

Amendment 1: February 17, 2010. Section IV.6. Other Submission Requirements, pages 23-24, Research Plan Component Sections; Appendix A, pages 47-50.

Part I Overview Information

United States Department of Health and Human Services (HHS)

Issuing Organization

Centers for Disease Control and Prevention (NCCDPHP/CDC), at <http://www.cdc.gov/nccdphp/>

Participating Organizations

Centers for Disease Control and Prevention (CDC), at 93.283<http://www.cdc.gov/>

Components of Participating Organizations

Coordinating Center for Health Promotion (CCHP) National Center for Chronic Disease Control and Prevention (NCCDPHP/CDC), at <http://www.cdc.gov/nccdphp/>

Title: RFA-DP-10-004: Translating Research into Healthy Eye and Vision Loss Prevention (U58)

The policies, guidelines, terms, and conditions of the HHS Centers for Disease Control and Prevention (CDC) stated in this announcement might differ from those used by the HHS National Institutes of Health (NIH). If written guidance for completing this application is not available on the CDC website, then CDC will direct applicants elsewhere for that information.

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.

The Catalog of Federal Domestic Assistance number: 93.283.

Announcement Type: NEW

Instructions for Submission of Electronic Research Applications:

NOTICE: Applications submitted in response to this Funding Opportunity Announcement (FOA) for Federal assistance must be submitted electronically through Grants.gov (<http://www.grants.gov>) using the SF424 Research and Related (R&R) forms and the SF424 (R&R) Application Guide.

This FOA must be read in conjunction with the application package instructions included with this announcement on Grants.gov/Apply for Grants (hereafter referred to as, Grants.gov/Apply.)

A registration process is necessary before submission, and applicants are strongly encouraged to start the process at least four weeks prior to the grant submission date. See [Section IV](#).

Two steps are required for on time submission:

1) The application must be successfully received by Grants.gov no later than 5:00 p.m. Eastern Standard Time on the application submission receipt date (see "[Key Dates](#)" below.)

2) Applicants must complete a verification step in the Electronic Research Administration (eRA [Commons](#)) within two business days of notification. Note: Since email can be unreliable, it is the responsibility of the applicant to periodically check on their application status in the eRA [Commons](#).

Funding Opportunity Announcement (FOA) Number: RFA-DP-10-004

Catalog of Federal Domestic Assistance Number(s): 93.283

Key Dates

Release/Posted Date: **December 30, 2009**

Letter of Intent Receipt Date: February 10, 2010

Application Submission Receipt Date(s): March 12, 2010

Peer Review Date(s): April 30, 2010

Council Review Date(s): Secondary Review will be conducted on June 11, 2010

Earliest Anticipated Start Date(s): September 14, 2010

Expiration Date: March 13, 2010

Due Date for E.O. 12372

Executive Order 12372 does not apply to this program.

Additional Overview Content

Executive Summary

- This funding opportunity announcement (FOA) solicits Research Program (U58) cooperative agreement applications to conduct applied public health research to close the gap between optimal evidence-based eye care and existing practice. The focus is to develop and implement a common research protocol to assess and evaluate system-level and individual-level factors that impact access to, and the quality of eye care; and to analyze existing data and identify barriers and enablers to the delivery of efficacious and cost-effective eye care that prevent vision loss and promote eye health.
- The participating organization is committing approximately \$900,000 per year (this amount includes direct and indirect costs) in FY2010 to fund up to 3 recipients. Applicants may request a project period of up to five years.
- The anticipated start date for new awards is September 14, 2010.
- The Budget Period will start on September 14, 2010 and end on September 13, 2011. The Project Period will start on September 14, 2010 and will end September 13, 2015 (five years).
- The total funding for all awards (direct and indirect costs) over the Project Period is anticipated to be \$4.5 million.
- Eligible Organizations: Public nonprofit organizations; private nonprofit organizations; for profit organizations; small, minority, and women-owned businesses; universities; colleges; research institutions; hospitals; community-based organizations; faith-based organizations; federally recognized or state-recognized American Indian/Alaska Native tribal governments; American Indian/Alaska Native tribally designated organizations; Alaska Native health corporations; urban Indian health organizations; tribal epidemiology centers; state and local governments or their Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau); and political subdivisions of states (in consultation with states.) 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 you are applying as a bona fide agent of a state or local government, you must provide required documentation from the state or local government as documentation of your status. Attach this documentation behind the first page of your application form or for electronic applications, use a PDF file and attach as "Other Documents" and label as appropriate.
- Awards issued under this FOA are contingent upon the availability of funds and the submission of a sufficient number of meritorious applications.
- Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size of each award will also vary. The total amount awarded and the number of awards

will depend upon the activity code, quality, and costs of the applications received.

- See [Section IV.1](#) for application materials. The SF424 (R&R) Application Guide for this FOA is located at these Web sites:
http://grants1.nih.gov/grants/funding/424/SF424_RR_Guide_General.doc (MS Word);
http://grants1.nih.gov/grants/funding/424/SF424_RR_Guide_General.pdf (PDF)
- For general information on SF424 (R&R) Application and Electronic Submission, see these the following Web sites: SF424 (R&R) Application and Electronic Submission Information:
<http://grants.nih.gov/grants/funding/424/index.htm>; General information on Electronic Submission of Grant Applications:
<http://era.nih.gov/ElectronicReceipt/>
- HHS/CDC Telecommunications for the hearing impaired is available at the following number: TTY 770-488-2783.

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Section I. Funding Opportunity Description

1. Research Objectives

The National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) of CDC within HHS is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010" and to measuring program performance as stipulated by the Government Performance and Review Act (GPRA). This FOA addresses the "Healthy People 2010" priority area of Vision and Hearing: Improve the visual and hearing health of the Nation through prevention, early detection, treatment, and rehabilitation. This FOA is in alignment with The NCCDPHP performance goal of Health Promotion: Chronic Disease Prevention, Health Promotion, and Genomics. For more information, www.healthypeople.gov and <http://intra-apps.cdc.gov/fmo/>

Nature of the research opportunity:

To solicit applications in the form of cooperative agreements that will conduct applied public health research to close the gap between optimal evidence-based eye care and existing practice. The focus is to develop and implement a common research protocol to assess and evaluate system-level and individual-level factors that impact access to and the quality of eye care; and to analyze existing data and identify barriers and enablers to the delivery of efficacious and cost-effective eye care that prevent vision loss and promote eye health. Study findings will be disseminated in peer reviewed journals and summarized on-line for health care providers and for the general public.

Background:

In recognition of nation's vision health problems, national vision objectives were first included in Healthy People 2010. Visual impairment and eye diseases are associated with increased morbidity, mortality and decreased quality of life. These problems are associated with other chronic diseases and affect people's activities of daily living, cause falls and injuries, and lead to depression and social isolation. In 2000, approximately 3.3 million American adults aged 40 years or older were visually impaired as a result of potentially preventable or treatable age-related eye diseases such as age-related macular degeneration, cataract, diabetic retinopathy, or open-angle glaucoma. In 2002, approximately 61 million adults in the United States were at high risk for serious vision loss. Based on the current trends, by 2020, the number of people with visual impairment and eye diseases could increase by 50% or more.

In 2004, the estimated annual economic impact (including direct medical costs and loss of income) of major vision problems in the U.S. adult population 40 years or older reached more than \$51 billion.

Successful population-level control of eye diseases and prevention of vision loss is beyond what can be achieved by clinical practice alone. Many conditions causing visual impairment are often asymptomatic in their early, treatable stages. Timely examination and treatment is recommended for people at high risk for visual impairment. However, national and state data suggest that only about a half of the persons at high risk for serious vision loss had visited an eye care provider in the past 12 months. Of particular concern is that even though diabetic retinopathy is the leading cause of new cases of legal blindness among adults aged 20-74 years in the U.S., 1 of 3 adults with diabetes did not have a dilated eye examination in the preceding year, a finding that has remained consistent across numerous studies for many years. In addition to modifiable individual behavior risk factors, many system features could influence delivery of high-quality eye care such as health insurance coverage, patient and provider education, organizational

characteristics, poor coordination between primary care providers and specialist within the health care systems, and cost-shifting strategies. System-level factors may also include public health legislative, health system-based and community-based initiatives that are aimed at influencing access to, and quality of eye care. In order to maximize the public health impact, better information is needed to identify the gap between optimal evidence-based eye care and existing practice using measurable quality indicators (especially outcome indicators). Moreover, better information is needed to assess and evaluate system- and individual-level factors and to identify barriers and enablers in order to implement effective public health interventions to improve quality of eye care in real-life settings resulting in reduced vision loss and improved eye health.

Scientific knowledge to be achieved:

The purpose of this translational research initiative is to establish (1) a multicenter network of Translational Research Centers (TRCs) and (2) a collaborative program of multidiscipline applied public health research (epidemiologic, health services, health policy, statistical modeling, economic evaluation, etc., research). The intent of this TRC network is to develop a knowledge- and evidence- base that will improve the population-based quality (structure, process, and outcome) of eye care services. The knowledge-base to be developed will address rigorous methods for and assessment of system- and individual-level factors and will identify barriers and enablers to improve access to and the quality of eye care. Study findings will be published in peer-reviewed journals; summarized on-line for health care providers and for the general public; and will be made available to professional organizations for inclusion in continuing education programs. Data and evidence will be used for policy development and assessment, and to increase the provision and utilization of preventive eye care.

