,000

Component B: Coordinating Center

Number of Awards: One (1)

Estimated Funding: $250,000

Applicants may apply for either Component A or Component B. Applications from one institution applying for both components will not be accepted.

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

Award Ceiling:
$950,000
Per Budget Period

Award Floor:
$0
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)

20 (Private institutions of higher education)

22 (For profit organizations other than small businesses)

23 (Small businesses)

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:

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."

2. Foreign Organizations

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

This is a new, competitive NOFO. Prior agreements, funding, collaborations, and other arrangements with CDC are not evidence of eligibility for this NOFO.

The purpose of this NOFO is to support comparative effectiveness trials to investigate the feasibility, effectiveness, and cost-effectiveness of telehealth-based interventions to detect and manage glaucoma among high-risk populations. This NOFO aims to support the study of replicable and scalable interventions that use real-world, payer-provider reimbursement structures within community-based, health care delivery settings in various regions of the United States. Outcomes should be relevant to clinical practice, public health, community implementation, and policy. This NOFO also supports the cost-effectiveness analyses of proposed interventions. The resulting data will assist policymakers, clinicians, and patients make informed decisions to reduce the burden of glaucoma and improve the quality of life for millions of people.

This NOFO will be accomplished through two components, Component A: Comparative effectiveness trials among high-risk populations within community-based settings, and Component B: a coordinating center to provide scientific and logistical support to Component A studies.

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

If your application is incomplete or non-responsive to these requirements, it will not enter into the review process.

Component A

1. Geographical location

Applications must define a geographical study location(s) that includes the target population.

Evidence must be submitted in tables and include timely and specific data that align the proposed geographical area with the target population characteristics. Sources of evidence may include data from the U S. Census Bureau; National Vision and Eye Health Surveillance System; Places: Local Data for Better Health; and state/local government data.

2. Access to target population

Applications must provide evidence of access to the target population in a real-world community setting.

Evidence must include an official document, such as a signed letter of commitment, memorandum of agreement, or memorandum of understanding that states that the proposed community-based entity will provide access and facilitate recruitment of participants.

Applications for Component A must place evidence in Appendix 1.

Component B

N/A

6. Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid 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

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

9. Cost Sharing

This 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.

Only one application per institution (normally identified by its UEI number) is allowed.

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

Applicants must use FORMS-G application packages for due dates on or before January 24, 2023 and must use FORMS-H application packages for due dates on or after January 25, 2023.

Application guides for FORMS-G and 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 SF424 (R&R) FORMS-H for applications due on or after January 25, 2023.

3. Letter of Intent

Due Date for Letter Of Intent 01/15/2024

01/15/2024
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 to plan the review. By the date listed above, prospective applicants are asked to provide a letter of intent by email that includes:

Name of the Applicant Institution

Descriptive title of proposed research

Contact information of the PI/PD, including co-PIs/PDs

Names of key personnel

Participating institutions and any co-PIs/PDs

Please provide the number, title of this funding opportunity, and the component in the subject line of the email. Send the email to:

Alison Amoroso, Scientific Program Official, at 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, or limitations to, providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security,

intellectual property, or other rights - this section should address access to identifiable and de-identified data);
- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified (this section should address archiving and preservation of identifiable and 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

Applicants must use FORMS-G application packages for due dates on or before January 24, 2023 and must use FORMS-H application packages for due dates on or after January 25, 2023.

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

Please use the form and instructions for SF424 (R&R) FORMS-H.

Component A. The applicant's research plan should describe:

- An innovative telemedicine intervention to detect and manage glaucoma in the target population. Applicants are encouraged to consider aforementioned CDC-funded research (Section 1.1 Background).
- Geographic location(s) with high proportions of people disproportionately affected by glaucoma, and who are also vulnerable and less likely to access eye care services.
- A real-world setting(s) that uses a payer-provider reimbursement structure(s) to conduct the research, for example Federally Qualified Health Centers.
- Approach to identifying and collaborating with partners to fully leverage existing community infrastructure and optimize the real-world applicability.
- Approach to test the real-world effectiveness of the intervention compared to usual care (usual care that is well-described and justified). The proposed study must have an intervention and a control arm.
- Data collection management, quality assurance, sample size, and power calculations.
- Enrollment and retention plans throughout the duration of the study.
- Approach to tracking patient-centered outcome measures such as vision-related quality of life, adherence to treatment and follow-up, and patient satisfaction.
- Approach to identifying and describing barriers throughout the study that contribute to delayed diagnosis and reduced disease management, considering the socio-ecological model including individual, interpersonal, and societal factors.
- Approach to transition the intervention to a health service in the community.

