

Centers for Disease Control and Prevention

Agency for Toxic Substances and Disease Registry Extramural Research Program Office

Continuing Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation
RFA-TS-13-0010501SUPP15
Application Due Date: 02/05/2015

Continuing Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation

RFA-TS-13-0010501SUPP15

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Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

Agency for Toxic Substances and Disease Registry Extramural Research Program Office (ATSDR ERPO)
Agency for Toxic Substances and Disease Registry (ATSDR)

Funding Opportunity Announcement (FOA) Title

Continuing Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation

Activity Code

U01; Cooperative Agreement

Funding Opportunity Announcement Type

Reissue of TS13-001

Funding Opportunity Announcement Number

RFA-TS-13-0010501SUPP15

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

93.161

Category of Funding Activity:

Health

FOA Purpose

The purpose of this FOA is to support investigator-initiated research that will continue to expand and advance our understanding of exposures to uranium among Navajo mothers and their infants. Priority areas for this supplement are to conduct detailed environmental home assessments to characterize potential exposures.

Key Dates

Publication Date: **To receive notification of any changes to RFA-TS-13-0010501SUPP15, 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: **N/A**

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

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

Scientific Merit Review: **02/25/2015**

This is an estimated date. The review will be conducted in February or March, 2015.

Secondary Review: **03/13/2015**

This is an estimated date. The review will be conducted in February or March, 2015.

Estimated Start Date: **04/13/2015**

This is an estimated date. The actual start date will be in March or April, 2015.

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

Due Dates for E.O. 12372: Due no later than 60 days after the application receipt date.

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 10 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 FOA is to support investigator-initiated research that will continue to expand and advance our understanding of exposures to uranium among Navajo mothers and their infants. Priority areas for this supplement are to conduct detailed environmental home assessments to characterize potential exposures.

Mechanism of Support: U01; Cooperative Agreement

Funds Available and Anticipated Number of Awards. The total level of funding available for this FOA is $360,000 (indirect and direct costs). One award is expected. The actual award level is contingent upon availability of funds and a meritorious application. The total award depends upon the project quality, duration and cost proposed.

Budget and Project Period. The estimated total funding (direct and indirect) for the single 12 month budget period is $360,000. The estimated project period will run from 04/13/2015 to 08/31/2015.

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. One.

Number of Applications. Institutions may submit only one application.

Application Type. Revision.

Special Date(s). None.

Application Materials. See **Section IV.1** for application materials.

Hearing Impaired. Telecommunications for the hearing impaired are available at: TTY: (770) 488-2783.

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

This program is authorized under Section 104(i)(15) of the Comprehensive Environmental Response Compensation and Liability Act (CERCLA),[42 U.S.C. Section 9604(i)(15)], as amended.

1. Background and Purpose

The Navajo Nation Reservation encompasses 16 million acres of New Mexico, Utah and Arizona, and is the largest Alaska Native / American Indian Reservation in the United States (1). From 1948 to 1986, hundreds of uranium mining and milling operations were conducted on the Navajo Nation (2). These mining and processing operations have left a legacy of potential uranium exposure from abandoned uranium mines/mills, drinking water and soil contamination, and homes and structures built with mining waste (3,4). Uranium is a naturally-occurring radioactive metal and may cause adverse health effects related to both its radiological and chemical properties (5,6). Exposure to uranium as a heavy metal, primarily damages the kidneys and urinary system (7,8). Although the renal health effects of uranium have been studied extensively, there have been very few studies to examine the reproductive toxicity from non-occupational exposure to natural uranium.

The majority of studies examining the reproductive toxicity of natural uranium have been in animals. These studies have shown that uranium exposure in mice resulted in decreased numbers of offspring, reduced fetal growth, and congenital malformations (7,9). In one study, female mice that drank water containing uranium at or below the US Environmental Protection Agency (EPA) maximum contaminant level (30 µg/L) exhibited indicators of early onset of puberty (10). The authors concluded that uranium is an endocrine-disrupting chemical and suggested that populations exposed to environmental uranium should be studied for elevated risk of reproductive cancers and fertility complications (10). Research shows that endocrine disruptors may pose the greatest risk to infants during prenatal and early postnatal development when organ and neural systems are developing (11,12). These early exposures have been associated with reproductive cancers later in life (12). The findings from these previous animal studies indicate further epidemiologic investigations are warranted.