This program also aims to improve the availability and accessibility of data from measurable health outcomes of eye-care services. This program will provide capacity-building at the national, state, and local levels with respect to research on eye care quality in a changing health environment and in an environment of limited healthcare resources. This program will foster the establishment of new partnerships and relationships among health care systems and between health care systems and public health agencies. TRCs will assemble a research and data infrastructure for vision loss prevention and eye health promotion that will be used by these partnerships for decision-support. That infrastructure will allow for the examinations of the trends and impact of health system strategies and policy changes.

Research objectives and experimental approach:

This program announcement will fund and support three TRCs to accomplish the following objectives:

- (1) To assess and evaluate system-level and individual-level factors that impact access to, and the quality of eye care;
- (2) To identify barriers and enablers to the delivery of efficacious and cost-effective eye care.

Applicants shall conduct applied public health research to close the gap between optimal evidence-based eye care and existing practice. This FOA is particularly interested in studies that ultimately affect access to, and the utilization of preventive eye care, sustainable practice, and the adoption of positive health behaviors that preserve sight and promote eye health. Moreover, CDC is particularly interested in the coverage and utilization in diverse geographic regions of the country and in the coverage and utilization of preventive eye care by at-risk racial/ethnic populations.

Quasi-experimental designs, time series designs, cluster-based randomized intervention designs and cohort studies are encouraged. Panel data and cross-sectional data may also be included in applications. This FOA is not intended to fund clinical trials or public health interventions.

Recipients will develop a common protocol and use a core of common definitions, quality indicators/data elements and associated methods so that the study results from TRC-specific studies can be compared across studies in evaluating system-level and individual-level factors that impact access to and of the quality of eye care.

Investigators are encouraged to assemble diverse sources of data, including those from available public survey data and medical information systems such as electronic medical records. Data sources may also include, among others, health plan based registries, administrative outcomes databases such as Medicare and Medicaid, HMO/PPO databases, and other non-traditional sources.

Studies shall: (a) investigate the existing quality indicators (especially outcome indicators) and clinical guidelines for eye care for people with or at risk for visual impairment and/or age-related eye diseases; (b) employ rigorous designs to identify barriers and enablers of both system- and individual-level factors that influence the delivery of efficacious and cost-effective eye care.

Examples of research topics may include, but not be limited to:

1. The effects of screening approaches implemented by healthcare systems, employers, and in community settings on changes in behavior, risk, and

morbidity.

2. Insurance reimbursement policies and benefit designs on adoption, adherence, utilization, and effectiveness of preventive eye care programs.
3. Impact of changes in Medicare and Medicaid policies on utilization of preventive eye care, and outcomes.
4. Impact of electronic health/medical records across a variety of health care delivery settings on access to, and the quality of eye care.
5. Effective patient and/or provider eye care education and utilization of preventive eye care.
6. Investigation of whether variation in clinical practice among eye care providers in the community results in different patient utilization rates and outcomes.
7. Fluctuation in cost among different vision and eye care settings and the impact of cost-containment strategies.
8. Assessment of the quantity and quality of eye care services offered to different segments of the American population, and how this affects outcomes.
9. How changing patterns of delivering eye care services influence person's access to appropriate and high quality eye care.

Funded TRCs will constitute and participate in a multi-center network. The network is expected to enhance collaborations between TRCs; develop and implement a common research protocol and establish a core set of common metrics and measures (e.g., quality indicators); stimulate new ideas and improve the quality of study designs and protocols; develop and implement totally at least 9 center-specific studies and 3 collaborative studies; facilitate the dissemination of study methods, data, and findings. Tools may include research protocols, quality indicators, a Web site, common databases, fact sheets, and policy briefs to inform and engage stakeholders and policy makers.

During the 5-year Project Period, the network of investigators shall engage with a variety of stakeholders to disseminate TRC information and study findings and ensure practical, innovative, and high quality studies that produce high impact findings. Stakeholders will include multi-center network collaborators and their partners, funding agencies and their partners, and other organizations that conduct or utilize the evidence-based findings of studies targeting the prevention and control of visual impairment and age-related eye diseases.

Stakeholder meetings will be held in years 2, 4, and 5 by different TRCs (one meeting by one TRC using partial CDC funding) to provide a review and give feedback on TRC-specific and collaborative TRC network study projects: i.e., methods, preliminary findings, study questions, abstracts, publications, presentations, and the implications of the studies' findings for improving access to and quality of eye care, as well as potential future initiatives.

The network will follow a general timeline consisting of 3 phases over 5 years:

Phase I (Year 1): Clarification of Study Objectives, Priorities, and Design, and the Establishment of Network Tools.

- First 6 months: Multi-center network collaborators (TRCs and CDC) will develop a common research protocol including measurable outcome indicators to assess and evaluate system-level and individual-level factors that impact access to and the quality of eye care.
- Second 6 months: Collaborators will refine, finalize, and begin implementing the study designs and procedures for their center-specific studies.
- 12 months: Network collaborators will also agree on, or develop expectations, procedures, and tools for collaboration across TRCs.

Phase II (Years 2-3): Implementation of Primary Studies and Identification of Ancillary Studies.

- During Phase II, multi-center network collaborators will continue implement their center-specific studies. They will also collaboratively identify and implement multi-center and collaborative study projects of major importance and shared interest.

Phase III: (Year 4-5): Study Findings, Publications, Translation, and Future Directions

- During years 4 and 5, the TRCs will complete center-specific study analyses, interpretation, sharing of findings, and publication, as appropriate.
- During years 4 and 5, the TRC network will continue implementing multi-center collaborative studies, including analysis, interpretation, sharing of findings, and publication, as appropriate.
- Network TRCs will provide decision-support information to partner organizations to advance efforts to translate the findings into public health practice.

- Last six months of Phase III: Multi-center network collaborators, CDC, and other partners will scrutinize the body of work and stakeholders' needs, and will identify future research gaps and priorities.

Investigators will confer and collaborate with CDC scientific staff in all phases of the study. CDC scientific staff will facilitate sharing of expertise, findings, methods, and progress across the multi-center network; contribute to scientific deliberations and decision making; and will ensure the relevance of the network's studies to CDC's mission (see Section VI.2.A.2., HHS/CDC Responsibilities).

See Section VIII, Other Information - Required Federal Citations, for policies related to this announcement.

Section II. Award Information

1. Mechanism(s) of Support

This funding opportunity will use the U58 activity code. The HHS/CDC U58 is a cooperative agreement assistance instrument. Under the cooperative agreement assistance instrument, the Recipient Organization retains the primary responsibility and dominant role for planning, directing, and executing the proposed project with HHS/CDC staff substantially involved as a partner with the Recipient Organization, as described in Section VI.2.A., "Cooperative Agreement."

2. Funds Available

NCCDPHP intends to commit approximately \$900,000 per year, starting in FY2010, to fund up to 3 awards for up to \$300,000 each (which includes direct and indirect costs). Applicants may request a Project Period of up to five years, which will begin on September 14, 2010 and end on September 13, 2015.

The anticipated start date for new awards is September 14, 2010.

Although the financial plans of the NCCDPHP provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds. Continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government.

CDC will not accept and review applications with budgets greater than the ceiling amounts of \$300,000 per award for the first 12 months (which includes total direct and indirect costs).

Section III. Eligibility Information

1. Eligible Applicants

1.A. Eligible Institutions

You may submit an application(s) if your organization has any of the following characteristics:

- Public nonprofit organizations
- Private nonprofit organizations
- For profit organizations
- Small, minority, and women-owned businesses
- Universities
- Colleges
- Research institutions
- Hospitals
- Community-based organizations
- Faith-based organizations
- Federally recognized or state-recognized American Indian/Alaska Native tribal governments
- American Indian/Alaska Native tribally designated organizations
- Alaska Native health corporations
- Urban Indian health organizations
- Tribal epidemiology centers
- State and local governments or their Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau)
- Political subdivisions of States (in consultation with States)

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 you are applying as a bona fide agent of a state or local government, you must provide a letter from the state or local government as documentation of your status. Attach this documentation behind the first page of your application form or for electronic applications, use a PDF file and attach as "Other Documents" and label as appropriate.

2. Cost Sharing or Matching

Cost sharing, matching funds, or cost participation are not required under this program.

The most current HHS Grants Policy Statement is available at:
http://www.hhs.gov/grantsnet/docs/HHSGPS_107.doc.

3. Other-Special Eligibility Criteria

Eligible applicants are limited to those that include eye care professionals in their proposed multi-disciplinary public health, vision health, and clinical research teams. Investigators from underrepresented racial and ethnic minority groups, as well as individuals with disabilities, are always encouraged to apply for CDC programs.

Eligible applicants must also have letters of support that demonstrate that they have access to, and have secured a commitment to be able to use clinical and administrative data sources (datasets and/or data systems) that are operational and provide service to a minimum of 2,000 active patients annually with age-related eye diseases (i.e., age-related macular-degeneration, cataract, diabetic retinopathy, or open-angle glaucoma).

If your application is incomplete or non-responsive to the special requirements listed in this section, it will not enter into the review process.

