



Centers for Disease Control and Prevention

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

Investigating New Approaches for Tobacco Surveillance Systems

RFA-DP-15-006

Application Due Date: 02/09/2015

Signature

Date

Investigating New Approaches for Tobacco Surveillance Systems

RFA-DP-15-006

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Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

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

National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)

Funding Opportunity Announcement (FOA) Title

Investigating New Approaches for Tobacco Surveillance Systems

Activity Code

AMENDMENT I. QUESTIONS FROM POTENTIAL APPLICANTS AND CDC RESPONSES added to Section VIII. Other Information on February 4, 2015

U01 Activity Code

Funding Opportunity Announcement Type

New

Funding Opportunity Announcement Number

RFA-DP-15-006

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

93.305

Category of Funding Activity:

Health

FOA Purpose

This funding opportunity announcement seeks to design and test new format, content and modes of administration for tobacco surveillance systems. The newly developed system(s) will be used by public health professionals and researchers to describe the patterns and correlates of tobacco use behaviors in the U. S. population and inform and evaluate tobacco prevention and control policies and interventions designed to reduce the burden of death, disease and disability associated with the consumption of tobacco products.

Key Dates

Publication Date: To receive notification of any changes to RFA-DP-15-006, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.

Letter of Intent Due Date: 01/09/2015

Application Due Date: 02/09/2015

On-time submission requires that electronic applications be error-free and made available to CDC for processing from eRA Commons on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov/eRA Commons no later than 5:00 PM U.S. Eastern Time. Note: HHS/CDC grant submission procedures do not provide a period of time beyond the application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

Scientific Merit Review: 04/24/2015

Secondary Review: 05/25/2015

Estimated Start Date: 09/30/2015

Expiration Date: 02/10/2015

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

Required Application Instructions

It is critical that applicants follow the instructions in the [SF 424 \(R&R\) Application Guide](#) except where instructed to do otherwise in this FOA. Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Note: The Research Strategy component of the Research Plan is limited to 25 pages.

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

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

Executive Summary

- **Purpose.** The purpose of this announcement is to design and test new format, content and mode of administration for tobacco surveillance systems. The new and improved system (s) will be used by public health professionals and researchers to describe the patterns and correlates of tobacco-related indicators in the U. S. population and inform and evaluate tobacco prevention and control programs, policies, and interventions designed to reduce the burden of death, disease and disability associated with tobacco use.
- **Mechanism of Support.** The funding mechanism is a cooperative agreement.
- **Funds Available and Anticipated Number of Awards.** The CDC intends to commit approximately \$3,500,000 (direct and indirect) over the entire project period. It is anticipated that one award will be made to a single recipient for up to \$700,000 in FY2015. The Award issued under this FOA is contingent upon availability of funds and a sufficient number of meritorious applications. The total amount awarded will depend upon the number, quality, duration and cost of the applications received.
- **Budget and Project Period.** The total funding (direct and indirect) for the first year (12 month budget period) is approximately \$700,000. The estimated total funding (direct and indirect) for the entire project period is \$3,500,000. The project period will run from 09/30/2015 to 09/29/2020.
- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in [Section IV. Application and Submission Information](#) of this announcement.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in [Section III, 1](#) are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.
- **Number of PDs/PIs.** Applications may include more than one PI; however, the first PI listed on the application will be the “contact PI” for all correspondence. Any additional PIs are permitted, but would be referred to as Co-PIs.
- **Number of Applications.** Only one application per institution (normally identified by having a unique DUNS Number) is allowed.
- **Application Type.** New
- **Special Date(s).** N/A

- **Application Materials.** See [Section IV.1](#) for application materials.
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: (770) 488-2783.
- This FOA will be posted at <http://www.cdc.gov/chronicdisease/about/foa.htm>

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

Awards for this FOA are made under the authorization of Sections 301(a) of the Public Health Service Act as amended, 42 U.S.C. 241(a).

1. Background and Purpose

The burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products. Despite the fact that cigarette smoking alone causes more than 480,000 deaths per year, an estimated 42.1 million adults (18.1%) currently smoke cigarettes (1-4).

Although there have been declines in cigarette smoking in recent decades, the use of other forms of combustible (e.g., cigar products, pipe tobacco, hookah) and non-combustible (e.g., smokeless tobacco) tobacco products have either increased or stayed the same (5-6). Additionally, although the long-term effects are still under investigation, available data demonstrate that the prevalence of use of some emerging non-cigarette tobacco products, such as electronic nicotine delivery systems (ENDS), has increased rapidly in recent years (7).

There is a need to update existing tobacco surveillance systems. Current surveillance instruments do not use standardized tobacco use scales, thus generating inconsistent estimates for tobacco use behaviors across systems (8). For example, survey questions that assess the prevalence of current smokers have not been updated for several years. There is also a growing debate among public health professionals about how the frequency of smoking should be assessed to capture the true prevalence of tobacco use. Since 1992, a smoker has been defined as someone “who has smoked at least 100 cigarettes or more in his/her entire life and smoked now every day or some days”. There is a concern that the existing national surveys are not capturing smokers who have not smoked at least 100 cigarettes in their lifetime, and may be capturing smokers who smoked more than 30 days ago. Additionally, most national surveys have focused on cigarette smoking or smokeless tobacco use; however, it is important to adequately assess the use of other types of tobacco products, such as cigars, traditional pipe tobacco, and other combustible tobacco products. The thresholds for what defines an ever established user of the product (i.e., 20 cigars, 100 cigarettes) for the different tobacco products are important to determine former users of the product and for comprehensive tobacco prevention and control efforts in general.

Limited data are available to detect emerging trends in the use of non-cigarette tobacco products, such as ENDS, or the specific factors that influence behaviors to initiate or maintain the use of these products, particularly among youth and young adults. For example, at the present time empirical data are insufficient to ascertain whether harm perceptions or exposure to e-cigarette industry promotions are associated with risk of using ENDS. In addition, it is unclear whether youth are using ENDS first and then progressing to use conventional cigarettes. It is also unknown whether established cigarette smokers successfully use ENDS to quit smoking conventional cigarettes, what proportion of conventional cigarette smokers use both ENDS and conventional cigarettes and do not reduce or quit cigarette consumption, or what proportion of former cigarette smokers relapse by using ENDS or other non-conventional tobacco products.