There is a paucity of recent studies examining uranium exposure and subsequent maternal and child health outcomes on the Navajo Reservation. A 1992 nested case-control study examined congenital anomalies, developmental disorders, and other adverse birth outcomes among Navajos born at the Shiprock Indian Health Service Hospital. The study found a statistically significant association between adverse birth outcomes and the mother's residence within 0.5 miles of uranium mill tailings or uranium mine waste dumps (13). In another study, the average age-adjusted incidence of reproductive cancer in New Mexico Native American children was eight times the incidence non-Native American children (14). Although cultural and social factors may influence birth and/or reproductive health outcomes among Navajo women (15), further study is warranted to better understand the potential associations between exposure of pregnant Navajo mothers and infants to environmental uranium and adverse birth outcomes and developmental delays.

American Indians and Alaska Natives experience considerable health disparities compared to the general U.S. population (16,17). These disparities are evident in maternal and child health on the Navajo Nation. Only 61 percent of Navajo mothers with live births received prenatal care in the first trimester as compared to 83 percent of all US mothers (18). The infant mortality rate among Navajos is 8.5 deaths per 1000 live births, compared to 6.9 deaths per 1000 live births among all races. Postnatal mortality rates for Navajo infants are 2.1 times higher than all races in the US, and the mortality rate for sudden infant death syndrome was 2.3 times the rate for the US in 2000. Additionally, congenital anomalies are the leading cause of infant death among Navajos (18). Several potential health effects of uranium are of particular

concern to susceptible populations such as infants, children, and those of reproductive age (18). Although uranium is a suspected teratogen, epidemiological studies are needed to document individual biomarker exposure to uranium and to differentiate the health effects of uranium from that of other teratogens (19,20).

The research efforts requested in this FOA complement and support current environmental investigations and possible future exposure mitigation efforts being conducted by a consortium of federal agencies to address uranium contamination on the Navajo Nation. In August 2008, the consortium, led by EPA and the Navajo Nation released the "Health and Environmental Impacts of Uranium Contamination in the Navajo Nation, Five-Year Plan". This plan was developed at the request of the US House Committee on Oversight and Government Reform. The objectives of the plan fall into three categories: assess structures and water sources that are likely to be contaminated, cleanup and/or mitigate harmful exposures, and assess health risks faced by individuals residing near mill sites or abandoned mine sites (3).

As part of the response to the Congressional charge, ATSDR awarded a research cooperative agreement to the University of New Mexico Community Environmental Health Program (UNM-CEHP) entitled "A Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation" in August 2010. In partnership with the Navajo Nation and Indian Health Service, this cooperative agreement supported the design and initial epidemiological studies of health conditions among Navajo mothers and their infants caused by non-occupational exposures to uranium released from past mining and milling operations on the Navajo Nation. In September 2013, ATSDR awarded a continuation cooperative agreement to the University of New Mexico Community Environmental Health Program (UNM-CEHP) entitled "Continuing Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation". This cooperative agreement was awarded to continue work on an epidemiologic study focusing on pregnant Navajo mothers and their infants and includes several important initiatives. As pregnant women are enrolled in the study they provide biological specimens (blood and urine). Additional samples are collected from the mother prior to delivery and from the infant at the time of delivery. The biological specimens are analyzed for body burden levels of heavy metals, including uranium. Post-partum and infant developmental surveys are administered following birth and when the infant is 2, 6, 9, and 12 months old. Additionally, home environmental assessments are conducted to assist with the characterization of potential sources of exposure to environmental contaminants. At the end of the first budget year (September 1, 2013 to August 31, 2014), 333 mother-infant pairs were participating in the study. The target enrollment for the second budget year (September 1, 2014 to August 31, 2015) is an additional 300 mother-infant pairs.

The project is currently funded through the budget year 2 (September 1, 2014-August 31, 2015). The funding level for the current budget year is sufficient to complete the targeted enrollment, collect and analyze the biological samples from the mothers and infants, and administer the infant developmental surveys. However, the funding is not sufficient to conduct the home environmental assessments for a portion of the women who enrolled during the first budget year or any of the women who enroll during the second budget year; approximately 350 women will need a home environmental assessment this year.