Note: Title 2 of the United States Code Section 1611 states that an organization described in Section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

Section IV. Application and Submission Information

To download a SF424 (R&R) Application Package and SF424 (R&R) Application Instructions for completing the SF424 (R&R) forms for this FOA, link to Grants.gov/Apply and follow the directions provided on that Web site.

A one-time registration is required for institutions/organizations at the following:

- Grants.gov Get Registered, http://www.grants.gov/applicants/get_registered.jsp
- eRA Commons Prepare to Apply, <http://era.nih.gov/ElectronicReceipt/preparing.htm>

IMPORTANT: both the applicant organization, as well as, the PD/PI must register in eRA Commons for an application to be accepted electronically. The Credentials Log-In, referenced in Section IV. 2. Content and Form of Application Submission, is obtained through Step #3 in the required actions below.

PD/PIs should work with their institutions/organizations to make sure they are registered in the eRA Commons.

The following three steps are required before an applicant institution/organization can submit an electronic application, as follows:

1) Organizational/Institutional Registration in Grants.gov Get Registered, http://www.grants.gov/applicants/get_registered.jsp

- Your organization will need to obtain a [Data Universal Number System \(DUNS\) number](#) and register with the [Central Contractor Registration \(CCR\)](#) as part of the Grants.gov registration process.
- If your organization does not have a Taxpayer Identification Number (TIN) or Employer Identification Number (EIN), allow for extra time. A valid TIN or EIN is necessary for CCR registration.
- The CCR also validates the EIN against Internal Revenue Service records, a step that will take an additional one to two business days.
- Direct questions regarding Grants.gov registration to:
[Grants.gov Customer Support](#)
Contact Center Phone: 800-518-4726
Business Hours: M-F 7:00 a.m. - 9:00 p.m. Eastern Time
Email support@grants.gov

2) Organizational/Institutional Registration in the eRA Commons Prepare to Apply, <http://era.nih.gov/ElectronicReceipt/preparing.htm>

- To find out if an organization is already eRA Commons-registered, see the "[List of Grantee Organizations Registered in eRA Commons.](#)"
- Direct questions regarding the eRA Commons registration to:
eRA Commons Help Desk
Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
Business hours M-F 7:00 a.m. – 8:00 p.m. Eastern Time
Email commons@od.nih.gov

3) Project Director/Principal Investigator (PD/PI) Registration in the eRA Commons: Refer to the [NIH eRA Commons System \(COM\) Users Guide](#).

- The individual designated as the PD/PI on the application must also be registered in the eRA Commons. It is not necessary for PDs/PIs to register with Grants.gov.
- The PD/PI must hold a PD/PI account in the eRA Commons and must be affiliated with the applicant organization. This account cannot have any other role attached to it other than the PD/PI.
- This registration/affiliation must be done by the Authorized Organization Representative/Signing Official (AOR/SO) or their designee who is already registered in the eRA Commons.

- Both the PD/PI and AOR/SO need separate accounts in the eRA Commons since both hold different roles for authorization and to view the application process.

Note that if a PD/PI is also an HHS peer-reviewer with an Individual DUNS and CCR registration, that particular DUNS number and CCR registration are for the individual reviewer only. These are different than any DUNS number and CCR registration used by an applicant organization. Individual DUNS and CCR registration should be used only for the purposes of personal reimbursement and should not be used on any grant applications submitted to the Federal Government.

Several of the steps of the registration process could take four weeks or more. Therefore, applicants should immediately check with their business official to determine whether their organization/institution is already registered in both [Grants.gov](https://www.grants.gov) and the eRA [Commons](https://eRA Commons). The HHS/CDC strongly encourages applicants to use the Grants.gov electronic applications process and have organizations and PD/PIs complete all necessary registrations.

1. Request Application Information

Applicants must download the SF424 (R&R) application forms and SF424 (R&R) Application Guide for this FOA through [Grants.gov/Apply](https://www.grants.gov/Apply).

Note: Only the forms package directly attached to a specific FOA can be used. You will not be able to use any other SF424 (R&R) forms (e.g., sample forms, forms from another FOA); although some of the "Attachment" files may be useable for more than one FOA.

For further assistance, contact PGO TIMS: Telephone 770-488-2700, Email: PGOTIM@cdc.gov

HHS/CDC Telecommunications for the hearing impaired: TTY 770-488-2783.

2. Content and Form of Application Submission

Prepare all applications using the SF424 (R&R) application forms and in accordance with the SF424 (R&R) Application Guide ([MS Word](#) or [PDF](#)).

The SF424 (R&R) Application Guide is critical to submitting a complete and accurate application to HHS/CDC. There are fields within the SF424 (R&R) application components that, although not marked as mandatory, are required by HHS/CDC (e.g., the "Credential" log-in field of the "Research & Related Senior/Key Person Profile" component must contain the PD/PI assigned eRA Commons User ID). Agency-specific instructions for such fields are clearly identified in the Application Guide. For additional information, see "Tips and Tools for Navigating Electronic Submission" on the front page of "[Electronic Submission of Grant Applications](#)."

The title and number of this funding opportunity must be typed on the face page of the application form.

The SF424 (R&R) application is comprised of data arranged in separate components. Some components are required, others are optional. The forms package associated with this FOA in Grants.gov/Apply will include all applicable components, mandatory and optional. A completed application in response to this FOA will include the following components:

Required Components:

SF424 (R&R) (Cover component)
Research & Related Project/Performance Site Locations
Research & Related Other Project Information
Research & Related Senior/Key Person
Research & Related Budget
PHS398 Cover Page Supplement
PHS398 Research Plan
PHS398 Checklist

Optional Components:

PHS398 Cover Letter File
Research & Related Sub award Budget Attachment(s) Form

Note: While both budget components are included in the SF424 (R&R) forms package, the CDC U58 (activity code) uses ONLY the detailed Research & Related Budget. (Do not use the PHS 398 Modular Budget.)

3. Submission Dates and Times

See Section IV.3.A for details

3. A. Submission, Review and Anticipated Start Dates

Application Submission Receipt Date(s): March 12, 2010
Peer Review Date(s): April 30, 2010
Council Review Date(s): Secondary Review will be conducted on June 11, 2010
Earliest Anticipated Start Date(s): September 14, 2010
Expiration Date: March 13, 2010

3.A.1. Letter of Intent

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

- Descriptive title of proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Number and title of this funding opportunity

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 CDC Program staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed in Section IV. 3.A

The letter of intent should be sent to:

Michael Dalmat, Dr.P.H.
Extramural Research Program Office
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention (CDC)
U.S. Department of Health and Human Services
Koger Center – Davidson Building, Room 1098
2858 Woodcock Boulevard
Atlanta, GA 30341 MS K-92
Telephone: (770) 488-6423
Fax: (770) 488-8046
Email: MDalmat@cdc.gov

3.B. Submitting an Application to CDC

If the instructions in this announcement differ in any way from the 424 R&R instructions, follow the instructions in this announcement.

To submit an application in response to this FOA, applicants should access this FOA via [Grants.gov/Apply](https://www.grants.gov/Apply) and follow steps 1-4. If submittal of the application is done electronically through Grants.gov (<http://www.grants.gov>), the application will be electronically time/date stamped by Grants.gov. The applicants' Authorized Organization Representative (AOR) will receive an e-mail notice of receipt from eRA Commons and Grants.gov when HHS/CDC receives the application.

All requested information must be received in the HHS/CDC Procurement and Grants Office by 5:00 p.m. Eastern Standard Time on the deadline date. If an applicant submits materials by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery by the closing date and time. If HHS/CDC receives your

submission after closing because of : (1) carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you have the opportunity to submit documentation of the carrier's guarantee. If the documentation verifies a carrier problem, HHS/CDC will consider the submission as having been received by the deadline.

This announcement is the definitive guide on Letter Of Intent (LOI) and application content, submission address, and deadline. It supersedes information provided in the application instructions. If your application does not meet the deadline described in Section IV.3.A, it will not be eligible for review, and HHS/CDC will discard it. You will receive notification that you did not meet the submission requirements.

Otherwise, HHS/CDC will not notify you upon receipt of your paper submission. If you have a question about the receipt of your application, first contact your courier. If you still have a question, contact the PGO-TIMS staff at: 770-488-2700. Before calling, please wait two to three days after the submission deadline. This will allow time for HHS/CDC to process and log submissions.

Technical Information Management Section – DP10-004
CDC, Procurements and Grants Office
U.S. Department of Health and Human Services
2920 Brandywine Road
Atlanta, GA 30341
Phone: 770-488-2700 EST

3.C. Application Processing

Applications **may** be submitted on or after the opening date and **must** be successfully received and validated by Grants.gov no later than **11:59 p.m. eastern time of the closing date**. If an application is not submitted by the due date(s) and time, the application may be delayed in the review process or not reviewed.

Once an application package has been successfully submitted through Grants.gov, any errors have been addressed, and the assembled application has been created in the eRA Commons, the PD/PI and the Authorized Organization Representative/Signing Official (AOR/SO) have two weekdays (Monday – Friday, excluding Federal holidays) to view the application image to determine if any further action is necessary.