Detecting and monitoring the use of emerging products, such as ENDS, is a challenge due to the cultural differences in perceptions, attitudes, and nomenclature currently used to describe these products. Inaccuracies in the assessment of these products have resulted from limited understanding of the best nomenclature to use

in surveillance, evaluation, and research instruments. An additional challenge has been the lack of discrete measures for use of non-cigarette products, which limits the opportunity for determining dose-response effects on death and disease attributed to tobacco use.

There is a growing need for new, more rapid, less-expensive methods for monitoring various tobacco products (9). Electronic health records (EHRs) are rapidly becoming the standard of care for office-based medical practices, and office-based EHRs provide an opportunity to potentially be used for population health surveillance including tobacco surveillance (10). Many entities including local, regional, and national governments, large health care organizations, insurance companies, and academic research centers are exploring ways to use data from EHRs to monitor health and inform health care policies and programs (11). This is in alignment with the meaningful use of EHRs as part of The American Reinvestment & Recovery Act (ARRA) which was enacted on February 17, 2009.

To support CDC's vision of a society free of tobacco-related death, disease, and disability there is a need for more timely and relevant data to inform the endgame strategies outlined in the 2014 Surgeon General's Report on the Health Consequences of Smoking (1). A modernized surveillance capacity is essential to sustain the national capability to produce and disseminate valid and timely data on tobacco use behaviors that are germane to the rapidly changing and increasingly diversified tobacco landscape in the United States. In alignment with this effort, WHO also advances its tobacco control efforts by embracing the MPOWER framework as the structure for implementing the Framework Convention on Tobacco Control (12).

The six evidence-based MPOWER strategies include:

- **Monitor** tobacco use and prevention policies
- **Protect** people from secondhand smoke
- **Offer** help to quit tobacco use
- **Warn** about the dangers of tobacco
- **Enforce** bans on tobacco advertising, promotion and sponsorship
- **Raise** taxes on tobacco

The purpose of this funding opportunity is to support applications that design and test new format(s), content and mode of administration(s) for updated tobacco surveillance systems. The system(s) developed will be used by public health professionals and researchers to describe the patterns and correlates of tobacco use behaviors in the U. S. population and inform and evaluate tobacco prevention and control policies and interventions designed to reduce the burden of death, disease and disability associated with the consumption of tobacco products.

Healthy People 2020 and other National Strategic Priorities

Healthy People 2020: Tobacco Use: Reduce illness, disability, and death related to tobacco use and secondhand smoke exposure. The Healthy People 2020 Tobacco Use objectives are organized into three key areas (13):

1. **Tobacco Use Prevalence:** Implementing policies to reduce tobacco use and initiation among youth and adults.

- **TU-1** Reduce tobacco use by adults.
- **TU-2** Reduce tobacco use by adolescents.
- **TU-3** Reduce the initiation of tobacco use among children, adolescents, and young adults.
- **TU-4** Increase smoking cessation attempts by adult smokers.
- **TU-5** Increase recent smoking cessation success by adult smokers.
- **TU-6** [Increase smoking cessation during pregnancy.](#)
- **TU-7** [Increase smoking cessation attempts by adolescent smokers.](#)

2. **Health System Changes:** Adopting policies and strategies to increase access, affordability, and use

of smoking cessation services and treatments.

- **TU-9** Increase tobacco screening in health care settings.
- **TU-10** Increase tobacco cessation counseling in health care settings.

3. Social and Environmental Changes: Establishing policies to reduce exposure to secondhand smoke, increase the cost of tobacco, restrict tobacco advertising, and reduce illegal sales to minors.

- **TU-11** Reduce the proportion of nonsmokers exposed to secondhand smoke.
- **TU-14** [Increase the proportion of smoke-free homes](#) [Increase the proportion of smoke-free homes](#).
- **TU-18** Reduce the proportion of adolescents and young adults in grades 6 through 12 who are exposed to tobacco marketing.
- **TU-19** Reduce the illegal sales rate to minors through enforcement of laws prohibiting the sale of tobacco products to minors.

CDC's Winnable Battles: To keep pace with emerging public health challenges and to address the leading causes of illness, injury, disability, and death, the Centers for Disease Control and Prevention (CDC) initiated an effort to achieve measurable impact on selected Winnable Battles. These Winnable Battles were chosen based on the magnitude of the health problems and our ability to make significant progress to improve outcomes. There are also evidence-based strategies available now to address the critical health challenges presented by each of the Winnable Battles areas. CDC has identified reducing tobacco use as a Winnable Battle (14).

Priorities of the Office on Smoking and Health: As the lead federal agency for comprehensive tobacco prevention and control, the Centers for Disease Control and Prevention (CDC), Office on Smoking and Health (OSH) develops, conducts, and supports strategic efforts to protect the public's health from the harmful effects of tobacco use. To achieve these goals, OSH works collaboratively with state and national partners and networks in providing strategic leadership, a solid science base, and technical assistance to advance evidence-based interventions at the state and local levels.

This project would help inform those efforts by generating strategic surveillance data that supports the following priorities of OSH:

- Educating the public about the dangers of tobacco use and promoting quitting.
- Ending combusted tobacco use, including long-term dual use, and increasing awareness, information and action on electronic nicotine delivery systems (ENDS), including e-cigarettes.
- Enhancing tobacco control surveillance, research, and evaluation.
 - Updating surveillance instruments to obtain valid and reliable estimates of factors associated with tobacco use initiation, maintenance and cessation.
- Advancing and sustaining tobacco control programs.
 - Assisting national, state, and local tobacco control partners to build sustainable capacity and infrastructure for comprehensive tobacco control programs by providing an evidence base for interventions to prevent tobacco use, promote cessation, expand smoke-free environments, and reduce tobacco-related disparities.

Public Health Impact

The range of tobacco products available to the U.S. marketplace has been greatly expanded in recent years and continues to change at a rapid pace. Current tobacco surveillance systems have been successful in monitoring and evaluating tobacco use patterns and correlates for the use of traditional tobacco products; however, there is a need for updated surveillance to capture new behaviors and correlates related to the use of conventional tobacco products as well as the rapidly changing market of new products and related indicators. There is also a need for new modes of administration of surveillance questionnaires to shorten the timeframe between data collection and dissemination. This project has the potential to enhance the infrastructure of current and future surveillance systems, which will ensure scientifically robust surveillance, evaluation, and research of the diversity of tobacco product use in the United States. The research also has the potential to strengthen efforts at the global, national, state, and local levels to effectively monitor tobacco use and to use this information to inform public health policy, planning, and practice.

