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Part 1. Overview Information

Participating Organization(s)	Centers for Disease Control and Prevention (CDC)
Components of Participating Organizations	National Center for Injury Prevention and Control (NCIPC)
Funding Opportunity Announcement (FOA) Title	**Research on Integration of Injury Prevention in Health Systems**
Activity Code	U01
Funding Opportunity Announcement Type	New
Funding Opportunity Announcement Number	**RFA-CE-14-004**
Catalog of Federal Domestics Assistance (CFDA) Number(s)	93.136. Injury Prevention and Control Research and State and Community Based Programs
Category of Funding Activity	Health
FOA Purpose	The purpose of this funding is to support research that informs the link between public health and clinical medicine in injury prevention by: 1) developing the evidence base for clinical preventive services in the area of prescription drug overdose and 2) investigating models for partnership between hospitals and state/local health departments in designing community health needs assessments and improvement plans that incorporate injury prevention.

Key Dates

Publication Date	To receive notification of any changes to CE14-004, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link An email address is needed for this service.
Letter of Intent Due Date	**Feb. 14, 2014**
Application Due Date	**March 19, 2014, by 5:00 PM U.S. Eastern Time**. 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	Month(s), Year
Secondary Review	Month, Year
Estimated Start Date	September 30, 2014
Expiration Date	March 20, 2014
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 20 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**

Although the health impact of unintentional injury is very high for both individuals and the entire health care system, injury prevention is not fully integrated in clinical settings. Primary care settings and emergency departments are key entry points in which patients can be screened for unintentional injury risk and referred to intervention programs in the community, and in which providers can adhere to clinical guidelines to reduce the burden of injury (for example, in the area of opioid prescribing). Yet, health professionals are not regularly implementing injury preventive services, adhering to guidelines, or expanding their reach through support of community-level policies and practices that can produce community benefit and influence population health. New opportunities have opened for prevention and enhancing the integration of public health and clinical care, in part due to the Patient Protection and Affordable Care Act (PPACA) [Patient Protection and Affordable Care Act § 9007, 26 U.S.C. 501(c) (2010]. These opportunities include (a) enhanced clinical preventive service delivery that focuses on unintentional injury prevention, and (b) enhanced integration of injury into Community Health Needs Assessments, a requirement of the PPACA for non-profit hospitals that wish to maintain their tax-exempt status. Research is needed to understand how these opportunities can be fully realized to address the burden of unintentional injury.

Key approaches to enhancing collaboration between public health and clinical care include: (1) better public health use of clinical data, and better clinical use of community population health data, (2) enhanced delivery of high impact clinical preventive services with linkage to community activities, and (3) improvements in drivers of clinical practice such as guidelines, incentive systems, capacity, and partnerships. If used, these approaches could foster inclusion of injury prevention services in the U.S. health care system.

The research objectives for this FOA support these three approaches by developing the evidence base for clinical services that reduce the burden of injury, and identifying models for hospital/health department partnerships that enhance the use of community population health data on injury to address community needs. Applicants

may apply to one of the following two priority areas. The research questions of interest are:

1. Developing the evidence base for clinical preventive services – special focus on prescription drug overdose:
    a. What types of clinical services are effective in improving the prescribing of opioid analgesics to reduce their abuse, and prevent morbidity and mortality? In particular, what preventive interventions or policies at a systems level are effective in changing prescriber behavior, leading to reductions in prescriptions for high dose opioids, co-prescribing of opioids with benzodiazepines, and prescriptions from multiple providers, while ensuring patients have access to safe, effective pain treatment (e.g., requiring use of prescription drug monitoring programs, team-based care)?
    b. What health systems drivers, such as guidelines, health information technology (e.g., clinical decision support integrated within electronic health records), and clinical-community partnerships (e.g., collaborations among public health, state agencies, and private organizations) can enhance service delivery and impact?
2. Integrating injury within CNHAs: What strategies can best facilitate partnerships between state and local health departments and non-profit hospitals in the design of Community Health Needs Assessments (CHNAs)? How can community-level injury data be incorporated within CHNAs? How can evidence-based, public health injury interventions be translated to facilitate adoption by hospitals as part of Community Health Improvement Plans (CHIPs)? What are the facilitators and barriers?