- If everything is acceptable, no further action is necessary. The application will automatically move forward for processing after two weekdays, excluding Federal holidays.
- Prior to the submission deadline, the AOR/SO can “Reject” the assembled application and submit a changed/corrected application within the two-day viewing window. This option should be used if it is determined that some part of the application was lost or did not transfer correctly during the submission

process, the AOR/SO will have the option to “Reject” the application and submit a Changed/Corrected application. In these cases, please contact the eRA Help Desk to ensure that the issues are addressed and corrected. Once rejected, applicants should follow the instructions for correcting errors in Section 2.12, including the requirement for cover letters on late applications. The “Reject” feature should also be used if you determine that warnings are applicable to your application and need to be addressed now. Remember, warnings do not stop further application processing. If an application submission results in warnings (but no errors), it will automatically move forward after two weekdays if no action is taken. Some warnings may need to be addressed later in the process.

- Both the AOR/SO and PD/PI will receive e-mail notifications when the application is rejected or the application automatically moves forward in the process after two weekdays.

Note: The application is not complete until it has passed the Grants.gov validation process. Applicants will receive a submission receipt email followed by an email from Grants.gov confirming that the application package passed the validation process or was rejected due to errors. Validation takes two (2) calendar days; however, applicants may check the status of the application to ensure submission is complete. To guarantee that compliance with the Funding Opportunity Announcement, allocate additional time to the submission process. Applications that have not passed the validation process within 48 hours of the submission deadline may not be accepted. If no validation e-mail from Grants.gov is received within two (2) calendar days of submission, you may contact Grants.gov. Please refer to the Grants.gov email message generated at the time of application submission for instructions on how to track your application or the [Application User Guide](#).

Upon receipt, applications will be evaluated for completeness and responsiveness by the CDC Procurements and Grants Office and the CIO. Incomplete and non-responsive applications will not be reviewed.

There will be an acknowledgement of receipt of applications from Grants.gov and the [Commons](https://commons.era.nih.gov/commons/). The submitting AOR/SO receives the Grants.gov acknowledgments. The AOR/SO and the PI receive Commons acknowledgments. Information related to the assignment of an application to a Scientific Review Group is also in the Commons.

Note: Since email can be unreliable, it is the responsibility of the applicant to check periodically on the application status in the Commons.

4. Intergovernmental Review

Executive Order 12372 does not apply to this program.

5. Funding Restrictions

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

Restrictions, which applicants must take into account while writing their budgets, are as follows:

- Funds relating to the conduct of research will be restricted until the appropriate assurances and Institutional Review Board approvals are in place.
- Reimbursement of pre-award costs is not allowed.
- Funds may be used to support travel to TRC Network Committee and other CDC-sponsored meetings each year.
- These funds do not support equipment purchases or direct services.

6. Other Submission Requirements

The research plan should include:

- **Analysis of Vision Health Challenges and Opportunities.** The applicant should include an analysis of vision health challenges that the United States is facing, and public health opportunities that exist that can prevent vision impairment and blindness, and promote eye health, with a special focus on high risk and underserved populations.
- **Proposed TRC-specific Studies.** The applicant should describe at least three (3) proposed TRC-specific studies that address existing public health challenges and opportunities to promote eye health and prevent vision impairment and blindness, with special emphasis given to at-risk and underserved populations. Each should describe:
 1. Objectives and how they related to the vision health challenges and opportunities of the United States.
 2. Potential value of the analysis for policy, health and related systems changes, provider practice changes, community changes, and patient/family behavioral changes related to promoting eye health and preventing vision impairment and blindness for high risk, underserved populations.
 3. Subjects included in the study, with special emphasis on underserved and at-risk populations.
 4. Eye care, policy, systems, and community settings.
 5. Hypotheses that will be tested.
 6. Sources of data, and the applicant's access to these:
 - **Describe the proposed clinical and administrative data sources (datasets and/or data systems) that the research team will use.**
 - **Provide evidence that these data sources are operational and provide service to a minimum of 2,000 active patients annually with age-related eye diseases (i.e., age-related macular-degeneration, cataract, diabetic retinopathy, or open-angle glaucoma.)**
 - **Provide evidence of experience using these datasets and/or data systems.**

making presentations at professional and scientific conferences; (d) his/her commitment to serve on the TRC Network Committee (the governing body of the network), including participating in at least two face-to-face meetings and four or more televideo conferences per year; and (e) the percentage of time allocated by the PI to this research and translation program.

For each proposed co-investigators and other members of the research team, the applicant should (a) describe the person's expertise; (b) provide evidence of their contributions to relevant complex studies, including their publications in peer-reviewed journals and presentations made at professional and scientific conferences; and (c) specify the percentage of time that will be committed to this research and translation program.

- **Management Plan.** The applicant's management plan should specify (a) the role to be played by the principal investigator in the Translating Research into Healthy Eye and Vision Loss Prevention research program (proposed TRC-specific studies and collaborative TRC network study); (b) the roles of the co-investigators and other members of the research team in the proposed TRC-specific studies and collaborative TRC network study. This should be reflected in an organization chart.

The management plan should also specify who and how quality oversight and supervision will be provided for the research team.

If a position is yet to be filled, provide a position description in the appendix. Include the percentage of time each will devote to the project.

A timeline for all TRC-specific study activities and outcomes should be provided. The timeline should also specify the contributions of individuals to each activity.

- **Detailed Budget and Line-item Justification.** A detailed budget and line-item justification for the first year that is consistent with the stated objectives. Applicants are asked to include travel for the Principal Investigator to attend one face-to-face meeting per year of the TRC Network Committee. For peer and secondary review purposes, the program narrative must be separate from the budget justification and budget summaries.
- **Letters of Support from Partner Organizations.** A letter of support from partner organizations, if applicable, should be provided. Letters should (a) describe prior collaborations with the applicant organization; (b) specify the contributions that the partner organization is committed to making to the proposed research; and (c) commit to adhering to decisions of the TRC Network Committee.

Applicants' research plan(s) should address activities they will conduct over the entire project period.

The proposal shall not exceed 25 pages. Supporting materials may be attached and shall show evidence of the applicant's ability to successfully conduct the proposed project and other evidence deemed necessary to support the contents of the proposal. The attachments may not exceed 20 pages.

Awardees upon acceptance of Notice of Award (NoA), must agree to the "Cooperative Agreement Terms and Conditions of Award" in Section VI. "Award Administration Information".

If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement should be less than 12 months of age. If submitting electronically, use a PDF version of the agreement, attach it in Grants.gov under "Other Attachments", and title it appropriately.

Applicants' research plan(s) should address activities they will conduct over the entire project period.

Required.

The HHS/CDC requires the PD/PI to fill in his/her eRA Commons User ID in the "PROFILE – Project Director/Principal Investigator" section, "Credential" log-in field of the "Research & Related Senior/Key Person Profile" component. The applicant organization must include its DUNS number in its Organization Profile in the eRA Commons. This DUNS number must match the DUNS number provided at CCR registration with Grants.gov. For additional information, see Registration FAQs – Important Tips -- [Electronic Submission of Grant Applications](#).

Research Plan Component Sections

While each section of the Research Plan component needs to be uploaded separately as a PDF attachment, applicants are encouraged to construct the Research Plan component as a single document, separating sections into distinct PDF attachments just before uploading the files. This approach will enable applicants to better monitor formatting requirements such as page limits. All attachments must be provided to HHS/CDC in PDF format, filenames must be included with no spaces or special characters, and a PDF extension must be used. Do not include any information in a header or footer of the attachments. A header will be system-generated that references the PD/PI. Page numbers for the footer will be system-generated in the complete application, with all pages sequentially numbered; therefore, do not number the pages of your attachments. **Your research plan must not exceed 25 pages. The 25 pages of the research plan should include the Plan for Sharing Research Data and the Sharing Research Resources sections. The detailed**

budget and line-item justification are not included in the 25 page limit for the research plan. If your research plan exceeds the page limitation, your application may be considered unresponsive and ineligible for review.

The following materials may be included in the Appendix: **Appendices (attachments) should be limited to 20 pages. The following materials may be included in Appendix/Attachments: curriculum vitae of members of the proposed research team, an organization chart, a timeline, a project plan flowchart, letters of commitment or support,** publications, manuscripts (accepted for publication), abstracts, patents, or other printed materials directly relevant to the proposed project. Do not include manuscripts submitted for publication.

Applicants should refer to Publications in press: Include only a publication list with a link to the publicly available on-line journal article or the NIH Pub Med Central (PMC) submission identification number. Do not include the entire article.

- Manuscripts accepted for publication but not yet published: The entire article may be submitted electronically as a PDF attachment.
- Manuscripts published but a publicly available online journal link is not available: The entire article may be submitted electronically as a PDF attachment.
- Surveys, questionnaires, data collection instruments, clinical protocols, and informed consent documents.

Do not to use the Appendix to circumvent the page limitations of the Research Plan component. An application that does not observe the relevant policies and procedures may not be considered in the review process. Applicants are reminded to review specific FOAs for any additional program-specific guidance on Appendix material and other application requirements.

Plan for Sharing Research Data

The precise content of the data-sharing plan will vary, depending on the data being collected and how the investigator is planning to share the data. Applicants should describe briefly the expected schedule for data sharing, the format of the final dataset, the documentation they will provide, whether or not any analytic tools also will be provided, whether or not a data-sharing agreement will be required and, if so, a brief description of such an agreement (including the criteria for deciding who can receive the data and whether or not the awardee will place any conditions on their use), and the mode of data sharing (e.g., under their own auspices by mailing a disk or posting data on their institutional or personal website, through a data archive or enclave). References to data sharing may also be appropriate in other sections of the application.

