

Centers for Disease Control and Prevention

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

Establish a Vision and Eye Health Surveillance System for the Nation - AMENDMENT I. QUESTIONS FROM POTENTIAL APPLICANTS AND CDC RESPONSES were added to Section VIII. as Appendix A. on January 27, 2015

RFA-DP-15-004

Application Due Date: 02/05/2015

Establish a Vision and Eye Health Surveillance System for the Nation - AMENDMENT I. QUESTIONS FROM POTENTIAL APPLICANTS AND CDC RESPONSES were added to Section VIII. as Appendix A. on January 27, 2015

RFA-DP-15-004

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 and Prevention

Components of Participating Organizations

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

Funding Opportunity Announcement (FOA) Title

Establish a Vision and Eye Health Surveillance System for the Nation - AMENDMENT I. QUESTIONS FROM POTENTIAL APPLICANTS AND CDC RESPONSES were added to Section VIII. as Appendix A. on January 27, 2015

Activity Code

Applications in response to this FOA will be funded using the U01 activity code.

Funding Opportunity Announcement Type

New

Funding Opportunity Announcement Number

RFA-DP-15-004

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.068

Category of Funding Activity:

Health

FOA Purpose

This funding opportunity announcement (FOA) solicits applications to develop, test, and implement a vision and eye health surveillance system using existing surveys, as well as administrative and electronic data sources. Such a system will be built to provide population estimates of vision loss function, eye diseases, health disparities, as well as barriers and facilitators to access vision and eye care at the national, state, and community levels. This surveillance system will provide data to prioritize new program interventions, inform policy changes, and improve public communications. The dissemination of these data to existing public health programs will encourage public health action to improve the vision and eye health of the nation.

Key Dates

Publication Date: **To receive notification of any changes to RFA-DP-15-004, 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: **01/05/2015**

Application Due Date: **02/05/2015**

On-time submission requires that electronic applications be error-free and made available to CDC for processing from eRA Commons on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov/eRA Commons no later than 5:00 PM U.S. Eastern Time. Note: HHS/CDC grant submission procedures do not provide a period of time beyond the application due date 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: **04/20/2015**

Secondary Review: **06/05/2015**

Estimated Start Date: **09/30/2015**

Expiration Date: **02/06/2015**

Due Dates for E.O. 12372: Executive Order 12372 does not apply to this program.

Required Application Instructions

It is critical that applicants follow the instructions in the SF 424 (R&R) Application Guide except where instructed to do otherwise in this FOA. Conformance to all requirements (both in the Application Guide and the FOA) 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.** To develop, test, and implement a vision and eye health surveillance system using various surveys, as well as administrative and electronic data sources. Such a system will be built to provide population estimates of vision loss function, eye diseases, health disparities, as well as barriers and facilitators to access vision and eye care at the national, state, and community levels. This system will be disseminated and shared with 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.
- **Mechanism of Support.** This funding opportunity will use the cooperative agreement funding mechanism (U-01).
- **Funds Available and Anticipated Number of Awards.** Total funding available for this cooperative agreement is expected to be $4,000,000 over the four-year project period. $1,000,000 total direct and indirect costs, is available in FY 2015 to fund one award. The award issued under this FOA is contingent upon availability of funds and a sufficient number of meritorious applications.
- **Budget and Project Period.** The estimated total funding (direct and indirect) for the first year is $1,000,000. The project period will run from September 30, 2015 to September 29, 2019 and the estimated total funding (direct and indirect) for the entire project period will be $4,000,000.
- **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 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 contain more than one PI; however, the first PI listed will be the "contact PI" for all correspondence.
- **Number of Applications.** Eligible applicant institutions may submit more than one application, provided that each application is scientifically distinct.
- **Application Type.** New (Type 1)

- **Special Date(s).** None
- **Application Materials.** See Section IV.1 for application materials.
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: (770) 488-2783.

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

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.

1. Background and Purpose

This FOA is aimed at improving the vision health of the nation by improving and strengthening the system of vision and eye health surveillance. The United States government, in conjunction with the vision and eye care communities, has identified the reduction of population disparities in vision loss and in access to eye care services as top public health priorities in Healthy People 2010 and 2020.

Background: Vision loss is recognized as a public health problem because it affects more than 3.3 million people aged 40 years and older in the United States (1): it is associated with higher prevalence of multiple chronic conditions such as diabetes (2), cardiovascular health (3), falls (4), injuries (5), depression (6), smoking (7), premature mortality (8), and overall poorer quality of life (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). Cases of cataract are expected to increase from 20.5 million in 2010 to 30.1 million in 2020 (15). Cases of early macular degeneration are expected to increase from 9.1 million in 2010 to 17.8 million in 2050 (16). Cases of diabetic retinopathy 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 disease progression and remaining vision can often be preserved, but lost vision 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 people 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, there is no public health surveillance system in the United States 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 U.S. is particularly problematic because of the variability in the concepts employed to measure vision and the lack of "gold standard" questions employed in surveys. No single survey would be able to capture all 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 adequate information to assess the burden and guide interventions and policy decisions.