- **Mechanism of Support.** Cooperative agreement

- **Funds Available and Anticipated Number of Awards.** The National Center for Injury Prevention and Control expects to make available $800,000 over 2 years to support 2 awards.
    - Awards issued under this FOA are contingent upon availability of funds and a sufficient number of meritorious applications.
    - The total amount awarded and the number of awards will depend upon the number, quality, duration and cost of the applications received and approved.

- **Budget and Project Period.**
  The estimated total funding (direct and indirect) for the first year (12 month budget period) is $400,000 and the estimated total funding (direct and indirect) for the entire project period is $800,000. The project period will run from 09/1/2014 to 08/30/2016.

- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. Application and Submission Information of this announcement.

- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III, 1.A. are eligible to apply.

- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.

- **Number of PDs/PIs.** Applications may name more than 1 PD/PI. However:
  - 1 PD/PI must be designated as the contact person for all correspondence related to the application.
  - 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.

- **Number of Applications.** Eligible applicant institutions may submit more than one application, provided that each application is scientifically distinct. If more than one proposal is submitted from a single institution or group of institutions sharing a common system, not more than one will be awarded.

- **Application Type.** New.

- **Special Date(s).**
  CDC will conduct a pre-application teleconference call on Wednesday, January 22, 2014 from 1:00-2:30 pm Eastern Time to address prospective applicants' questions regarding RFA-CE14-004, Research on Integration of Injury Prevention in Health Systems.

  PARTICIPANT ACCESS INFORMATION
  ==========
  CALL DATE: January 22, 2014
  CALL TIME: 1:00 pm (EST)
  CALL DURATION: 1 hour 30 minutes
  LEADER: Donald Blackman
  Toll-Free Number: 888-793-2154
  Passcode: 4424802

- **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 Announcement Description

Statutory Authority

This program is authorized under Section 301 (a) [42 U.S.C 241(a)] of the Public Health Services Act, and Section 391(a) [42 U.S.C 280 b (a)] of the Public Health Services Act, as amended

1. Background and Purpose

Over 120,000 people died from unintentional injuries in the United States in 2010, and approximately 1 in 10 people experienced a nonfatal injury serious enough to require a visit to the emergency department. Unintentional injuries are the leading cause of death for people aged 1-44 years, and kill more people in this age group than heart disease, cancer, chronic respiratory disease, or stroke. Unintentional injuries take a dramatic economic toll on the nation, with medical costs alone estimated to be $81.6 billion in 2010 (CDC, 2013).

Although the health impact of unintentional injury is very high for both individuals and the entire health care system, injury prevention is not fully integrated in clinical settings. Primary care settings and emergency departments are key entry points in which patients can be screened for unintentional injury risk and referred to intervention programs in the community, and in which providers can adhere to clinical guidelines to reduce the burden of injury (for example, in the area of opioid prescribing). Yet, health professionals are not regularly implementing injury preventive services, adhering to guidelines, or expanding their reach through support of community-level policies and practices that can produce community benefit and influence population health. New opportunities have opened for prevention and enhancing the integration of public health and clinical care, in part due to the Patient Protection and Affordable Care Act (PPACA) [Patient Protection and Affordable Care Act § 9007, 26 U.S.C. 501(c) (2010]. These opportunities include (a) enhanced clinical preventive service delivery that focuses on unintentional injury prevention, and (b) enhanced integration of injury into Community Health Needs Assessments, a requirement of the PPACA for non-profit hospitals that wish to maintain their tax-exempt status. Research is needed to understand how these opportunities can be fully realized to address the burden of unintentional injury through better data use, service delivery, and partnerships.

Developing the Evidence Base for Clinical Preventive Services: Prescription Drug Overdose

Poisoning deaths, of which nearly 90% are drug poisoning or overdose deaths, surpassed motor vehicle deaths for the first time in 2008 (CDC, 2013). In 2011, drug misuse and abuse caused about 2.5 million emergency department (ED) visits. Of these, more than 1.4 million ED visits

were related to pharmaceuticals (SAMHSA, 2013). Overdose death rates from opioid analgesics, such as oxycodone, hydrocodone, and methadone have increased four-fold between 1999 and 2010 (CDC, 2011). Even though the health impact of prescription drug overdose is very large, there are limited evidence-based, systems-level interventions that have been identified to impact provider prescribing of opioids and reduce patient risk that can be implemented in clinical settings.

