

Part I Overview Information

United States Department of Health and Human Services (HHS)

Issuing Organization

Centers for Disease Control and Prevention (CDC) / Office of the Chief Science Officer (OCSO) / Office of Public Health Research (OPHR), (<http://www.cdc.gov/od/science/PHResearch/>)

Participating Organizations

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

Components of Participating Organizations

Office of Public Health Research (OPHR/OCSO/CDC),
<http://www.cdc.gov/od/science/PHResearch/>

Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER/CDC),
<http://www.cdc.gov/about/organization/cotper.htm>

Coordinating Office for Global Health (COGH/CDC),
<http://www.cdc.gov/about/organization/cogh.htm>

National Center for Injury Prevention and Control (NCIPC/CDC), (<http://www.cdc.gov/ncipc/>)

National Center for Environmental Health (NCEH/CDC), <http://www.cdc.gov/nceh/default.htm>

National Center for Health Statistics (NCHS/CDC), <http://www.cdc.gov/nchs/>

National Center for Health Marketing (NCHM/CDC), <http://www.cdc.gov/healthmarketing/>

National Center for Public Health Informatics (NCPHI/CDC), <http://www.cdc.gov/ncphi/>

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

National Center on Birth Defects and Developmental Disabilities (NCBDDD/CDC),
<http://www.cdc.gov/ncbddd/>

National Center for Immunization and Respiratory Diseases (NCIRD/CDC),
<http://www.cdc.gov/ncird/default.htm>

National Center for Zoonotic, Vector-Borne and Enteric Disease (NCZVED/CDC),
<http://www.cdc.gov/nczved/>

National Center for HIV, Viral Hepatitis, STDs and Tuberculosis Prevention (NCHHSTP/CDC),
<http://www.cdc.gov/nchhstp/>

National Center for Preparedness, Detection and Control of Infectious Diseases (NCPDCID/CDC) <http://www.cdc.gov/ncpdcid/>

National Institute for Occupational Safety and Health (NIOSH/CDC),
<http://www.cdc.gov/niosh/homepage.html>

Office of the Chief of Public Health Practice (OCPHP/CDC), <http://www.cdc.gov/od/ocphp/>

Title: Translating Research to Protect Health through Health Promotion, Prevention, and Preparedness (R18)

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

Authority: Section 301 of the Public Health Service Act (42 U.S.C. Section 241), as amended and the Occupational Safety and Health Act of 1970, Section 20(a) and 21(a) (29 USC 669(a) and 29 USC 670).

Announcement Type: New

Instructions for Submission of Electronic Research Applications:

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

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

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

Two steps are required for on time submission:

- 1) The application must be successfully received by Grants.gov no later than 5:00 p.m. Eastern Standard Time on the application submission receipt date (see "[Key Dates](#)" below.)
- 2) Applicants must complete a verification step in the Electronic Research Administration (eRA [Commons](#)) within two business days of notification. Note: Since email can be unreliable, it is the responsibility of the applicant to periodically check on their application status in the eRA [Commons](#).

Funding Opportunity Announcement (FOA) Number:
RFA-CD-09-001

Catalog of Federal Domestic Assistance Number(s): 93.061
Innovations in Applied Public Health Research and 93.262 Occupational Safety and Health Program

Key Dates

Release/Posted Date: February 20, 2009
Letter of Intent Receipt Date: March 23, 2009
Submission Receipt Date(s): April 21, 2009
Peer Review Date(s): June, 2009
Council Review Date(s): June, 2009
Earliest Anticipated Start Date(s): September, 2009
Additional Information to Be Available Date: NA
Expiration Date: April 22, 2009

Due Date for E.O. 12372

Executive Order 12372 does not apply to this program.

Additional Overview Content

Executive Summary

- Critical to CDC's mission is new scientific knowledge that can accelerate the translation of research findings into public health practice. Moving the best science into practice is essential to protect and improve health. To that end, the purpose of this FOA is to accelerate the translation of proven effective interventions into public health practice through implementation, dissemination, and diffusion research.

Funding Opportunity Announcement Glossary: [FOA Glossary Terminology](#)

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Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

This funding opportunity announcement (FOA) is intended to solicit applications that support translation of health protection research into public health practice with an emphasis on achieving health equity. This FOA will also contribute to achieving the health promotion and disease prevention objectives of "Healthy People 2010" and to measuring program performance as stipulated by the Government Performance and Review Act (GPRA). This FOA addresses "Healthy People 2010" priority area(s) of Prevention Research (Chapter 23, Section 17) and is in alignment with CDC's performance goal(s).

CDC is committed to protecting people's health and achieving the fair distribution of health determinants, outcomes, and resources within and between segments of the population, regardless of social standing (i.e. health equity). Understanding the best approaches, methods and strategies for moving the best science to practice is essential to protect and improve health. Much translation research and practice has historically occurred in biomedical research and the healthcare delivery system, but making people healthier also requires protection of health and prevention of poor health through health protection research and public health practice, programs, and policy. As we look ahead, the translation of research to practice will be an important consideration in the nation's effort to reform the health system. These investments will support the development and refinement of the evidence-base for clinical and community-based prevention and wellness strategies.

For all types of research, there is a major "translation gap" keeping relevant and high-quality research from moving into practice, and consequently there is an urgent need to move the research results off the shelf and into the world faster and more efficiently. For biomedical research, that means facilitating a path from basic bench research through clinical trials and clinical practice guidelines to clinical practice to assure positive health outcomes for

individuals. For health protection research, the gap is bridged by moving the applied bench, community, and systems research through intervention studies to health protection practices, programs, and policies via dissemination and communication strategies and mechanisms that ultimately create knowledge, tools, and networks that people and communities need to protect and improve their health.

Research translation approaches in healthcare and public health systems are similar in many ways, but also have important differences. Compared with healthcare interventions, public health interventions and policies typically are more reliant on interdisciplinary collaboration, and on observational or quasi-experimental, rather than experimental studies; have a more limited evidence base; face greater challenges in generalizing scientific results to actual conditions in communities and in measuring appropriate outcomes; and must incorporate communication, marketing, and dissemination strategies for more diverse and larger audiences.

Translation research for the purpose of this FOA is defined as that which characterizes the sequence of events (i.e., process) in which a proven scientific discovery (i.e., evidence based public health intervention) is successfully institutionalized (i.e., seamlessly integrated into established practice and policy). Specifically, translation research is comprised of implementation, dissemination, and diffusion research and attempts to understand how evidence-based health protection interventions move into public health practice, programs, or policy. Translation research does not include the conduct of an initial, or replication of a previous, intervention efficacy or effectiveness trial/study.