In 2010, a panel of national and international experts convened at CDC to: 1) define surveillance approaches to capture the burden of vision loss and vision health disparities; 2) identify strategies to bridge gaps in existing surveillance systems that would increase the utility for assessing and monitoring disparities in eye health, vision loss, and access to eye care; and 3) identify properties of a surveillance system to guide public health interventions (24).

The panel outlined six 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 measures 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.
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.

An integrated vision and eye health surveillance system would contribute to improved population estimates and improved understanding of population trends, and health disparities, as well as barriers and facilitators to access to vision care. Building a vision and eye health surveillance system would allow consumers, providers, public health, and other organizations to be more responsive to the particular needs of this growing population. Therefore, the aim of this announcement is to conduct research to examine the feasibility of using valid sources of existing data and analytical techniques to build a reliable and efficient, web-based, vision and eye health surveillance system for the nation.

The intended outcome of this announcement is the initial establishment and piloting of an integrated, web-based, vision and eye health surveillance system built upon various existing surveys, as well as administrative and electronic data sources, capable of determining population estimates, trends, and health disparities, as well as identifying barriers and facilitators to access to vision and health care at the national, state, and community levels.

There is a need to create an integrated eye health surveillance system that identifies how various surveys, as well as administrative and electronic data systems, contribute to an overall understanding of population estimates, trends, and health disparities, as well as barriers and facilitators to access to vision and health care. Building an eye health surveillance system would allow consumers,

providers, public health, and other systems to be more responsive to the particular needs of this growing population. Therefore, the aim of this announcement is to conduct research using valid sources of data, analytical techniques, and data elements to build a reliable and efficient eye health surveillance system for the nation.

Purpose: The purpose of this announcement is to develop, test, and implement a vision and eye health surveillance system using various existing surveys, as well as traditional and non-traditional data sources, to assess population estimates, trends, and health disparities. This project will be characterized by the capacity to assess various data for inclusion and propose a plan to assemble, analyze, integrate, implement, and disseminate information from this eye health surveillance system. This system will provide necessary information to decision makers to enable government agencies, academic institutions, and other interested parties to monitor the burden and trends of vision loss; major eye diseases, risk factors for vision loss; social, economic, racial, and ethnic disparities; and to establish effective public health interventions to address problems of access and utilization. This surveillance system will also be instrumental in monitoring trends in the Healthy People 2020 healthy vision objectives.

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 RFA addresses “Healthy People 2020” focus area to “Improve the visual health of the Nation through prevention, early detection, treatment, and rehabilitation,” listed are the relevant vision objectives;

V-3 Reduce occupational eye injuries.
V-4 Increase the proportion of adults who have a comprehensive eye examination including dilation, within the past two years.
V-5 Reduce visual impairment.
V-5.1 reduce visual impairment due to uncorrected refractive errors.
V- 5.2 reduce visual impairment due to diabetic retinopathy.
V- 5.3 reduce visual impairment due to glaucoma.
V- 5.2 reduce visual impairment due to cataract.

V-6 Increase the use of personal protective eyewear.
V-6.1 Increase the use of personal protective eyewear in recreational activities and hazardous situations around the home among Children and adolescents aged 6-17 years.
V-6.2 Increase the use of personal protective eyewear in recreational activities and hazardous situations around the home among adults aged 18 years and older.

V-7 Increase rehabilitation services.
V-7.1 Increase the use of rehabilitation services by persons with visual impairment.
V-7.1 Increase the use of assistive and adaptive devices by persons with visual impairment.

V-8 Increase the proportion of Federally Qualified Health Centers (FQHCs) that provide comprehensive vision health services.

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. For more information, see www.health.gov/healthypeople and www.whitehouse.gov/omb

/mgmt-gpra/index-gpra.

Public Health Impact

A national vision and eye health surveillance system will help assess where the nation is meeting or failing to meet 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 four-year project, a proposed national vision and eye health surveillance system will be in place to provide comprehensive, integrated, and accessible information to inform academic institutions, state and national governmental agencies, and private organizations in efforts to reduce vision loss and related disability.

Relevant Work

Refer to Background and Purpose section.

2. Approach

Vision and Eye Health Surveillance System solicits applications to develop a comprehensive, integrated national eye health surveillance system to monitor vision loss, eye diseases, and access to eye care at the state and national level.

Objectives/Outcomes

The goal of this research is to build and develop a national integrated vision and eye health surveillance system to measure and monitor the burden of vision loss and eye diseases and ultimately improve the vision and eye health of the nation.

1. Determine the feasibility of establishing the National Vision and Eye Health Surveillance System using existing data sources. Applicants should identify, evaluate, test, and validate multiple existing data sources and develop an inventory of existing vision and eye related surveys, and other topic related resources. Applicants should use both traditional and nontraditional population-based national and state surveys (including NHANES and NHIS, and Behavioral Risk Factor Surveillance System [BRFSS]), census (American Community Survey), administrative data (Department of Veterans Affairs, Indian Health Service, Medicare /CMS, managed care registries, national health system registries), and non-traditional data sources (electronic health records, social media, marketing, and behavioral data) in order to establish the capacity to accurately estimate the proportion and population of people with vision loss, major eye diseases, and with access to eye care at the national and state levels as well as determine trends in each of these factors.