The PPACA has made preventive services more accessible by requiring health plans to cover recommended preventive services without cost sharing [Patient Protection and Affordable Care Act § 2713 (2010)]. Preventive services with a grade of A or B issued by the US Preventive Services Task Force are now covered. Currently, there are no recommended preventive services with A or B grades that address prescription drug overdose. There is an interest in building the evidence base, with a focus on approaches that are at the systems level, focus on provider behavior, and link together clinical and public health services.

For example, studies are underway to rigorously test different models of screening and intervention for prescription drug misuse using the Screening, Brief Intervention, and Referral to Treatment (SBIRT) model in emergency departments with prospective, randomized controlled trials (D'Onofrio, 2013; Merchant, 2013). Evidence for the utility of SBIRT for prescription drug misuse and overdose in other primary care settings, such as family practice and general internal medicine clinics, is needed (Saitz, 2010). There are also innovative systems-level initiatives that have been shown to change provider behavior across a group practice. For example, Group Health, a Seattle-based nonprofit healthcare system, implemented a major initiative to improve opiate prescribing and was successful in getting 85% of a chronic non-cancer pain population enrolled in a care plan that included treatment goals, medication regimen, frequency of monitoring visits, and requirements for urine drug screening. It is unknown the degree to which this approach has impacted receipt of excess prescriptions of opioids and prescription opioid overdose events. Thus, although evidence is emerging on such preventive services and systems changes, rigorous research on public health interventions that focus on reducing patient risk (e.g., coordinated care plans, overdose education with naloxone) and changing provider prescribing behavior (e.g., models for enhancing prescription drug monitoring program use and guideline implementation) is lacking.

Integration of Injury into Community Health Needs Assessments (CHNAs)

Although hospitals are expected to engage in activities that promote health for the benefit of the entire community (particularly when such activities are offered in exchange for tax exemptions), the degree to which hospitals integrate injury prevention, a leading cause of injury and death, into community health improvement plans is uncertain.

The PPACA has implemented new requirements for non-profit hospitals that wish to maintain their tax-exempt status [Patient Protection and Affordable Care Act § 9007, 26 U.S.C. 501(c) (2010]. Non-profit hospitals must conduct a community health needs assessment every three years. The CHNA must take into account input from persons who represent the broad interests

of the community serviced by the hospital facility, including those with special knowledge of or expertise in public health, and must be made widely available to the public. To assess the health needs of a community, a hospital must identify significant health needs, prioritize the health needs (e.g., based on burden, scope, or severity; existence of disparities; or availability of effective interventions), and identify potential measures and resources (e.g., programs, organizations, facilities in the community) available to address the needs. Improvements might include improving access to care by removing financial and other barriers to care. Annually, the hospitals must report how the facility plans to address the health need (or identify the health needs as one the facility does not intend to address and explain why the facility does not intend to address the need); identify the programs and resources the facility plans to commit; and discuss any planned collaboration between the hospital facility and other organizations.

Given the public health burden of injury, it is expected that topics such as older adult falls, prescription drug overdose, or motor vehicle injuries might arise as a key areas of concern. This might be particularly true for hospitals that include Level I trauma centers, which must already support research in injury prevention to maintain their Level I status. It is important that there are CHNA best practice models available for adoption by hospitals with trauma centers that include engagement of state and/or local health departments, and address injury as a leading cause of injury and death in the community. Such models might include innovative data collection; data sharing; selection of programs, policies, and practices based on the best available evidence; and improvement strategies based on translation research approaches. Models might expand the type of strategies considered for implementation, including not only individual patient-based interventions (e.g., injury preventive screening), but also community-based interventions (e.g., local policies). Research is needed to determine which models can best facilitate health department collaboration, and ensure that the leading causes of injury and death, such as unintentional injury, are included in CHNAs and CHIPs to address community needs.

Healthy People 2020 and other National strategic priorities

IVP-1 Reduce fatal and nonfatal injuries

This FOA takes advantage of the unique opportunity provided by PPACA to link together clinical and public health community services.