In this FOA, *evidence-based* means that the proposed intervention has undergone sufficient scientific evaluation to be proven *effective* (e.g., intervention is considered valid or “proven” because it is strongly linked to the desirable outcome [s]). Scientific evaluation might include but is not limited to peer review publications of quantitative or qualitative research, evaluation reports, systematic reviews of the literature (e.g., meta-analysis), or descriptive or survey research. *Under this FOA, it is the responsibility of the investigative team to demonstrate that sufficient evidence exists when proposing the conduct of translation research of a specific intervention.*

Research Priorities and Topics

CDC is committed to achieving true improvements in people’s lives by achieving health protection and health equity. [Healthy People 2010](#) (HP 2010) provides a framework for health prevention and health equity for the Nation. By focusing on HP 2010 goals of increasing quality and health years of life and eliminating health disparities, CDC can fulfill its mission “to collaborate to create the expertise, information, and tools that people and communities need to protect their health – through health promotion, prevention of disease, injury and disability, and preparedness for new health threats” and be able to demonstrate success through measurable improvements in health and achievements towards reaching health equity.

Listed below are specific research topics of interest to CDC that are aligned with HP 2010 goals and leading health indicators. Applications submitted in response to this funding announcement must identify the research topic the application is responding to. Each application will compete for available funds with all other eligible applications. Applications that do not identify and align with any of research topics, and do not address the submission requirements in Section IV.3.C.will be considered non-responsive.

I. Healthy People

Healthy Infants and Toddlers

Public health efforts have improved infant and toddler health significantly in the United States during the past 50 years. Because of advances in disease research, sanitation, vaccines and immunization coverage, widespread availability of safe water and nutritious foods, and strategies for health promotion and disease prevention, infants and toddlers today have a greater opportunity for growing up as healthy and productive adolescents and adults. Yet the lives, health, and development of unacceptable numbers of the youngest members of our society are still compromised.

Healthy parenting is a key element in the healthy development of infants and toddlers and impacts every aspect of children's lives and. When these experiences and relationships occur in safe, stable, nurturing and health-promoting environments they provide protection against adverse experiences that compromise physical, cognitive, and psychological health and development.

Child maltreatment, which includes neglect and physical, sexual, and emotional abuse, represents the most extreme form of unhealthy parenting/caregiving. It is defined as any act or series of acts of commission or omission by a parent or other caregiver that results in harm, potential for harm, or threat of harm to a child (Leeb, Paulozzi, Malanson, Simon, and Arias [2008]). Effective and promising strategies for preventing child maltreatment exist, but they have not been widely or effectively translated. A specific topic of interest for this FOA is:

- Translation of evidence-based child maltreatment interventions that focus on the promotion of safe, stable and nurturing relationships between caregivers and young children (e.g., nurse home visitation, parent-child interaction therapy, skills-based parent training programs). Research should address the appropriate outcomes measures, processes, and methodologies needed for translation, and it should identify any barriers and facilitators in the translation process.

Healthy Children

To date, public health has played a vital role in the health of this age group, making notable advances such as high immunization rates, reduced blood lead levels, and reduced rates of dental caries (cavities) through water fluoridation. Building on this historic role and working with its partners in other agencies and organizations, public health researchers and practitioners are in a unique position to further improve children's health through translation of effective and evidence-based interventions. Specific topics of interest include:

- Identification of barriers and facilitators to translation of evidence-based interventions aimed at promoting healthy eating and physical activity among children.
- Development of measures and methodologies for translation of evidence-based public and organizational policies and interventions that support and promote healthy parenting and safe, stable, nurturing relationships, particularly among families from diverse backgrounds, at high risk, or those who are hard to reach.

Healthy Adolescents

Although youth are often thought of as healthy, adolescents in the United States continue to have high morbidity and mortality rates as well as high rates of behaviors associated with negative health consequences (Irwin, Burg, and Cart [2002]). Adolescents live within a large social system in which their health choices are influenced by their family, friends, community, and society. To achieve and sustain healthy behaviors and outcomes for adolescents, public health must better understand these multiple layers of influence and develop prevention initiatives that incorporate strategies to address these layers of influence in adolescents' lives.

Although many interventions have the potential to improve multiple adolescent health risk behaviors, research has focused on their effects on individual health outcomes and/or has not developed the tools and partnerships necessary to move them into use at the population level.

Available, evidence-based interventions to prevent adolescent health risk behaviors must be translated for broader dissemination and implementation. Specific topics of interest include:

- Translation of evidence-based parenting programs to improve adolescent health
- Translation of evidence-based youth development programs to improve adolescent health
- Translation of evidence-based approaches to improve adolescent motor vehicle safety
- Identification of barriers and facilitators to the translation of evidence-based interventions aimed at promoting healthy weight and fitness levels among youth
- Translation of evidence-based suicide prevention programs to improve adolescent health

Healthy Adults

Adults 20–49 years old represent nearly 43% of the US population. Public health intervention and health promotion are critical for this life stage and may carry into the future, preventing future health problems that compromise length and quality of life and functional independence. In addition, screening and evidence-based health care interventions may improve, for example, reproductive health outcomes and may reduce the burden of sexually transmitted diseases (STDs) and life-threatening HIV infections. By identifying translation approaches that will promote and maintain healthy behaviors and increase the use of evidence-based health protection measures, the potential for increased health impact across the lifespan is significant. Specific topics of interest include:

- Development and evaluation of strategies and systems approaches to translate evidence-based interventions to prevent and control obesity and resulting chronic diseases, particularly heart disease, stroke, and diabetes, as well as cancer and its related risk factors
- Translation of evidence-based health promotion interventions for adults for successful adoption and implementation in workplace settings
- Translation of evidence-based interventions for use in community organizations and settings used by adults, including strategies to impact organizational structure, climate, culture, and processes to enable adoption, dissemination and implementation

Healthy Older Adults

The U.S. population is aging at a rate unprecedented in the nation's history. Nearly 29% of Americans are 50 years old or older (CDC [2003]). The current growth in the number and proportion of older adults has far-reaching implications for the US public health system and will increase the demands on US health care systems and the need for social services and long-term care. It is essential for public health to focus on opportunities that will prevent or delay onset of disease, injury, and disability. Among the most critical areas for translation research are preventive services and other evidence-based interventions for preventing and controlling disease, injury, and disability in the aging population. Specific topics of interest include:

- Development and evaluation of strategies and systems approaches to translate evidence-based public health interventions aimed at:
 - Reducing health disparities associated with chronic diseases and related risk factors;
 - Prevention and control of chronic diseases and conditions, particularly obesity, heart disease, stroke, cancer and related risk factors and conditions (including hypertension, lipid disorders or elevated cholesterol, diabetes, physical inactivity and poor nutrition);
 - Prevention of falls; or
 - Prevention and control of chronic obstructive pulmonary disease

- Development and evaluation of strategies to translate evidence-based clinical preventive services for older adults in alternative venues. (e.g., pharmacies, community centers, etc.), including strategies to impact organizational structure, climate, culture, and processes to enable adoption, dissemination and implementation.