2. Identify, evaluate, and develop valid and reliable vision and eye health indicators that address risk factors for eye diseases (modifiable and non- modifiable, age, race/ethnicity, gender, SES, diabetes), major eye diseases and refractive errors, indicators of vision loss burden (disability, comorbid conditions, depression, falls, and death), and preventive care practices (comprehensive eye exam, awareness and education), collaborating with partners that are engaged in vision and eye health surveillance, research, and evaluation. Ensure data sources provide valid data for the selected indicators.

3. Determine the feasibility of implementing 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. Standardized measures of visual acuity would allow for comparability across surveys and the integration of data from multiple sources into a national vision and eye health surveillance system.

4. Develop, describe, and execute appropriate methodologies to assemble, analyze, and test data to provide estimates, among U.S. adults, of the burden of vision loss, major eye diseases, risk factors, measures of access and utilization of eye care, treatment, comorbid conditions, and disability.

5. Prepare and deliver final data set(s) to include data sources and all relevant and related information (e.g. data use agreements, privacy impact assessment). Ensure data use agreements (if any) allow for public access to and use of data. Collaborate with National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) Office of Informatics and Science Office to review data and indicators for dissemination through NCCDPHP's open data platform. Load 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. Make revisions as necessary to address accessibility and usability.

6. Evaluate the usefulness of the vision and eye health surveillance system for end users such as public health professionals, health care providers and policy makers.

7. Develop a dissemination plan that includes but is not be limited to: 1) publishing in peer-reviewed journals on the feasibility of a surveillance system, 2) presentations to end-user audiences, and 3) a report with recommendations for use and adoption of the National Vision and Eye Health Surveillance System.

8. Develop a final project report that includes but is not limited to describing the components of the system, 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.

Outcomes: At the end of this four-year award, a national vision and eye health surveillance system for vision loss, eye diseases, and eye health will be developed for implementation in the US. The system will provide valid data regarding social, economic, racial, and ethnic disparities among people reporting vision and eye health problems. The vision and eye health surveillance system will enable governmental agencies, academic institutions, private agencies, and the public to monitor the burden and trends of vision loss and its risk factors over time and to establish effective public health approaches to address this condition. It will also be instrumental in monitoring trends in the Healthy People 2020 vision health objectives. With input from stakeholders and partners, the knowledge gained from this project will add novel surveillance approaches by assembling big data systems to assess and monitor the vision health of the nation.

Target Population

The vision and eye health surveillance system 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 be representative of the U.S. adult population to enable users to draw inferences to the general population.

Collaboration/Partnerships

Applicants are expected to develop substantial collaborations and partnerships with a variety of academic institutions, private sector organizations, and governmental agencies representing both producers and users of vision health data. A variety of partners should contribute to establishing the rigor, comprehensiveness, and utility of the system as well as assuring that the content is accessible and useful to users. Establishing a national vision and eye health surveillance system needs partnerships among many stakeholders in order to monitor trends of the nation's eye health and eye care utilization.

Evaluation/Performance Measurement

The applicant is expected to develop and implement an evaluation plan that includes the following characteristics:

I. Broad goals, objectives, and activities that are Specific, Measurable, Achievable, Realistic, and Time-limited (SMART);
II. A description of mechanisms for engaging partners and stakeholders in evaluation activities;
III. Key activity-specific evaluation questions;
IV. Evaluation methods; and
V. A description of how evaluation results are intended to be used to overcome any barriers identified and to improve program effectiveness and rigor.

Translation Plan

The applicant is expected to develop and implement a translation plan that:

- Describes the plan to disseminate study findings targeting users of the vision and eye health surveillance system through web sites, interactive data manipulation or portals, webinars, journal articles, professional presentations, facts sheets, etc.
- Describes the plan for dissemination and translation of the research findings using collaborators and external partners.
- Describes how the vision and eye health surveillance system will be integrated with health care delivery systems.
- Provide recommendations for how to sustain and implement the plan beyond the funding period

OMB/PRA may apply.

References:

1. Congdon N, O'Colmain B, Klaver CC, et al. Causes and prevalence of visual impairment among adults in the United States. Arch Ophthalmol 2004;122(4):477– 485.
2. Eye Diseases Prevalence Research Group. The prevalence of diabetic retinopathy among adults in the United States. Arch Ophthalmol 2004;122(4):552–563.
3. Klein R, Marino EK, Kuller LH, et al. The relation of atherosclerotic cardiovascular disease to retinopathy in people with diabetes in the Cardiovascular Health Study. Br J Ophthalmol 2002;86(1):84 –90.
4. Lord SR, Dayhew J. Visual risk factors for falls in older people. JAGS 2001;49:508–515.
5. Kulmala J, Era P, Pärssinen O, et al. Lowered vision as a risk factor for injurious accidents in older people. Aging Clin Exp Res 2008;20(1):25–30.
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Behavioral Risk Factor Surveillance System. Ophthalmic Epidemiol. 2014 Oct;21(5):287-96.
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11. Saaddine JB, Narayan KM, Vinicor F. Vision loss: a public health problem? Ophthalmology. 2003 Feb;110(2):253-4.
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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.
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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: $4,000,000

Total funding (direct and indirect) for the four-year project period is $4,000.000. It is anticipated that one award will be made available to a single recipient for approximately $1,000,000 in FY 2015.