All applicants must include a plan for sharing research data in their application. The HHS/CDC data sharing policy is available at <http://www.cdc.gov/od/pgo/funding/ARs.htm> under Additional Requirements 25 Release and Sharing of Data. All investigators responding to this funding opportunity should include a description of how final research data will be shared, or explain why data sharing is not possible.

The reasonableness of the data sharing plan or the rationale for not sharing research data will be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score.

Sharing Research Resources

HHS policy requires that grant award recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication (see the HHS Grants Policy Statement http://www.hhs.gov/grantsnet/docs/HHSGPS_107.doc.) Investigators responding to this funding opportunity should include a plan for sharing research resources addressing how unique research resources will be shared or explain why sharing is not possible.

The adequacy of the resources sharing plan and any related data sharing plans will be considered by the HHS/CDC Program staff of the funding organization when making recommendations about funding applications. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report (PHS 2590, <http://grants.nih.gov/grants/funding/2590/2590.htm>). See [Section VI.3. Reporting](#).

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

2. Review and Selection Process

Applications that are complete and responsive to this FOA will be evaluated for scientific and technical merit by an appropriate peer review group convened by **CCHP/ERPO** and in accordance with HHS peer review procedures (<http://grants1.nih.gov/grants/peer/>), using the review criteria stated below.

As part of the scientific peer review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific and technical merit, generally the top half of applications under review, will be discussed and assigned an impact/ priority score;
- Receive a written critique; and
- Receive a second level of review by **HHS/CDC/CCHP**.

Applications submitted in response to this FOA will compete for available funds with all other recommended applications submitted in response to this FOA. The following will be considered in making funding decisions:

- Scientific merit of the proposed project as determined by peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- **Diverse geographic regions.**
- **Focus on the coverage and utilization of preventive eye care by at-risk and underserved racial/ethnic populations.**

The mission of HHS/CDC is to promote health and quality of life by preventing and controlling disease, injury, and disability. As part of this mission, applications submitted to the HHS/CDC for grants or cooperative agreements to public health research are evaluated for scientific and technical merit through the HHS/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 five core review criteria, and additional review criteria (as applicable for the project proposed).

Core Review Criteria. Reviewers will consider each of the five review criteria below in the determination of scientific and technical 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?

Center-specific research project

Does the applicant address the research objectives stated in the FOA?

Is there a convincing rationale based on theory, conceptual models, or data presented in the application that suggests that the policy or intervention focus of the study will plausibly lead to important change in care, individual and systems behaviors, and outcomes?

If the applicant achieves the aims of the application, how will it advance scientific knowledge or clinical practice and behavioral changes? What will be the effect of these studies on the concepts, methods, technologies, treatments, or preventative interventions that drive this field?

Do the proposed studies address policy and system-level interventions that may be applied to broad segments of the population and are they potentially generalizable to diverse settings?

Collaborative multi-center research project

Does the applicant provide a well substantiated rationale for a multi-center research study that addresses important policy changes or systems-changes that are likely to be effective in preventing diabetes and its complications for a significant segment of the U.S. population?

Investigator(s). Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, 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 application identify who will conduct the proposed studies? For co-investigators, does the application provide clear evidence of ability to carry out complex studies and developing scientific articles for peer-reviewed journals?

Does the application show that investigators will have a sufficient amount of dedicated time to conduct the needed analyses and prepare manuscripts?

Does the application demonstrate broad and multidisciplinary public health, clinical, and vision health research capacity?

Does the proposed research team have demonstrate knowledge and experience with the clinical, epidemiological, statistical, and health services research aspects of age-related eye disease studies?

Do the proposed members of the research team have extensive experience in research collaboration with other institutions and information sharing?

Do the proposed members of the research team demonstrate a strong record of publication in peer-reviewed journals?

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 elucidate how proposed studies might lead to the design of practical interventions?

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?

Has the applicant described the specific rationale for proposed TRC-specific and collaborative TRC network studies based on previous literature, significance, relevance, and potential impact of the studies on health policy and the eye health of the population?

Does the applicant provide evidence of continuous access and use of clinical and administrative data sources (datasets and/or data systems) that are operational and provide service to a minimum of 2,000 active patients annually with age-related eye diseases (i.e., age-related macular-degeneration, cataract, diabetic retinopathy, or open-angle glaucoma)?

If the project involves research involving human subjects or a clinical investigation, are the 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?

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?

Do the proposed clinical, administrative, and public health data systems and/or datasets represent large numbers of persons from racial or ethnic minorities with age-related eye diseases?

Additional Review Criteria. As applicable for the project proposed, reviewers will consider **the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items.**

Protections for Human Subjects. The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed. See the "Human Subjects Sections" of the PHS398 Research Plan component of the SF424 (R&R).

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. Additional HHS/CDC Requirements under AR-1 Human Subjects Requirements are available on the Internet at the following address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

Inclusion of Women, Minorities, and Children. When the proposed project involves human subjects research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. Please see <http://www.cdc.gov/OD/foia/policies/inclusio.htm> for more information.

Does the application adequately address the HHS/CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research? This includes: (1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation; (2) The proposed justification when representation is limited or absent; (3) A statement as to whether the design of the study is adequate to measure differences when warranted; and (4) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits (see Section 2, item 9 Inclusion of Women and Minorities of the Research Plan component of the SF424 (R&R)).

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.

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.

Additional Review Considerations. As applicable for the project proposed, reviewers will address 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.

Budget and Period Support. Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

Select Agent Research. Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource and Data Sharing Plans. HHS/CDC policy requires that recipients of grant awards make unique 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/foia/policies/sharing.htm>. Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

Program staff will be responsible for the administrative review of the plan for sharing research resources and data.

The adequacy of the resources and data sharing plan will be considered by Program staff of the funding organization when making recommendations about funding applications. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report (HHS/PHS 2590 <http://grants.nih.gov/grants/funding/2590/2590.htm>). See Section VI.3. Reporting.

Section VI. Award Administration Information

1. Award Notices

After the peer review of the application is completed, the applicant organization will receive a written critique called a "Summary Statement." The applicant organization and the PD/PI will be able to access the Summary Statement via the eRA Commons.

HHS/CDC will contact those applicants under consideration for funding for additional information.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization. The NoA signed by the Grants Management Officer (GMO) is the authorizing document. HHS/CDC will mail and/or e-mail this document to the recipient fiscal officer identified in the application.

Selection of the application for award is not an authorization to begin performance. Any cost incurred before receipt of the NoA is at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs. See also Section IV.5. Funding Restrictions.

2. Administrative and National Policy Requirements

The Code of Federal Regulations 45 CFR Part 74 and Part 92 have details about requirements. For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>. Additional requirements are available Section VIII. Other Information of this document or on the HHS/CDC website at the following Internet address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>. These will be incorporated into the NoA by reference.

The following terms and conditions will be incorporated into the NoA and will be provided to the appropriate institutional official and a courteous copy to the PD/PI at the time of award.

2.A. Cooperative Agreement

Add Sections 2.A. and 2.A.1 through 2.A.3, only if the announcement contains a cooperative agreement assistance instrument.

The following terms of award are in addition to, and not in lieu of, otherwise applicable Office of Management and Budget (OMB) administrative guidelines, HHS 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/CDC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement U58 an "assistance" instrument (rather than an "acquisition" instrument), in which substantial HHS/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; it is 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 the HHS/CDC may share specific tasks and activities, as defined above.

2.A.1. Recipient Rights and Responsibilities

The Recipient will have the primary responsibility for the following:

1. Designing and conducting research to address the described research objectives of this cooperative agreement.
2. Establishing goals and objectives that are realistic, measurable, and time-oriented for the project.
3. Submittal for approval to local Institutional Review Board (s) (IRB).
4. Participating in regular TRC Network Committee and subcommittee meetings as scheduled by the TRC Network Committee.
5. Conducting studies and disseminating findings in peer-reviewed journals, presentations at professional and scientific conferences and other meetings, as appropriate, and contributing scientific findings to appropriate Web sites or other channels for sharing findings.
6. Make use of local analytic support, TRC-specific and shared datasets, including administrative datasets.
7. The Principal Investigator shall attend up to two in-person and four or more televideo conference calls each year, as scheduled by the Committee and in consultation with CDC.
8. Ensure adequate staffing, oversight, and mentoring in support of the TRC research team and its activities.

Recipient Organization will retain custody of and have primary rights to the information, data and software developed under this award, subject to U.S. Government rights of access consistent with current HHS/CDC policies.

2.A.2. HHS/CDC Responsibilities

An HHS/CDC Project Scientist will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

An HHS/CDC Project Scientist will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

1. CDC project scientist will provide consultation and collaborate and provide assistance with the design of studies, analytic strategies, statistical methods, analyses, and the interpretation of data and findings from clinical, administrative, public health, and other datasets or systems.
2. Provide scientific and programmatic oversight.

Collaborate with the recipient as co-authors to produce technical reports or manuscripts for peer-reviewed publications, as appropriate.

3. Provide assistance for joint analyses with aggregate data.
4. Serve as members and consultants on the TRC Network Committee and subcommittees.
5. Monitor the progress of the study and assist with the planning.
6. Conduct site visits as deemed necessary.
7. Participate in Network Committee and subcommittee meetings.
8. Ensure that the provisions of the Federal Advisory Committee Act (FACA) are adhered to with respect to the composition and functioning of the Network Committee.