- Approach to modify the intervention to detect other eye diseases or functional vision loss to generate evidence for how glaucoma detection programs can be used in a real-world setting.
- An economic assessment plan or model to estimate the effectiveness of the proposed intervention in terms of number of cases detected and follow-up care of the identified cases with glaucoma, other major eye diseases, and vision impairment; and the cost-effectiveness of expanding glaucoma detection compared with no expansion or status quo.
- How the intervention could be replicable and scalable to other locations in the United States.

Component B. The applicant's research plan should describe its approach to:

- Promoting and facilitating a multi-study, collaborative environment among Component A recipients who will independently implement the community-based interventions.
- Providing expertise and support to Component A recipients regarding data collection methods, data analysis, data management, statistical analysis, and refining study design.
- Organizing, facilitating, and developing the governance for a steering committee (and work groups) with representation from Component A recipients, study sites, and CDC as needed; ensuring it has primary responsibility for developing common study protocols, indicators, manuals, and reporting standards. Recommend and support a chairperson with proven evidence of leadership ability and an adequate time commitment.
- Maintaining study-wide timeline management. Organizing periodic study meetings including planning agendas, securing meeting facilities for face-to-face meetings, and preparing minutes.
- Leading the development of common measures to enable the comparison of outcomes across Component A studies, including the cost-effectiveness assessment.
- Facilitating the exchange of abstracts, manuscripts, presentations, fact sheets, and other scientific materials and drafts among the recipients and CDC.
- Supporting high-impact translation activities and the efficient dissemination/publication of findings to advance the evidence-base throughout the period of performance.
- Developing and maintaining a study website with internal and external access. The website should include communication of methodological themes; information for researchers who may want to replicate the studies or include studies in literature reviews; features such as up-to-date study protocols, presentations, work group rosters, and contact information. Internal pages should also include timelines, meeting dates and reports, and CDC information.

Timeline

Provide a detailed timeline, including realistic and measurable milestones for proposed project activities and distinct benchmarks of how each of the proposed activities will be sequenced and scaled over the period of performance.

Management and Staffing

Component A applicants:

Briefly describe the expertise of project team lead/manager, including leadership or management of a multi-site, multi-partner program as relevant to the study approach. The research team/partners should possess knowledge of culturally competent public health practice for the population under study, and include experts such as epidemiologists, statisticians, demographers, health services researchers, and vision health technicians. Briefly describe the following:

- expertise in designing, implementing, evaluating public health strategies; identifying geographic disparities; geospatial mapping, and engaging with partners and local communities.
- expertise measuring social determinants of health and improved health equity.
- percentage of time each person will devote to project activities and how the team members complement each other.

Component B applicants:

Briefly describe the team's experience supporting multi-site projects with vulnerable populations, including:

- coordinating a diverse array of professionals.
- statistical, data, evaluation, translation activities.
- website publishing expertise.

Consortium/Contractual Arrangements

It is expected that the applicant organization will directly conduct the majority of the activities outlined in this NOFO throughout the entire period of performance. It is expected that the work plan described in the Research Strategy section of the application and the SF-424 Research and Related Budget will demonstrate the applicant organization's involvement throughout the entirety of the period of performance. The applicant organization cannot serve as a pass-through to fund another entity to conduct the majority of the activities.

Letters of Support

Include letters of support from proposed participating partners outlining their commitment to participating and their expected contributions. Letters should demonstrate prior experience serving the study population or support from organizations serving the study population.

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.

As applicable, applicants can provide links to publications and other information in lieu of attaching PDF documents.

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 100 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.

Applicants must use FORMS-G application packages for due date on or before January 24, 2023 and must use FORMS-H application packages for due dates on or after January 25, 2023.

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

Please use the form and instructions for SF424 (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 02/05/2024

02/05/2024
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.

Applicants must directly perform the majority of the activities throughout the entirety of the project period. This must be evidenced in the SF-424 Research and Related Budget and narrative (as well as the MPI plan if applicable).

Travel expense to an annual meeting is limited to two people (including subawards and consultants).

11. Other Submission Requirements and Information

Risk Assessment Questionnaire Requirement

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

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

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

Duplication of Efforts

Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e., grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than

one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award.

Report Submission: The applicant must upload the report under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

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 clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

- To what extent will this proposed research aid in developing scalable, sustainable interventions to improve access to and increase utilization of vision care among high-risk populations to reduce the burden of glaucoma?
- How will this research influence public health policy to address population health and disparities in glaucoma detection and management?
- How will this research lead others to further investigate the problem of glaucoma detection and management, and change clinical or public health practice?