If an applicant requests a funding amount greater than the ceiling of the award range for the first year ($1,000,000), HHS/CDC will consider the application non-responsive, and it will not enter into the review process. HHS/CDC will notify the applicant that the application did not meet the submission requirements.

Anticipated Number of Awards: 1

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

Award Ceiling: $1,000,000 Per Budget Period

Award Floor: $0 Per Budget Period

Total Project Period Length: 4 year(s)

Throughout the project period, 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/asfr/ogapa/aboutog/hhsgps107.pdf) will apply to the applications submitted and awards made in response to this FOA.

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

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" when submitting via www.grants.gov.

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

None

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

The application must be received by 5:00 p.m., ET, on the due date. Failure to submit by the due date and time will result in the application being deemed non-responsive and will not be entered into the review process.

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/#1.
- 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 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 registration process at least four (4) weeks prior to the application due date.

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 grantee 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 grantee 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/ asfr/ ogapa/ aboutog/ hhsgps107.pdf).

10. Number of Applications

As defined in the HHS Grants Policy Statement, (http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf), applications received in response to the same funding opportunity announcement 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 FOA that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity from www.Grants.gov.

If access to the Internet is not available or if the applicant encounters difficulty accessing the forms on-line, contact the HHS/CDC Procurement and Grants Office Technical Information Management Section (PGO TIMS) staff at (770) 488-2700 or pgotim@cdc.gov for further instructions. Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Standard Time. CDC Telecommunications for the hearing impaired or disabled is available at: TTY 1-888-232-6348.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/ 424/SF424_RR_Guide_General_VerC.pdf), except where instructed in this Funding Opportunity Announcement 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 forms package associated with this FOA includes all applicable components, mandatory and optional. Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow the instructions in the SF 424 (R&R) Application Guide to ensure you complete all appropriate “optional” components.

In conjunction with the SF424 (R&R) components, CDC grants applicants should also complete and submit additional components titled “PHS398.” Note the PHS398 should include assurances and certifications, additional data required by the agency for a complete application. While these are not identical to the PHS398 application form pages, the PHS398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete application to CDC will include SF424 (R&R) and PHS398 components.

These forms can be downloaded and uploaded as Attachment A from the following link: http://www .cdc.gov/od/pgo/funding/grants/foamain.shtm

3. Letter of Intent

Due Date for Letter of Intent: **01/05/2015**

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.

By the date listed above and in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

Name of the 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
National Center for Chronic Disease Prevention and Health Promotion
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE M/S F-80
Atlanta, GA 30341
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 FOA in Grants.gov includes all applicable components for this FOA, required and optional.

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 16 components. Not all 16 components of the Research Plan apply to all Funding Opportunity Announcements (FOAs). Specifically, some of the following 16 components are for Resubmissions or Revisions only. See Part I, Section 5.5 of the SF 424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Funding Opportunity Announcement Description).

Follow the page limits stated in the SF 424 unless otherwise specified in the FOA. As applicable to and specified in the FOA, 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 FOA.
2. Specific Aims – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.
3. Research Strategy – the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and timeline.
4. Inclusion Enrollment Report (Renewal and Revision applications ONLY)
5. Progress Report Publication List (for Continuation ONLY)

Human Subjects Section

6. Protection of Human Subjects
7. Inclusion of Women and Minorities
8. Targeted/Planned Enrollment Table (for New Application ONLY)
9. Inclusion of Children

Other Research Plan Sections

10. Vertebrate Animals
11. Select Agent Research
12. Multiple PD/PI Leadership Plan.
13. Consortium/Contractual Arrangements
14. Letters of Support
15. Resource Sharing Plan(s)
16. Appendix

Component 4 (Inclusion Enrollment Report) applies only to Renewal and Revision applications for clinical research. Clinical research is that which is conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies). Follow the page limits in the SF 424 **unless otherwise specified in the FOA.**

All instructions in the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) must be followed along with any additional instructions provided in the FOA.

Research Plan

The applicant's research plan should address activities that will be conducted over the entire 4-year project period, and should include the following items:

- Describe the experience and expertise of the project team-including a) leadership in project coordination b) subject matter expertise, and c) publication record in major peer-reviewed journals - outlining key roles and time commitments, and expected contributions of key/collaborative partners. Describe how the team members will complement each other's skills and work together. Include the percentage of time each person will devote to project activities.
- 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. Provide a detailed project timeline including realistic and measurable quarterly milestones for proposed project activities, with a description on how each of the proposed activities will be sequenced and scaled up over the 4-year project period.
- Identify key milestones including data collection, data management, data analysis, report writing.
- Describe the collaboration plan with stakeholders that include grantee collaborators and its partners, funding agency and its partner, and other experts and organizations that conduct or utilize data sources targeting the vision and eye health surveillance.
- Describe how the collaboration and partnerships will be utilized throughout the four-year project period including the identification of data sources and indicators.
- 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.

- Include signed letters of support from participating partners outlining their participation, contributions, and evidence of their commitment and cooperation in the appendix. Describe detailed plan to Identify, evaluate and validate existing data sources.
- Describe detailed plan to obtain, assemble, and standardize data. Provide regular Data Use Agreements (DUAs) and ensure following CDC technical and security standards, processes, and procedures.
- Describe detailed plan to identify, evaluate, and develop eye heath indicators.
- Describe strategies to explore novel approaches to measure vision loss across a variety of surveys and data sources.
- Develop a plan to estimate cross-sectional and trend data for vision loss and eye diseases, disparity, and level and quality of eye care.
- Describe plan and appropriate methodologies to assemble and analyze the identified existing and diversified data sources, and to assess the validity and representativeness of the estimates.
- Describe proposed strategies to create a web-based dissemination platform that is capable of providing tabular and graphic representation of vision loss, eye diseases, and access and utilization of eye care estimates.
- Describe proposed strategies to create web-based platform that will conform to all CDC security and regulatory standards to be mounted on the CDC website.
- Prepare and deliver final data set(s) to include data sources and all relevant and related information (e.g. data use agreements, privacy impact assessment).
- Develop and implement dissemination plan.
- Deliver final management plan describing all component of the health surveillance system, including data source, indicators, data management and compliance with standards for appropriate format.
- Provide detailed staffing plan for the four-year project period to include:
  1) staff experience designing, implementing, and evaluating health surveillance systems, including identification, validation, and assembling of existing data sources; experience analyzing national, regional and local data; developing and evaluating health surveys, indicator development and validation, and data analysis and interpretation;
  2) describe 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 team complements each others skills and they work together; and
  3) describe the research team member's contributions to similar studies and publications in peer-reviewed journals and presentations made at professional and scientific conferences.
- Describe stakeholders meetings to provide a review and give feedback on study projects (data sources, indicators, assembly, analysis, presentation of data) and the implications of the surveillance system for improving the vision health of the nation.
- Describe approaches for identifying and selecting valid and reliable data sources that are both qualitative and quantitative to assess vision loss, major eye diseases, access and utilization of eye care services. This may include paper-based medical records, electronic medical records, and administrative data such as claims data, annual reports, and ad hoc surveys.
- Describe the plan to determine the feasibility of assembling and analyzing traditional and non-traditional data sources.
- Describe plans to purchase, obtain, assemble, and standardize data for the computation of estimates of vision loss, major eye diseases, access and utilization of eye care services. Include a rationale for the proposed structure and selection of proposed data elements.

- Describe 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.
- Describe planned approach for identifying and selecting valid and reliable indicators for the National Vision and Eye Health Surveillance System.
- 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 health outcomes.
- Describe planned approach to identify criteria for including measures from population-based national surveys or administrative data that offer robust sample sizes and reliable coding.
- Describe planned approach to identify novel measures capturing performance-based and self-reported vision loss.
- Describe proposed plan to include, at a minimum, appropriate methodologies to combine and analyze the identified existing and diversified data sources to provide cross-sectional estimates and trend data, when appropriate, for vision loss and eye diseases, disparity, and level and quality of eye care. Describe plans to validate the estimates and assess the degree of representativeness of the different data sources.
- Describe proposed strategies for creating web-based platform that is capable of describing trends in vision loss, eye diseases, and access and utilization of eye care.
- Describe planned approach for conducting and evaluating a pilot test of the National Vision and Eye Health Surveillance System.
- Describe how partners will be engaged to development and evaluation of the National Vision and Eye Health Surveillance System throughout the project period.
- Describe plans for disseminating the findings from this study and for promoting the Vision and Eye Health Surveillance system, such as fact sheets, reports, peer-reviewed journal articles, and to end users (research scientists, state departments of public health, vision care providers, blindness prevention organizations, vision rehabilitation organizations, educational institutions, or state and federal policy makers).
- Describe how key project activities will be sequenced and scaled up over the four-year cycle of this project.

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 FOA must be followed. For this specific FOA, 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 (Part I, Section 2) (http://grants.nih.gov/ grants/funding/424/ SF424_RR_Guide_General_VerC.pdf).

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit in advance of the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications via Grants.gov (http://www.grants.gov), the online portal to find and apply for grants across all Federal agencies. The eRA Commons systems retrieve the application from Grants.gov and check the application against CDC business rules. If no errors are found, the application will be assembled in the eRA Commons for viewing by the applicant before moving on for further CDC processing.

If errors are found, the applicant will be notified in the eRA Commons. They must make required changes to the local copy of their application and submit again through Grants.gov.

Applicants are responsible for viewing their application in the eRA Commons to ensure accurate and successful submission.

Once you can see your application in the Commons, be sure to review it carefully as this is what the reviewer will see. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (http:// grants.nih. gov/grants /guide/url_ redirect .htm? id=11123).

Information on the submission process is provided in the SF424 (R&R) Application Guide.

Note: HHS/CDC grant submission procedures do not provide a period of time beyond the grant application due date 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).

The application package is not complete until it has passed the Grants.gov/eRA Commons validation process. This process and email notifications of receipt, validation or rejection may take two (2) business days.

Applicants are strongly encouraged to allocate additional time prior to the submission deadline to submit their applications and to correct errors identified in the validation process. Applicants are encouraged also to check the status of their application submission to determine if the application packages are complete and error-free. Applicants who encounter system errors when submitting their applications must attempt to resolve them by contacting the Grants.gov Contact Center (1-800-518-4726; support@grants.gov). If the system errors cannot be resolved, applicants must contact CDC PGO TIMS at 770-488-2700; www.pgotim@cdc.gov for guidance at least 3 calendar days before the deadline date.