The CDC ERPO/NCCDPHP will appoint a Scientific Program Official (SPO) who will:

1. Serve as the Program Official for the funded site.
2. Carry out continuous review of all activities to ensure objectives are being met.
3. Attend committee meetings and participate in conference calls for the purposes of assessing overall progress and for program evaluation purposes.

4. Provide scientific consultation and technical assistance in the conduct of the project as requested.
5. Conduct site visits to determine the adequacy of the research.
6. Monitor performance against approved project objectives.

2.A.3. Collaborative Responsibilities

The TRC Network Committee will be made up of a Principal Investigator from each of the three (3) TRCs and the HHS/CDC Project Scientist and Project Administrator. This Committee will collaboratively establish research, publication, and presentation priorities; come to a working consensus on common indicators/data elements and methods; and establish policies and procedures that govern the research and translation work of the TRC network.

Each full member will have one vote. The HHS/CDC will have only one vote. Awardees or members of the TRC Network Committee will be required to accept and implement policies approved by the TRC Network Committee.

Additionally, an HHS/CDC 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 NoA.

3. Reporting

Recipient Organization must provide HHS/CDC with an original, plus two hard copies of the following reports:

1. 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>, no less than 120 days prior to the end of the current budget period. The progress (interim) report will serve as the non-competing continuation application.
2. Financial status report, no more than 90 days after the end of the budget period.
3. Final financial and performance reports, no more than 90 days after the end of the project period.

Recipient Organization must forward these reports by the U.S. Postal Service or express delivery to the Grants Management Specialist listed in the "Agency Contacts" section of this FOA.

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.

Section VII. Agency Contacts

HHS/CDC encourages your inquiries concerning this FOA and welcomes the opportunity to answer questions from potential applicants. Inquiries can fall into three areas: scientific/research, peer review, and financial or grants management issues:

1. Scientific/Research Contacts:

Michael Dalmat, Dr.P.H.
Extramural Research Program Office
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention (CDC)
U.S. Department of Health and Human Services
Koger Center – Davidson Building, Room 1098
2858 Woodcock Boulevard
Atlanta, GA 30341 MS K-92
Telephone: (770) 488-6423
Fax: (770) 488-8046
Email: MDalmat@cdc.gov

2. Peer Review Contacts:

Extramural Research Program Office
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention (CDC)
U.S. Department of Health and Human Services
Koger Center – Davidson Building, Room 1098
2858 Woodcock Boulevard
Atlanta, GA 30341 MS K-92
Telephone: (770) 488-8390
Fax: (770) 488-8046
Email: ERO@cdc.gov

3. Financial or Grants Management Contacts:

Use minimum information necessary in all addresses.
FAX Number is optional, Email address is required.

Lucy Picciolo
Procurement and Grants Office
Center for Disease Control and Prevention
U.S. Department of Health and Human Services
Koger Center, Colgate Building, Room 3731
2929 Brandywine Road

MS-E09
Atlanta, GA 30341-4146
Telephone: (770) 488-2683
Fax: (770) 488-2777
Email: lip6@cdc.gov

4. General Questions Contacts:

Technical Information Management Section
CDC Procurement and Grants Office
U.S. Department of Health and Human Services
2920 Brandywine Road
Atlanta, GA 30341
Telephone: 770-488-2700
Email: PGOTIM@cdc.gov

Section VIII. Other Information

Required Federal Citations

Human Subjects Protection

Federal regulations (45 CFR Part 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained

(<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>).

Additional HHS/CDC Requirements under AR-1 Human Subjects Requirements can be found on the Internet at the following address:

<http://www.cdc.gov/od/pgo/funding/ARs.htm>.

Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian or Other Pacific Islander. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity, and/or sex of subjects. Further guidance to this policy is contained in the Federal

Register, Vol. 60, No. 179, pages 47947-47951, and dated Friday, September 15, 1995.

INCLUSION OF PERSONS UNDER THE AGE OF 21 IN RESEARCH

The policy of CDC is that persons under the age of 21 must be included in all human subjects research that is conducted or supported by CDC, unless there are scientific and ethical reasons not to include them. This policy applies to all CDC-conducted or CDC-supported research involving human subjects, including research that is otherwise exempt in accordance with Sections 101(b) and 401(b) of 45 C.F.R. Part 46, HHS Policy for the Protection of Human Subjects. Therefore, proposals for research involving human subjects must include a description of plans for including persons under the age of 21. If persons under the age of 21 will be excluded from the research, the application or proposal must present an acceptable justification for the exclusion.

In an extramural research plan, the investigator should create a section titled "Participation of persons under the age of 21." This section should provide either a description of the plans to include persons under the age of 21 and a rationale for selecting or excluding a specific age range, or an explanation of the reason(s) for excluding persons under the age of 21 as participants in the research. When persons under the age of 21 are included, the plan must also include a description of the expertise of the investigative team for dealing with individuals at the ages included, the appropriateness of the available facilities to accommodate the included age groups, and the inclusion of a sufficient number of persons under the age of 21 to contribute to a meaningful analysis relative to the purpose of the study. Scientific review groups at CDC will assess each application as being acceptable or unacceptable in regard to the age-appropriate inclusion or exclusion of persons under the age of 21 in the research project, in addition to evaluating the plans for conducting the research in accordance with these provisions.

The inclusion of children (as defined by the applicable law of the jurisdiction in which the research will be conducted) as subjects in research must be in compliance with all applicable subparts of 45 C.F.R. Part 46, as well as with other pertinent federal laws and regulations.

The policy of inclusion of persons under the age of 21 in CDC-conducted or CDC-supported research activities in foreign countries (including collaborative activities) is the same as that for research conducted in the United States.

HIV/AIDS Confidentiality Provisions

Recipients must have confidentiality and security provisions to protect data collected through HIV/AIDS surveillance, including copies of local data release policies; employee training in confidentiality provisions; State laws, rules, or regulations pertaining to the protection or release of surveillance information; and physical security of hard copies and electronic files containing confidential surveillance information.

Describe laws, rules, regulations, or health department policies that require or permit the release of patient-identifying information collected under the HIV/AIDS surveillance system to entities outside the public health department; describe also the measures the health department has taken to ensure that persons reported to the surveillance system are protected from further or unlawful disclosure.

Some projects may require Institutional Review Board (IRB) approval or a certificate of confidentiality.

HIV Program Review Panel Requirements

Compliance with Content of AIDS-Related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions (June 1992) is required.

To meet the requirements for a program review panel, you are encouraged to use an existing program review panel, such as the one created by the State health department's HIV/AIDS prevention program. If you form your own program review panel, at least one member must be an employee (or a designated representative) of a State or local health department. List the names of the review panel members on the Assurance of Compliance form, CDC 0.1113. Submit the program review panel's report that all materials have been approved.

If the proposed project involves hosting a conference, submit the program review panel's report stating that all materials, including the proposed conference agenda, have been approved. Submit a copy of the proposed agenda with the application.

Before funds are used to develop educational materials, determine whether suitable materials already exist in the CDC National Prevention Information Network (NPIN). The website can be found at;
<http://www.nchstp.cdc.gov/od/infocenter/npin.htm>.

Executive Order 12372 Review

Applications are subject to Intergovernmental Review of Federal Programs, as governed by Executive Order (E.O.) 12372. The order sets up a system for State and local governmental review of proposed Federal assistance applications. Applicants should contact their State single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications and to receive instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC for each State affected.

Click on the following link to get the current SPOC list

<http://www.whitehouse.gov/omb/grants/spoc.html>

Indian tribes must request tribal government review of their applications.

Specs or tribal governments that have recommendations about an application submitted to HHS/CDC should send them, in a document bearing the program announcement number, no more than 60 days after the application deadline date, to:

Add GMS Name Here, Grants Management Specialist
Procurement and Grants Office
Announcement Number Add RFA Number Here
Centers for Disease Control and Prevention (CDC)
2920 Brandywine Road
Atlanta, Georgia 30341-4146

HHS/CDC does not guarantee to accept or justify its non-acceptance of recommendations that are received more than 60 days after the application deadline.

Public Health System Reporting Requirements

This program is subject to the Public Health System Reporting Requirements. Under these requirements, all community-based non-governmental organizations submitting health services applications must prepare and submit the items identified below to the head of the appropriate State and/or local health agency(s) in the program area(s) that may be impacted by the proposed project no later than the application deadline date of the Federal application. The appropriate State and/or local health agency is determined by the applicant. The following information must be provided:

- A. A copy of the face page of the application (SF 424).
- B. A summary of the project that should be titled "Public Health System Impact Statement" (PHSIS), not exceed one page, and include the following:
 - 1. A description of the population to be served.
 - 2. A summary of the services to be provided.
 - 3. A description of the coordination plans with the appropriate state and/or local health agencies.

If the State and/or local health official should desire a copy of the entire application, it may be obtained from the State Single Point of Contact (SPOC) or directly from the applicant.

Paperwork Reduction Act Requirements

Under the Paperwork Reduction Act, projects that involve the collection of information from 10 or more individuals and funded by a grant or a cooperative agreement will be subject to review and approval by the Office of Management and Budget (OMB).