The research conducted under the current cooperative agreement will provide information about the body burden of uranium and other heavy metals in pregnant women and the infant's development during the first year for the study population. This FOA seeks research to provide information on whether the home environment contributes to the participant's exposure to uranium or heavy metals. The results of the research from this FOA may provide information on whether potential sources of uranium exposure exist in the homes of study participants at levels that could harm human health.

Purpose

The purpose of the program is to support investigator-initiated research that will continue to expand and advance our understanding of exposures to uranium among Navajo mothers and their infants. Priority areas for this supplement are to conduct detailed environmental home assessments to characterize potential exposures. This program addresses the "Healthy People 2020" priority areas of Environmental Health and

Public Health Infrastructure, and is in alignment with ATSDR's performance goals to determine human health effects associated with exposures at hazardous waste sites to Superfund-related priority hazardous substances.

References

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Healthy People 2020 and other National Strategic Priorities

This program addresses the "Healthy People 2020" priority areas of Environmental Health and Public Health Infrastructure, and is in alignment with ATSDR's performance goals to determine human health effects associated with exposures at hazardous waste sites to Superfund-related priority hazardous substances.

Public Health Impact

Previous uranium mining and milling activities in the Navajo Nation have resulted in contamination of soil and drinking water near homes throughout the area. Uranium exposure is associated with adverse health effects related to both its radiological and chemical properties; however, most studies have focused on the renal system. Toxicological studies of uranium exposure in mice have documented health effects in the reproductive system that include reduced fetal growth and congenital malformation. A few epidemiological studies have documented adverse birth outcomes and a higher incidence of reproductive cancer amoung Navajo women. This study will provide additional information on non-occupational exposure to environmental uranium and subsequent health effects on the Navajo Nation. This knowledge is essential to prevent and mitigate current and future exposures and adverse health outcomes on the Navajo Nation.

Relevant Work

ATSDR is directed by congressional mandate to perform specific functions concerning the effect on public health of hazardous substances in the environment. ATSDR works with communities, environmental groups, tribal governments and local, state and federal agencies to evaluate exposures to hazardous substances in communities to protect the public's health. ATSDR's work on the Navajo Nation Reservation began in September 2008, when CDC and ATSDR were asked to participate in an effort requested by Rep. Henry Waxman (D-CA), then-Chair of the House Oversight & Government Reform Committee. Initially, NCEH collaborated with EPA Region 9 on a water quality study to investigate public health impacts of hauling water from unregulated water wells. In 2009, ATSDR initiated what has now known as the Navajo Birth Cohort Study.

ATSDR's involvement with the Navajo Nation Birth Cohort Study is only one aspect of ATSDR's work to identify, evaluate and offer mitigation recommendations for communities exposed to harmful levels of environmental contaminants. Additional examples about ATSDR's evaluations are available and can be found at http://www.atsdr.cdc.gov/stories/index.html.

Previous related research efforts funded by ATSDR have evaluated the level of PCB and DDE in mothers consuming contaminated fish from the Great Lakes region during pregnancy, and whether their exposure was associated with adverse health effects in the children. The health outcomes evaluated include neurobehavioral deficits in children and adolescents, and the gene activity involved in sex steroid production and breakdown.

2. Approach

Research funded under this FOA will continue to expand and advance our understanding of exposures to uranium among Navajo mothers and their infants. Specifically, this FOA is to conduct detailed environmental home assessments to characterize potential exposures at the home of pregnant women enrolled in the Navajo Nation Birth Cohort study.

Objectives/Outcomes

Research Objectives

The epidemiologic study conducted under the current cooperative agreement focuses on pregnant Navajo mothers and their infants and includes several important initiatives. As pregnant women are enrolled in the study they provide biological specimens (blood and urine). Additional samples are collected from the mother prior to delivery and from the infant at the time of delivery. The biological specimens are analyzed for body burden levels of heavy metals, including uranium. Post-partum and infant developmental surveys are administered following birth and when the infant is 2, 6, 9, and 12 months old. Home environmental assessments are conducted to assist with the characterization of potential sources of exposure to environmental contaminants.

The funding level for the current budget year is not sufficient to conduct the home environmental assessments. The research objectives of this FOA focus on the objectives of the home environmental assessments. The research to be conducted under this supplement will characterize the potential exposures study participants have to environmental contaminants at their home environment. The results will improve our understanding of whether and how the home environment contributes to the mother and infant's exposure to uranium and other environmental contaminants. The home environmental sampling will include, but is not limited to:

- Collection and analysis of at least one indoor air radon test.
- Collection and analysis of at least one vacuum and one swipe dust sample from the floor and work surfaces.
- Collection and analysis of gamma radiation scans.

Target Population

Navajo women who receive care at one of the five clinic sites located in the Navajo Nation Reservation.

Collaboration/Partnerships

The applicant shall work in coordination with ATSDR, the Indian Health Service and Navajo Nation to identify study participants eligible for the home environment assessment, and to conduct the assessments and review the results.

Evaluation/Performance Measurement

Applicants should include an analytical plan that describes the research design, data collection measures, and data analysis design. Outcomes to be evaluated should be clearly specified.

Translation Plan

Research findings should be disseminated through publications, including articles in peer reviewed journals and "Research Briefs" for diverse audiences, as well as presentations at professional conferences and other venues. An explanation for how the scientific findings will be translated into public health programs, policies or practice should be included in the application.

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:

Revision (formerly Competing Supplement) - Request for additional funds for a current award to expand the scope of work. Applicants should contact the awarding agency for advice on submitting any revision/supplement application.

Estimated Total Funding: $360,000

The ceiling is $360,000 for a single 12-month budget period (including direct and indirect costs).

Anticipated Number of Awards: 1

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

Award Ceiling: $360,000 Per Project Period

Award Floor: $360,000 Per Project Period

Total Project Period Length: 1 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: Public and State controlled institutions of higher education

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

Limited eligibility. This FOA is intended to provide supplemental funds to complete efforts proposed in the original scope of the approved project for FOA #TS13-001. The University of New Mexico is uniquely qualified to conduct this research. They have the technical expertise to conduct the required sampling, scientific background to analyze the results, and established partnerships within the community to achieve the necessary level of participation by pregnant mothers.

4. Justification for Less than Maximum Competition

The University of New Mexico (UNM) is uniquely qualified to conduct the efforts requested in this supplemental FOA. UNM has established partnerships to coordinate with area health clinics sponsored by the Indian Health Service (IHS) to ensure the biomonitoring samples obtained from the pregnant women and infants are properly collected and prepared for laboratory analyses. UNM established partnerships with the Navajo Nation health and environmental agencies and community members to be able to recruit pregnant women to the study.

UNM successfully worked with ATSDR on the earlier cooperative agreement funded under TS10-001, A Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation. UNM worked with Navajo Nation agencies and community, IHS, and ATSDR to investigate community concerns about living in close proximity to elevated levels of uranium. The research from TS10-001 resulted in the design and initial epidemiological studies of health conditions among Navajo mothers and their infants caused by non-occupational exposures to uranium released from past mining and milling operations on the Navajo Nation. This study was designed to both address the community's greatest concerns regarding birth outcomes and provide valuable epidemiological information to the scientific community about the reproductive effects of exposure to elevated levels of environmental uranium.

During the first budget year of the current cooperative agreement funded by TS13-001, UNM successfully enrolled over 333 mother-infant pairs and conducted home environmental assessments for most of the enrollees (approximately 50 women did not receive the home evaluation assessment). The mother-infant pairs provide urine samples that will be analyzed to assess their body burden of uranium and other heavy metals. The infants are periodically assessed to evaluate their development according to medical norms. The home environmental assessments are conducted to determine whether and how the home environment contributes to the mother and infant's exposure to uranium and other heavy metals.

The funds available for the second year of the cooperative agreement funded by TS13-001 were not sufficient to conduct home environmental assessments for a portion of the women who enrolled in the first budget year or any of the 300 women who will be enrolled during the second year. This supplemental funding will ensure all women enrolled during the first or second year receive a home environmental assessment. Approximately 350 home environmental assessments will be conducted; this includes the homes of the 300 women expected to be enrolled this year (budget year 2) and a small number of women (approximately 50) enrolled during the end of budget year 1.

The University of New Mexico is a public institution of higher education. Similar limited or single-source eligibility requests were made prior to releasing the original TS10-001 FOA and the following TS13-001 FOA. Both were accepted.

With the research funded by this supplement, ATSDR will gain a better understanding of the relationship between the level of exposure the pregnant women have to uranium in their homes, the concentration of uranium in their urine, the concentration of uranium in the urine of infants, and the infants' development. Without this supplement the research results will be unable to demonstrate whether the uranium levels measured in the mothers and infants are associated with exposures at home or from other locations; limiting the ability of the researchers to provide meaningful information to the community on actions they can take to reduce harmful exposures.

5. Responsiveness

Application must not exceed page limits

Application must clearly define methodolgy to meet research objects defined in this FOA

6. Required Registrations

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

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https://eportal.nspa.nato. int/AC135Public/Docs/US%20Instructions%2 0for%20NSPA%20NCAGE.pdf
- System for Award Management (**SAM**) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, https://www.sam.gov/portal/SAM/#1.
- Grants.gov
- eRA Commons

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

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

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

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

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

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

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

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

9. Cost Sharing

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

10. Number of Applications

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

Only one application per institution (normally identified by having a unique DUNS number) is allowed.

Section IV. Application and Submission Information

1. Address to Request Application Package

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.

All page limitations described in this individual FOA must be followed. For this FOA, the Research Strategy section is limited to 10 pages.

3. Letter of Intent

Due Date for Letter of Intent:

N/A

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.

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 10 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 5 PDF files with a maximum of 30 pages for all appendices.

8. Format for Attachments

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

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

9. Submission Dates & Times

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

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

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

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

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

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

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

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

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

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

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

1. Track his/her submission and verify the submission status (tracking should be done initially regardless of rejection or success).

    a. If the status states "***rejected***," do #2a or #2b.

2. Check his/her emails from both Grants.gov and eRA Commons for rejection notices.

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

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

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

10. Intergovernmental Review (E.O. 12372)

Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order 12372 (http://www.archives.gov/federal-register/codification/executive-order/12372.html). This order sets up a system for state and local review of proposed federal assistance applications. You should contact your state single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your state's process. Click on the following link to get the current SPOC list: http://www.whitehouse.gov/omb/grants_spoc/.

11. Funding Restrictions

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

For more information on expanded authority and pre-award costs, go

to: http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf.

12. Other Submission Requirements and Information

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

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

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

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

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

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

See more resources to avoid common errors and submitting, tracking, and viewing applications: http:// grants.nih. gov/grants/ Electronic Receipt /avoiding_ errors.htm or http:// grants. nih.gov/grants/ Electronic Receipt/submit_ app.htm

Upon receipt, applications will be evaluated for completeness by the CDC Procurement and Grants Office (PGO) and responsiveness by PGO and the Center, Institute or Office of the CDC. Applications that are incomplete and/or nonresponsive will not be reviewed.

Section V. Application Review Information

1. Criteria

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

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

Scored Review Criteria

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

Significance

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

Does the applicant demonstrate an understanding of the objectives of this research effort? Does the applicant demonstrate a history of working with the Navajo Nation on public health issues? Does the applicant demonstrate how this specific effort relates to, and builds upon previous research in this area?

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?

Has the applicant identified key professional personnel from other participating or collaborating institutions, agencies, and organizations outside the applicant's agency that will be assigned to key research activities? Is a curriculum vitae provided for each in the appendix? Does the applicant provide descriptions of participants' experience in conducting work similar to that proposed in this announcement? Does the applicant describe all support staff and services to be assigned to this proposal? If the project involves research involving human subjects or a clinical investigation, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

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?

Approach

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

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

Does the applicant describe the agency's structure, and support from partnering programs and/or agencies? Does the applicant describe the ability to develop and maintain cooperative relationship with the Navajo Nation? Is support from partnering agencies, institutions, organizations, laboratories, and individuals included in the operational plan? Does the applicant provide (in an appendix) letters of support indicating collaborators' commitments to participate in this public health initiative and describe their anticipated role?

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?

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.

- The relevance and balance of proposed research relative to the HHS/CDC/ATSDR programs and priorities.

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 only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review), will be discussed and assigned an overall impact/priority score.

- Will receive a written critique.

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

- Scientific and technical merit of the proposed project as determined by scientific peer review.

- Availability of funds.
- Relevance of the proposed project to program priorities.

5. Anticipated Announcement and Award Dates

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

Section VI. Award Administration Information

1. Award Notices

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

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

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

2. CDC Administrative Requirements

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

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

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

Specific requirements that apply to this FOA are the following:

CIOs must insert all relevant additional requirements.

Generally applicable ARs:

AR-1: Human Subjects Requirements

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

AR-3: Animal Subjects Requirements

AR-7: Executive Order 12372 Review

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2020

AR-12: Lobbying Restrictions

AR-14: Accounting System Requirements

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

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

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Release and Sharing of Data

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

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

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

AR 31 - Distinguishing Public Health Research and Public Health Nonresearch

AR 32 –; FY 2012 Enacted General Provisions

ARs applicable to ATSDR Awards:

AR-18: Cost Recovery –; ATSDR

AR-19: Third Party Agreements –; ATSDR (AR-19)

ARs applicable to Conference Awards:

AR-20: Conference Support

AR-27: Conference Disclaimer and Use of Logos

Organization Specific ARs:

AR-8: Public Health System Reporting Requirements

AR-15: Proof of Non-profit Status

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

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

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

3. Additional Policy Requirements

The following are additional policy requirements relevant to this FOA:

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

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

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

Federal Funding Accountability and Transparency Act of 2006

Public Law 109-282, the Federal Funding Accountability and Transparency Act of 2006 as amended

(FFATA), requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single publicly accessible Web site, www.USASpending.gov (http:// www.usaspending. gov/). For the full text of the requirements, please review the following website: https:// www.fsrs.gov/.

Plain Writing Act

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

Tobacco and Nutrition Policies

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

Tobacco:

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

Nutrition:

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

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

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

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

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

4. Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable 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/ATSDR programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC/ATSDR 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/ATSDR Project Officers are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and HHS/CDC/ATSDR as defined below.

This FOA is for a cooperative agreement. Under the cooperative agreement, the Agency for Toxic Substances and Disease Registry's (ATSDR) purpose is to support the awardee's activities. CDC/ATSDR does not assume direction, prime responsibility, or a dominant role in the project activities. CDC/ATSDR staff are involved in various aspects of data collection and analyses. These activities are conducted under the approval of OMB Control Number 0923-0046, and expire February 29, 2016. Additionally, for this cooperative agreement, CDC/ATSDR personnel may serve as co-authors on publications and reports at the request of the grantee. CDC/ATSDR will also conduct post-award monitoring of project performance, including review of progress reports, holding conference calls, and making visits.

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

- Protocol development and implementation, data analysis, interpretation of results, and dissemination of findings including report writing and oral presentations.
- Create a community liaison group that will establish and implement a communication plan that delineates processes and products for sharing the scientific research objectives, progress, and results with stakeholders from the Navajo Nation community, the Indian Health Service, and ATSDR in a timely fashion. The main purpose of the community liaison group will be to provide a forum for dialogue about the study among all stakeholders and to ensure that stakeholder feedback and concerns are addressed. This community liaison group will not involve Federal Advisory Committee Act implications.
- Maintain a working relationship with the Navajo Nation community, state, local, and chapter organizations and familiarity with Navajo Institutional Review Board Guidelines in order to accomplish the objectives.
- Participate in site visits or other program meetings as needed for constructive feedback on program activities and to address potential barriers.
- Obtain the appropriate Institutional Review Board approvals for research involving human subjects for all participating sites.
- Provide ATSDR with monthly updates on current enrollment status including, but not limited to, number of enrolled mothers, fathers and infants, and number of biological samples collected and analyzed for mothers, fathers, and infants for each enrollment area.
- Provide ATSDR with monthly updates on currant status of the home environmental assessments conducted including, but not limited to, number of assessments conducted (including number and type of samples collected, and number and type of analyses completed).
- In context with the established research (TS13-001), publish and disseminate study results to a broad audience to include, but not limited to, study participants, study partners, and scientific community.
- Provide ATSDR with monthly updates on other related activities related to the Navajo Birth Cohort Study, including abstracts, presentations, and publications submitted and/or presented.

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

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

- Assist with development of methods to identify environmental exposures and affected populations relevant to the current epidemiological study design.
- Conduct biomonitoring analysis through the National Center for Environmental Health (NCEH) laboratory.
- Assist in the protocol development and study implementation.
- Collaborate with the grantee on data analysis, interpretation of results, and dissemination of findings including report writing, manuscript preparation and oral presentation.
- Provide technical assistance in the development of training and education materials on environmental hazards associated with uranium exposures for the affected population.
- Obtain IRB approvals as required by CDC/ATSDR when CDC/ATSDR is engaged in research involving human subjects.
- Conduct a technical review of abstracts, presentations and publications generated from this cooperative agreement.
- When CDC/ATSDR staff are co-authors, the document will be reviewed, prior to publication, using the agency's clearance process.
- Conduct site visits, as needed, for constructive feedback on program activities to address potential concerns/barriers.
- Additionally, an agency program official or CDC/ATSDR program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

Areas of Joint Responsibility include:

- All responsibilities are collaborative efforts between awardees and CDC/ATSDR staff as described above.

5. Reporting

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

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

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

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

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

subawards over $25,000. See the HHS Grants Policy Statement (http:// www.hhs.gov/asfr/ ogapa/aboutog/ hhsgps107.pdf) for additional information on this reporting requirement.

A. Submission of Reports

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

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

B. Content of Reports

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

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

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

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

  - How will the scientific findings be translated into public health practice or inform public health policy?
  - How will the project improve or effect the translation of research findings into public health practice or inform policy?

- How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs or practices?
- How will the findings advance or guide future research efforts or related activities?

- Public Health Relevance and Impact (1 page maximum). This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques, inform policy, or use of technology in public health. *Questions to consider in preparing this section include*:

    - How will this project lead to improvements in public health?
    - How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
    - How will the findings, results, or recommendations contributed to documented or projected reductions in morbidity, mortality, injury, disability, or disease?

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

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

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

2. Annual Federal Financial Reporting

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

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

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

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

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

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

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

The individual designated as the PI on the application must also be registered in the Commons. The PI must hold a PI account and be affiliated with the applicant organization. This registration must be done by an organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide found at: http:// era.nih.gov/ commons /index.cfm.

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

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

- Publications; Presentations; Media Coverage: Include information regarding all publications, presentations or media coverage resulting from this CDC funded activity. Please include any additional dissemination efforts that did or will result from the project.

Section VII. Agency Contacts

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

Application Submission Contacts
Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading or navigating forms)
Contact Center Phone: 800-518-4726
Email: support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking application status, post submission issues, FFR submission)
Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
Email: commons@od.nih.gov
Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time

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

Scientific/Research Contact(s)
Susan Neurath, PhD
Scientific Program Officer
Extramural Research Program Office
Supporting the Agency for Toxic Substances and Disease Registry, NCEH, and NCIPC
Centers for Disease Control and Prevention (CDC)
Telephone: 770-488-3368
Email: SFN8@cdc.gov

Scientific/Technical Review Contact(s)
Mildred Williams-Johnson, PhD, DABT
Director, Extramural Research Program Office
Supporting the Agency for Toxic Substances and Disease Registry, NCEH, and NCIPC
Centers for Disease Control and Prevention (CDC)
Telephone: 770-488-4281
FAX: 770-488-4422
Email: JXS8@cdc.gov

Financial/Grants Management Contact(s)
Valerie McCloud, Grants Management Specialist
Procurement and Grants Office

Center for Disease Control and Prevention
2920 Brandywine Road, Mail Stop E-15
Atlanta, GA 30341
Telephone: 770-488-4790
Email: fyq4@cdc.gov

Section VIII. Other Information

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

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

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

This program is authorized under Section 104(i)(15) of the Comprehensive Environmental Response Compensation and Liability Act (CERCLA), [42 U.S.C. Section 9604(i)(15)], as amended.

Successful grantees will be permitted expanded authorities in the administration of this award as provided for in the Code of Federal Regulations, Title 2, Subtitle A, Chapter II, Part 200, Subpart D, §200.308(d)(4).