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. This validation process may take as long as two (2) business days. A third and final e-mail message is generated once the applicant's

application package has passed validation and the grantor has confirmed receipt of the application.

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

1. Track his/her 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 his/her emails from both Grants.gov and eRA Commons for rejection notices.

    a. If the deadline has passed, he/she should email the Grant Management Specialist listed in the FOA (pgotim@cdc.gov) explaining why the submission failed.
    b. If there is time before the deadline, he/she should correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **02/05/2015**

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 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.

12. Other Submission Requirements and Information

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/ Electronic Receipt /avoiding_ errors.htm or http:// grants. nih.gov/grants/ Electronic Receipt/submit _app.htm

Upon receipt, applications will be evaluated for completeness by the CDC Procurement and Grants Office (PGO) and responsiveness by PGO 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?

- Will the work be influential in that it will lead others to investigate the problem, open new areas of research, or change the scientific approach or public health practice?
- How will the results of this research improve and be of value to public health?
- Do the research results have the potential to be scalable and reach a large portion of the population at risk?

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 health surveillance system, including identification, validation, and assembling of existing data sources?
- Does the project team include members with expertise in vision and eye health, biostatistics, and epidemiology?
- Are the staff roles clearly defined?
- As described, will the staff be sufficient to accomplish the project objectives?
- Does the team bring complementary and integrated expertise to the project?
- Does the project team has extensive, demonstrable experience in managing, integrating, and analyzing large datasets containing vision and eye health information?

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 timely and important data to public health users?

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 novel and robust approach to develop the vision and eye health surveillance system?
- Does the applicant propose a sufficient plan for identifying and selecting 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 propose approaches to identify valid indicators, and to harmonize measures of vision loss and methods to assess access and utilization of eye care?
- Does the applicant propose data sources that can identify social, economic, racial, and ethnic disparities among US adult population reporting or at risk of vision and eye health problems?
- Does the proposed National Vision and Eye Health Surveillance system innovative, robust, and engaging for multiple audiences, including governmental agencies, academic institutions, private agencies, and the public?
- Does the applicant describe plans to collaborate with experts on obtaining data sources and identification of indicators?
- Does the applicant describe the analysis plan required to provide populations estimates of vision and eye health indicators?
- Does the applicant propose strategies to create multi-source web-based information that is capable of describing trends in vision loss, eye diseases, and access and utilization of eye care?
- Does the proposed dissemination plan employ multiple novel avenues to reach potential users of the knowledge generated from the surveillance system?
- Does the proposed four-year plan demonstrate an increasing level of sophistication, evolution, and precision to be sustained over the four-year cycle of this project?
- Does the applicant describe appropriate staffing for the four-year project period?
- Does the applicant include plans to engage key partners and stakeholders throughout the 4-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?

- Does the applicant have appropriate access to data and data systems?

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

(http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm#ar1).

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 (http://www.cdc.gov/maso/Policy/Policy_women.pdf and http://www.gpo.gov/fdsys/pkg/FR-1995-09-15/pdf/95-22950.pdf#page=1) and the policy on the Inclusion of Persons Under 21 in Research (http://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

(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

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.

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 Plans - Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

- Applicants are expected to collaborate with the CDC Office of Informatics and Science to review data and indicators for dissemination through NCCDPHP's open data platform.
- Applicants are expected to establish data use agreements to allow for public access to and use

of data.

Resource Sharing Plans
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: http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm#ar25. Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

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/od/pgo/funding/budgetguide.htm.

4. Review and Selection Process

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

As part of the scientific peer review, all applications:

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

Applications will be assigned to the appropriate HHS/CDC Center, Institute, or Office. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. 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.

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 FOA 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 (http:// www.hhs.gov/ asfr/ogapa/aboutog/ 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.

Awardees 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

All HHS/CDC grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the NoA. For these terms of award, see the HHS Grants Policy Statement Part II: Terms and Conditions of Award (http:// www.hhs.gov/ asfr/ogapa/ aboutog/ hhsgps107.pdf).

Awardees must comply with the administrative requirements (AR) outlined in 45 Code of Federal Regulations (CFR) Part 74 or Part 92, as appropriate, as well as any additional requirements included in the FOA.

Specific requirements that apply to this FOA are the following:

Generally applicable ARs:

AR-1: Human Subjects Requirements

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

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-16: Security Clearance Requirement

AR-17: Peer and Technical Reviews of Final Reports of Health Studies –; ATSDR

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

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Release and Sharing of Data

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 - Distinguishing Public Health Research and Public Health Nonresearch

AR 32 –; FY 2012 Enacted General Provisions

Organization Specific ARs:

AR-8: Public Health System Reporting Requirements

AR-15: Proof of Non-profit Status

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

For more information on the Code of Federal Regulations, visit the National Archives and Records Administration at: http://www.archives.gov/.

To view brief descriptions of relevant CDC requirements visit: http:// www.cdc.gov/ od/pgo/funding/ grants /additional_ req.shtm.

3. Additional Policy Requirements

The following are additional policy requirements relevant to this FOA:

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:

http:// www.hhs.gov/ asfr/ogapa/acquisition/ effspendpol_ memo.html)

Federal Funding Accountability and Transparency Act of 2006

Public Law 109-282, the Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), 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 Web site, www.USASpending.gov (http:// 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 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.

Tobacco and Nutrition Policies

The CDC supports implementing evidence-based programs and policies to reduce tobacco use and secondhand smoke exposure, and to promote healthy nutrition. CDC encourages all awardees to implement the following *optional* evidence-based tobacco and nutrition policies within their organizations. These policies build on the current federal commitment to reduce exposure to secondhand smoke, which includes The Pro-Children Act, 20 U.S.C. 7181-7184 that prohibits smoking in certain facilities that receive federal funds.

Tobacco:

- Tobacco-free indoors – no use of any tobacco products (including smokeless tobacco) or electronic cigarettes in any indoor facilities under the control of the applicant.
- Tobacco-free indoors and in adjacent outdoor areas – no use of any tobacco products or electronic cigarettes in any indoor facilities, within 50 feet of doorways and air intake ducts, and in courtyards

under the control of the applicant.
- Tobacco-free campus – no use of any tobacco products or electronic cigarettes in any indoor facilities and anywhere on grounds or in outdoor space under the control of the applicant.

Nutrition:

- Healthy food service guidelines that at a minimum align with Health and Human Services and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations for cafeterias, snack bars, and vending machines in any facility under the control of the recipient organization and in accordance with contractual obligations for these services. The following are resources for healthy eating and tobacco free workplaces:

  - http://www.gsa.gov/graphics/pbs/Guidelines_for_Federal_Concessions_and_Vending_Operations.pdf

  - http://www.cdc.gov/nccdphp/dnpao/hwi/toolkits/tobacco/index.htm

  - http://www.cdc.gov/chronicdisease/resources/guidelines/food-service-guidelines.htm

Applicants should state whether they choose to participate in implementing these two optional policies. However, no applicants will be evaluated or scored on whether they choose to participate in implementing these optional policies.

4. Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable US Office of Management and Budget (OMB) administrative guidelines, US Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and CDC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial CDC programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; CDC Project Officer are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and HHS/CDC as defined below.

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.
- Collaborating with CDC on the design of the study, data analysis, report writing and dissemination of the finding
- 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.
- Develop the research protocol and submit the protocol for human subjects review.
- If OMB-PRA applies, develop OMB submission package and coordinate with CDC to obtain and maintain appropriate approvals through the life cycle of the award.
- 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.
- Develop 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 measures.
- Coordinating and conducting data sources collection, assembling, analyses, and reporting.
- Disseminating findings in peer-reviewed journals and other venues.

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 has substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below. Additionally, an agency program official or CIO program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

There are two separate CDC roles – Scientific Collaborator and the Scientific Program Official (SPO). In this cooperative agreement, a CDC Scientist (Scientific Collaborator) within the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) provides scientific and programmatic assistance during the conduct of the project through technical assistance, advice and coordination. It is expected that CDC Project Scientists will have substantial programmatic involvement in this cooperative agreement.

CDC Scientific Collaborators will:

- 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 investigator in achieving the study objectives.
- Facilitate distribution and dissemination of results.
- Contribute to analyses, publications and other products as a co-authors within the CDC authorship guidelines.
- Obtain Institutional Review Board approvals as required by CDC when CDC is engaged in research involving human subjects.

Additionally, an HHS/CDC NCCDPHP project officer or other HHS/CDC staff will provide day-to-day programmatic, administrative, and fiscal management in support of this project.

The NCCDPHP Extramural Research Program Operations and Services (ERPOS) 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.

5. Reporting

Awardees will be required to submit the Non-Competing Continuation Grant Progress Report (PHS 2590) annually 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 awardees 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 awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees 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 (http:// www.hhs.gov/asfr/ ogapa/aboutog/ hhsgps107.pdf) for additional information on this reporting requirement.

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**, (use form PHS 2590, posted on the HHS/CDC website, http:// www. cdc.gov/ od/pgo/ funding/ forms.htm and at http:// grants.nih.gov/grants/ funding/2590/ 2590.htm, **is due 90 to 120 days prior to the end of the current budget period.** 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 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 project period.**

B. Content of Reports

1. Yearly Non-Competing Grant Progress Report: The grantee's continuation application/progress report should include:

- Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the PHS 2590 (http:// grants1.nih.gov/ grants/funding/ 2590/2590.htm)
  http:// grants.nih.gov/grants/ funding/2590/2590.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.

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. **All CDC Financial Expenditure data due on/after October 1, 2012 must be submitted using the FFR via the eFSR/FFR system in the eRA Commons.** All Federal Reporting in the Payment Management System is unchanged. All new submissions should be prepared and submitted as FFRs.

CDC's implementation of the FFR retains a financial reporting period that coincides with the budget period of a particular project. However, **the due date for annual FFRs will be 90 days after the end of the calendar quarter in which the budget period ends**. Note that this is a change in due dates of annual FFRs and may provide up to 60 additional days to report, depending upon when the budget period end date falls within a calendar quarter. For example, if the budget period ends 1/30/2012, the annual FFR is due 6/30/2012 (90 days after the end of the calendar quarter of 3/31/2012). Due dates of final reports will remain unchanged. The due date for final FFRs will continue to be 90 days after the project period end date.

Grantees must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, grantees 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 grantees are now available at http:// grants.nih.gov/ grants/forms.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: http://www. cdc.gov/od/pgo/ funding/grants/eramain. shtm.

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: http://era.nih.gov/commons/. Organizations not yet registered can go to https:// commons. era.nih.gov/ commons/ registration/ registration Instructions. jsp 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: http:// era.nih.gov/ commons /index.cfm.

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 project period. 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.

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)
Procurement and Grants Office
Telephone 770-488-2700
Email: PGOTIM@cdc.gov
Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Standard Time

Scientific/Research Contact

Sue Shaw, MPH
National Center for Chronic Disease Prevention and Health Promotion
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE M/S F-80
Atlanta, GA 30341
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Peer Review Contact

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Email: eeo6@cdc.gov

Financial/Grants Management Contact(s)

Tesa Wright
Procurement and Grants Office
Chronic Diseases and Birth Defects Services Branch
Centers for Disease Control and Prevention (CDC)
2920 Brandywine Road, Mailstop E-14
Atlanta, GA 30341
Telephone: 770-488-2789
Email: xcf8@cdc.gov

Section VIII. Other Information

Other CDC funding opportunity announcements 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).

Appendix A.
Questions from Potential Applicants and Answers by CDC

1. Is there a minimum effort for the PI?

   Response: The funding opportunity announcement does not specify a minimum effort for the PI. However, Section VI. Award Administration Information, item 4. Cooperative Agreement Terms and

Conditions of Award includes a list of the PD(s)/PI(s) primary responsibilities.

2. Since this study will involve survey data that are publicly available and de-identified, we are thinking that this is a human subject research exempt from federal regulation. Will we still need to provide a Planned Enrollment Report?

Response**:** Part 2. Section IV. Application and Submission Information, states that the Targeted/Planned Enrollment Table is a requirement for new applications as part of the Human Subjects Section of the application, and a complete application to CDC will include SF424 (R&R) and PHS 398 components.

3. I am writing to request an extension of the submission deadline for RFA-DP-15-004, Establish a Vision and Eye Health Surveillance System for the Nation.

Response: The funding opportunity announcement DP15-004 is a competitive announcement and is published for approximately 60 days for all potential applicants. Therefore, please submit your application by the published due date of February 5, 2015.

4. Is there interest in improved methods of detection (and subsequent prevention) of the primary adult causes of vision loss in rural, underserved areas.

Response**:** The purpose of this funding opportunity is to develop, test, and implement a vision and eye health surveillance system using various surveys, as well as administrative and electronic data sources, to provide population estimates of vision loss function, eye diseases, health disparities, as well as barriers and facilitators to access to vision and eye care at the national, state, and community levels. As a potential applicant, you will need to decide the approach.

5. Is there an opportunity for us to participate as a contributor in this project, or is there a related grant opportunity focused more on children for which we might be better suited?

Response: The purpose of the funding opportunity is to develop, test, and implement a vision and eye health surveillance system using various surveys, as well as administrative and electronic data sources. Such a system will be built to provide population estimates of vision loss function, eye diseases, health disparities, as well as barriers and facilitators to access vision and eye care at the national, state, and community levels.

The vision and eye health surveillance system 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 be representative of the U.S. adult population to enable users to draw inferences to the general population.

Applicants may include a variety of collaborators/partners as part of their application. If you are not planning to submit an application, you might consider contacting and partnering with another organization who is applying. This is currently the only eye-health-related funding opportunity being supported by CDC's Vision Health Program. For other federal funding opportunities, please continue to refer to www.Grants.gov.

6. In reference to the RFA on Vision Impairment Surveillance, I was wondering if the CDC would consider a fully pediatric site for surveillance, or if the surveillance sites have to be adult.

Response: As stated in the FOA, the purpose of the funding opportunity is to develop, test, and implement a vision and eye health surveillance to provide population estimates of vision loss function, eye diseases, health disparities, as well as barriers and facilitators to access vision and eye care at the national, state, and community levels.

The FOA identified the target population for the vision and eye health surveillance system to include racial/ethnic, gender, and socioeconomic (income/education) and geographic location differences (both

U.S. Census region and urban-rural) with data representative of the U.S. adult population to enable users to draw inferences to the general population.

7. I have a question about the application. The package I downloaded from grants.gov uses the PHS 398 Research Training Program Plan, not the PHS 398 Research Plan. The former lacks sections for Specific Aims and Research Strategy and so does not match the RFA instructions (section 5, p. 14). I agree the RFA describes an implementation project more than a research project so I am hoping you can clarify the discrepancy between the RFA and the application package.

Response: The FOA includes hyper-links to the SF424 (R&R) in the following two sections. Both links will take you to the appropriate document.

- Part 1. Overview, Required Application Instructions, includes a hyper-link to the SF424 (R&R) Application Guide. http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf
- Part Section IV.2. Content and Form of Application Submission is a link to SF424 (R&R) Application Guide to the SF424 (R&R) http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf