

Centers for Disease Control

National Center for Chronic Disease Prevention and Health Promotion Extramural Research Program Office

Research to Enhance the US Vision and Eye Health Surveillance System
RFA-DP-19-005
Application Due Date: 02/14/2019

Research to Enhance the US Vision and Eye Health Surveillance System
RFA-DP-19-005
TABLE OF CONTENTS

Part 1. Overview Information
- Key Dates
- Required Application Instructions
- Executive Summary

Part 2. Full Text
- Section I. Funding Opportunity Description
- Section II. Award Information
- Section III. Eligibility Information
- Section IV. Application and Submission Information
- Section V. Application Review Information
- Section VI. Award Administration Information
- Section VII. Agency Contacts
- Section VIII. Other Information

Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control

Components of Participating Organizations

National Center for Chronic Disease Prevention and Health Promotion Extramural Research Program Office (NCCDPHP ERPO)

Notice of Funding Opportunity (NOFO) Title

Research to Enhance the US Vision and Eye Health Surveillance System

Activity Code

U01

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-DP-19-005

Assistance Listings (CFDA) Number(s)

93.068

Category of Funding Activity:

Health

NOFO Purpose

The purpose of this Notice of Funding Opportunity (NOFO) is to expand the Vision and Eye Health Surveillance System (VEHSS) by identifying and incorporating new data sources and validating data and key indicators in VEHSS, maintaining the existing system, and promoting the VEHSS to stakeholders.

Key Dates

Publication Date:	**To receive notification of any changes to RFA-DP-19-005, 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:	**01/14/2019**
Application Due Date:	**02/14/2019**

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 5:00 PM U.S. Eastern Time. Applications must be submitted using the Application Submission System & Interface for Submission Tracking (ASSIST) module which is a web-based service used for the preparation and submission of grant applications to CDC through Grants.gov. ASSIST provides

the ability for applicants to prepare their applications online, and offers the applicant additional capabilities including the ability to preview the application image, validate the application against required business rules, and prepopulate data from an applicant organization's records, therefore identifying issues earlier in the application submission process.

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

Scientific Merit Review:	**04/03/2019**
Secondary Review:	**05/15/2019**
Estimated Start Date:	**09/30/2019**
Expiration Date:	**02/15/2019**
Due Dates for E.O. 12372:	**Executive Order 12372 does not apply to this program.**

Required Application Instructions

ELECTRONIC APPLICATION SUBMISSION VIA ASSIST IS PREFERRED

It is recommended that applicants use ASSIST for the electronic preparation and submission of applications through Grants.gov to CDC. ASSIST is an alternative method to prepare and submit applications, and provides many features to facilitate the application submission process which improves data quality (e.g., pre-population of organization data, pre-submission validation of business rules, and preview of the application image used for review). Use of the Grants.gov downloadable Adobe application packages and submission process will still be supported.

It is critical that applicants follow the instructions in the SF 424 (R&R) 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 25 pages.

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

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

Executive Summary

- **Purpose.** This NOFO solicits applications to expand the Vision and Eye Health

Surveillance System (VEHSS) by identifying and incorporating new data sources and validating data and key indicators in VEHSS, maintaining the existing system, and promoting the VEHSS to stakeholders.

- **Mechanism of Support.** Cooperative Agreement
- **Funds Available and Anticipated Number of Awards.** The estimated total funding (direct and indirect) for the 3-year period of performance is $2,550,000. One award will be issued under this NOFO. The award is contingent upon availability of funds and a sufficient number of meritorious applications.
- **Budget and Period of Performance.** The estimated total funding (direct and indirect) for the first budget period, 09/30/2019 ? 09/29/2020, is $850,000. The estimated total funding (direct and indirect) for the period of performance, 09/30/2019 ? 09/29/2022, is $2,550,000.
- **Application Research Strategy Length.** Page limits for the Research Strategy are clearly specified in Section IV. Application and Submission Information of this announcement.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III, 1.A. are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.
- **Number of PDs/PIs.** Applications may include more than one PI; however, the first PI listed on the application will be the ?contact PI? for all correspondence. Any additional PIs are permitted, but would be referred to as Co-PIs.
- **Number of Applications.** Eligible applicant institutions may submit only one application.
- **Application Type.** New
- **Special Date(s).** None
- **Application Materials.** See Section IV.1 for application materials. Please note that Form E is to be used when downloading the application package 424 (R&R) Application Guide Version E.

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

A link to this NOFO will be available Notice of Funding Opportunities | Our Programs | National Center for Chronic Disease Prevention and Health Promotion | CDC

Part 2. Full Text

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

This NOFO is aimed at improving the vision health of the nation by improving and strengthening the recently created Vision and Eye Health Surveillance System (VEHSS). Surveillance is a core public health function, yielding data used to monitor the burden of disease, identify high-risk groups, inform decision makers, and evaluate the effectiveness of interventions. The United States government in Healthy People 2010 and 2020, in conjunction with the vision and eye care communities, have identified the reduction of population disparities in vision loss and access to eye care services as top public health priorities (1).

The 2016 National Academies for Sciences, Engineering, and Medicine (NASEM) report ?Making Eye Health a Population Health Imperative: Vision for Tomorrow? recommended the development of a coordinated surveillance system for vision and eye health in the United States that includes: standardizing definitions of clinical vision loss and quality of care measures; integrating eye health outcomes; and analyzing and disseminating information in a timely manner (2).