Relevant Work

Increasing the capacity to conduct rapid response surveillance is a key strategy for monitoring the tobacco use epidemic at the federal, state, and local levels. The CDC's Office on Smoking and Health (OSH) has been working towards building rapid response surveillance capacity at the federal level. This effort is intended to enhance tobacco control's ability to promptly assess the effect and impact of policies, current trends, programs, and interventions.

2. Approach

The overarching aim of this funding opportunity is to identify new tobacco use surveillance content, format and mode of administration that would result in enhanced national tobacco use surveillance capacity that captures the rapidly changing and increasingly diverse tobacco product landscape and the expanding surveillance opportunities and technologies now available in the United States.

Objectives/Outcomes

Objective 1: To document the strengths, limitations and opportunities for improvement of current tobacco surveillance systems. This may include activities such as:

- a) conducting a systematic review of the literature, emerging science and existing surveillance instruments focused on tobacco use metrics and scales, including case definitions, use thresholds, and nomenclature for traditional and emerging tobacco products that is sensitive to cultural diversity,
- b) Identifying new, improved methods for collecting data that uses electronic media and ultimately lessens the burden on study participants, and
- c) Developing an inventory of existing tobacco-related surveys (both federal and non-federal) that provides data, questionnaires, and information on employed methods. This may serve as a clearing house of currently available tobacco surveys (federal and non-federal).

Objective 2: To utilize existing or establish new partnerships with agencies and organizations that are engaged in tobacco prevention and control surveillance, evaluation, and research to conduct qualitative research. This may include key informant interviews and focus groups to assess cultural differences in perceptions, attitudes, and vernacular associated with tobacco products and use behaviors. The qualitative research may also include focus groups about use behaviors with emerging products to determine associations with the continuum of tobacco use behaviors.

Objective 3: To develop new survey tools or questionnaires that supports the systematic collection of data on the continuum of tobacco use behaviors for multiple tobacco products among U.S. adults, young adults and youth. The goal of this objective is to develop tools that will result in the capability to obtain valid and reliable estimates of tobacco use behaviors and correlates in the current climate of diverse tobacco products. The research strategies can include qualitative and quantitative methods, such as focus groups, key informant

interviews, and cognitive testing.

Objective 4: To test new, improved methods for collecting data that uses electronic media and ultimately lessens the burden on study participants.

Objective 5: To pilot test the survey questions, and develop a report with recommendations regarding the feasibility for tobacco surveillance systems. The findings should describe the data sources examined, barriers encountered to integrate the new questions, and a summary of pilot data including identification of important gaps in information or systems. The recommendations should address specifically:

- a) The potential usefulness of the surveillance system for the National Tobacco Control Program,
- b) The potential usefulness of the surveillance system for other interested public and private organizations operating at local, state, and national level, and
- c) The feasibility of using electronic platforms designed to reduce the burden on survey respondents and foster rapid data collection and dissemination of findings.

Objective 6: To disseminate results in peer-reviewed publications, reports, websites, and presentations to multiple audiences, including federal, state, and local tobacco control programs. Dissemination strategies may include a secure web portal or similar web-based technology to foster data sharing and information exchange between a wide audience with an interest in tobacco prevention and control, including public health practitioners, health-care providers, educators, decision-makers and the American public. The proposed web-based data access portal is intended to allow submitting web-queries and download tobacco-related surveillance data.

Target Population

The target population is U.S. adults and youth.

Collaboration/Partnerships

Applicants are expected to collaborate and form partnerships or consortia with eligible organizations within the public health system to conduct the proposed research and implement research outcomes to enhance tobacco surveillance systems. Applicants should discuss how the proposed research will be informed by input from professional partners, including formulation of the research questions and design, as an aspect of their collaboration with public health practitioners and researchers to ensure the relevance, appropriateness, and feasibility of the proposed research for supporting the enhanced surveillance.

Evaluation/Performance Measurement

Applicants are expected to propose a plan that measures performance with goals, objectives, milestones and outputs for each phase of the proposed research and a plan for how to evaluate the impact of the research findings on the content, format and mode of administration of the revised surveillance system when implemented. Resources to assist the development of the evaluation plan are available at www.cdc.gov/eval.

Translation Plan

Applicants are expected to submit progress reports to CDC documenting the methodology, results, conclusions and recommendations emanating from this project. Applicants are expected to present research findings at relevant conferences and meetings and publish research findings in peer-reviewed journals.

Some of the information collection conducted under this FOA is expected to be subject to the Paperwork Reduction Act of 1995 (PRA) (Pub. L. No. 96-511, 94 Stat. 2812, codified at [44 U.S.C. § ;3501-3521](#)).

References:

1. U.S. Department of Health and Human Services. The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Coordinating Center for Health Promotion, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014. <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf>.
2. U.S. Department of Health and Human Services. Preventing tobacco use among youth and young adults. Atlanta, GA: US Department of Health and Human Services, CDC; 2012. Available at http://www.cdc.gov/tobacco/data_statistics/sgr/2012/index.htm.
3. U.S. Department of Health and Human Services. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Coordinating Center for Health Promotion, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2006. Available at http://www.cdc.gov/tobacco/data_statistics/sgr/2006/index.htm.
4. Centers for Disease Control and Prevention. Best Practices for Comprehensive Tobacco Control Programs — 2014. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014. Available at http://www.cdc.gov/tobacco/stateandcommunity/best_practices/index.htm.
5. Agaku IT, King BA, Dube SR. Current cigarette smoking among adults - United States, 2005 - 2012. Morbidity & Mortality Weekly Report 2014; 63(2):30-34.
6. Arrazola RA, Dube SR, King BA. Tobacco Product Use Among Middle and High School Students — United States, 2011 and 2012. Morbidity & Mortality Weekly Report 2013; 62(45):893-897.
7. Corey C, Wang B, Johnson SE, Apelberg B, Husten C, King BA, McAfee TA, Bunnell R, Arrazola RA, Dube SR. Notes from the Field: Electronic Cigarette Use Among Middle and High School Students — United States, 2011–2012. Morbidity & Mortality Weekly Report 2013 / 62(35);729-730
8. Delnevo CD, Bauer UE. Monitoring the tobacco use epidemic III. The host: data sources and methodological challenges, Preventive Medicine, vol. 48, no. 1, pp.S16-S23, 2009.
9. CDC. Rapid Response Surveillance in Tobacco Control. Atlanta, GA: US Department of Health and Human Services, CDC; 2012. Available at <https://nctoh.confex.com/nctoh/2012/webprogram/paper/Paper2419.html>.
10. McVeigh KH, Newton-Dame R, Perlman S, Chernov C, Thorpe L, Singer J, Greene C. Developing an Electronic Health Record-Based Population Health Surveillance System. New York: New York City Department of Health and Mental Hygiene, 2013.
11. Gfroerer J, Dube SR, King BA, Garrett BE, Babb S, McAfee TA. Vital Signs: Current Cigarette Smoking Among Adults Aged ≥18 Years with Mental Illness — United States, 2009–2011. Morbidity & Mortality Weekly Report 2013 / 62(05);81-87
12. WHO Report on the Global Tobacco Epidemic, 2008: The MPOWER package. Geneva, World Health Organization, 2008.
13. US Department of Health and Human Services. Tobacco use objectives. Healthy People 2020. Washington, DC: US Department of Health and Human Services. <http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=41>.
14. Centers for Disease Control and Prevention. Winnable Battles Progress Report 2010-2015. Available at <http://www.cdc.gov/winnablebattles/targets/pdf/winnablebattlesprogressreport.pdf>