Smoke-Free Workplace Requirements

HHS/CDC strongly encourages all recipients to provide a smoke-free workplace and to promote abstinence from all tobacco products. Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, or early childhood development services are provided to children.

Healthy People 2010

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This FOA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at www.healthypeople.gov

Lobbying Restrictions

Applicants should be aware of restrictions on the use of HHS funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352, recipients (and their sub-tier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition no part of HHS/CDC appropriated funds, shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State or local legislature, except in presentation to the Congress or any State or local legislature itself. No part of the appropriated funds shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State or local legislature.

Any activity designed to influence action in regard to a particular piece of pending legislation would be considered "lobbying." That is lobbying for or against pending legislation, as well as indirect or "grass roots" lobbying efforts by award recipients that are directed at inducing members of the public to contact their elected representatives at the Federal or State levels to urge support of, or opposition to, pending legislative proposals is prohibited. As a matter of policy, HHS/CDC extends the prohibitions to lobbying with respect to local legislation and local legislative bodies.

The provisions are not intended to prohibit all interaction with the legislative branch, or to prohibit educational efforts pertaining to public health. Clearly there are circumstances when it is advisable and permissible to provide information to the legislative branch in order to foster implementation of

prevention strategies to promote public health. However, it would not be permissible to influence, directly or indirectly, a specific piece of pending legislation

It remains permissible to use HHS/CDC funds to engage in activity to enhance prevention; collect and analyze data; publish and disseminate results of research and surveillance data; implement prevention strategies; conduct community outreach services; provide leadership and training, and foster safe and healthful environments.

Recipients of HHS/CDC grants and cooperative agreements need to be careful to prevent CDC funds from being used to influence or promote pending legislation. With respect to conferences, public events, publications, and "grassroots" activities that relate to specific legislation, recipients of HHS/CDC funds should give close attention to isolating and separating the appropriate use of HHS/CDC funds from non-CDC funds. HHS/CDC also cautions recipients of HHS/CDC funds to be careful not to give the appearance that HHS/CDC funds are being used to carry out activities in a manner that is prohibited under Federal law.

Prohibition on Use of HHS/CDC Funds for Certain Gun Control Activities

The Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act specifies that: "None of the funds made available for injury prevention and control at the Centers for Disease Control and Prevention may be used to advocate or promote gun control."

Anti-Lobbying Act requirements prohibit lobbying Congress with appropriated Federal monies. Specifically, this Act prohibits the use of Federal funds for direct or indirect communications intended or designed to influence a member of Congress with regard to specific Federal legislation. This prohibition includes the funding and assistance of public grassroots campaigns intended or designed to influence members of Congress with regard to specific legislation or appropriation by Congress.

In addition to the restrictions in the Anti-Lobbying Act, HHS/CDC interprets the language in the HHS/CDC's Appropriations Act to mean that HHS/CDC's funds may not be spent on political action or other activities designed to affect the passage of specific Federal, State, or local legislation intended to restrict or control the purchase or use of firearms.

Accounting System Requirements

The services of a certified public accountant licensed by the State Board of Accountancy or the equivalent must be retained throughout the project as a part of the recipient's staff or as a consultant to the recipient's accounting personnel. These services may include the design, implementation, and maintenance of an accounting system that will record receipts and

expenditures of Federal funds in accordance with accounting principles, Federal regulations, and terms of the cooperative agreement or grant.

Capability Assessment

It may be necessary to conduct an on-site evaluation of some applicant organization's financial management capabilities prior to or immediately following the award of the grant or cooperative agreement. Independent audit statements from a Certified Public Accountant (CPA) for the preceding two fiscal years may also be required.

Proof of Non-profit Status

Proof of nonprofit status must be submitted by private nonprofit organizations with the application. Any of the following is acceptable evidence of nonprofit status: (a) a reference to the applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in section 501(c)(3) of the IRS Code; (b) a copy of a currently valid IRS tax exemption certificate; (c) a statement from a State taxing body, State Attorney General, or other appropriate State Official certifying that the applicant organization has a nonprofit status and that none of the net earnings accrue to any private shareholders or individuals; (d) a certified copy of the organization's certificate of incorporation or similar document that clearly establishes nonprofit status; (e) any of the above proof for a State or national parent organization and a statement signed by the parent organization that the applicant organization is a local nonprofit affiliate.

Security Clearance Requirement

All individuals who will be performing work under a grant or cooperative agreement in a HHS/CDC-owned or leased facility (on-site facility) must receive a favorable security clearance, and meet all security requirements. This means that all awardees employees, fellows, visiting researchers, interns, etc., no matter the duration of their stay at HHS/CDC must undergo a security clearance process.

Third Party Agreements – HHS/ATSDR

Applicant must justify the need to use a contractor. If contractors are proposed, the following must be provided: (1) name of contractor, (2) method of selection, (3) period of performance, (4) detailed budget, (5) justification for use of contractor, and (6) assurance of non-conflict of interest.

Project activities which are approved for contracting pursuant to the prior approval provisions shall be formalized in a written agreement that clearly establishes the relationship between the recipient and the third party.

The written agreement shall, at a minimum:

1. State or incorporate by reference all applicable requirements imposed on the contractors under the terms of the grant and/or cooperative agreement, including requirements concerning technical review (ATSDR selected reviewers), ownership of data, and the arrangement for copyright when publications, data, or other copyrightable works are developed under or in the course of work under a PHS grant-supported project or activity.
2. State that any copyrighted or copyrightable works shall be subject to a royalty-free, nonexclusive, and irrevocable license

to the government to reproduce, publish, or otherwise use them, and to authorize others to do so for Federal government purposes.

3. State that whenever any work subject to this copyright policy may be developed in the course of a grant by a contractor under a grant, the written agreement (contract) must require the contractor to comply with these requirements and can in no way diminish the government's right in that work.

4. State the activities to be performed, the time schedule for those activities, the policies and procedures to be followed in carrying out the agreement, and the maximum amount of money for which the grantee may become liable to the third party under the agreement.

5. State non-conflict of interest concerning activities conducted for HHS/ATSDR and site-remediation activities for other parties.

The written agreement required shall not relieve the recipient of any part of its responsibility or accountability to PHS under the cooperative agreement. The agreement shall, therefore, retain sufficient rights and control to the recipient to enable it to fulfill this responsibility and accountability.

Small, Minority, And Women-owned Business

It is a national policy to place a fair share of purchases with small, minority and women-owned business firms. The Department of Health and Human Services is strongly committed to the objective of this policy and encourages all recipients of its grants and cooperative agreements to take affirmative steps to ensure such fairness. In particular, recipients should:

1. Place small, minority, women-owned business firms on bidders mailing lists.
2. Solicit these firms whenever they are potential sources of supplies, equipment, construction, or services.
3. Where feasible, divide total requirements into smaller needs, and set delivery schedules that will encourage participation by these firms.
4. Use the assistance of the Minority Business Development Agency of the Department of Commerce, the Office of Small and Disadvantaged Business Utilization, DHHS, and similar state and local offices.

Research Integrity

The signature of the institution official on the face page of the application submitted under this Funding Opportunity Announcement is certifying compliance with the Department of Health and Human Services (DHHS) regulations in Title 42 Part 93, Subparts A-E, entitled PUBLIC HEALTH SERVICE POLICIES ON RESEARCH MISCONDUCT.

The regulation places requirements on institutions receiving or applying for funds under the PHS Act that are monitored by the DHHS Office of Research Integrity (ORI) (<http://ori.hhs.gov./policies/statutes.shtml>).

For example:

Section 93.301 Institutional assurances. (a) General policy. An institution with PHS supported biomedical or behavioral research, research training or activities related to that research or research training must provide PHS with an assurance of compliance with this part, satisfactory to the Secretary. PHS funding components may authorize [[Page 28389]] funds for biomedical and behavioral research, research training, or activities related to that research or research training only to institutions that have approved assurances and required renewals on file with ORI. (b) Institutional Assurance. The responsible institutional official must assure on behalf of the institution that the institution-- (1) Has written policies and procedures in compliance with this part for inquiring into and investigating allegations of research misconduct; and (2) Complies with its own policies and procedures and the requirements of this part.

Compliance with Executive Order 13279

Faith-based organization are eligible to receive federal financial assistance, and their applications are evaluated in the same manner and using the same criteria as those for non-faith-based organizations in accordance with Executive Order 13279, Equal Protection of the Laws for Faith-Based and Community Organizations. All applicants should, however, be aware of restrictions on the use of direct financial assistance from the Department of Health and Human Services (DHHS) for inherently religious activities. Under the provisions of Title 45, Parts 74, 87, 92 and 96, organizations that receive direct financial assistance from DHHS under any DHHS program may not engage in inherently religious activities, such as worship, religious instruction, or proselytization as a part of the programs or services funded with direct financial assistance from DHHS. If an organization engages in such activities, it must offer them separately, in time or location, from the programs or services funded with direct DHHS assistance, and participation must be voluntary for the beneficiaries of the programs or services funded with such assistance. A religious organization that participates in the DHHS funded programs or services will retain its independence from Federal, State, and local governments, and may continue to carry out its mission, including the definition, practice, and expression of its religious beliefs, provided that it does not use direct financial assistance from DHHS to support inherently religious activities such as those activities described above. A faith-based organization may, however, use space in its facilities to provide programs or services funded with financial assistance from DHHS without removing religious art, icons, scriptures, or other religious symbols. In addition, a religious organization that receives financial assistance from DHHS retains its authority over its internal governance, and it may retain religious terms in its organization=s name, select its board members on a religious basis, and include religious references in its organization=s mission statements and

other governing documents in accordance with all program requirements, statutes, and other applicable requirements governing the conduct of DHHS funded activities. For further guidance on the use of DHHS direct financial assistance see Title 45, Code of Federal Regulations, Part 87, Equal Treatment for Faith-Based Organizations, and visit the internet site: <http://www.whitehouse.gov/government/fbci/>

Health Insurance Portability and Accountability Act Requirements

Recipients of this grant award should note that pursuant to the Standards for Privacy of Individually Identifiable Health Information promulgated under the Health Insurance Portability and Accountability Act (HIPAA) (45 CFR Parts 160 and 164) covered entities may disclose protected health information to public health authorities authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions. The definition of a public health authority includes a person or entity acting under a grant of authority from or contract with such public agency. HHS/CDC considers this project a public health activity consistent with the Standards for Privacy of Individually Identifiable Health Information and HHS/CDC will provide successful recipients a specific grant of public health authority for the purposes of this project.

Release and Sharing of Data

The Data Release Plan is the Grantee's assurance that the dissemination of any and all data collected under the HHS/CDC data sharing agreement will be released as follows:

- a. In a timely manner.
- b. Completely, and as accurately as possible.
- c. To facilitate the broader community.
- d. Developed in accordance with CDC policy on Releasing and Sharing Data.

April 16, 2003, <http://www.cdc.gov/od/foia/policies/sharing.htm>, and in full compliance with the 1996 Health Insurance Portability and Accountability Act (HIPAA), (where applicable), The Office of Management and Budget Circular A110, (2000) revised 2003, www.whitehouse.gov/omb/query.html?col=omb&qt=Releasing+and+Sharing+of+Data and Freedom of Information Act (FOIA) <http://www.cdc.gov/od/foia/index.htm>.

Applications must include a copy of the applicant's Data Release Plan. Applicants should provide HHS/CDC with appropriate documentation on the reliability of the data. Applications submitted without the required Plan may be ineligible for award. Award will be made when reviewing officials have approved an acceptable Plan. The successful applicant and the Program

Manager will determine the documentation format. HHS/CDC recommends data is released in the form closest to micro data and one that will preserve confidentiality.

Conference Disclaimer and Use of Logos

{Mandatory for all grants and cooperative agreements.}

Disclaimer: Where a conference is funded by a grant or cooperative agreement, a sub grant or a contract the recipient must include the following statement on conference materials, including promotional materials, agenda, and internet sites:

"Funding for this conference was made possible [in part] by [insert grant or cooperative agreement award number] from the Centers for Disease Control and Prevention(CDC) or the Agency for Toxic Substances and Disease Registry (ATSDR) . The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government."

Logos: Neither the HHS nor the CDC ("CDC" includes ATSDR) logo may be displayed if such display would cause confusion as to the source of the conference or give the false appearance of Government endorsement. A non-federal entity's unauthorized use of the HHS name or logo is governed by U.S.C. § 1320b-10, which prohibits the misuse of the HHS name and emblem in written communication. The appropriate use of the HHS logo is subject to the review and approval of the Office of the Assistant Secretary for Public Affairs (OASPA). Moreover, the Office of the Inspector General has authority to impose civil monetary penalties for violations (42 C.F.R. Part 1003). Neither the HHS nor the CDC logo can be used on conference materials under a grant, cooperative agreement, contract or co-sponsorship agreement without the expressed, written consent of either the Project Officer or the Grants Management Officer. It is the responsibility of the grantee (or recipient of funds under a cooperative agreement) to request consent for the use of the logo in sufficient detail to assure a complete depiction and disclosure of all uses of the Government logos, and to assure that in all cases of the use of Government logos, the written consent of either the Project Officer or the Grants Management Officer has been received.

Appendix A: Questions from Potential Applicants and Responses

Questions from Potential Applicants	CDC Responses
Is the focus of this FOA on children and adults, or just adults?	The focus of this FOA is on the prevention of vision loss and promotion of eye health among adults ages 40 and older.
1. From reading the RFA, our understanding is that the data sources referred to on p. 20, under #6, must not simply be historical data sets (i.e., covering some period in the past only), but rather, must be data sets that are "live" -- meaning that patients are being added and followed (as applicable) over time. Is our reading correct?	Yes.
2. In order to study "individual-level factors" which is referred to repeatedly in the RFA, it appears that de-identified (in the HIPAA sense) data sets will not be sufficient. So it seems that data sets for the purpose of studying individual-level factors must have patient identifiers. Is our reading correct?	Yes
3. It appears that in proposing a potential TRC Network Study (requirement of application), the data source would have to be available to all TRCs, correct? Yet the TRCs won't be identified until later and thus are unknown to the applicants now, for obvious logical reasons. For many relevant research questions, it seems that it would be difficult, if not impossible, to know several relevant items ahead of time. TRCs are likely to be located in different geographic parts of the country. For example, different geographic regions (e.g., states) or different types of eye care entities have varying access to	A TRC Network Study will likely be initiated in the second year of the 5-year Project Period. The potential applicant only needs to propose something conceptually as part of their application. Details will be worked out during the first year, in time for TRC Network members to include costs in their continuation application for the second year of funding.

<p>databases for legal and practical reasons, and also, even if accessible, the data elements in these databases could vary widely. For this application, is the idea to propose something that appears to be conceptually possible, and then the above types of details will be worked out once the TRC sites are named? Any clarification on this part of the application would be very helpful to us as we move ahead.</p>	
<p>4. Is it permissible to collect new data or do all of the proposed studies have to rely upon existing data sources?</p>	<p>Collecting or adding new data to the existing system is fine and sometimes necessary. However, the funding is not for a new clinical trial or building a new data system from the beginning.</p>
<p>5. If an existing data source is used, can that be used to then add novel data to the data source? For example, many administrative data sources will allow you to identify glaucoma, cataract, etc. pts. but these data sources won't have information on, for example, whether a pt. has a hard time accessing eye care. The same could be said for eye care providers. One could use Medicare/Medicaid data to identify them but this data source would not provide information on their practices or knowledge.</p>	<p>Yes</p>
<p>6. Can we use the PHS398 new biosketch form with personal statement that is in MS Word and save this on our own computers and upload in PDF? We have submitted several other Dept of Defense grants using Grants.gov and these do not allow you to save the biosketch form, just scan and upload. I understand Biosketch and research support should be submitted separately. Does the biosketches and other support count towards the attachment page limit of less than 20.</p>	<p>Follow the instructions precisely in the RFA. The biosketches can be included in the Appendix as attachments, and not count toward the 25 page limit for the research plan.</p>

<p>7. Regarding the 3 page limit that is suggested for the Research Plan(s) on page 24 (second paragraph of the RFA), Is that a total of only 3 pages for the 3 TRC-specific studies and the TRC Network study or can we use 3 pages for each study and another 3 pages for the network study? This seems like a very small amount of space to devote to the main content of the grant.</p>	<p>You may submit up to 25 pages for the research plan that focuses on the TRC-specific studies and discusses in conceptual terms the TRC Network Study that you propose can be explained in general terms--once the Network Collaborators agree on the study to be jointly implemented in year two, the methods, etc. will be worked out. The TRC Network Study will likely begin in the second year.</p>
<p>8. How many pages would you suggest for each of the sections below that this grant requests depending on your answer to #2 to total the 25 page limit? In the past, Aims was 2 pages, Background was 3 pages, Prelim studies was 10, and research plan was 25 pages to total 40. Analysis of Vision Health Challenges and Opportunities (Background and Sig) Proposed TRC-specific Studies Proposed Collaborative TRC Network Study Skills and Experience of the Proposed TRC Research Team Management Plan.</p>	<p>The 25 pages for the research plan should address: Analysis of Vision Health Challenges and Opportunities; Skills and Experience of the Proposed TRC Research Team; Management Plan; Plan for Sharing Research Data; Sharing Research Resources. Make sure you address the Overall Impact and other criteria that will be used to score your application. Note that the Detailed Budget and Line-Item Justification, while part of the application, don't count toward the 25 pages of the research plan. Also, the "Letter of Commitment or Memorandum of Understanding that assures the applicant continuous access and use of the datasets and/or data systems throughout the Project Period" can be included as an appendix, along with biosketches, an organization chart, and timeline.</p>
<p>9. Am I correct to assume that the Line-item budget Justification is not included in the 25 page limit for the Research Plan? Is it part of the <20 page limit for attachments or not?</p>	<p>Correct, the budget and the line-item justification are not included in the 25 page limit for the research plan.</p>
<p>10. Does the Research Sharing Plan and Sharing Research Resources and the Human Subjects descriptions count in the less than 20 attachment pages? I understand that the Letters of Support do count in this limit.</p>	<p>Yes, the Research Sharing Plan and Sharing Research Resources count toward the 25 page limit.</p>
<p>11. Will CDC select one of the 3 Center-specific studies? Is CDC</p>	<p>CDC is expecting each Center to complete three Center-specific</p>

expecting that the three studies will be implemented at the same time?	studies during the 5-year Project Period. The applicant should determine which Center-specific study or studies to initiate during the first year of funding.
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