In 2017, CDC?s Vision Health Initiative (VHI) Program convened a national panel of experts to review the NASEM recommendations and provide guidance to build VHI future strategies. One of the suggested strategies was to strengthen the national vision and eye health surveillance system (published report on the VHI website).

Vision loss is recognized as a public health problem because it affects more than 4 million people aged 40 years and older in the United States (3). It is associated with higher prevalence of multiple chronic conditions such as diabetes, cardiovascular health, falls, injuries, depression, smoking, premature mortality and overall poorer quality of life (4-9). It costs the nation more than $130 billion annually (10), and it is amenable to prevention by early detection and timely treatment (11). Vision loss is more likely to affect women, racial/ethnic minorities, and people who are older and poorer (12, 13). The most common eye diseases that may cause irreversible vision loss include age-related macular degeneration, diabetic retinopathy, and glaucoma. Other treatable forms of vision loss, such as cataract and refractive errors, affect millions of Americans. Forecasting studies indicate the number of people with eye diseases will surge in the coming decades. The population of people with glaucoma is expected to increase from 2.2-2.7 million to 7.3 million by 2050 (14). Cataract cases are expected to increase from 20.5 million in 2010 to 30.1 million in 2020. (15) Early macular degeneration cases are expected to increase from 9.1 million in 2010 to 17.8 million in 2050 (16) and diabetic retinopathy cases will triple from 5.5 million in 2005 to 16 million in 2050 (17).

The prevalence and risk factors for some eye diseases are well documented. For example, compared to non-Hispanic Whites, the prevalence of glaucoma is substantially higher among Blacks, Hispanics/Latinos, and Asians (18, 19). Fifty percent of people with glaucoma do not know they have the disease (20). However, once detected, appropriate management can slow glaucoma progression and remaining vision can often be preserved. Lost vision, however, cannot be restored. Early macular degeneration more often occurs in Whites and males, is infrequent before age 55, and is associated with smoking (21). Diabetic retinopathy affects approximately two-fifths of those individuals who identify themselves as having diabetes mellitus - about 4.1 million in 2000. Diabetic retinopathy is more prevalent among blacks and

Hispanics compared to whites (22).

Despite the knowledge about the individual and societal burden of vision loss and eye diseases, the public health surveillance system in the United States has only just begun to systematically understand and monitor the magnitude and implications of vision loss, access to eye care, and effectiveness of services that potentially improve health and quality of life of those who are at risk of or experience vision loss (23).

Vision and eye health surveillance in the US is particularly problematic because of the concepts employed to measure vision vary and ?gold standard? survey questions are lacking. No single survey can capture all the elements needed to assess the burden of vision loss, vision function and disability, and access to eye care. Therefore, assembling a variety of existing national surveys that meet the key requirements of vision and eye health surveillance - representative sample, standard data elements, and timely access to data - may provide a basis from which to begin to assess the burden of vision health and guide interventions and policy decisions designed to address that burden.

In 2010, CDC?s VHI convened a panel of national and international experts to define surveillance approaches and metrics to capture the burden of vision health disparities and to identify properties of a surveillance system to guide public health interventions (24).

The panel outlined 6 strategies to improve vision surveillance and help reach the vision related objectives of Healthy People 2020. The strategies outlined to achieve the goal were to:

1. Link data collection and analysis with ongoing public health interventions to improve eye health disparities;
2. Effectively assess vision loss (performance-based and self-reported measures);
3. Effectively assess utilization of eye care;
4. Include defined populations to assess the disparities in vision loss and in utilization of eye care services;
5. Include and sustain ophthalmic/vision measurements and question components within national surveys; and
6. Strengthen partnerships among federal agencies and other stakeholders to establish a national vision surveillance system to monitor the nation?s eye health and eye care utilization for trends in disparity. Federal agencies and other stakeholders work together to monitor the nation?s eye health and eye care utilization.

As a result of the panel?s recommendations, CDC created an integrated vision and eye health surveillance system to improve population estimates and understanding of population trends, health disparities, as well as barriers and facilitators to access to vision care. The result of that effort was the Vision and Eye Health Surveillance System (VEHSS). The aim of this announcement is to validate, enhance, extend, and maintain the recently established VEHSS. In particular, an extensive review and reprioritization of the current vision and eye health indicators are needed to ensure that they meet rigorous scientific criteria for validity and utility.

The existing VEHSS provides access to various surveys, as well as administrative and electronic data systems. Beyond maintaining and keeping the existing system current, efforts are needed to establish the scientific validity of the indicators currently being used, identify data gaps, document and prioritize potential data sources to support key data elements for

surveillance and research. Efforts are also needed to evaluate outreach, educate end users, and the VEHSS?s impact on understanding vision health population estimates, trends, and health disparities, as well as barriers and facilitators to access to vision and health care. Such efforts are vital if consumers, providers, public health, and other stake holders are to be able to use VEHSS to meet the needs of those at risk for vision impairment and the country?s visually impaired populations.

Healthy People 2020 and other National Strategic Priorities

The CDC and the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) are committed to achieving the health promotion and disease prevention objectives of "Healthy People 2020," and to measuring program performance as stipulated by the Government Performance and Review Act (GPRA). This NOFO addresses ?Healthy People 2020? focus area to ?Improve the visual health of the Nation through prevention, early detection, treatment, and rehabilitation (1). Surveillance for vision health is an important component to track and meet Healthy People Objectives. Examples of healthy vision objectives that could be monitored with the VEHSS;

V-4 Increase the proportion of adults who have a comprehensive eye exam, including dilation, within the past 2 years.
V-5 Reduce visual impairment.
V-5.1 Reduce visual impairment due to uncorrected refractive error.
V-5.2 Reduce visual impairment due to diabetic retinopathy.
V.5-3 Reduce visual impairment due to glaucoma.
V.5-4 Reduce visual impairment due to cataract.
V.5-5 Reduce visual impairment due to age-related macular degeneration**.**

The announcement is in alignment with the NCCDPHP performance goal(s) to improve the lives of racial and ethnic populations who suffer disproportionately from the burdens of disease and disability, and develop tools and strategies that will enable the nation to eliminate these health disparities.

Public Health Impact

The Vision and Eye Health Surveillance System will have a direct impact on vision public health by providing timely, accurate, and scientifically valid estimates of the burden of vision impairment at the national, state, and local levels. This will enable national and local public health partners to promote eye health and reduce the burden of vision impairment throughout the nation. The surveillance system will: 1) measure the burden of the vision impairment and its complications; 2) help stakeholders and researchers understand the etiology, risk factors, and natural history of vision impairment and its complications; 3) allow them to assess the impact of the vision impairment on quality of life; 4) help guide research focused on the prevention and treatment of vision impairment and its complications; and 5) effectively evaluate public health interventions.

Validation of the National Vision and Eye Health Surveillance System (VEHSS) is vital to assess progress toward meeting the healthy vision objectives in Healthy People 2020. Having such a system will further national efforts to prevent vision loss and promote eye health and will serve as an infrastructure resource to improve access and utilization of eye care services. At the

end of this three-year project, the National Vision and Eye Health Surveillance System (VEHSS) will be comprehensive, up-to-date and have established scientific validity. Having met those criteria, it can then serve to provide comprehensive, integrated, and accessible information to inform academic institutions, state and national governmental agencies, and private organizations in their efforts to reduce vision loss and related disability.

Relevant Work

CDC?s Vision Health Initiative (VHI) and NORC at the University of Chicago partnered to develop the National Vision and Eye Health Surveillance System (VEHSS). The current VEHSS leverages new and existing data sources to help health professionals, researchers, policy makers, and patients understand the scope of vision loss, eye disorders, and eye care services in the United States. VEHSS is intended to grow and improve over time based on input and needs of the vision health community (25).

2. Approach

The purpose of this NOFO is to expand the VEHSS by identifying and incorporating new data sources and validating data and key indicators, maintain the existing VEHSS system and promote the VEHSS to stakeholders to monitor the burden of vision loss and eye diseases and ultimately to improve the vision and eye health of the nation.

The system will be extended using additional years and data sources, including surveys and administrative and electronic data sources. It will incorporate new data sources with characteristics such as representativeness, timeliness, accuracy, and geographic details and be rigorously evaluated. This project will enhance and expand dissemination and outreach to researchers, epidemiologists, decision makers, providers, and other end users for implementation and evaluation of programs aimed to improve the vision and eye health of the nation.

Objectives/Outcomes

1. Obtain expert input and review of the VEHSS?s indicators scientific validity and public health utility, and prioritize potential data sources and key indicators
2. Review and validate existing and new indicators to ensure face, construct, concurrent, and predictive validity. Indicators should address modifiable and non-modifiable risk factors and evidence-based preventive care and treatment for eye disease, major eye diseases and refractive errors, as well as indicators of quality of life and well-being.
3. Identify, test, and validate new data sources for the VEHSS, particularly those which address data gaps in disparities and for minority populations. Data sources should be evaluated with characteristics such as representativeness, timeliness, accuracy, and geographic details to accurately estimate the proportion and population of people with vision loss, major eye diseases, and access and utilization of eye care.
4. Identify and rank potential data sources to support key indicators for surveillance and research.
5. Evaluate potential sources and methods to generate county-level estimates (or alternative geographic-level variation) to identify disparities in vision loss and eye health and determine how factors such as socioeconomic status, race, and ethnicity explain

geographic variability.

6. Consider analysis to calculate rates, prioritize indicators, evaluate emerging problems and monitor vision loss, major eye diseases, and access to care.
7. Plan for face-to-face meeting with CDC at the start of the project and annually thereafter to provide detailed measurable milestones for proposed project activities and distinguishable benchmarks.
8. Ensure continuation of ongoing data use agreements (if any) or establishing new DUA or mechanism to allow for public access to and use of data.
9. Collaborate with National Center for Chronic Disease Prevention and Health Promotion?s (NCCDPHP) Office of Informatics and Science Office to review data and indicators for dissemination through NCCDPHP?s open data platform. Following CDC technical and security standards, place key data and indicators into NCCDPHP?s open data platform and evaluate accessibility and usability of the data with end users such as government agencies, academic institutions, and other interested parties.
10. Develop a plan to educate end-users of vision and eye health data including but not limited to: 1) publishing in peer reviewed journals on the utility of the surveillance system; 2) presentations to end user audiences including state and local partners; and 3) a report with recommendations on the use and adoption of the National Vision and Eye Health Surveillance System; and 4) publications such as newsletters, webinars, and quick fact sheets.
11. Develop a final project report which describes the components of the VEHSS, data sources used to develop the system, development of the indicators, how the system?s data is managed (e.g., entry, editing, storage, backup, etc.) and the system?s compliance with applicable standards for data format, such as 508 compliance.