II. Healthy Places and Environments

Healthy Communities

Since the 1940s, health has been increasingly acknowledged as “a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity” (World Health Organization [1946]). This perspective on health is leading to more holistic approaches to community health. In this context, the places where we live, work, learn, and play influence health. Environmental factors, both physical and social, are as important to good health as behavior choices or genetic make-up.

Community health improvement approaches may require assessment and modification of many interdependent community characteristics as part of a larger system. Some of these characteristics are social attributes (e.g., social networks and cohesion), biological characteristics (e.g., age, gender), built environments (e.g., bike paths, buildings), availability and accessibility of health services (e.g., qualified providers, accessible facilities), economic resources (e.g., community member employment), population-based health programs (e.g., influenza vaccinations, tobacco control), and health practices (e.g., using stairs vs. elevators, neighborhood crime watch). Addressing these characteristics of community health and hazards supports a crosscutting public health system approach. Specific topics of interest include:

- Development and evaluation of strategies to translate into practice evidence-based interventions related to physical and social environment risk factors for youth violence in high risk communities. Risk factors that may be a focus of universal and targeted interventions and policies for youth violence in high-risk communities include the built environment, the role of gangs and illicit drug markets, the nature and quality of public housing, the concentration of poverty, social norms, and the influence of business development.
- Development and evaluation of strategies to translate evidence-based community-level communications and marketing activities related to increasing adoption of proven effective injury prevention interventions. The community-level communications should be developed and evaluated to determine the effectiveness of communication techniques, audience segmentation, dissemination strategies and communication channels, tailored messaging, and collaboration models to speed dissemination and widen adoption.
- Determination of local, state or systems capacity for translation of research to practice as outlined by the *Community Guide to Preventive Services* (Task Force on Community Preventive Health [2004], <http://www.thecommunityguide.org/>). . The Guide recommends evidence-based interventions for alcohol, cancer, diabetes, mental health, motor vehicle, nutrition, obesity, oral health, physical activity, pregnancy, sexual behavior, social environment, tobacco, vaccines, violence and worksite topic. Based on high quality systematic reviews of the scientific literature, the Guide is a valuable resource for identifying evidence-based interventions.

Healthy Homes

Home is a place that can support not only basic physical needs (such as air, water, food, and shelter), but also the psychological and social health of its occupants. Home is a place where people spend much of their lives, yet most people do not realize the close connection between their home and health. A home's standard physical features can support occupants through a wide range of developmental stages, promote health and safety, and support mental and

emotional health. For instance, the physical environment can be designed and constructed to prevent elderly occupants from experiencing falls in showers and on stairs. Proper air ventilation and filtration and ample natural light not only support physical health and prevent injury, but also may improve mental health. Home design and construction materials can support a clean and sustainable environment, conserve natural resources, and promote health and well-being. Specific topics of interest include:

- Development and evaluation of strategies to translate evidence-based community-level or home-based interventions aimed at fall prevention.
- Development and evaluation of strategies to translate evidence-based interventions aimed at maintaining health and safety in the home (e.g., smoke alarm use).

Healthy Schools

Next to the family, schools have the greatest influence on the growth, development, and well-being of children and adolescents. More than 53 million US students (Snyder, Dillow, and Hoffman [2007]) spend at least six hours a day, approximately 180 days of the year, in school during 13 of the most formative years of their development. Public health professionals must collaborate with educators to ensure that our nation's young people learn in a physical, social, and instructional environment that protects their health and promotes safety, healthy behavioral choices, and academic success. By implementing policies, programs, and services that enable young people to adopt health-enhancing behaviors and maintain these behaviors throughout their lives, schools will also be advancing their fundamental mission of producing productive members of society. Specific topics of interest include:

- Identification of barriers and facilitators to translation of evidence-based interventions that promote student safety and health.
- Development and evaluation of strategies to translate evidence-based school health interventions among school districts with high minority student enrollment and students of low-income families.

Healthy Workplaces

More than 146 million people in the United States were employed in the civilian workforce in 2007 (US Bureau of Labor Statistics (BLS) [2007]). These workers spend a quarter of their lifetime and up to half of their waking lives at work or commuting to and from work. They also continue to suffer work-related deaths, injuries, and illnesses despite improvements in workplace safety and health over the last several decades. Working Americans are also substantially affected by illnesses, such as heart disease and diabetes, resulting from individual health risks. The workplace, therefore, provides a unique forum for public health action.

Addressing safety and health in the workplace poses numerous challenges. First, the US workforce is becoming increasingly diverse, reflecting the changing social and demographic characteristics of the country. These changes are accompanied by new safety and health issues. Moreover, US workplaces are also rapidly evolving. Jobs in our economy continue to shift from manufacturing to services, with service-providing industries now employing nearly 75% of all workers (US BLS, [2007]). Major changes are also occurring in the way work is organized. Longer hours, compressed workweeks, shift work, reduced job security, and part-time and temporary work are realities of the modern workplace and are increasingly affecting the health and lives of workers and their families.

Formed from an authority separate but in addition to the CDC authority, the National Institute for Occupational Safety and Health (NIOSH) is the portion of CDC concentrating on US workers and their workplaces. NIOSH was the leader in developing the National Occupational Research Agenda (NORA), a research framework and a partnership program to stimulate

innovative research and improved workplace practices. Participation in NORA is broad, including stakeholders from universities, large and small businesses, professional societies, government agencies, and worker organization. The NORA priority setting process is based upon the following types of information: (1) the numbers of workers at risk for a particular injury or illness, (2) the seriousness of the hazard or issue, and (3) the probability that new information and approaches will make a difference.