- How will the research affect current/prospective community-based providers in communities with high-risk populations?

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?

Component A:

- To what extent does the research team demonstrate a record of providing high-quality output that has contributed to addressing eye health disparities?
- Does the research team demonstrate expertise conducting research with high-risk populations?
- Does the research team demonstrate sufficient expertise in detection and management of glaucoma and other eye diseases?
- Does the research team demonstrate understanding of eye care access, utilization, and the role of social determinants of health within the broad health care system?

Component B:

- Does the applicant provide evidence to demonstrate statistical expertise in data collection methodology, data analysis, and refining study design?
- Does the applicant's team include professionals that demonstrate accomplishments managing cross-institutional collaboration?
- Does the applicant have demonstrated logistical and project management expertise?
- To what extent does the applicant demonstrate expertise in developing, maintaining, and measuring the effectiveness of a website with internal and external access, publishing timely information, and publishing information for external users?

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?

Component A:

- To what extent does the proposed research offer innovative strategies to improve access and utilization of eye care to detect glaucoma and other eye diseases by overcoming barriers and creating facilitators for improved care?
- To what extent does the proposed research include innovative options for cost savings and increased efficiency for glaucoma detection and care?

- To what extent does the proposed research aim to harness existing healthcare payer-provider reimbursement structures to study glaucoma detection and management?
- Does the proposed project include innovative strategies to plan for expansion and scaling to other communities?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed?

If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Component A:

1. Does the intervention approach have sufficient rigor and fidelity to be replicated and scaled-up in communities across the nation?
2. To what extent does the novel intervention design have a sample size that tests the real-world effectiveness with a test and control arm, and conducted in a real-world setting(s)?
3. Does the applicant adequately describe plans for data collection management, quality assurance, and analysis including information on sample size calculations for the intervention and control arms?
4. To what extent does the study leverage existing infrastructure and payer/provider reimbursement models to optimize the real-world applicability of study findings?
5. To what extent does the applicant identify meaningful outcome measures such as patient-centered outcomes, vision-related quality of life, and patient satisfaction among those identified with glaucoma or other major eye diseases?
6. Does the study include outcome measures that can identify and assess reductions in health disparities?
7. Does the approach to assess the cost-effectiveness of the intervention incorporate assessing other major eye disease and vision impairment?
8. Is the applicant's outline of a translation and dissemination plan likely to reach and encourage varied stakeholders, including patient advocacy groups, policy makers, the target population, public health organizations, and the scientific community to utilize the findings?

Component B:

1. To what extent does the applicant present a collaboration strategy that will enable comparison of outcomes across Component A studies?
2. How will the applicant achieve a high-functioning system of collaboration?
3. To what extent does the approach support optimal translation and dissemination findings from Component A studies to diverse stakeholders, including patient advocacy groups, policymakers, providers, public health organizations, and the scientific community?

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?

Component A:

- To what extent does the proposed research identify and engage partners and collaborators in real-world settings that are critical to the success of the project?
- To what extent does the applicant demonstrate appropriate and consistent access to the study population?
- Does the applicant have adequate scientific resources to achieve the intended results of the proposed research?

Component B:

- Does the applicant have adequate scientific resources to assist component A recipients achieve the intended results?
- To what extent does the applicant have adequate marketing resources to maintain the website, as well as support translation and dissemination activities to promote the impact of the proposed studies?

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

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 undergo a selection process in which all responsive applications will be discussed and assigned an overall impact/priority score.
- Will receive a written critique.

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

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

Programmatic Priorities and Other Cost Limitations (e.g., excluding Facilities & Administrative costs for R13s). See also Section IV.5. Funding Restrictions.

- Inclusion of proposed study participants that reflect a range of characteristics of the target population.
- Larger study group.
- Distribution of the locations of proposed study sites that reflect the regions of the United States.

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

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

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

(1) Financial stability;
(2) Quality of management systems and ability to meet the management standards prescribed in this part;
(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
(4) Reports and findings from audits performed under 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.

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

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

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

with limited English proficiency. Recipients of federal financial assistance must take 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. 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.

The recipient's PD/PI will have the primary responsibility for:

- Complying with the responsibilities for the extramural investigators as described in the *Policy on Public Health Research and Non-research Data Management and Access* ***https://www.cdc.gov/grants/additional-requirements/ar-25.html***
- Administration and management of scientific, programmatic, and fiscal aspects of the cooperative agreement and the day-to-day management of the research outlined in the NOFO.
- Maintaining an adequate staffing plan to support project activities.
- Ensuring data security and quality/accuracy.
- Serving on, or ensuring personnel serve on, the steering committee and any work groups; providing progress reports to the steering committee; and active collaboration with NOFO recipients.

- Communicating with the CDC program representatives, and providing accurate and timely reports.
- Participating in routine monitoring activities such as technical assistance calls and site visits. Attending periodic in-person or periodic meetings, as appropriate, to collaborate and provide progress updates.
- Submitting requests to CDC for changes in scope.
- Ensuring the protection of human subjects through ethical review of all protocols involving human subjects at the local institution; obtaining the appropriate Institutional Review Board approvals for all institutions or individuals engaged in the conduct of the research project; maintaining current approvals or waivers; and providing documentation to CDC of appropriate human subjects protections. Protocols must be designed to adequately describe implementation and evaluation of the proposed research at all sites and meet CDC Office of Human Research Protections standards.
- Executing agreed-upon protocols. Oversight of data collection, analysis, and reporting.
- Using appropriate statistical techniques to analyze data.
- Implementing a rigorous evaluation of the intervention.
- If OMB-PRA applies to the applicant's research plan, the PI will ensure the information collection request is developed for OMB and coordinate with CDC to obtain and maintain appropriate approvals through the life cycle of the award.

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

- Assisting the PI, as needed, in complying with the investigator responsibilities described in the Policy on Public Health Research and Non-research Data Management and Access ***https://www.cdc.gov/grants/additional-requirements/ar-25.html***
- Ensure that research conducted aligns with CDC public health priorities and the goals and objectives of this NOFO.
- Provide scientific consultation, support, expertise, and technical assistance in the development, implementation, and analysis of the study to assist the recipient achieve research objectives.
- Advise in the development of the research protocol for Institutional Review Board review, and other reviews and approvals as necessary.
- Make recommendations regarding recipient proposals for changes in scope that deviate from the approved peer-reviewed application.
- Provide expertise related to data collection methods, data analysis, and tools to aid in standardization across the multiple recipients and sites.
- Provide technical assistance for manuscript development as requested by the recipient, and may be a co-author if invited by the recipient and meets CDC authorship criteria.
- Facilitate dissemination of research findings within CDC.
- Support the recipient's activities by collaborating and providing ongoing scientific and public health consultation, including conducting site visits to recipient institutions and sites.
- Provide input into the cost-effectiveness assessment, outcome variables/measurements, and the detailed translation plan and evaluation plan.

Areas of joint responsibility include:

- Serve on the steering committee and work groups as needed. The CDC scientist is a non-voting member on the steering committee.
- Collaborate on presentations for conferences as.

Additionally, an agency program official or CIO program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice. The scientific program official will:

- Provide oversight and ensure overall scientific and programmatic stewardship of the award.
- Monitor performance against approved project objectives.
- Assess the public health impact of the research conducted under this NOFO.

An HHS/CDC Project Officer will be named in the Notice of Grant award as the project officer. The project officer will:

- Monitor performance against approved budgets, budget justifications, annual action plan objectives, and activities.
- Provide oversight of the scientific, programmatic, administrative, and fiscal management of the award.
- Facilitate the exchange of information with other CDC programs to address recipients' technical assistance needs.
- Promote translation and dissemination of promising practices, products, interventions, and other research findings to improve public health programs, practices, and policy.

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).
Certification that any personnel or contributors involved in the design or conduct of research involving human subjects throughout the duration of the study have completed an educational program in the protection of human subjects. Certification must be current.

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 **90 days after the end of the period of performance.**

B. Content of Reports

1. Yearly Non-Competing Grant Progress Report: The grantee's continuation application/progress should include:
    - Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the RPPR form in eRA Commons (https://grants.nih.gov/grants/rppr/index.htm). Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.
    - Research Aims: list each research aim/project

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

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

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

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

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

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

estimated FFR.

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

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

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

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

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

- Additional Reporting Requirements:

2. Annual Federal Financial Reporting The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through the Payment Management System (PMS) within 90 days after the end of the budget period. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The final FFR 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 90 days 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

Alison Amoroso, Scientific Program Official

NCCDPHP, Office of Medicine and Science

Telephone: 770-488-1750; Email: uxl8@cdc.gov

Peer Review Contact

Catherine Barrett, Scientific Review Official

NCCDPHP, Office of Medicine and Science

Telephone: 440-718-7664; Email: ohi6@cdc.gov

Financial/Grants Management Contact

Angie N. Willard, Grants Management Officer, Team Lead

Office of the Chief of Staff, 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.