Target Population

The Vision and Eye Health Surveillance System (VEHSS) should capture racial/ethnic, gender, and socioeconomic (income/education) and geographic location differences (both U. S. Census region and urban-rural) in vision status and access to and utilization of eye health care services. Data should remain representative of the adult population so that users can draw inferences to the general population.

Collaboration/Partnerships

Applicants are expected to collaborate with a variety of academic institutions, private sector organizations, and governmental agencies representing both producers and users of vision health data. The partners are expected to contribute regularly to establishing the rigor, comprehensiveness, and utility of the system as well as assuring that the content is accessible and useful to users.

The applicant is expected to establish an expert panel in vision health to review existing and new indicators, to ensure face, construct, concurrent, and predictive validity, and to explore and evaluate data collection of vision and eye health using existing surveys.

Evaluation/Performance Measurement

Evaluation during the first year should be measured by the refinement and validation made to the data sets and indicators, commitments made to potential collaborators, and updated review

to the current system.

In subsequent funded year, evaluation should be measured by the inclusion of additional methods for county-level estimate, identification of new indicators, timeliness of analyses, and the education of end users about the usability of the system.

Translation Plan

Applicants are expected to develop a plan to target and educate end users about the usability of the system including but not limited to: 1) publishing in peer reviewed journals on the utility of the surveillance system, 2) presentations to end user audiences including state and local partners, and 3) a report with recommendations for use and adoption of the National Vision and Eye Health Surveillance System, 4) newsletters and quick fact sheets.

OMB/PRA approval may be required.

References

1. Healthy People 2020. https://www.healthypeople.gov/2020/topics-objectives/topic/vision.
2. National Academies for Sciences, Engineering, and Medicine 2016. ?Making Eye Health a Population Health Imperative: vision for tomorrow?. Washington, DC: the National Academies Press. Doi: 10.17226/23471).
3. Varma R, Vajaranant TS, Burkemper B, et al. Visual impairment and blindness in adults in the United States: Demographic and geographic variations from 2015 to 2050. *JAMA ophthalmology*. 2016;134(7):802-9.
4. Klein R, Klein BE, Moss SE. Visual impairment in diabetes. *Ophthalmology*. 1984 Jan;91(1):1-9.
5. Patino CM, McKean-Cowdin R, Azen SP, et al. Central and peripheral visual impairment and the risk of falls and falls with injury. *Ophthalmology*. 2010;117(2):199-206. e1.
6. Zhang X, Bullard KM, Cotch MF, et al. Association between depression and functional vision loss in persons 20 years of age or older in the United States, NHANES 2005-2008. JAMA ophthalmology. 2013 May;131(5):573-81.
7. Zhang X, Kahende J, Fan AZ, et al. Smoking and visual impairment among older adults with agerelated eye diseases. Prev Chronic Dis 2011;8(4):A84.
8. McCarty CA, Nanjan MB, Taylor HR. Vision impairment predicts 5 year mortality. Br J Ophthalmol 2001;85:322?326.
9. Crews JE, Chou CF, Zhang X, Zack MM, Saaddine JB. Health-Related Quality of Life Among People Aged ?65 Years with Self-reported Visual Impairment: Findings from the 2006-2010 Behavioral Risk Factor Surveillance System. Ophthalmic Epidemiol. 2014 Oct;21(5):287-96.
10. Prevent Blindness America. The Cost of Vision Problems. Accessed September 24, 2014 from http://costofvision.preventblindness.org.
11. Saaddine JB, Narayan KM, Vinicor F. Vision loss: a public health problem? Ophthalmology. 2003 Feb;110(2):253-4.
12. Zambelli-Weiner A, Crews JE, Friedman DS. Disparities in adult vision health in the United States. Am J Ophthalmol. 2012 Dec;154(6 Suppl):S23-30.

13. Zhang X, Cotch MF, Ryskulova A, Primo SA, Nair P, Chou CF, Geiss LS, Barker LE, Elliott AF, Crews JE, Saaddine JB. Vision health disparities in the United States by race/ethnicity, education, and economic status: findings from two nationally representative surveys. Am J Ophthalmol. 2012 Dec;154(6 Suppl):S53-62.
14. The Eye Diseases Prevalence Research Group. Causes and prevalence of visual impairment among adults in the United States. Arch Ophthalmol 2004;122(4):477? 485.
15. The Eye Diseases Prevalence Research Group. Prevalence of cataract and pseudophakia/aphakia among adults in the United States. Arch Ophthalmol. 2004;122(4):487-494.
16. Rein DB, Wittenborn JS, Zhang X, Honeycutt AA, Lesesne SB, Saaddine J Forecasting age-related macular degeneration through the year 2050: the potential impact of new treatments. Arch Ophthalmol. 2009 Apr;127(4):533-40.
17. Saaddine JB, Honeycutt AA, Narayan KM, Zhang X, Klein R, Boyle JP. Projection of diabetic retinopathy and other major eye diseases among people with diabetes mellitus: United States, 2005?2050. Archives of Ophthalmology, 2008;126(12):1740?1747.
18. 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.
19. Stein JD, Kim DS, Niziol LM, Talwar N, Nan B, Musch DC, Richards JE. Differences in Rates of Glaucoma among Asian Americans and Other Racial Groups, and among Various Asian Ethnic Groups, Ophthalmology 2011;118:1031?1037.
20. Saw S-M, Gazzard G, Friedman D, Foster PJ, Devereuz JG, Wong ML, Seah S. Awareness of glaucoma, and health beliefs of patients suffering primary acute angle closure. Br J Ophthalmol. 2003 Apr;87(4):446-9.
21. Klein R, Klein BE, Linton KL. Prevalence of age-related maculopathy. The Beaver Dam Eye Study. Ophthalmology. 1992 Jun;99(6):933-43.
22. The Eye Diseases Prevalence Research Group. The prevalence of diabetic retinopathy among adults in the United States. Arch Ophthalmol. 2004;122:552-563.
23. Zambelli-Weiner A, Friedman DS. Building a basis for action: enhancing public health surveillance of vision impairment and eye health in the United States. Am J Ophthalmol. 2012 Dec;154(6 Suppl):S8-22.
24. Lee PP, West SK, Block SS, Clayton J, Cotch MF, Flynn C, Geiss LS, Klein R, Olsen TW, Owsley C, Primo SA, Rubin GS, Ryskulova A, Sharma S, Friedman DS, Zhang X, Crews JE, Saaddine JB. Surveillance of disparities in vision and eye health in the United States: an expert panel's opinions. Am J Ophthalmol. 2012 Dec;154(6 Suppl):S3-7.
25. Vision Health Initiative web site . https://www.cdc.gov/visionhealth/vehss/index.html

Section II. Award Information

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

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

Estimated Total Funding:	$2,550,000
Anticipated Number of Awards:	1

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

Award Ceiling:	$850,000 Per Budget Period
Award Floor:	$0 Per Budget Period
Total Period of Performance Length:	3 year(s)

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

HHS/CDC grants policies as described in the HHS Grants Policy Statement (http://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.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:	State governments County governments City or township governments Special district governments Independent school districts Public and State controlled institutions of higher education Native American tribal governments (Federally recognized) Public housing authorities/Indian housing authorities Native American tribal organizations (other than Federally recognized tribal governments) Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher

education
Private institutions of higher education
For profit organizations other than small businesses
Small businesses
Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility"

Additional Eligibility Category:

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

Hispanic-serving Institutions
Historically Black Colleges and Universities (HBCUs)
Tribally Controlled Colleges and Universities (TCCUs)
Alaska Native and Native Hawaiian Serving Institutions

Nonprofits Other Than Institutions of Higher Education:

Nonprofits (Other than Institutions of Higher Education)

Governments:

Eligible Agencies of the Federal Government
U.S. Territory or Possession

Other:

Native American tribal organizations (other than Federally recognized tribal governments)
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 Organizations are not eligible to apply.

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

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

3. Special Eligibility Requirements

NA

4. Justification for Less than Maximum Competition

NA

5. Responsiveness

NA

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 Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https:// eportal.nspa.nato. int/ AC135Public/ Docs/ US%20Instructions%2 0for%20NSPA%20NCAGE.pdf
- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, https://www.sam.gov/portal/SAM/.
- 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 Program Directors/Principal Investigators (PD/PIs) must also work with their institutional officials to register with the eRA Commons or ensure their existing Principle 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 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 DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the US D&B D-U-N-S Number Request Web Form or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number. Additionally, all applicant organizations must register in the **System for Award Management (SAM)**. 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 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 the SAM internet site at https://www.sam.gov/index.html.
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 DUNS 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 FOA 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 having a unique DUNS number) is allowed.

Section IV. Application and Submission Information

1. Address to Request Application Package

In order to use ASSIST, applicants must visit https://public.era.nih.gov/assist 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:

- E-mail: http://grants.nih.gov/support/index.html
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552. The NIH eRA Service desk is available Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding federal holidays.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide.htm and here: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf, 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 (R&R) Application Guide to ensure you complete all appropriate “optional” components.
When using ASSIST, all mandatory forms will appear as separate tabs at the top of the Application Information screen; applicants may add optional forms available for the NOFO by selecting the Add Optional Form button in the left navigation panel.

3. Letter of Intent

Due Date for Letter of Intent: **01/14/2019**

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows CIO staff to estimate the potential review workload and plan the review.

Prospective applicants are asked to submit a letter of intent that includes the following information:

- Name of the Applicant
- Descriptive title of proposed research
- Name, address, and telephone number of the PD(s)/PI(s)
- Names of other key personnel
- Participating institutions
- Number and title of this funding opportunity

The letter of intent should be sent to:

Sue Shaw, MPH
Scientific Program Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE
Mailstop #F80
Atlanta, GA 30342
Telephone: (770) 488-6142
Email: zgx7@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 https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/generalforms-e.pdf and https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf 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 https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf 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:
• Descriptions of the data to be produced in the proposed project
• How access will be provided to the data (including provisions for protection of privacy, confidentiality, security, intellectual property, or other rights)
• 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
• Plans for archival and long-term preservation of the data, or explaining why long-term preservation and access cannot be justified
Examples of DMPs may be found here: University of California https://dmp.cdlib.org/, or USGS, http://www.usgs.gov/datamanagement/plan/dmplans.php

Research Plan

The applicant's research plan should address activities that will be conducted over the entire three-year period of performance and should include the following items.

Research Strategies

1. Describe plans for engaging experts to review and provide critique of the VEHSS's data sources, indicators scientific validity and public health utility, and prioritize indicators.
2. Describe plans and appropriate methodologies to analyze the existing VEHSS data sources, indicators, and estimates to assess their validity and representativeness.
3. Describe approaches for identifying and selecting valid new and novel reliable data sources not currently part of VEHSS that are both qualitative and quantitative to assess vision loss, major eye diseases, and access and utilization of eye care services. This may include paper-based medical records, electronic medical records, and administrative data.
4. Describe plans to evaluate potential sources and methods to generate county-level estimates to identify disparities in vision loss and eye health and explain geographic variability.
5. Describe an approach to identify gaps and shortfalls in existing data sources and data elements and determine additional effective and novel approaches to accurately and more easily evaluate and monitor vision loss, eye diseases, and access to eye care.
6. Describe planned approach to overcome barriers posed by the variability of vision measures in surveys. Describe the plan to harmonize existing survey questions to capture eye health outcomes.
7. Describe planned approach to identify novel measures capturing performance-based and self-reported vision loss.
8. Describe plans to work with CDC informatics through NCCDPHP's open data platform, place key data and indicators into the platform, and evaluate accessibility and usability of the data with end users.
9. Describe planned activities to educate researchers, government agencies, decision makers, providers, and other interested parties about how the VEHSS can be used for research and for implementation and evaluation of programs aimed to improve the vision and eye health of the nation.

Management and Staffing

1. Describe the experience and expertise of the project lead investigator including: a) leadership in project coordination; b) subject matter expertise and c) publication record in major peer reviewed journals; d) the percentage of time will devote to project activities.
2. Provide a detailed staffing plan for the three year period of performance to include: 1) staff experience in designing, implementing, and evaluating health surveillance systems, including identification, validation, and assembling of existing vision data sources; experience analyzing national, regional and local data; 2) the multi-disciplinary experience of the research team (including, but not limited to epidemiologists, statisticians, survey methodologists, demographers, health services researchers, informaticians, and analysts) and how the members of the research team will

complement each other's skills and work together; and 3) the percentage of time each person will devote to project activities.
3. Provide a detailed timeline, including realistic and measurable quarterly milestones for proposed project activities and distinguishable benchmarks with a description on how each of the proposed activities will be sequenced and scaled up over the 3-year period of performance.
4. Describe how and by whom will the quality oversight and supervision be provided for the research team.

Evaluation

1. Describe approaches for conducting and evaluating a sustainable National Vision and Eye Health Surveillance System.

Collaboration

1. Describe plans for collaboration with experts, partners, CDC, and other organization throughout the period of performance include timeline with key activities and anticipated time commitment.
2. Describe how the experts will be engaged to review and validate the system including time commitment throughout the three period of performance.

Meetings and Budget

1. Include in the budget planned travel each year for two key staff (including the PI) to attend an annual meeting in Atlanta, GA to discuss study progress and any issues related to accomplishing project objectives.
2. A detailed budget justification for the first year with the stated objectives and estimates for each of the other budget periods.

Timeline and Milestones

1. Provide a detailed timeline, including realistic and measurable milestones for proposed project activities and distinguishable benchmarks. Include a budget plan that is linked to activities and milestones.
2. Identify key milestones including expert panel meetings and reports, data updates, data management, data analysis, report writing.
3. Describe how key project activities will be sequenced and scaled over the 3 year period of performance.

Letters of Commitment

1. Include signed letters of commitment from participating partners outlining their participation, contributions, and evidence of their commitment and cooperation in Appendix A.

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

7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 25 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 35 pages for all appendices.

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 https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf.

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.
Organizations must submit applications using the ASSIST web-based application preparation and submission process.
ASSIST will validate applications before submission. If the system detects errors, then the applicant must correct errors before their application can be submitted.
Applicants are responsible for viewing their application 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 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)
If the applicant encounters problems that prevent the ability to submit an application which cannot be resolved by Grants.gov or NIH eRA Service Desks, then applicants must contact CDC Technical Information Management Section (TIMS) at 770-488-2700; ogstims@cdc.gov for guidance at least 3 calendar days before the deadline date. Therefore, 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**", 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 and ogstims@cdc.gov 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: **02/14/2019**

Electronically submitted applications must be submitted no later than 5:00 p.m., ET, on the listed application due date.

10. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review (http:// www. whitehouse.gov/ omb/ grants_spoc).

11. Funding Restrictions

All HHS/CDC awards are subject to the federal regulations, 45 CFR 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.

In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability (https://www.cdc.gov/grants/additionalrequirements/ar-35.html).

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.

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. 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/additionalrequirements/ar-25.html for revised AR-25.

Funds will be restricted until:

1. IRB and OMB/PRA (if needed) approvals are obtained.
2. Human subjects education requirement documentation is provided for any new key personnel or other significant contributors involved in the design or conduct or research involving human subjects.

Applicants are advised that any activities involving standard information collection (i.e., surveys, questionnaires, data requests, etc.) from 10 or more non-federal individual/entities are subject to Paperwork Reduction Act (PRA) requirements and may require the CDC to

coordinate an OMB/PRA approval request).

Reimbursement of pre-award costs is not allowed. All HHS/CDC awards are subject to the terms and conditions, cost principles, 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.

For more information on expanded authority and pre-award costs, go to: http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf or speak with the Grants Management Specialist (GMS).

12. 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 DUNS.

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 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.
The applicant organization must ensure that the DUNS 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 (http:// 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?

- Does the work address national surveillance for vision and eye health that are major public health problems in the US?
- What is the potential or actual impact of refining and enhancing the vision and eye health surveillance system?
- Will enhancing the national surveillance for vision and eye health be influential in that it will lead others to investigate these problems, open new areas of research, or change the scientific approach or public health practice, and how will this improve and be of value to public health?
- Will this project change the scientific approach toward surveillance of vision and eye

health?
- If successful, does the surveillance system have the potential to be sustainable and reach all stakeholders and a large portion of the communities affected by vision and eye problems?

Investigator(s)

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

- Does the research team have appropriate experience in designing, implementing, and evaluating vision and eye health surveillance systems, including identification, validation, and assembling of existing eye health data sources
- Does the project team include members with expertise in vision and eye health indicators and their utility for surveillance and research purposes, biostatistics, and epidemiology?
- Are the staff roles clearly defined?
- As described, will the staff be sufficient to accomplish the project objectives?
- Does the team have a successful track records in surveillance, epidemiology, big data relevant to vision, eye health, and access to eye care?
- Does the project team bring complementary and integrated expertise to the project?
- Does the project team have extensive, demonstrable experience in managing, integrating, and analyzing large data sets containing vision and eye health information?
- Does the research team have publications in the proposed areas of work during the most recent years?

Innovation

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

- Does the application challenge and seek to shift current vision and eye health surveillance paradigms by utilizing novel concepts, large data systems, approaches or methodologies, instrumentation, or interventions?
- Does the proposal include exploration of novel and effective approaches to accurately and more easily assess and monitor vision loss by testing standardized measures of visual acuity that are inexpensive and readily available to assess vision loss within surveys and across a variety of settings
- Does the project have the potential to increase efficiency and reduce cost in obtaining

and providing timely and useful data to public health users?
- Does the application challenge and seek to include new paradigms or approaches to improve vision and eye health surveillance?

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?

- Does the applicant propose a method to engage committed experts in the review of the system?
- Does the application clearly define the evaluation criteria to determine validity of measures?
- Does the applicant propose a sufficient plan for identifying and selecting new valid and reliable existing data sources that are both qualitative and quantitative to assess vision loss, major eye diseases, access, and utilization of eye care services?
- Does the applicant describe a plan to ensure that the population's estimates of vision and eye health indicators are rigorous, robust, and scientifically valid?
- Does the proposed dissemination plan employ multiple novel avenues to reach potential users of the knowledge generated from the surveillance system?
- Does the proposed three year plan demonstrate an increasing level of sophistication, evolution, and precision to be sustained over the three year cycle of this project?
- Does the applicant describe appropriate staffing for the three year period of performance?
- Does the applicant include plans to engage key partners and stakeholders throughout the three year project?

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?

- Is there a description of the applicants' physical facilities, data management and computer resources, and facilities for data retrieval and storage?
- Does the applicant have access to relevant data sources and data systems for surveillance?
- Does the project support key stakeholders and partners involvement throughout the

project process?

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/additionalrequirements/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/maso/Policy/Policy_women.pdf 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 five 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) adequacy of veterinary care; 4) 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 5) 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.

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/additionalrequirements/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:

• Type of data to be produced in the proposed project;

• Mechanisms for providing access to and sharing of the data (including provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights);
• 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.

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.

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 guidance for completing a detailed justified budget on the CDC website, at the following Internet address: http://www.cdc.gov/grants/interestedinapplying/applicationresources.html
The budget can include both direct costs and indirect costs as allowed.
Indirect costs could include the cost of collecting, managing, sharing and preserving data.
Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of modified total direct costs exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.
Indirect costs on training grants are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and sub-awards in excess of $25,000.
If requesting indirect costs in the budget based on a federally negotiated rate, a copy of the indirect cost rate agreement is required. Include a copy of the current negotiated federal indirect cost rate agreement or cost allocation plan approval letter.

4. Review and Selection Process

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

- Will receive a written critique.

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

decisions:

- 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.

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

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 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 subpart F 45 CFR 75 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 DUNS, 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).

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

Administrative and National Policy Requirements, Additional Requirements (ARs) outline the administrative requirements found in 45 CFR Part 75 and the HHS Grants Policy Statement and other requirements as mandated by statute or CDC policy. Recipients must comply with administrative and national policy requirements as appropriate. For more information on the

Code of Federal Regulations, visit the National Archives and Records Administration: http://www.access.gpo.gov/nara/cfr/cfr-table- search.html.

Specific requirements that apply to this NOFO are the following:

AR-1: Human Subjects Requirements

AR-2: Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR-7: Executive Order 12372 Review ;

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2020

AR-12: Lobbying Restrictions

AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities ;

AR-14: Accounting System Requirements

AR-8: Public Health System Reporting Requirements

AR-15: Proof of Non-profit Status

AR 23: Compliance with 45 C.F.R. Part 87

AR-16: Security Clearance Requirement

AR-21: Small, Minority, And Women-owned Business

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Data Management and Access

AR-26: National Historic Preservation Act of 1966

AR-28: Inclusion of Persons Under the Age of 21 in Research

AR-29: Compliance with EO13513, “Federal Leadership on Reducing Text Messaging while Driving”, October 1, 2009

AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973

AR-31: Research Definition

AR-32: Appropriations Act, General Provisions

AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

AR-34: Language Access for Persons with Limited English Proficiency

AR-36: ; Certificates of Confidentiality

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 apply 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: http://www.plainlanguage.gov/plLaw/index.cfm.

Pilot Program for Enhancement of Employee Whistleblower Protections All applicants will be subject to a term and condition that applies the terms of 48 CFR section 3.908 to the award and requires that grantees inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

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 the 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/additionalrequirements/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/additionalrequirements/ar-36.html.

4. Cooperative Agreement Terms and Conditions

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

- Providing oversight of the management and administrative aspects of the project, including maintaining an adequate staffing plan to support project activities.
- Developing all materials required for IRB submission (e.g., protocol, consent forms, data collection materials, recruitment materials). The protocols must be designed to adequately describe implementation and evaluation of the proposed intervention and meet Office of Human Research Protections (OHRP) standards.
- Developing the research protocol and submit the protocol for human subjects review.
- Developing and implementing stringent safeguards for protecting the rights and confidentiality of participants.
- Attending periodic meeting(s), as appropriate, at CDC and elsewhere to develop and finalize the intervention and the research protocol, and provide progress updates.
- Developing a process evaluation of key milestones of the project.
- Ensuring data entry, security, and quality/accuracy.
- Using appropriate statistical techniques to analyze data and provide the required

population estimates
- Convening partners and stakeholders to define the project priorities.
- Developing the methodology to assess vision and eye health indicators.
- Coordinating and conducting data sources collection, assembling, analyses, and reporting.
- Disseminating findings in peer-reviewed journals and other venues.
- Complying with the responsibilities for the Extramural Investigators as described in the Policy on Public Health Research and Nonresearch Data Management and Access http ://intranet.cdc.gov/od/oads/spa/dma/index.html

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

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

- Serve as technical advisor and scientific consultant for the project activities related to this cooperative agreement overall and monitor its progress, including conducting site visits to recipient institutions.
- Provide scientific and technical assistance advice as needed to assist the investigators in achieving the study objectives
- Ensure that work plans are feasible and consistent with the aims of the NOFO
- Contribute to analyses, publications and other products at the PIs discretion
- Facilitate distribution and dissemination of research findings
- Assisting the PI, as needed, in complying with the Investigator responsibilities described in the Policy on Public Health Research and Nonresearch Data Management and Access http://intranet.cdc.gov/od/oads/spa/dma/index.html

Additionally, an HHS/CDC Project Officer or other HHS/CDC staff will provide day-to-day programmatic, administrative, and fiscal management in support of the project as defined above.

Additionally, an HHS/CDC agency Program Official will be responsible for the normal scientific and programmatic stewardship of the award. The SPO will be:

- Named in the Notice of Grant Award (NGA) as the Program Official to provide oversight and assure overall scientific and programmatic stewardship of the award;
- Monitor performance against approved project objectives; and
- Assure assessment of the public health impact of the research conducted under this funding opportunity announcement and promote translation of promising practices, programs, interventions, and other results from the research.

Areas of Joint Responsibility - All responsibilities are divided between awardees and CDC staff, with certain responsibilities requiring a close collaboration, as described above.

5. Reporting

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

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

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

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.
Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients:
1) Information on executive compensation when not already reported through the SAM Registration; and
2) Similar information on all sub-awards/ subcontracts/ consortiums over $25,000. It is a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.
All recipients of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

A. Submission of Reports

The Recipient Organization must provide HHS/CDC with an original, plus one hard copy of the following reports:

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** (https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm) is required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which 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 contributed 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:

NA

https://era.nih.gov/docs/Commons_UserGuide.pdf

2. Annual Federal Financial Reporting The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through eRA Commons within 90 days after the end of the calendar quarter in which the budget period ends. 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.
The due date for final FFRs will continue to be 90 days after the Period of Performance end date.
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 end of grant period. 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).

FFR (SF 425) instructions for CDC recipients are now available at https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm. For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: https://grants.nih.gov/support/index.html

FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) (https:// commons. era.nih.gov/ commons/). CDC recommends that this one time registration process be completed at least 2 weeks prior to the submittal date of a FFR submission.

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.

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

CDC Technical Information Management Section (TIMS)
Telephone 770-488-2700
Email: ogstims@cdc.gov
Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Standard Time

Scientific/Research Contact(s)

Sue Shaw
Scientific Program Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE
Mailstop #F80
Atlanta, GA 30342
Telephone: (770) 488-6142
Email: zgx7@cdc.gov

Peer Review Contact(s)

Jaya Raman, Ph.D.
Scientific Review Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE, Mailstop #F80
Atlanta, GA 30342
Telephone: (770) 488-6511
Email: kva@cdc.gov

Financial/Grants Management Contact(s)

Sharon Cassell
Grants Management Specialist
Office of Grants Services
Office of Financial Resources
Centers for Disease Control and Prevention
Telephone: 770-488-2703
Email: scassell@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 Federal Regulations.

This program is authorized under 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.