Public Health Impact -- Like diseases, injuries are preventable. This research will help CDC address the deficiencies in the evidence base for clinical preventive services by identifying interventions that can reduce risks, change health behaviors, and improve health outcomes, particularly injuries and mortality related to prescription drug overdose. This research will also assist CDC in understanding the best practices for hospitals to use in collaboration with state and local health departments to facilitate the identification and implementation of strategies that reduce the burden of injury at a population level by incorporating injury into their community health needs assessments and response plans.

Relevant work

CDC's research on health systems has focused on chronic disease prevention (e.g. cancer, diabetes, hypertension, stroke, and heart disease), and infectious diseases. For example, CDC has worked to support the uptake of clinical preventive services—recommended tests and screenings that can detect diseases early, or vaccinations that protect against infectious diseases. Other focus areas have included improving health and healthcare surveillance activities to get better data on health status and healthcare activities, enhancing the Community Preventive Services Task Force's capacity to assess and disseminate scientific evidence for prevention, enhancing the capacity of laboratories to detect diseases, and improving programs to address healthcare-associated infections.

The National Center for Injury Prevention and Control has recently turned its attention to the intersection of public health and healthcare delivery, by creation of a health systems team to, in part, support the integration of public health injury prevention with clinical medicine. Early work of the Injury Center has focused on drivers, such as translating clinical guidelines into tools for practitioners to enhance adoption of evidence-based practice. For example, CDC has developed the STEADI Tool Kit – Stopping Elderly Accidents, Deaths, and Injuries (http://www.cdc.gov/homeandrecreationalsafety/Falls/steadi/index.html). This tool kit provides resources for health care providers who treat older adults who are at risk of falling or who may have fallen in the past. The tool kit is based on an algorithm adapted from the American and British Geriatric Societies' clinical practice guideline for fall risk assessment. CDC has funded states to support provider adoption of STEADI and implement evidence-based community fall prevention programs to which patients with fall risk can be referred. States are also working with clinics and health plans to include fall risk assessment and referral within the electronic health record.

NCIPC has also focused on the prescription drug overdose epidemic within health systems, and has identified the connection between high-risk, inappropriate opioid prescribing and increases in opioid misuse, abuse, and overdose. Addressing this driver of the epidemic is a priority for CDC. NCIPC's approach for reversing the epidemic focuses on three primary strategies: strengthening surveillance, informing policy solutions by building the evidence base, and improving clinical practice. This FOA advances the last strategy. NCIPC believes that the most effective interventions in combating the prescription drug overdose epidemic include those designed to identify and address high-risk patients at a stage when their risky behaviors can be most effectively addressed. Focus on improving clinical practice has included the development of indicators to measure inappropriate prescribing (see, for example, Ying et al, 2013), as well as on the use of prescription drug monitoring programs (PDMPs). Strong yet accessible PDMPs that promote proactive patient interventions are a critical component of a high-risk focused strategy. By enabling providers to identify high-risk

patients at the point of care, via improved access to and use of PDMPs and improved comprehensiveness of PDMP data, providers can intervene with patients and address their high-risk behaviors, including providing or redirecting patients to substance abuse treatment as necessary.

Thus, integrating public health approaches to injury prevention within clinical care is a priority for CDC. The current FOA aims to advance CDC's work in this area by fostering the development of provider initiated, evidence-based injury prevention strategies and injury-specific community health needs assessments and improvement plans.

2. Approach

The research objectives for this FOA support these three approaches by developing the evidence base for clinical services that reduce the burden of injury, and identifying models for hospital/health department partnerships that enhance the use of community population health data on injury to address community needs. Applicants may apply to one of the following two priority areas. The research questions of interest are:

1. Developing the evidence base for clinical preventive services – special focus on prescription drug overdose:
    a. What types of clinical services are effective in improving the prescribing of opioid analgesics to reduce their abuse, and prevent morbidity and mortality? In particular, what preventive interventions or policies at a systems level are effective in changing prescriber behavior, leading to reductions in prescriptions for high dose opioids, co-prescribing of opioids with benzodiazepines, and prescriptions from multiple providers, while ensuring patients have access to safe, effective pain treatment (e.g., requiring use of prescription drug monitoring programs, team-based care)?
    b. What health systems drivers, such as guidelines, health information technology (e.g., clinical decision support integrated within electronic health records), and clinical-community partnerships (e.g., collaborations among public health, state agencies, and private organizations) can enhance service delivery and impact?
2. Integrating injury within CNHAs: What strategies can best facilitate partnerships between state and local health departments and non-profit hospitals in the design of Community Health Needs Assessments (CHNAs)? How can community-level injury data be incorporated within CHNAs? How can evidence-based, public health injury interventions be translated to facilitate adoption by hospitals as part of Community Health Improvement Plans (CHIPs)? What are the facilitators and barriers?

Research addressing question 1 may be designed as a small pilot study or leverage an existing study (e.g., by adding preventive services for prescription drug overdose prevention to other

health system models). Preventive services and system changes must build on existing knowledge and focus on methods that are practical for scaling up. Proposals that investigate drivers such as guidelines, clinical decision support systems within electronic health records, or public health-private partnerships are of particular interest. Rigorous evaluation research methods are expected. Methods may include quasi-experimental designs, randomized controlled trials, or prospective cohorts. Qualitative data collection may be proposed to supplement the evaluation to investigate barriers and success factors for adoption by health systems. Projects may be directed at the population level or toward groups that are at particularly high risk. Outcomes might include process variables (e.g., use of PDMP systems, prescribed morphine equivalents, random drug screening, uncoordinated opioid prescriptions from multiple providers, timeliness of monitoring visits) and health impact variables (e.g., 911 calls, emergency department visits, hospitalizations, and deaths linked to prescription drug abuse).

Research addressing question 2 may include qualitative and quantitative approaches. Methods might include surveys to understand the data and information needs of hospitals in developing community health needs assessments (CHNAs), identifying improvement plans (CHIPs), and evaluating outcomes achieved (community benefit). Interviews or focus groups could be used to understand the facilitators and barriers of hospitals partnering with state and/or local health departments and community-based organizations. Outcomes are expected to include inclusion of injury topics in the CHNAs and CHIPs, as reported on the IRS Form 990 and Schedule H (the federal tax return for nonprofit hospitals). The applicant must provide a detailed explanation for how the data are to be obtained and used and how the analytic methods will successfully address the research questions. Measures specific to injury burden and prevention must be incorporated. It is anticipated that lessons learned from building collaborations between hospitals and health departments based on the data would be summarized in a best practices guide.

Section II. Award Information

Funding Mechanism	Applications in response to this FOA will be funded using the **cooperative agreement** mechanism. Cooperative Agreement: A support mechanism used when there may be Federal scientific or programmatic involvement. Involvement means that, after award, scientific or program staff may assist, guide, coordinate, or participate in project activities. CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction,

	prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and HHS/CDC as defined below.
Application Types Allowed	New - An application that is submitted for funding for the first time.
Funds Available and Anticipated Number of Awards	The estimated total funding (direct and indirect costs) for the first year (12 month budget period) is **$400,000.** The estimated total funding (direct and indirect) for the entire project period is **$800,000.** Awards issued under this FOA are contingent on the availability of funds and submission of a sufficient number of meritorious applications.
Ceiling and Floor of Individual Award Range	Maximum $ amount (total costs): $200,000 Minimum $ amount: None
Project Period Length	The project period will be 2 years, from 9/1/2014 to 8/30/2016. 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://dhhs.gov/asfr/ogapa/aboutog/grantsnet.html) will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions:

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

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)

For- Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- 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** include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

3. Special Eligibility Requirements

- The principal investigator or other key personnel must demonstrate expertise in the area of unintentional injury and health systems research (e.g., public health/health care collaboration; preventive service delivery and prescription drug overdose prevention for priority 1). Expertise is illustrated by evidence of at least one peer-reviewed publication or serving as an investigator on a grant or cooperative agreement in the subject matter areas (include in the biographical sketch).
- The applicant must demonstrate well-defined working relationships with organizations expected to participate in the research, including clinical care settings, primary care practices, emergency departments, or hospitals. This should be demonstrated by letters of support detailing the nature and extent of the involvement from the performing organization and outside entities (include in the appendices).
- The applicant must demonstrate the ability to access existing data or collect necessary health data to evaluate the strategies, such as through an MOU or letter of agreement (include in the appendices).

4. Responsiveness

- The principal investigator or other key personnel must demonstrate expertise in the area of unintentional injury and health systems research (e.g., public health/health care collaboration; preventive service delivery and prescription drug overdose

prevention for priority 1). Expertise is illustrated by evidence of at least one peer-reviewed publication or serving as an investigator on a grant or cooperative agreement in the subject matter areas (include in the biographical sketch). Applicants should clearly identify the relevant publications or research grant support in their SF 424 Biographical Sketch. **Applications where the key personnel do not meet these requirements will be considered nonresponsive.**

- The application must include letters of support detailing the nature and extent of the working relationships and involvement that can be expected from the outside organizations that will participate in the research. **Applications which do not include letters of support from participating organizations will be considered nonresponsive.**

- The application must include memoranda of understanding or letters of agreement identifying the data that will be available to complete the proposed project. The data may be existing data or new data to be collected as part of project work. This documentation should be included in an appendix. **Applications which do not include documentation of access to project data will be considered nonresponsive.**

5. 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: http://www.dlis.dla.mil/Forms/Form_AC135.asp
- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, http://www.grants.gov/applicants/org_step2.jsp.
- 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.

6. Universal Identifier Requirements and Central Contractor Registration

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)**, the replacement system for the Central Contractor Registration (CCR) database. 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 sub award under the grant unless the organization has provided its DUNS number to the grantee organization.

7. 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.

Cost Sharing

This FOA **does not** require cost sharing as defined in the HHS Grants Policy Statement (http://dhhs.gov/asfr/ogapa/aboutog/grantsnet.html).

Number of Applications

Eligible applicant institutions may submit more than one application, provided that each application is scientifically distinct. If more than one proposal is submitted from a single institution or group of institutions sharing a common system, not more than one will be awarded.

As defined in the HHS Grants Policy Statement, (http://dhhs.gov/asfr/ogapa/aboutog/grantsnet.html), 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/guide/url_redirect.htm?id=12000), except where instructed in this Funding Opportunity Announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

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

In conjunction with the SF424 (R&R) components, CDC grants applicants should also complete and submit additional components titled “PHS398.” Note the PHS398 should include assurances and certifications, additional data required by the agency for a complete application. While these are not identical to the PHS398 application form pages, the PHS398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete application to CDC will include SF424 (R&R) and PHS398 components. These forms can be downloaded and uploaded as Attachment A from the following link: http://www.cdc.gov/od/pgo/funding/grants/foamain.shtm

3. Letter of Intent

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

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

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

The letter of intent should be sent to:

Jane Suen, DrPH
Scientific Review Officer
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention (CDC)
4770 Buford Hwy, NE, Mailstop F-63
Atlanta, GA 30341
Telephone: 770-488-4281
FAX: 770-488-4422
Email: jxs8@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/guide/url_redirect.htm?id=12000) 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. – N/A
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)—N/A
5. Progress Report Publication List (for Continuation ONLY)—N/A

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_Adobe_VerB.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 20 pages. The Research Plan narrative is limited to 25 pages, including the Research Strategy.

Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 50 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/guide/url_redirect.htm?id=12000).

9. Submission Dates and 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 CDC PGO TIMS (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.

10. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11142).

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 authorized as an expanded authority, but only if authorized by CDC. Funds relating to the conduct of research involving human subjects will be restricted until the appropriate assurances and Institutional Review Board approvals are in place.

CDC/HHS grantees may use CDC funds to engage in activities to enhance prevention; collect and analyze data; publish and disseminate results of research and surveillance data; implement prevention strategies; conduct community outreach services; foster coalition building and consensus on public health initiatives; provide leadership and training, and foster safe and healthful environments. However, awardees may not use funds for any kind of impermissible lobbying activity designed to influence proposed or pending legislation, appropriations, regulations, administrative actions, or Executive Orders ("legislation and other orders"). These restrictions include grass roots lobbying efforts and direct lobbying. Direct lobbying includes any attempt to influence legislation, appropriations, regulations, administrative actions or Executive Orders ("legislation or other orders"), or other similar deliberations at all levels of government through communications that directly express a view on proposed or pending legislation or other orders and which are directed to members of staff, or other employees of a legislative body or to government officials or employees who participate in the formulation of legislation or other orders. Grass Roots lobbying includes efforts directed at inducing or encouraging members of the public to contact their elected representatives at the Federal, State or local levels to urge support of, or opposition to, proposed or pending legislative proposals. Certain activities within the normal and recognized executive-legislative relationships within the executive branch of that government are permissible. See Additional Requirement (AR) 12 for further guidance on this prohibition.

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. Eligibility Information 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 Central Contractor Registration (CCR). Additional information may be found in the SF424 (R&R) Application Guide.

Applicants are reminded to enter the approved Federal Wide Assurance (FWA) that the applicant has on file with the Office for Human Research Protections, if available. If the applicant has a FWA number, enter the 8-digit number. Do not enter the 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 this Application Guide and in the HHS Grants Policy Statement.

See more resources to avoid common errors and submitting, tracking, and viewing applications: http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm or 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 incompleteand/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? For projects evaluating preventive services, does the project further extend what is known about the effectiveness of systems level changes for prescription drug overdose prevention? Do the strategies evaluated have the potential to be adapted and implemented by health professionals in different contexts with different populations? Are novel collaborations with community-based agencies forged to improve referral and follow up that could be adapted in similar communities? For projects addressing community health needs assessments, will the project generate data that can inform other hospitals on how to collaborate with health departments to develop needs assessments and implementation plans that address injury? Will qualitative data reveal facilitators and barriers to incorporating injury prevention into the CHNA requirement?

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? Have the investigators previously conducted research on service delivery in the area of prescription drug overdose prevention? Have the investigators demonstrated experience collaborating with health professionals in clinical care settings, including primary care practices, emergency departments, and/or hospitals? Have the investigators worked with community-based injury prevention groups and/or studied screening in the clinical setting with referral to community-based agencies? Have the investigators demonstrated experience in accessing and analyzing health data? Do the investigators demonstrate extensive knowledge in the areas of unintentional injury and health systems research (e.g., preventive service delivery, public health/healthcare collaboration)? Do the publications and experience of the principal investigator or key personnel reflect extensive knowledge in the areas of unintentional injury and health systems research?

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? Will this project generate innovations in approaches to evidence-based injury preventive service delivery? Will this project generate innovations in approaches that hospitals might use to assess community health needs and develop implementation plans that incorporate injury prevention and injury outcomes? Will the project reveal approaches that local, state, and federal public health agencies could use to enable collection of injury data and the creation and implementation of prevention strategies?

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? Does this project incorporate rigorous research methods? For projects evaluating preventive services, is an experimental or quasi-experimental design proposed? Are randomized controlled trials considered? For projects addressing community health needs assessments, does the project include at least one hospital that has a Level I trauma center? Are robust mixed-methods employed to glean from hospitals the barriers or enablers to injury surveillance and prevention through the CHNA mechanism?

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?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements? Is there evidence that adequate partnerships have been developed between collaborating health organizations that are participating in the proposed research or sharing data? Is there evidence that the applicant can access health data, such as injury and mortality data, hospital needs assessment data, and electronic health records?

2. <u>Additional Review Criteria</u>

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/OD/foia/policies/inclusio.htm) and the policy on the Inclusion of Persons Under21 in Research (http://aops-mas-iis.cdc.gov/Policy/Doc/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/foia/policies/sharing.htm. 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 application awarded in response to this FOA will be subject to the DUNS, CCR 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://dhhs.gov/asfr/ogapa/aboutog/grantsnet.html).

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 described in Section IV.5. 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://dhhs.gov/asfr/ogapa/grantinformation/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-7: Executive Order 12372 Review

AR-9: Paperwork Reduction Act Requirements
AR-10: Smoke-Free Workplace Requirements
AR-11: Healthy People 2010
AR-12: Lobbying Restrictions
AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities
AR-14: Accounting System Requirements
AR-16: Security Clearance Requirement
AR-17: Peer and Technical Reviews of Final Reports of Health Studies – ATSDR
AR-21: Small, Minority, And Women-owned Business
AR-22: Research Integrity
AR-24: Health Insurance Portability and Accountability Act Requirements
AR-25: Release and Sharing of Data
AR-26: National Historic Preservation Act of 1966
AR-28: Inclusion of Persons Under the Age of 21 in Research
AR-29: Compliance with EO13513, "Federal Leadership on Reducing Text Messaging while Driving", October 1, 2009
AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973
AR 31 - Distinguishing Public Health Research and Public Health Nonresearch
AR 32 – FY 2012 Enacted General Provisions

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)

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: http://frwebgate.access.gpo.gov/cgibin/getdoc.cgi?dbname=109_cong_bills&docid=f:s2590enr.txt.pdf

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.

3. 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 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 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 as defined below.

Projects that request approval or significant input from CDC for the development of study design, research methods, participant recruitment, or information collection instruments may require review and approval by the Office of Management and Budget (OMB). OMB approval may require up to 10 months. During the OMB approval process, the awardee may not pursue information collection activities.

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

- Retaining custody of and exercising primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.
- Designing and conducting research to address the described research objectives of this cooperative agreement.
- Partnering effectively with any outside entities expected to participate in the proposed research. Such partnerships should be well-defined and documented, detailing the nature and extent of involvement.
- Establishing goals and objectives that are realistic, measureable, and time-oriented for all phases of the project.
- Developing a research protocol involving human subjects for Institutional Review Board (IRB) review and approval by all cooperating institutions participating in the research project, including CDC if applicable.
- Assuring that IRB approvals are current for research involving human subjects for all participating sites.

- Considering input from CDC on the design and implementation of research and the analysis, interpretation, and dissemination of study findings.
- Developing, designing, and piloting research protocols and instruments; recruiting participants; and conducting appropriate data management procedures.
- Analyzing data and disseminating findings in peer-reviewed journals and presentations at scientific conferences and other meetings.
- Requesting consultation and technical assistance from CDC, as needed.
- Collaborating with CDC in translating and disseminating research findings.
- Participating in one reverse site visit with CDC in Atlanta on an annual basis.

CDC staff will work collaboratively with the PI(s)/PD(s), as described below:

- Providing input, as requested by the awardee, in designing research protocols (e.g., for sampling, recruitment, assessment, and data management), and participating in analysis, interpretation, and dissemination of study findings.
- Collaborating with the grantee to ensure human subjects assurances are in place as needed. As necessary, collaborating in the development or amendment of a research protocol involving human subjects for Institutional Review Board (IRB) review by all collaborating institutions, including CDC if applicable.
- Obtaining IRB approvals as required by CDC when CDC is engaged in research involving human subjects. If applicable, the CDC IRB will review the protocol initially and on an annual basis until the project is complete.
- Monitoring and evaluating the scientific and operational accomplishments of the project through conference calls, site visits, and review of technical reports.
- Additionally, an agency scientific program official or CIO program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

Areas of Joint Responsibility include:

None; all responsibilities are divided between awardees and CDC staff as described above.

4. 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 Central Contractor Registry; 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://dhhs.gov/asfr/ogapa/grantinformation/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 each budget period.**
3. **A final progress report**, invention statement, equipment/inventory report , and the expenditure data portion of the Federal Financial Report (FFR) Standard Form ("SF") 425 Form are required **within 90 days of 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 to policy or 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 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 policy or practice?

  – How will the project improve or effect the translation of research findings into policy or practice?

  – 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, 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 contribute 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 cooperative agreement 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 each budget period. 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 promote, enhance or advance the research findings and the impact on public health policy and 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 influenced 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, policy, technology or systems improvement 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)

Donald Blackman
Scientific Program Officer
National Center for Injury Prevention and Control (NCIPC)
Centers for Disease Control and Prevention (CDC)
Telephone: 770-488-0641
Email: dblackman@cdc.gov

Peer Review Contact(s)

Jane Suen, DrPH
Scientific Review Officer
National Center for Injury Prevention and Control
Telephone: 770-488-4281
FAX: 770-488-4422
Email: jxs8@cdc.govS

Financial/Grants Management Contact(s)

Corey Taylor, Grants Management Specialist
CDC Procurement and Grants Office (PGO)
Telephone: 770-488-2730
Fax: 770-488-2670
Email: CTaylor8@cdc.gov

Section VIII. Other Information

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

Authority and Regulations

This program is authorized under Section 301 (a) [42 U.S.C 241(a)] of the Public Health Services Act, and Section 391(a) [42 U.S.C 280 b (a)] of the Public Health Services Act, as amended