NIOSH and its partners have formed eight NORA Sector councils with agendas to provide guidance to the entire occupational safety and health community for moving research to practice in workplaces. The agendas for each sector are dynamic documents that address specific goals and promote improved workplace practices. Many of the goals are oriented to translation research. For this announcement, CDC/NIOSH solicits applications aimed at transferring and translating knowledge, technologies, and evidence-based interventions into prevention practices and products that promote and protect worker health in the following Sectors (<http://www.cdc.gov/NIOSH/NORA/sector.html>):

- Healthcare and Social Assistance
- Services
- Agriculture, Forestry and Fishing

Healthy Healthcare Settings

Healthcare services play an important role in ensuring and protecting health and quality of life. Healthcare settings are places where healthcare services are delivered. Ideally, these settings would be organized to effectively deliver appropriate, safe, patient-centered care that promotes health and prevents or manages disease. Unfortunately, many healthcare settings are also a significant source of morbidity and mortality, but they can be made safer and healthier with, for example, reductions in healthcare-associated infections and application of evidence-based design. At the same time, healthcare settings must be used more effectively to promote healthy behaviors and deliver preventive services such as routine cancer screenings and tobacco use counseling. Achieving healthier and safer, and more effective healthcare settings will require a commitment to improve collaboration between public health and the healthcare delivery systems. Specific topics of interest include:

- Development and evaluation of strategies or system approaches to translate evidence-based interventions aimed at preventing adverse events (e.g. medication errors, injuries) and improving patient safety and healthcare quality in healthcare settings.
- Translation of evidence-based worksite influenza vaccination programs into existing care systems and health care settings and measuring the extent to which such procedures are adopted, implemented, maintained and adhered to, by providers and consumers.
- Development and evaluation of strategies to translate evidence-based infection control practices (e.g., hand hygiene) to prevent and control multidrug-resistant organism infections (MDROs) in healthcare settings.
- Identification and characterization of facilitators, impediments, and strategies for the successful translation of evidence-based recommendations and practices for preventing obesity, diabetes, and their complications among healthcare setting providers and clients.

Healthy Travel, Transportation & Recreation

Every day, Americans face choices about how to move about, within, and between their communities. These choices have safety and health implications related to physical activity rates, injury risks, air quality, mental health stresses and other factors. Since 1969, the number of miles driven and the number of trips made by people in cars and trucks in the

United States have skyrocketed (US Bureau of Transportation Statistics (U.S. Bureau of Transportation Statistics [2006])). Furthermore, the overall trend in motor vehicle miles traveled in the United States continues to rise and is likely to continue to increase. At the same time, the recreation and leisure choices in the United States have health and safety implications. Studies have shown that watching TV occupies more leisure than any other leisure activity during an American's average day, accounting for about half of all leisure-time activity. This has contributed to the Nation's growing obesity epidemic (CDC [2007a]), which results partly from the trends of increased travel time (US Department of Transportation [1995]) and of limited leisure-time physical activity (CDC [2007b]). Unless mediating measures are used, these increases will continue to result annually in millions of unintentional injuries from motor vehicle crashes (CDC [2005]) and in harmful physiological effects (such as respiratory disease) from travel-related by-products (such as air pollution). Specific topics of interest include:

- Evaluation of strategies to translate evidence-based interventions for reducing alcohol-impaired driving. Research should include strategies and systems approaches drawn from health communication, policy development, enforcement, advocacy, and other approaches relevant to improving dissemination and adoption of effective interventions.
- Development and evaluation of methodologies and processes for translation of evidence-based transportation or recreation programs directed at improving physical activity and decreasing obesity.

People Healthy and Safe from Threats

During the response and recover phase of a disaster or emergency situation, activities undertaken are designed to minimize morbidity and mortality from all infectious, occupational, environmental, and terrorist threats of national significance. These activities focus on the systematic response to, and investigation and control of public health threats. Public health systems and support for these systems are critical to providing resources and technical assistance to state, local, and territorial health departments and others to implement public health programs and interventions for public health emergencies. Research in public health systems support will help to develop and deliver optimal resources and technical assistance to state, local, tribal and territorial health departments and other partners. Although surge capabilities to meet public health threats have improved, public health response operations have been based largely on historical practices and the evidence base for many of these capabilities is limited. Yet despite the limited evidence-base, these activities are critical to the safety and wellbeing of all Americans. The specific topic of interest includes:

- Development and evaluation of strategies and systems approaches to translate evidence-based emergency preparedness, response, and recovery interventions.

Healthy Nations Around the World

Extraordinary potential is created by the connectedness of our world: a world empowered by the potential for unprecedented opportunity on a global scale. Yet, documented health disparities demonstrate that when examining opportunities for optimal health, inequalities and injustices persist. In developing regions of the world, the ability to prevent illness and strengthen preparedness for unexpected health threats is uncommon even when mechanisms to do so exist in developed regions. Improvement in health status for developing regions is stalled by HIV/AIDS, tuberculosis, polio, injury, and infrastructure limitations such as access to clean and safe water, sanitation, and electricity. Fortunately, societal changes such as increased visibility of advocacy efforts and transnational collaborations have spawned awareness and concern for the poor health experienced by much of the world's population. A specific topic of interest includes:

- Identification and evaluation of facilitators, impediments, and strategies for the successful translation of evidence-based interventions at scale into a country's public health system.

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For information of translation research terminology relevant to the FOA, please see the section called Definition of Terms under Research Objectives at the following link: <http://grants.nih.gov/grants/guide/rfa-files/RFA-CD-07-005.html>

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

Section II. Award Information

1. Mechanism(s) of Support

This funding opportunity will use the R18 activity code.

2. Funds Available

The participating Centers, Institutes and Offices (CIO)(s) The Office of Public Health Research (OPHR/OCSO/CDC) intends to commit approximately \$5 million dollars (including indirect and direct costs) in FY2009 to fund 10-12 applications. The average award amount will be \$425,000 in total costs for a 12 month budget period. An applicant may request a project period of up to 3 years. An applicant may request up to \$450,000 in total costs per 12 month budget period. The approximate total 3 year project period funded amount is \$1,350,000. The anticipated start date for new awards is September 1, 2009.

All estimated funding amounts are subject to availability of funds.

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

Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the CIO (s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

Section III. Eligibility Information

1. Eligible Applicants

1.A. Eligible Institutions

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

- Public nonprofit organizations
- Private nonprofit organizations
- For profit organizations
- Small, minority, and women-owned businesses
- Universities
- Colleges
- Research institutions
- Hospitals
- Community-based organizations
- Faith-based organizations
- Federally recognized or state-recognized American Indian/Alaska Native tribal governments
- American Indian/Alaska Native tribally designated organizations

- Alaska Native health corporations
- Urban Indian health organizations
- Tribal epidemiology centers
- State and local governments or their Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau)
- Political subdivisions of States (in consultation with States)

A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under state eligibility in lieu of a state application. If you are applying as a bona fide agent of a state or local government, you must provide a letter from the state or local government as documentation of your status. Attach this documentation behind the first page of your application form or for electronic applications, use a PDF file and attach as "Other Documents" and label as appropriate.

Note: Applications will not be accepted from foreign institutions. Applicants wishing to form foreign collaborations may do so as long as the primary domestic grant recipient performs a substantive role in the project and is not acting solely as a conduit to another party.

2. Cost Sharing or Matching

This program does not require cost sharing or matching.

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

3. Other-Special Eligibility Criteria

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

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

Section IV. Application and Submission Information

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. Request Application Information

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

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

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

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

2. Content and Form of Application Submission

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

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

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

Required Components:

- SF424 (R&R) (Cover component)
- Research & Related Project/Performance Site Locations
- Research & Related Other Project Information
- Research & Related Senior/Key Person
- Research & Related Budget

- PHS398 Cover Page Supplement
- PHS398 Research Plan
- PHS398 Checklist

Optional Components:

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

- o Note: While both budget components are included in the SF424 (R&R) forms package, the CDC R18 (activity code) uses ONLY the detailed Research & Related Budget. (Do not use the PHS 398 Modular Budget.)

3. Submission Dates and Times

See Section IV.3.A for details

3. A. Submission, Review and Anticipated Start Dates

Letter of Intent Receipt Date: March 23, 2009
Application Submission Receipt Date(s): April 21, 2009
Peer Review Date(s): June, 2009
Council Review Date(s): June, 2009
Earliest Anticipated Start Date(s): September, 2009

3.A.1. Letter of Intent

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

- Descriptive title of proposed research
- Brief paragraph describing the proposed research
- Specific research topic and the relevant CC/NC/CIO the application will address
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Number and title of this funding opportunity

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

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

The letter of intent should be mailed to:

Juliana Cyril, Ph.D.
Office of Public Health Research
CDC Office of the Chief Science Officer
1600 Clifton Rd., MS D-72
Atlanta, GA 30333
Telephone: (404) 639-4639
Fax: 404-639-4903
Email: jcyril@cdc.gov

3.B. Submitting an Application to CDC

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

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

A registration process is necessary before submission, and applicants are strongly encouraged to start the process at least four weeks prior to the grant submission date.

3.C. Application Processing

HHS/CDC must receive applications on or before 5:00 P.M. Eastern Standard Time on the application submission date(s) described above (Section IV.3.A.). If HHS/CDC receives an application after that submission date and time, the application may be delayed in the review process or not reviewed.

Once an application package has been successfully submitted through Grants.gov, any errors have been addressed, and the assembled application has been created in the eRA Commons, the PD/PI and the Authorized Organization Representative/Signing Official (AOR/SO) have two business days to view the application image.

- If everything is acceptable, no further action is necessary. The application will automatically move forward for processing by the CDC, PGO, Technical Information Management Section, after two business days.
- Prior to the submission deadline, the AOR/SO can “Reject” the assembled application and submit a changed/corrected application within the two day viewing window. This option should be used if the AOR/SO determines that warnings should be addressed. Reminder: warnings do not stop further application processing. If an application submission results in warnings (but no errors) it will automatically move forward after two business days if no action is taken. Please remember that some warnings may not be applicable or may need to be addressed after application submission.
- If the two day window falls after the submission deadline, the AOR/SO will have the option to “Reject” the application if, due to an eRA Commons or Grants.gov system issue, the application does not correctly reflect the submitted application package (e.g., some part of the application was lost or didn’t transfer correctly during the submission process). The AOR/SO should first contact the [eRA Commons Helpdesk](#) to confirm the system error, document the issue, and determine the best course of action. HHS/CDC will not penalize the applicant for an eRA Commons or Grants.gov system issue.
- If the AOR/SO chooses to “Reject” the image after the submission deadline for a reason other than an eRA Commons or Grants.gov system failure, a changed/corrected application still can be submitted but it will be subject to the CDC late policy guidelines and may not be accepted. The reason for this delay should be explained in the cover letter attachment and must refer only to Commons errors and/or technical errors.
- Both the AOR/SO and PD/PI will receive e-mail notifications when the application is rejected or the application automatically moves forward in the process after two days.

Upon receipt, applications will be evaluated for completeness and responsiveness by participating National Centers, Coordinating Centers, and Institutes and HHS/CDC Procurement and Grants Office (PGO). HHS/CDC will not review incomplete and non-responsive applications.

There will be an acknowledgement of receipt of applications from Grants.gov and the eRA [Commons](#).

All applicants must address the following requirements in their applications. Applicants that do not address items I-V below will be considered non-responsive. Specifically, applicants must address the following in their Research Plan:

I. Relevant CDC Research Topic and Coordinating Office, National Center, or Institute

In a cover letter attached to the application, applicants must provide the following information: 1) the relevant research topic (from Section I.2.) that the application is responding to, and 2) the relevant Coordinating Offices, National Centers, or Institute (see Participating Organization, Part I). Applications that are complete and responsive to the FOA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the Office of Public Health Research or participating Coordinating Offices, National Centers, or Institute. Each application will compete for available funds with all other eligible applications. Applications that do not identify and align with any of the research topics listed in Section I. will be considered non-responsive.

II. Study Approach and Documentation of Scientific Evaluation of Intervention

For the purpose of this FOA, an intervention is an intentional action (singular or constellation) designed for an individual, a community, or a region that alters a behavior, reduces risk or improves outcome. Interventions should be evidence-based, may have a medical or behavioral focus, and may consist of a modification to the natural or built environment, engineering controls, public health policy, public health program, health communication, or public health law. *Evidence-based* means that the intervention has undergone sufficient scientific evaluation to be proven to be *effective* (e.g., intervention is considered valid or “proven” because it is strongly linked to desirable outcome). Scientific evaluation might include but is not limited to peer review publications of quantitative or qualitative research, evaluation reports, systematic reviews of the literature (e.g., meta-analysis), or descriptive or survey research. *Under this FOA, it is the responsibility of the investigative team to demonstrate that sufficient evidence exists when proposing the conduct of translation research of a specific intervention.*

Research projects submitted can approach the topics of focus in this FOA through the analysis of major data sets that include information on the translation of health recommendations or policies through various populations and the factors that inhibit or facilitate that penetration. For applicants proposing to study policies/regulations/laws and/or conduct secondary data analysis, the underlying scientific evidence and evaluation that lead to the policy or recommendation under study must be adequately described.

Applicants are encouraged to select CDC developed or supported evidence-based interventions or major data sets if appropriate for the proposed research.

III. Target Population to be Studied

The target population should be well-defined and a justification for the population(s) chosen should be included. Applicants should present a clear understanding of population characteristics, demographics, and health status. The information needs of the target population, and the barriers as well as available resources, should be understood and well described. The portion of target population to be reached by the project should be identified.

IV. Assessing and Reporting the Intervention’s Translatability

Applicants must include a plan to estimate and report the potential translatability and public health impact of the intervention. If appropriate, the plan should include methodology to measure the interplay between fidelity, the necessary adaptation of the intervention, and scalability. Novel evaluation models are acceptable with justification or applicants may elect to use but are not limited to previously published models and frameworks. Key translation research questions to consider in the plan:

- Reach – What were the key factors that determined who in the target audience were successfully or unsuccessfully reached?

- Uptake (adoption) – What factors influenced organizations or individuals' acceptance of the intervention (e.g., organizational structure, regulation, opinion leaders, and cultural norms)?
- Feasibility – What is the realistic cost, time, facility space and human resources (e.g., number of staff and type of training) needed?
- Fidelity – Describe how the fidelity of the intervention or system was compromised or deviated from the original research setting in which it was tested.
- Adaptability – What key components of the intervention or the system were modified to increase adoptability or use? Can the intervention vary, as needed, depending on the audience?
- Health outcome – Measure the effectiveness of the intervention as a secondary measure.
- Economic Cost – Was cost a factor in the implementers or target populations willingness to adopt the intervention? What opportunity (non-fiscal) costs were incurred?
- Cultural context – Did the adaptation of the intervention to make it more culturally relevant result in loss of fidelity? Did this result in decreased effectiveness?
- Maintenance and sustainability – What is the extent to which a program or policy became institutionalized or part of the routine organizational practices and policies?

V. Community Action Plan (CAP)

Applicants must include a Community Action Plan that demonstrates a clear understanding of the stakeholders' roles and incentives; factors that influence decision-making for stakeholders, implementers and target population (e.g., training); and the organizational capacity (e.g., need and fit for the proposed intervention). Broad stakeholder involvement should be outlined from the outset to include traditional and non-traditional research partners (e.g., federal/state or local government, education, community, public policy, politicians, private sector, non-profits, health systems, academics, coalitions and media). Detailed, complete and substantive plans for ensuring the meaningful involvement of partners and stakeholders must be included in applications responsive to this FOA. Note: Projects that propose to conduct secondary data analysis do not have to submit a community action plan.

4. Intergovernmental Review

Executive Order 12372 does not apply to this program.

5. Funding Restrictions

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

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

- Funds relating to the conduct of research involving human subjects will be restricted until the appropriate assurances and Institutional Review Board approvals are in place.
- Pre-award costs will not be reimbursed.

6. Other Submission Requirements

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

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

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

Research Plan Component Sections

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

The following materials may be included in the Appendix:

Up to 3 publications, manuscripts (accepted for publication), abstracts, patents, or other printed materials directly relevant to the proposed project. Do not include manuscripts submitted for publication. Applicants should refer to instruction guides and specific Funding Opportunity Announcements (FOAs) to determine the appropriate limit on the number of publications that may be submitted for a particular program. Note that not all grant activity codes allow the inclusion of publications.

- Publications in press: Include only a publication list with a link to the publicly available on-line journal article or the NIH Pub Med Central (PMC) submission identification number. Do not include the entire article.
- Manuscripts accepted for publication but not yet published: The entire article may be submitted electronically as a PDF attachment.
- Manuscripts published but a publicly available online journal link is not available: The entire article may be submitted electronically as a PDF attachment.
- Surveys, questionnaires, data collection instruments, clinical protocols, and informed consent documents.
- Graphic images of gels, micrographs, etc. provided that the image (may be reduced in size) is also included within the (stated) page limit of Items 2-5 of the Research Plan component. No images may be included in the Appendix that are not also represented within the Research Plan.

Please note the following restriction on appendix attachments: The Research Plan Appendix attachments are limited to 10 attachments. Appendices are uploaded as attachments in the PHS 398 Research Plan form, in field #18, within the electronic application package. An applicant will receive an error message if the number of appendix attachments exceeds 10, which will result in an unsuccessful submission of the application. You may include more than one publication, or other allowable appendix material, within one attachment; however, do not let your attachments exceed 10."

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

Plan for Sharing Research Data

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

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

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

Sharing Research Resources

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

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

Section V. Application Review Information

1. Criteria

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

- Scientific merit of the proposed project as determined by peer review
- Availability of funds
- Relevance of program priorities and the priorities of the U.S. Department of Health and Human Services

2. Review and Selection Process

Applications that are complete and responsive to the FOA will be evaluated for scientific and

technical merit by an appropriate peer review group convened by the Office of Public Health Research (OPHR/OCSO/CDC) and/or the participating Coordinating Offices, National Centers, and Institute in accordance with the review criteria stated below.

As part of the initial merit review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score
- Receive a written critique; and
- Receive a second level of review by HHS/CDC appropriate national advisory council, board or participating Coordinating Office, Coordinating Center, National Center or Institute

The goals of HHS/CDC-supported research are to advance the understanding of health promotion and the prevention of disease, injury, and disability, and enhance preparedness. In the written comments, evaluate the application to judge the likelihood the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed by the reviewers and considered in assigning the overall score.

- Significance
- Approach
- Innovation
- Investigators
- Environment

Note that an application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

Significance: Does this study address an important problem? If the applicant achieves the aims of the application, how will it advance scientific knowledge or clinical practice? What will be the effect of these studies on the concepts, methods, technologies, treatments, or preventative interventions that drive this field? How will these research findings improve an understanding of the gap between knowledge and public health practice? Does this new understanding aid future dissemination, implementation or diffusion efforts of evidence-based public health interventions to result in the greatest public health impact?

Approach: Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Are the key variables for translation research included and sufficiently described? Has the applicant adequately documented that the intervention, policy, etc. is evidence-based? Has the applicant described and justified the target health disparity population(s) sufficiently? Is there a plan for estimating translatability and public health impact? Is there a community action plan that is appropriate to the aims of the project and involves key stakeholders and partners? (Community actions plans not relevant for studies conducting secondary data analysis)

Innovation: Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

Investigators: Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

Environment: Does the scientific environment in which the applicant will do the work contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

2.A. Additional Review Criteria

In addition to the above criteria, the following items will be considered in the determination of scientific merit and the priority score:

Protection of Human Subjects from Research Risk: When human subjects are involved, HHS/CDC will assess the available protections from research risk that relate to their participation in the proposed research. [see the Research Plan, Section 2, item 8 on Human Subjects in the SF424 (R&R)]
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>. Additional HHS/CDC Requirements under AR-1 Human Subjects Requirements are available on the Internet at the following address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

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

Care and Use of Vertebrate Animals in Research: If applicants plan to use vertebrate animals in the project, HHS/CDC will assess the five items described under Section 2, item 12 Vertebrate Animals of the Research Plan component of the SF424 (R&R). Additional HHS/CDC Requirements under AR-3 Animal Subjects Requirements are available on the Internet at the following address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

Biohazards: If applicants propose the applicant has proposed materials or procedures that are potentially hazardous to research personnel and/or the environment, HHS/CDC will determine if the proposed protection is adequate.

2.B. Additional Review Considerations

Budget and Period of Support: The reasonableness of the proposed budget and the appropriateness of the requested period of support in relation to the proposed research may be assessed by the reviewers. Is the number of person months listed for the effort of the PD/PI appropriate for the work proposed? Is each budget category realistic and justified in terms of the aims and methods? The evaluation of the budget should not effect the priority score.

2.C. Sharing Research Data

Data Sharing Plan: HHS/CDC will assess the reasonableness of the data sharing plan. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score. The presence of a data sharing plan will be part of the terms and conditions of the award. The funding organization will be responsible for monitoring

the data sharing policy. Reviewers' comments on the adequacy of the data sharing plan will be used by the program staff responsible for monitoring the award.

2.D. Sharing Research Resources

HHS policy requires that recipients of grant awards make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication. Please see <http://grants.nih.gov/grants/policy/gps/8postnew.htm#phs>. Investigators responding to this funding opportunity should include a plan on sharing research resources.

Reviewers will not factor the proposed research resources sharing plan into the determination of scientific merit or the priority score. However, reviewers' comments on the adequacy of the plan will be used by program staff responsible for monitoring the award.

3. Anticipated Announcement and Award Dates

Not applicable.

Section VI. Award Administration Information

1. Award Notices

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

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

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

2. Administrative and National Policy Requirements

The Code of Federal Regulations 45 CFR Part 74 and Part 92 have details about requirements. For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address:

<http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>. Additional requirements are available Section VIII. Other Information of this document or on the HHS/CDC website at the following Internet address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>. These will be incorporated into the NoA by reference.

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

3. Reporting

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

1. Non-Competing Grant Progress Report, (use form PHS 2590), posted on the HHS/CDC website, <http://www.cdc.gov/od/pgo/funding/forms.htm> and at <http://grants.nih.gov/grants/funding/2590/2590.htm>, no less than 90 days prior to the end of the current budget period. The progress report will serve as the non-competing continuation application.
2. Financial status report, no more than 90 days after the end of the budget period.
3. Final financial and performance reports, no more than 90 days after the end of the project period.

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

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

Section VII. Agency Contacts

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

1. Scientific/Research Contacts:

Juliana Cyril, Ph.D., M.P.H.
Associate Director
Office of Public Health Research
CDC Office of the Chief Science Officer
Also serves as contact for COGH, NCHM, OMHD and OCPHP
1600 Clifton Road NE, MS D-72
Atlanta, GA 30333
Telephone: (404) 639-4639
Fax: 404-639-4903
Email: jcyril@cdc.gov

Rick Waxweiler, Ph.D.
Director
Extramural Research Program Office
National Center for Injury Prevention and Control (NCIPC)
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS K-02
Atlanta, GA 30333
Telephone: 770-488-4850
Fax: 770-488-4422
Email: rwaxweiler@cdc.gov

Adele Childress, Ph.D.
Scientific Program Administrator
National Center for Environmental Health (NCEH)
Agency for Toxic Substance and Disease Registry (ATSDR)
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS F-62
Atlanta, GA 30333
Telephone: 770-488-4233
Fax: 770-488-1665
Email: achildress@cdc.gov

Virginia S. Cain, Ph.D.
Director of Extramural Research
National Center for Health Statistics (NCHS)
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS P-08
Atlanta, GA 30333
Telephone: 301-458-4395
Fax: 301-458-4020
Email: vcain@cdc.gov

Lee Husting, Ph.D.
Scientific Program Administrator
National Center for Public Health Informatics
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS E-78
Atlanta, GA 30333
Telephone: 404-498-1186
Email: eih8@cdc.gov

Brenda Colley Gilbert, Ph.D. M.S.P.H.
Director, Extramural Research Program Office
Coordinating Center for Health Promotion (CoCHP)
National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)
National Center on Birth Defects and Developmental Disabilities (NCBDDD)
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS K-92
Atlanta, GA 30333
Telephone: 770-488-6295
Fax: 770-488-8046
Email: bcolleygilbert@cdc.gov

Trudy Messmer, Ph.D.
Director, Extramural Research Team
Coordinating Center for Infectious Diseases (CCID)
National Center for Immunization and Respiratory Diseases (NCIRD)
National Center for Zoonotic, Vector-Borne and Enteric Disease (NCZVED)
National Center for HIV, Viral Hepatitis, STDs and Tuberculosis Prevention (NCHHSTP)
National Center for Preparedness, Detection and Control of Infectious Diseases (NCPDCID)
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS E-77
Atlanta GA 30333
Telephone: 404-498-2271
Fax: 404-639-2469
Email: tym2@cdc.gov

Jim Newhall, Ph.D.
Director, Office of Extramural Programs
National Institute for Occupational Safety and Health (NIOSH)

Centers for Disease Control and Prevention
1600 Clifton Road, NE, MS E-74
Atlanta, GA 30333
Phone: 404-498-2530
Fax: 404-498-2571
E-mail: jnewhall@cdc.gov

Mildred William Johnson, Ph.D., D.A.B.T.
Scientific Program Administrator
Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER)
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS D-44
Atlanta, GA 30333
Telephone: 404-639-7719
Fax: 404-639-7977
Email: mwillians-johnson@cdc.gov

2. Peer Review Contacts:

Christine Morrison, Ph.D.
Office of Public Health Research
CDC Office of the Chief Science Officer
1600 Clifton Road NE, MS D-72
Atlanta, GA 30333
Telephone: (404) 639-3098
Fax: 404-639-4903
Email: cjm3@cdc.gov

3. Financial or Grants Management Contacts:

Mattie Jackson
CDC Procurement and Grants Office
U.S. Department of Health and Human Services
2920 Brandywine Road NE
Atlanta, GA 30341
Telephone: (770)-488-2696
Fax: 770-488-2044
Email: MIJ3@cdc.gov

4. General Questions Contacts:

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

Section VIII. Other Information

Required Federal Citations

Human Subjects Protection

Federal regulations (45 CFR Part 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>). Additional HHS/CDC Requirements under AR-1 Human Subjects Requirements can be found on the Internet at the following address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

Use of Animals in Research

Recipients of PHS support for activities involving live, vertebrate animals must comply with the PHS Policy on Humane Care and Use of Laboratory Animals (<http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>) as mandated by the Health Research Extension Act of 1985 (<http://grants.nih.gov/grants/olaw/references/hrea1985.htm>), and the USDA Animal Welfare Regulations (<http://www.nal.usda.gov/awic/legislat/usdaleg1.htm>) as applicable. Additional HHS/CDC Requirements under AR-3 Animal Subjects Requirements can be found ~~on~~ at <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

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

It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian or Other Pacific Islander. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity, and/or sex of subjects. Further guidance to this policy is contained in the Federal Register, Vol. 60, No. 179, pages 47947-47951, and dated Friday, September 15, 1995.

Inclusion of Persons Under the Age of 21 in Research

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

In an extramural research plan, the investigator should create a section titled "Participation of persons under the age of 21." This section should provide either a description of the plans to include persons under the age of 21 and a rationale for selecting or excluding a specific age range, or an explanation of the reason(s) for excluding persons under the age of 21 as participants in the research. When persons under the age of 21 are included, the plan must also include a description of the expertise of the investigative team for dealing with individuals at the ages included, the appropriateness of the available facilities to accommodate the included age groups, and the inclusion of a sufficient number of persons under the age of 21 to contribute to a meaningful analysis relative to the purpose of the study. Scientific review

groups at CDC will assess each application as being acceptable or unacceptable in regard to the age-appropriate inclusion or exclusion of persons under the age of 21 in the research project, in addition to evaluating the plans for conducting the research in accordance with these provisions.

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

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

HIV/AIDS Confidentiality Provisions

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

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

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

HIV Program Review Panel Requirements

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

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

If the proposed project involves hosting a conference, submit the program review panel's report stating that all materials, including the proposed conference agenda, have been approved. Submit a copy of the proposed agenda with the application. Before funds are used to develop educational materials, determine whether suitable materials already exist in the CDC National Prevention Information Network (NPIN). The website can be found at; <http://www.nchstp.cdc.gov/od/infocenter/npin.htm>.

Patient Care

Ensure that all STD or HIV infected patients enrolled in the proposed project will be linked to an appropriate local care system that can address their specific needs, such as medical care, counseling, social services, and therapy.

Public Health System Reporting Requirements

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

The appropriate State and/or local health agency is determined by the applicant. The following information must be provided:

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

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

Paperwork Reduction Act Requirements

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

Smoke-Free Workplace Requirements

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

Healthy People 2010

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

Lobbying Restrictions

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

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

Any activity designed to influence action in regard to a particular piece of pending legislation would be considered "lobbying." That is lobbying for or against pending legislation, as well as

indirect or "grass roots" lobbying efforts by award recipients that are directed at inducing members of the public to contact their elected representatives at the Federal or State levels to urge support of, or opposition to, pending legislative proposals is prohibited. As a matter of policy, HHS/CDC extends the prohibitions to lobbying with respect to local legislation and local legislative bodies.

The provisions are not intended to prohibit all interaction with the legislative branch, or to prohibit educational efforts pertaining to public health. Clearly there are circumstances when it is advisable and permissible to provide information to the legislative branch in order to foster implementation of prevention strategies to promote public health. However, it would not be permissible to influence, directly or indirectly, a specific piece of pending legislation

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

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

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

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

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

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

Accounting System Requirements

The services of a certified public accountant licensed by the State Board of Accountancy or the equivalent must be retained throughout the project as a part of the recipient's staff or as a consultant to the recipient's accounting personnel. These services may include the design, implementation, and maintenance of an accounting system that will record receipts and expenditures of Federal funds in accordance with accounting principles, Federal regulations, and terms of the cooperative agreement or grant.

Capability Assessment

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

Proof of Non-profit Status

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

Security Clearance Requirement

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

Small, Minority, And Women-owned Business

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

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

Research Integrity

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

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

For example:

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

misconduct; and (2) Complies with its own policies and procedures and the requirements of this part.

Compliance with Executive Order 13279

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

<http://www.whitehouse.gov/government/fbci/>

Health Insurance Portability and Accountability Act Requirements

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

Release and Sharing of Data

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

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

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

Applications must include a copy of the applicant's Data Release Plan. Applicants should provide HHS/CDC with appropriate documentation on the reliability of the data. Applications submitted without the required Plan may be ineligible for award. Award will be made when reviewing officials have approved an acceptable Plan. The successful applicant and the Program Manager will determine the documentation format. HHS/CDC recommends data is released in the form closest to micro data and one that will preserve confidentiality.

National Historic Preservation Act of 1966

(Public Law 89-665, 80 Stat. 915)

The grantee's signature on the grant application attests to their: (1) knowledge of the National Historic Preservation Act of 1966 (Public Law 89-665, 80 Stat. 915); and (2) intent to ensure all grant related activities are in compliance with referenced public law, as stated:

- a. Section 106 of the National Historic Preservation Act (NHPA) states:

The head of any Federal agency, having direct or indirect jurisdiction over a proposed Federal or Federally assisted undertaking in any State and the head of any Federal department or independent state agency having authority to license any undertaking, shall, prior to the approval of the expenditure of any Federal funds on the undertaking or prior to the issuance of any license, as the case may be, take into account the effect of the undertaking on any district, site, building, structure, or object that is included in or is eligible for inclusion in the National Register. The head of any such Federal agency shall afford the Advisory Council on Historic Preservation established under Title II of this ACT a reasonable opportunity to comment with regard to such undertaking.

- b. Additionally, the NHPA also contains the following excerpt that forbids "anticipatory demolition:"

Each Federal agency shall ensure that the agency will not grant a loan, loan guarantee, permit, license, or other assistance to an applicant who, with intent to avoid the requirements of Section 106 of this Act, has intentionally, significantly, adversely affected a historic property to which the grant would relate or, having legal power to prevent it, allowed such significant adverse effect to occur, unless the agency, after consultation with the Council, determines that circumstances justify granting such assistance despite the adverse effect created or permitted by the applicant.

Conference Disclaimer and Use of Logos

{Mandatory for all grants and cooperative agreements.}

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

"Funding for this conference was made possible [in part] by [insert grant or cooperative agreement award number] from the Centers for Disease Control and Prevention(CDC) or the Agency for Toxic Substances and Disease Registry (ATSDR) .

The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government."

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