Section II. Award Information

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

Application Types Allowed:

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

Estimated Total Funding: \$3,500,000

Anticipated Number of Awards: 1

In 2015 the CDC intends to commit a total of approximately \$700,000 (direct and indirect) for the first 12 month budget period for one award.

If an applicant requests a funding amount greater than the ceiling of the award range for the first year (\$700,000), HHS/CDC will consider the application non-responsive, and it will not enter into the review process. HHS/CDC will notify the applicant that the application did not meet the submission requirements.

The CDC intends to commit a total of approximately \$3,500,000 (direct and indirect) for the five (5) year project period (09/30/2015 to 09/29/2020).

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

Award Ceiling: \$700,000 Per Budget Period

Award Floor: \$0 Per Budget Period

Total Project Period Length: 5 year(s)

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

HHS/CDC grants policies as described in the HHS Grants Policy Statement (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>) will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:

- State governments
- County governments
- City or township governments
- Special district governments
- Independent school districts
- Public and State controlled institutions of higher education
- Native American tribal governments (Federally recognized)
- Public housing authorities/Indian housing authorities
- Native American tribal organizations (other than Federally recognized tribal governments)
- Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education

Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education
Private institutions of higher education
For profit organizations other than small businesses
Small businesses

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

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

Nonprofits Other Than Institutions of Higher Education:

Nonprofits (Other than Institutions of Higher Education)

Governments:

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

Other:

Native American tribal organizations (other than Federally recognized tribal governments)
Faith-based or Community-based Organizations
Regional Organizations
Bona Fide Agents: a Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms" when submitting via www.grants.gov.
Federally Funded Research and Development Centers (FFRDCs): FFRDCs are operated, managed, and/or administered by a university or consortium of universities, other not-for-profit or nonprofit organization, or an industrial firm, as an autonomous organization or as an identifiable separate operating unit of a parent organization. A FFRDC meets some special long-term research or development need which cannot be met as effectively by an agency's existing in-house or contractor resources. FFRDC's enable agencies to use private sector resources to accomplish tasks that are integral to the mission and operation of the sponsoring agency. For more information on FFRDCs, go to <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=512ff78311f427c00454772dcf21523a&rgn=div8&view=text&node=48:1.0.1.6.34.0.1.18&idno=48>

2. Foreign Organizations

Foreign Organizations are not eligible to apply.

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

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

3. Special Eligibility Requirements

N/A

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

If an applicant requests a funding amount greater than the ceiling of the award range for the first year (\$700,000), HHS/CDC will consider the application non-responsive, and it will not enter into the review process. HHS/CDC will notify the applicant that the application did not meet the submission requirements.

6. Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: <https://eportal.nspa.nato.int/AC135Public/Docs/US%20Instructions%20for%20NSPA%20NCAGE.pdf>
- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, <https://www.sam.gov/portal/SAM/#1>.
- [Grants.gov](https://www.Grants.gov)
- [eRA Commons](https://www.eRA Commons)

All applicant organizations must register with **Grants.gov**. Please visit www.Grants.gov at least 30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The “one-time” registration process will take three to five days to complete. However, it is best to start the registration process at least two weeks prior to application submission.

All Program Directors/Principal Investigators (PD/PIs) **must** also work with their institutional officials to register with the **eRA Commons** or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization. **All registrations must be successfully completed and active before the application due date.** Applicant organizations are strongly encouraged to start the registration process at least four (4) weeks prior to the application due date.

7. Universal Identifier Requirements and System for Award Management (SAM)

All applicant organizations **must obtain** a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the [US D&B D-U-N-S Number Request Web Form](#) or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program

Directors/Principal Investigators do not need to register for a DUNS number.

Additionally, all applicant organizations must register in the **System for Award Management (SAM)**. Organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM internet site at <https://www.sam.gov/index.html>.

If an award is granted, the grantee organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the grantee organization.

8. Eligible Individuals (Project Director/Principal Investigator) in Organizations/Institutions

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

9. Cost Sharing

This FOA does not require cost sharing as defined in the HHS Grants Policy Statement (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>).

10. Number of Applications

As defined in the HHS Grants Policy Statement, (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>), applications received in response to the same funding opportunity announcement generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit. HHS/CDC will not accept any application in response to this FOA that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

Section IV. Application and Submission Information

1. Address to Request Application Package

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

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

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf), except where instructed in this Funding Opportunity Announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

The forms package associated with this FOA includes all applicable components, mandatory and optional. Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow the instructions in the SF 424 (R&R) Application Guide to ensure you complete all appropriate “optional” components.

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

3. Letter of Intent

Due Date for Letter of Intent: **01/09/2015**

Michael A. Brown, M.P.H.

Scientific Program Official

Extramural Research Program Operations and Services

Centers for Disease Control and Prevention

4770 Buford Hwy, NE

Mailstop F-80

Atlanta, GA 30341

Telephone: (770) 488-5118

E-mail: mab5@cdc.gov

4. Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this FOA in Grants.gov includes all applicable components for this FOA, required and optional.

5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of 16 components. Not all 16 components of the Research Plan apply to all Funding Opportunity Announcements (FOAs). Specifically, some of the following 16 components are for Resubmissions or Revisions only. See Part I, Section 5.5 of the SF 424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Funding Opportunity Announcement Description).

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

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

Human Subjects Section

6. Protection of Human Subjects

7. Inclusion of Women and Minorities

8. Targeted/Planned Enrollment Table (for New Application ONLY)

9. Inclusion of Children

Other Research Plan Sections

10. Vertebrate Animals

11. Select Agent Research

12. Multiple PD/PI Leadership Plan.

13. Consortium/Contractual Arrangements

14. Letters of Support

15. Resource Sharing Plan(s)

16. Appendix

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

All instructions in the SF424 (R&R) Application Guide

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

Research Plan

Applicants' research plan should address activities that will be conducted over the entire 5-year project period.

- 1) Describe planned approach to identifying existing surveillance data sources or existing surveillance systems for tobacco use.
- 2) Describe each data source or system, including accessibility, frequency for data collection, the data elements (variables) available from each source or system, and the respective mode of administration and response rates. Document key similarities and differences, as well as strengths and limitations, of the data sources and data elements for the various systems.
- 3) Describe the planned approach to assess cultural, regional, and other differences in perceptions, attitudes, and vernacular associated with new and emerging tobacco products and use behaviors across subpopulations.
- 4) Describe the planned approach to identify various definitions for tobacco use in diverse populations and to incorporate this information into surveillance instruments for pilot testing of validity, reliability and mode of administration using electronic media.
- 5) Describe planned protocol for assessing various electronic modes of administration or new methods to collect data related to tobacco use that will reduce burden on survey respondents and support rapid dissemination of findings. Identify approaches to establishing a denominator (population base) for new surveillance systems that may use new methods, such as internet panels.
- 6) Describe approach for integrating all major data sources into a functional surveillance system. Include a rationale for the proposed structure and selection of proposed data elements.

- 7) Describe planned approach for conducting and evaluating a pilot test of the surveillance system. Include measures for evaluating validity and reliability of information collected related to new and emerging tobacco products and associated use behaviors.
- 8) Describe planned approach for developing a web portal or similar web-based technology to foster data sharing and information exchange between a wide audience with an interest in tobacco prevention and control, including public health practitioners, health-care providers, educators, decision-makers and the American public.
- 9) Prepare a plan to disseminate the findings, such as in peer-reviewed publications, reports, websites, and presentations to multiple audiences, including federal, state, and local tobacco control programs.
- 10) Describe a management and staffing plan that includes roles and responsibilities for each key team member.
- 11) Describe the project's timeline with specific activities and expected accomplishments for each year.
- 12) Provide a budget that includes at least one trip per year to Atlanta, Georgia.

6. Appendix

Do not use the appendix to circumvent page limits. A maximum of 10 PDF documents are allowed in the appendix. Additionally, up to 3 publications may be included that are not publically available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

7. Page Limitations

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

8. Format for Attachments

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

CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide (Part I, Section 2) (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf).

9. Submission Dates & Times

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

Organizations must submit applications via [Grants.gov](http://www.grants.gov) (<http://www.grants.gov>), the online portal to find and apply for grants across all Federal agencies. The eRA Commons systems retrieve the application from

Grants.gov and check the application against CDC business rules. If no errors are found, the application will be assembled in the eRA Commons for viewing by the applicant before moving on for further CDC processing.

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

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

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

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

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

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

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

After submission of your application package, applicants will receive a “submission receipt” email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. This validation process may take as long as two (2) business days. A third and final e-mail message is generated once the applicant’s application package has passed validation and the grantor has confirmed receipt of the application.

Unsuccessful Submissions:

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

1. Track his/her submission and verify the submission status (tracking should be done initially regardless of rejection or success).
 - a. If the status states “*rejected*,” do #2a or #2b.
2. Check his/her emails from both Grants.gov and eRA Commons for rejection notices.
 - a. If the deadline has passed, he/she should email the Grant Management Specialist listed in the FOA

(pgotim@cdc.gov) explaining why the submission failed.

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

Due Date for Applications: **02/09/2015**

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

10. Intergovernmental Review (E.O. 12372)

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

11. Funding Restrictions

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

For more information on expanded authority and pre-award costs, go to: <http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>.

12. Other Submission Requirements and Information

Application Submission

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

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

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

Important reminders:

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

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

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

See more resources to avoid common errors and submitting, tracking, and viewing applications: [http:// grants.nih.gov/grants/ Electronic Receipt /avoiding_ errors.htm](http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm) or [http:// grants.nih.gov/grants/ Electronic Receipt/submit_ app.htm](http://grants.nih.gov/grants/ElectronicReceipt/submit_app.htm)

Upon receipt, applications will be evaluated for completeness by the CDC Procurement and Grants

Office (PGO) and responsiveness by PGO and the Center, Institute or Office of the CDC. Applications that are incomplete and/or nonresponsive will not be reviewed.

Section V. Application Review Information

1. Criteria

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

Overall Impact

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

Scored Review Criteria

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

Significance

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

- Does the work address a scientific problem of great importance to public health research and/or practice for tobacco use prevention and control?
- What is the potential or actual impact of the research on public health in the US and/or globally?
- Will the work be influential in that it will lead others to investigate the problem, open new areas of research, or change the scientific approach or public health practice, and how will this improve and be of value to public health?

Investigator(s)

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

- Do the investigators have a successful track record in public health research?
- Is there evidence of past collaborations with the proposed research team?
- Have previous research results provided high quality outputs and contributed to improvements in public health practice and population health?
- Do the investigators demonstrate experience with surveillance, questionnaire design and testing, and information technology?

Innovation

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

- Does the application challenge and seek to shift current public health practice paradigms or approaches?
- Is the proposed research innovative and yet offer reasonable potential for concrete applications of interest and value to CDC?
- Does the project have the potential to increase efficiency or lead to cost savings?

Approach

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

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

- Does the application propose to use evidence-based interventions or strategies in the research plan?
- Does the application describe how the results from the research will be disseminated and ultimately used?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

- Does the project utilize critical partnerships or collaborations?
- Does the project support key stakeholder involvement throughout the research process?
- Does the project identify key partners or potential collaborators with the skills and resources to achieve the objectives of the project?

2. Additional Review Criteria

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

Protections for Human Subjects

If the research involves human subjects but does not involve one of the six categories of research that are exempt under [45 CFR Part 46](#), the committee will evaluate the justification for involvement of

human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

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

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

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

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research

(http://www.cdc.gov/maso/Policy/Policy_women.pdf and

<http://www.gpo.gov/fdsys/pkg/FR-1995-09-15/pdf/95-22950.pdf#page=1>) and the policy on the Inclusion of Persons Under 21 in Research (<http://www.cdc.gov/maso/Policy/policy496.pdf>).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section

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

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

3. Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but *will not give scores* for these items, and should not consider them in providing an overall impact/priority score.

Resource Sharing Plans

HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm#ar25. Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: <http://www.cdc.gov/od/pgo/funding/budgetguide.htm>.

4. Review and Selection Process

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

As part of the scientific peer review, all applications:

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

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

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

5. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) and other pertinent information via the eRA Commons.

Section VI. Award Administration Information

1. Award Notices

Any applications awarded in response to this FOA will be subject to the DUNS, SAM Registration, and Transparency Act requirements. If the application is under consideration for funding, HHS/CDC will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the Grants Management Officer is the authorizing document and will be sent via email to the grantee's business official.

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

2. CDC Administrative Requirements

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

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

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

Specific requirements that apply to this FOA are the following:

Generally applicable ARs:

[AR-1: Human Subjects Requirements](#)

[AR-2: Inclusion of Women and Racial and Ethnic Minorities in Research](#)

[AR-9: Paperwork Reduction Act Requirements](#)

[AR-10: Smoke-Free Workplace Requirements](#)

[AR-11: Healthy People 2020](#)

[AR-12: Lobbying Restrictions](#)

[AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities](#)

[AR-14: Accounting System Requirements](#)

[AR-22: Research Integrity](#)

[AR-24: Health Insurance Portability and Accountability Act Requirements](#)

[AR-25: Release and Sharing of Data](#)

[AR-26: National Historic Preservation Act of 1966](#)

[AR-28: Inclusion of Persons Under the Age of 21 in Research](#)

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

[AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973](#)

[AR 31 - Distinguishing Public Health Research and Public Health Non-research](#)

[AR 32 –; FY 2012 Enacted General Provisions](#)

[AR-8: Public Health System Reporting Requirements](#)

For more information on the Code of Federal Regulations, visit the National Archives and Records Administration at: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>

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

3. Additional Policy Requirements

The following are additional policy requirements relevant to this FOA:

HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items and Printing Publications

This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy apply to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website at:

[http:// www.hhs.gov/ asfr/ogapa/acquisition/ effspendpol _memo.html](http://www.hhs.gov/asfr/ogapa/acquisition/effspendpol_memo.html))

Federal Funding Accountability and Transparency Act of 2006

Public Law 109-282, the Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single publicly accessible Web site, www.USASpending.gov ([http:// www.usaspending. gov/](http://www.usaspending.gov/)). For the full text of the requirements, please review the following website: [https:// www.fsrcs.gov/](https://www.fsrcs.gov/).

Plain Writing Act

The Plain Writing Act of 2010 was signed into law on October 13, 2010. The law requires that federal agencies use "clear Government communication that the public can understand and use" and requires the federal government to write all new publications, forms, and publicly distributed documents in a "clear, concise, well-organized" manner. For more information on this law, go to: [http:// www.plainlanguage.gov/ plLaw/index.cfm](http://www.plainlanguage.gov/plLaw/index.cfm).

Tobacco and Nutrition Policies

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

Tobacco:

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

Nutrition:

- Healthy food service guidelines that at a minimum align with Health and Human Services and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations for cafeterias, snack bars, and vending machines in any facility under the control of the

recipient organization and in accordance with contractual obligations for these services. The following are resources for healthy eating and tobacco free workplaces:

- http://www.gsa.gov/graphics/pbs/Guidelines_for_Federal_Concessions_and_Vending_Operations.pdf
- <http://www.cdc.gov/nccdphp/dnpao/hwi/toolkits/tobacco/index.htm>
- <http://www.cdc.gov/chronicdisease/resources/guidelines/food-service-guidelines.htm>

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

4. Cooperative Agreement Terms and Conditions of Award

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

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

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

- The oversight of all management, administrative, and scientific aspects of the research project;
- Assuring and maintaining confidentiality of all relevant data and documents;
- Ensuring that the research protocol complies with the terms and conditions of human subjects protection and preparing and coordinating the submission of the protocol(s) to the grantee's IRB(s) if needed (grantee is responsible for obtaining IRB approval for all collaborators);
- Coordinate with CDC to develop OMB submission package and obtain and maintain appropriate approvals through the life cycle of the award.
- Maintaining an adequate management and staffing plan to support all project activities;
- Recruiting technical and content experts if necessary and scheduling and organizing the meetings for these experts;
- Attending an annual project review meeting, and any additional working meetings, with CDC;
- Establishing and maintaining communication with key research partners;
- Reporting to CDC and publishing in peer-review journals all research findings.

Awardees will retain custody of and have primary rights to the data and software developed under this award, subject to Government rights of access consistent with current DHHS, PHS, and CDC applicable law, regulations, and policies. A Data Use Agreement may be required to govern how and when the data are shared and to maintain confidentiality of the data."

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.

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

There are two separate CDC roles – Scientific Collaborator and the Scientific Program Official (SPO).

In this cooperative agreement, a CDC Scientist (Scientific Collaborator) within the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) is a partner involved with all aspects of the scientific and programmatic matters of the project through technical assistance, advice and coordination. It is expected that CDC's Project Scientists will have substantial programmatic involvement in this cooperative agreement. The SC will:

- Support the grantee by providing scientific and public health technical assistance in the development of the activities of the project.
- Ensure adherence of human subjects requirements and approval of the study protocol by appropriate IRBs. Ensure compliance with federal regulatory guidelines such as OMB/PRA.
- Assist in facilitating communication among study investigators/project teams.
- Convene technical assistance calls, meetings, web forums, conference calls, and site visits with the awardee.
- Provide ongoing guidance, consultation, and technical assistance to support the planning, implementation, monitoring, and evaluation of research activities.
- Assist awardee in fostering relationships with established CDC partners who are involved in tobacco prevention and control, such as federal, state and local agencies, advocacy groups and professional organizations.
- Provide scientific guidance and input to the awardee on methodological issues such as case findings and case definitions, data management and security and data quality and analysis. Participate as co-authors on manuscripts, presentations and other products that are generated from this project.

Additionally, a CDC Scientific Program Official (SPO), will be responsible for the normal scientific and programmatic stewardship of the award. The SPO will:

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

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

Areas of Joint Responsibility include:

- Participating in periodic conference calls and meetings
- Participate in regular PI calls
- Sharing data and collaborating with other investigators to answer common research questions, if appropriate
- Developing common outcome measures, if appropriate

5. Reporting

Awardees will be required to submit the [Non-Competing Continuation Grant Progress Report \(PHS 2590\)](#) annually and financial statements as required in the HHS Grants Policy Statement.

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

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

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients: **1) information on executive compensation when not already reported through the SAM Registration; and 2) similar information on all sub-awards/ subcontracts/ consortiums over \$25,000.** It is a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrc.gov on all subawards over \$25,000. See the HHS Grants Policy Statement ([http:// www.hhs.gov/asfr/ ogapa/aboutog/ hhsgps107.pdf](http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf)) for additional information on this reporting requirement.

A. Submission of Reports

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

1. **Yearly Non-Competing Grant Progress Report**, (use form PHS 2590, posted on the HHS/CDC website, [http:// www. cdc.gov/ od/pgo/ funding/ forms.htm](http://www.cdc.gov/od/pgo/funding/forms.htm) and at [http:// grants.nih.gov/grants/ funding/2590/ 2590.htm](http://grants.nih.gov/grants/funding/2590/2590.htm), **is due 90 to 120 days prior to the end of the current budget period.** The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.
2. **Annual Federal Financial Report (FFR)** SF 425 is required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which the budget period ends.**
3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the project period.**

B. Content of Reports

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

- Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the PHS 2590 ([http:// grants1.nih.gov/ grants/funding/ 2590/2590.htm](http://grants1.nih.gov/grants/funding/2590/2590.htm)) [http:// grants.nih.gov/grants/ funding/2590/2590.htm](http://grants.nih.gov/grants/funding/2590/2590.htm): Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current

budget period proposal.

- Research Aims: list each research aim/project
 - a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned
 - b) Leadership/Partnership: list project collaborations and describe the role of external partners.
- Translation of Research (1 page maximum). When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that were translated into public health policy or practice and how the findings have been or may be adopted in public health settings. Or, if they cannot be applied yet, this section should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. *Questions to consider in preparing this section include:*
 - How will the scientific findings be translated into public health practice or inform public health policy?
 - How will the project improve or effect the translation of research findings into public health practice or inform policy?
 - How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs or practices?
 - How will the findings advance or guide future research efforts or related activities?
- Public Health Relevance and Impact (1 page maximum). This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques, inform policy, or use of technology in public health. *Questions to consider in preparing this section include:*
 - How will this project lead to improvements in public health?
 - How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
 - How will the findings, results, or recommendations contributed to documented or projected reductions in morbidity, mortality, injury, disability, or disease?
- Current Budget Period Financial Progress: Status of obligation of current budget period funds and an estimate of unobligated funds projected provided on an estimated FFR.
- New Budget Period Proposal:
 - Detailed operational plan for continuing activities in the upcoming budget period, including updated Measures of Effectiveness for evaluating progress during the upcoming budget period. Report listed by Research Aim/Project.
 - Project Timeline: Include planned milestones for the upcoming year (be specific and provide deadlines).
- New Budget Period Budget: Detailed line-item budget and budget justification for the new budget period. Use the CDC budget guideline format.

- **Publications/Presentations:** Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate "Not applicable: No publications or presentations have been made."
- **IRB Approval Certification:** Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.

2. Annual Federal Financial Reporting

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

Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information. **All CDC Financial Expenditure data due on/after October 1, 2012 must be submitted using the FFR via the eFSR/FFR system in the eRA Commons.** All Federal Reporting in the Payment Management System is unchanged. All new submissions should be prepared and submitted as FFRs.

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

Grantees must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, grantees must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

FFR (SF 425) instructions for CDC grantees are now available at <http://grants.nih.gov/grants/forms.htm>. For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: <http://www.cdc.gov/od/pgo/funding/grants/eramain.shtm>.

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

Organizations may verify their current registration status by running the "List of Commons Registered Organizations" query found at: <http://era.nih.gov/commons/>. Organizations not yet registered can go to <https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp> for instructions. It generally takes several days to complete this registration process. This registration is independent of Grants.gov and may be done at any time.

The individual designated as the PI on the application must also be registered in the Commons. The PI must hold a PI account and be affiliated with the applicant organization. This registration must be done by an

organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide found at: <http://era.nih.gov/commons/index.cfm>.

3. Final Reports: Final reports should provide sufficient detail for CDC to determine if the stated outcomes for the funded research have been achieved and if the research findings resulted in public health impact based on the investment. The grantee's final report should include:

- **Research Aim/Project Overview:** The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.
- **Translation of Research Findings:** The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the project period. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.
- **Public Health Relevance and Impact:** This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.
- **Publications; Presentations; Media Coverage:** Include information regarding all publications, presentations or media coverage resulting from this CDC funded activity. Please include any additional dissemination efforts that did or will result from the project.

Section VII. Agency Contacts

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

Application Submission Contacts

[Grants.gov Customer Support](#) (Questions regarding Grants.gov registration and submission, downloading or navigating forms)

Contact Center Phone: 800-518-4726

Email: support@grants.gov

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

[eRA Commons Help Desk](#) (Questions regarding eRA Commons registration, tracking application status, post submission issues, FFR submission)

Phone: 301-402-7469 or 866-504-9552 (Toll Free)

TTY: 301-451-5939

Email: commons@od.nih.gov

Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time

CDC Technical Information Management Section (TIMS)

Procurement and Grants Office

Telephone 770-488-2700

Email: PGOTIM@cdc.gov

Hours: Monday - Friday, 7am - 4:30pm U.S. Eastern Standard Time

Scientific/Research Contact(s)

Michael A. Brown, M.P.H.

Scientific Program Official

Extramural Research Program Operations and Services

Centers for Disease Control and Prevention

4770 Buford Hwy, NE

Mailstop F-80

Atlanta, GA 30342

Telephone: (770) 488-5118

E-mail: mab5@cdc.gov

Peer Review Contact(s)

Chris Langub, Ph.D.

Scientific Review Official

Extramural Research Program Office

Centers for Disease Control and Prevention

4770 Buford Hwy, NE

Mailstop F-80

Atlanta, GA 30342

Telephone: (770) 488-3584

E-mail: ee06@cdc.gov

Financial/Grants Management Contact(s)

Patricia French

Procurement and Grants Office, Grants Office, Branch III

2920 Brandywine Road, Mailstop E-09

Atlanta, GA 30341

Telephone: 770 488-2849

Email: pff6@cdc.gov

Section VIII. Other Information

Other CDC funding opportunity announcements can be found at www.grants.gov.

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

Authority and Regulations

Awards are made under the authorization of Sections of the Public Health Service Act as amended and under the Code Federal Regulations.

Awards for this FOA are made under the authorization of Sections 301(a) of the Public Health Service Act as amended, 42 U.S.C. 241(a).

Appendix A.

Questions from Potential Applicants and Answers by CDC

1. How is this FOA tailored to meet the needs of American Indian/Alaska Native communities?

Response: The overarching aim of this funding opportunity is to identify and test new tobacco use surveillance content, as well as determine the format and modes of administration that would result in enhanced national tobacco use surveillance capacity. This research FOA was developed with the intent to enhance tobacco surveillance systems in the U.S. population, including American Indian/Alaska Native communities.

2. One year to test surveillance of all populations is unreasonable, particularly in Indian Country. Can you explain the short time frame?

Response: The total project period is five years from September 30, 2015 to September 29, 2020. CDC does not expect that the awardee will test surveillance of all populations in one year. Applicants' research plan should address activities that will be conducted over the entire five-year project period. Applicants are to describe the project's timeline with specific activities and accomplishments for each year, including the planned approach for conducting and evaluating a pilot test of the surveillance system.

3. For almost all tribes, in order to do research, there must be tribal consultation and approval by the tribe to do research and survey the tribal community. Is tribal consultation required for this FOA?

Response: Conducting focus groups and key informant interviews, and developing partnerships with key stakeholders, which could include tribes and tribal organizations, are key components to this FOA. As outlined in section I, Funding Opportunity Description applicants are expected to collaborate and form partnerships and consortia with eligible organizations within the public health system to conduct the proposed research.

4. There is an emphasis on electronic media in the FOA. How will information about people in rural and remote areas that do not have cell phone or internet be accessed?

Response: The intent of the FOA is to test new, improved methods for collecting data that uses electronic media and ultimately lessens the burden on study participants. As a result of their research, the selected awardee will be responsible for developing a report with recommendations that specifically address the feasibility of using electronic platforms (Objective/Outcomes – Objective 5(c)).

5. Tobacco is a sacred gift given by the creator of most tribes. How would surveillance distinguish among sacred tobacco and commercial tobacco?

Response: As outlined in Section IV, Application and Submission Information, Research Plan, applicants' research plan should describe the planned approach to identify various definitions for tobacco use in diverse populations and to incorporate this information into surveillance instruments for pilot testing of validity, reliability, and mode of administration using electronic media. This activity may inform surveillance approaches to distinguish between sacred tobacco and commercial tobacco.

6. Is there an opportunity to consult on the development of a tobacco surveillance system?

Response: Collaboration and partnerships are important to achieving the goals and objectives of

this FOA. For example, in section VI, Award and Administration Information it states that Program Directors/Principal Investigators will have responsibility for recruiting technical and content experts as necessary, and establishing and maintaining communication with key research partners in order to achieve the goals and objectives of the FOA. In addition, the CDC Scientific Collaborator will assist the selected awardee in fostering relationships with established CDC partners who are involved in tobacco prevention and control, such as federal, tribal, state, and local agencies, advocacy groups and professional organizations.

7. For any data collection that the awardee proposes for this project, will an OMB package and clearance be needed?

Response: In Section I. Funding Opportunity Description, it states that: Some of the information collection conducted under this FOA is expected to be subject to the Paperwork Reduction Act of 1995 (PRA) (Pub. L. No. 96-511, 94 Stat. 2812, codified at 44 U.S.C. § 3501-3521). Further, in Section VI. Award Administration, item 4. Cooperative Agreement Terms and Conditions of Award, the FOA states that the PD(s)/PI(s) will have the primary responsibility for coordination with CDC to develop OMB submission package and obtain and maintain appropriate approvals through the life cycle of the award.

8. Can you please indicate if there is a cap on indirect costs?

Response: Indirect cost rate agreements are negotiated between the applicant organization and the cognizant federal agency.

9. For surveillance systems, is CDC as the funder interested in approaches to monitoring tobacco industry tactics, such as marketing (a correlate of tobacco use behavior)?

Response: The purpose of this announcement is to design and test new format, content and mode of administration for tobacco surveillance systems. The new and improved system (s) will be used by public health professionals and researchers to describe the patterns and correlates of tobacco-related indicators in the U. S. population and inform and evaluate tobacco prevention and control programs, policies, and interventions designed to reduce the burden of death, disease and disability associated with tobacco use.

Section IV. Application and Submission Information, Research Plan includes information applicants should address over the entire 5-year project period, in their application. Specific approaches and content to achieve the FOA purpose and intent are left to the applicant to decide.

10. How developed must the proposal be? ...survey instruments, collaborative partnerships firmed?

Response: The content of the application is determined by the Principal Investigator. The FOA does address these issues. In Part 2. Section I. Funding Opportunity Description, under Approach, the Collaboration/Partnerships section says that applicants are expected to collaborate and form partnerships or consortia with eligible organizations within the public health system to conduct the proposed research. The FOA does not have any specific requirements to provide survey instruments as part of the special eligibility criteria.

11. Do you know if this funding will be opened again? I would appreciate your advice in terms of how to work with this time frame. It has been a while since I have seen surveillance funding opportunities, and I have been frustrated by the limitations of the data available.

Response: This announcement is a Request for Applications (RFA), indicating one-time funding, not an ongoing open announcement. This funding opportunity announcement is competitive, and all potential applicants have the same time to prepare their application. For other federal funding opportunities, please continue to refer to www.Grants.gov.

12. Specific Aims – is this section required? On RFA page 13/31 under 5. PHS 398 Research Plan Component, it suggests having a Specific Aims section, however this is not listed in the application

materials. Is this a required, optional, not needed section?

Response: Please refer to section 5.5 PHS 398 Research Plan Form of the SF424 (R&R) Application Guide, available at http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf

13. Should we prepare specific aims, such as they are suggested in the annual reporting (RFA page 27/31), which sound more like deliverables?

Response: As a potential applicant you will need to determine the specific aims of your project. Upon award, each year grantees provide updates on their progress (including but not limited to attending an annual project review meeting, and any additional working meetings, with CDC) and address progress on their specific aims.

14. Please confirm if we should include a human subjects section – also listed on RFA page 13, but not in the PDF application package.

Response: Please refer to Section 1.1 Application Package Format, Part II. Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan, in the SF424 (R&R) Application Guide that is available at http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf