

OCCUPATIONAL HEALTH AND SAFETY RESEARCH (R01)

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Department of Health and Human Services (DHHS)

PARTICIPATING ORGANIZATIONS:

Centers for Disease Control and Prevention (CDC)  
National Institute for Occupational Safety and Health (NIOSH)  
(<http://www.cdc.gov/niosh>)  
National Institutes of Health (NIH)  
(<http://www.nih.gov>)

COMPONENTS OF PARTICIPATING ORGANIZATIONS:

National Cancer Institute (NCI)  
(<http://www.nci.nih.gov/>)  
National Heart, Lung, and Blood Institute (NHLBI)  
(<http://www.nhlbi.nih.gov/>)  
National Institute on Aging (NIA)  
(<http://www.nia.nih.gov/>)  
National Institute on Alcohol Abuse and Alcoholism (NIAAA)  
(<http://www.niaaa.nih.gov/>)  
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)  
(<http://www.niams.nih.gov/>)  
National Institute on Deafness and Other Communication Disorders (NIDCD)  
(<http://www.nidcd.nih.gov/>)  
National Institute of Environmental Health Sciences (NIEHS)  
(<http://www.niehs.nih.gov/>)

CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER(S): This program is described in the Catalog of Federal Domestic Assistance Nos. 93.262 NIOSH; 93.393 NCI; 93.837, 93.838, and 93.839 NHLBI; 93.866 NIA; 93.273 NIAAA; 93.855, 93.856 NIAID; 93.846 NIAMS; 93.173 NIDCD; and 93.113 and 93.115 NIEHS.

THIS PA CONTAINS THE FOLLOWING INFORMATION

- o Purpose of the PA
- o Research Objectives
- o Mechanism(s) of Support
- o Eligible Institutions
- o Individuals Eligible to Become Principal Investigators

- o Where to Send Inquiries
- o Submitting an Application
- o Peer Review Process
- o Review Criteria
- o Award Criteria
- o Required Federal Citations

#### PURPOSE OF THIS PA

The National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC) and participating Institutes and Centers, National Institutes of Health (NIH) invite grant applications for research related to occupational safety and health. NIOSH research programs support priority areas identified in the National Occupational Research Agenda (NORA) and other significant programs related to occupational safety and health. Visit the NIOSH homepage for a full description of occupational safety and health program areas <http://www.cdc.gov/niosh/homepage.html>. Research areas described in the RESEARCH OBJECTIVES section provide an example of NORA and other occupational safety and health research program areas.

The overall purpose of this grants program is to develop knowledge that can be used in preventing occupational diseases and injuries and to understand better their underlying pathophysiology. This purpose is shared by several components of the Public Health Service (PHS) within the CDC and the NIH. Within CDC, NIOSH is the lead Federal Institute responsible for conducting research and making recommendations for the prevention of work-related illnesses and injuries. However, there are other Federal components that contribute significantly to the research base for understanding the causes of occupational illnesses and injuries. Interest statements from the sponsors of this program announcement are given below, and more information about their individual interests may be found on their respective Internet sites. Applications will be assigned to an institute on the basis of established PHS referral guidelines.

NIOSH supports research to identify and investigate the relationships between hazardous working conditions and associated occupational diseases and injuries; to develop more sensitive means of evaluating hazards at work sites, as well as methods for measuring early markers of adverse health effects and injuries; to develop new protective equipment, engineering control technology, and work practices to reduce the risks of occupational hazards; and to evaluate the technical feasibility or application of a new or improved occupational safety and health procedure, method, technique, or system.

The National Cancer Institute (NCI) supports training and research related to the causes, detection, prevention, diagnosis, prognosis, and treatment of cancer. Of special interest is basic, applied, methodological, and statistical research that can advance cancer control

activities, including surveillance, dissemination of public health information, and elucidation of susceptibility factors associated with cancer risk in individuals and population subgroups. NCI-relevant NORA priority areas include applicable research approaches and methods (for example: exposure and risk assessment, bio-monitoring and surveillance techniques, analysis of cancer risk factors, and characterization of possible carcinogens in mixed exposures).

The National Heart, Lung and Blood Institute (NHLBI) supports an integrated and coordinated program of basic research, clinical investigations and trials, observational studies, and demonstration and education projects. Research is related to the causes, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases; and sleep disorders. The NHLBI plans and directs research in the development and evaluation of interventions and devices related to prevention, treatment, and rehabilitation of patients suffering from such diseases and disorders. It also supports research on clinical use of blood and all aspects of the management of blood resources.

The National Institute on Aging (NIA) supports training and research on basic mechanisms involved in aging processes and the onset of age-related disease; social and behavioral research on aging processes and the place of older people in society; the structure and function of the aging nervous system and the behavioral manifestations of the aging brain; and topics related to the causes, prevention, and treatment of health problems in older persons. The NIA supports a variety of data collections related to work and retirement including the Panel Study of Income Dynamics, the Health and Retirement Study, and the English Longitudinal Study on Aging. Specific to this PA, NIA is interested in expanding research on the health needs of older workers, and occupations such as physicians, researchers, air traffic controllers, computer programmers, accountants, and others working in an environment of high cognitive complexity. The development of tools to define functional work abilities similar to the concept of ADLs and IADLs used to assess function in general settings is also encouraged. A helpful tool in this regard is a prepublication report of the Workshop on Technology for Adaptive Aging from the National Research Council of the National Academy of Sciences located at <http://books.nap.edu/catalog/10857.html>. NIA also looks forward to the imminent publication of the NAS Panel report on The Health and Safety of Older Workers. This report, among other items, will call for: the development of longitudinal data sets that focus on job demands and health and safety risks; the addition of modules to existing longitudinal surveys (HRS, PSID) to investigate workplace health and safety risks; examination of the effect of environmental exposures on normal aging and/or comorbidities; cost/benefit analyses of job design interventions for the older worker. NIA is also interested in studies that better quantify the impact of lifetime exposures on health outcomes. Such exposures include work-related stress, negative affect related to work, and low job control and autonomy. Conversely, the NIA is also interested in studies of any positive effects that work may have on the health and functioning of older workers. Studies are also encouraged on health and other workplace

determinants on the timing of retirement, and the net of public and private pensions. The examination of gender effects in any of these areas is encouraged.

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) supports basic and applied research on the causes, consequences, treatment and prevention of alcohol-related problems including research into the effects of alcohol on the human mind and body, prevention and treatment of alcohol abuse and alcoholism among general and specific populations, the epidemiology of alcoholism and alcohol-related problems, and health services research.

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) supports basic, clinical, and epidemiologic research and research training and disseminates information on many forms of arthritis and diseases of the musculoskeletal system and the skin, including (1) the normal structure and function of joints, muscles, bones, and skin and (2) clinical research in the fields of rheumatology, orthopedics, dermatology, metabolic bone diseases, heritable disorders of bone and cartilage, inherited and inflammatory muscle diseases, and sports and rehabilitation medicine.

The National Institute on Deafness and Other Communication Disorders (NIDCD) supports biomedical and behavioral research and research training in the normal and disordered processes of hearing, balance, smell, taste, voice, speech and language; disease prevention and health promotion; special biomedical and behavioral problems associated with people who have communication impairments or disorders; and creation of devices which substitute for lost and impaired sensory and communication function.

The National Institute of Environmental Health Sciences (NIEHS) supports research to reduce the burden of human illness and dysfunction from exposure to physical and chemical agents in the environment by understanding the interactions between environmental exposures, individual susceptibility and time.

## RESEARCH OBJECTIVES

In today's society, Americans are working more hours than ever before. The workplace environment profoundly affects health; simply by going to work each day, we may face hazards that threaten our health and safety. Risking one's life or health should never be considered merely part of the job. In 1970, Congress passed the Occupational Safety and Health Act to ensure Americans the right to "safe and healthful working conditions," yet workplace hazards continue to inflict a tremendous toll in both human and economic costs. In 2000, private industry employers reported 5.3 million work injuries and 363,000 cases of occupational illness. An average of 16 American workers die each day from injuries on the job (in 2000, there were 5915 fatal work injuries). Moreover, even

the most conservative estimates find that about 137 additional workers die each day from workplace diseases. Additionally, in 1999, occupational injuries and deaths have cost approximately \$123 billion in wages and lost productivity, administrative expenses, health care and other costs. This does not include the cost of occupational disease. These occupational injuries and diseases create needless human suffering, a tremendous burden upon health care resources, and an enormous drain on U.S. productivity.

NIOSH is the lead Federal institute responsible for conducting research and making recommendations for the prevention of work-related illnesses and injuries. NIOSH's mandate includes the support of research in numerous occupational safety and health areas in addition to the topics identified in the NORA, described below. Investigators are encouraged to discuss their research topics with NIOSH to determine the relevance to occupational health and safety.

Because of the diverse nature of occupational safety and health issues, many research topics are supported by NIOSH in addition to the NORA topics described below. Thus, NIOSH supports research in other areas related to occupational disease and injury including: violence, biomarkers, emergency response, mining, bio-terrorism, agricultural related illnesses and injuries, and other occupational safety and health issues. Visit the NIOSH homepage for more information on NIOSH's research program areas <http://www.cdc.gov/niosh/homepage.html>.

In 1996, NIOSH and its partners in the public and private sectors developed the NORA to provide a framework to guide occupational safety and health research into the next decade. Approximately 500 organizations and individuals outside NIOSH provided input into the development of NORA. The agenda identifies 21 research priorities and reflects an attempt to consider both current and emerging needs. The priority areas are not ranked; each is considered to be of equal importance. The NORA priority research areas are grouped into three categories: Disease and Injury, Work Environment and Workforce, and Research Tools and Approaches.

NORA Priority Research Areas are:

#### Disease and Injury

1. Allergic and Irritant Dermatitis
2. Asthma and Chronic Obstructive Pulmonary Disease
3. Fertility and Pregnancy Abnormalities
4. Hearing Loss
5. Infectious Diseases
6. Low Back Disorders
7. Musculoskeletal Disorders of the Upper Extremities
8. Traumatic Injuries

## Work Environment and Workforce

9. Emerging Technologies
10. Indoor Environment
11. Mixed Exposures
12. Organization of Work
13. Special Populations at Risk

## Research Tools and Approaches

14. Cancer Research Methods
15. Control Technology and Personal Protective Equipment
16. Exposure Assessment Methods
17. Health Services Research
18. Intervention Effectiveness Research
19. Risk Assessment Methods
20. Social and Economic Consequences of Workplace Illness and Injury
21. Surveillance Research Methods

Potential applicants may obtain a copy of the "National Occupational Research Agenda" (HHS, CDC, NIOSH Publication No.96-115) from the National Institute for Occupational Safety and Health, telephone (800) 356-4674 or on the internet at <http://www.cdc.gov/niosh/nora.html>.

Applicants should provide a statement about which NIOSH/NIH research area is being addressed and a rationale for how the proposal will contribute to the specified priority area (this information should be placed in the "Background and Significance" section of the "Research Plan" of the application). Assignment of applications to sponsoring Institutes will be made on the basis of matching the research topics with the appropriate programmatic interests. Applicants are encouraged to contact individuals listed under INQUIRIES if they wish to discuss the relevance of their research ideas.

## MECHANISM(S) OF SUPPORT

This PA will use the NIH R01 award mechanism. As an applicant, you will be solely responsible for planning, directing, and executing the proposed project. The total requested project period for an application submitted in response to this PA may be up to five (5) years.

This PA uses just-in-time concepts. It also uses the modular budgeting format as well as the non-modular budgeting formats (see <http://grants.nih.gov/grants/funding/modular/modular.htm>, for more information). Specifically, if you are submitting an application with direct costs in each year of \$250,000 or less, use the modular budget format. Otherwise follow the instructions for non-modular budget research grant applications. This program does not require cost sharing as defined in the current NIH Grants Policy Statement at

[http://grants.nih.gov/grants/policy/nihgps\\_2001/part\\_i\\_1.htm](http://grants.nih.gov/grants/policy/nihgps_2001/part_i_1.htm).

## ELIGIBLE INSTITUTIONS

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

- o For-profit or non-profit organizations
- o Public or private institutions, such as universities, colleges, hospitals, and laboratories
- o Units of State and local governments
- o Eligible agencies of the Federal government
- o Domestic or foreign institutions/organizations
- o Faith-based organizations
- o Indian Tribes, Tribal Government, College and/or Organizations

## INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from under-represented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for CDC/NIOSH and NIH programs.

## WHERE TO SEND INQUIRIES

We encourage your inquiries concerning this PA and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into two areas: scientific/research and financial or grants management issues.

- o Direct your questions about NIOSH scientific/research issues to:

For exposure assessment method, control technology, emerging technology, surveillance, and mixed exposure studies contact:

Susan B. Board, M.S.  
Office of Extramural Programs  
National Institute for Occupational Safety and Health  
Centers for Disease Control and Prevention  
1600 Clifton Road, N.E.  
Executive Park Building 24, Room 1415, MS E-74  
Atlanta, GA 30333  
Telephone: (404) 498-2512  
FAX: (404) 498-2517  
Email: [sboard@cdc.gov](mailto:sboard@cdc.gov)

For dermatitis, cancer research methods, fertility and pregnancy abnormalities, hearing loss, health services research, infectious diseases, indoor environment, organization of work, and special populations contact:

Adele Childress, Ph.D., M.S.P.H.  
Office of Extramural Programs  
National Institute for Occupational Safety and Health  
Centers for Disease Control and Prevention  
1600 Clifton Road, N.E.  
Executive Park Building 24, Room 1429, MS E-74  
Atlanta, GA 30333  
Telephone: (404) 498-2509  
FAX: (404) 498-2571  
Email: [achildress@cdc.gov](mailto:achildress@cdc.gov)

For asthma and COPD, social and economic consequences, intervention effectiveness, musculoskeletal disorders, risk assessment methods, traumatic injuries and all other occupational safety and health issues contact:

Michael J. Galvin, Jr., Ph.D.  
Office of Extramural Programs  
National Institute for Occupational Safety and Health  
Centers for Disease Control and Prevention  
1600 Clifton Road, N.E.  
Executive Park Building 24, Room 1536, MS E-74  
Atlanta, GA 30333  
Telephone: (404) 498-2524  
FAX: (404) 498-2571  
Email: [mgalvin@cdc.gov](mailto:mgalvin@cdc.gov)

o Direct your questions about NIH scientific/research issues to:

Kumiko Iwamoto, M.D., Dr.P.H.  
Epidemiology and Genetics Research Program  
National Cancer Institute, NIH  
6130 Executive Boulevard, ROOM 5115  
Bethesda, MD 20892-7324  
Telephone: (301) 435-4911  
FAX: (301) 402-4279  
Email: <mailto:ki6n@nih.gov>

Hector Ortega, M.D., Sc.D.  
Division of Lung Diseases  
National Heart, Lung, and Blood Institute, NIH  
6701 Rockledge Drive, Suite 10018, MSC 7952  
Bethesda, MD 20892

Telephone: (301) 435-0202  
FAX: (301) 480-3557  
Email: <mailto:ho28y@nih.gov>

Jeffrey Elias, PhD  
Behavioral and Social Research Program  
National Institute on Aging  
Gateway Building, Suite 533  
Bethesda, MD 20892-9205  
Telephone: (301) 402-4156  
Email: [eliasj@nia.nih.gov](mailto:eliasj@nia.nih.gov)

Kathy Salaita, Sc.D.  
Prevention Research Branch  
National Institute on Alcohol Abuse and Alcoholism, NIH  
Willco Bldg., Suite 505  
6000 Executive Blvd.  
Rockville, MD 20892-7003 (Fed-Ex Zipcode: 20852)  
Telephone: (301) 443-0633  
FAX: (301) 443-8774  
Email: <mailto:ksalaita@mail.nih.gov>

Alan Moshell, M.D.  
Skin Diseases Branch  
National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH  
One Democracy Plaza  
6701 Democracy Boulevard, Suite 800  
MSC 4872  
Bethesda, MD 20892-4872  
Telephone: (301) 594-5017  
FAX: (301) 480-4543  
Email: <mailto:am40j@nih.gov>

James S. Panagis, M.D., M.P.H.  
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National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH  
One Democracy Plaza  
6701 Democracy Boulevard, Suite 800  
MSC 4872  
Bethesda, MD 20892-4872  
Telephone: (301) 594-5055  
FAX: (301) 480-4543  
Email: <mailto:jp149d@nih.gov>

Amy Donahue, Ph.D.  
Chief, Hearing and Balance/Vestibular Section  
National Institute on Deafness and Other Communication Disorders, NIH  
6120 Executive Boulevard, EPS Room 400 MSC-7180  
Bethesda, MD 20892-7180  
Telephone: (301) 402-3458  
FAX: (301) 402-6251  
Email: [mailto:amy\\_donahue@nih.gov](mailto:amy_donahue@nih.gov)

J.Patrick Mastin, Ph.D.  
Division of Extramural Research and Training  
National Institute of Environmental Health Sciences, NIH  
P.O. Box 12233, MD EC-21  
Research Triangle Park, NC 27709  
Telephone: (919) 541-3289  
FAX: (919) 541-4937  
Email: <mailto:jm436j@nih.gov>

o Direct your questions about financial or grants management matters to:

John Columbia  
Acquisition and Assistance Field Branch  
Procurement and Grants Office  
Centers for Disease Control and Prevention  
626 Cochran Mill Road  
Pittsburgh, Pennsylvania 15236-0070  
Telephone: (412) 386-4458  
Fax (412)386-6429  
Email: <mailto:jcolumbia@cdc.gov>

Crystal Wolfrey  
Grants Administration Branch  
National Cancer Institute, NIH  
6120 Executive Boulevard, Room 243  
Bethesda, MD 20892-7150  
Telephone: (301) 496-8634  
FAX: (301) 496-8601  
Email: <mailto:wolfreyc@mail.nih.gov>

Suzanne White  
Division of Extramural Affairs  
National Heart, Lung, and Blood Institute, NIH  
6701 Rockledge Drive, Suite 7128  
Bethesda, MD 20892-7128  
Telephone: (301) 435-0182

FAX: (301) 480-3310  
Email: <mailto:sw52h@nih.gov>

Carol Lander  
Grants and Contracts Management Office  
National Institute on Aging, NIH  
7201 Wisconsin Avenue, Suite 2N212, MSC 9205  
Bethesda, MD 20892-9205  
Telephone: (301) 496-1472  
FAX: (301) 402-3672  
Email: <mailto:LanderC@mail.nih.gov>

Judy Fox Simons  
Grants Management Officer  
National Institute on Alcohol Abuse and Alcoholism, NIH  
6000 Executive Boulevard MSC 7003  
Bethesda, Maryland 20892-7003  
Telephone: (301) 443-4704  
FAX: (301) 443-3891  
Email: <mailto:js182a@nih.gov>

Melinda B. Nelson  
Chief Grants Management Officer  
National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH  
One Democracy Plaza  
6701 Democracy Boulevard, Suite 800  
MSC 4872  
Bethesda, MD 20892-4872  
Phone: (301) 594-3535  
Fax: (301) 480-5450  
E-mail: <mailto:mn23z@nih.gov>

Sara Stone  
Chief, Grants Management Branch  
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6120 Executive Boulevard, EPS Room 400-B, MSC 7180  
Bethesda, MD 20892-7180  
Telephone: (301) 402-0909  
Fax: (301) 402-1758  
Email: <mailto:stones@nidcd.nih.gov>

Dorothy Williams  
Chief, Grants Management Branch  
Division of Extramural Research and Training  
National Institute of Environmental Health Sciences, NIH  
P.O. Box 12233, MD E1-03

Research Triangle Park, NC 27709-2233  
Telephone: (919) 541-3827  
Email: <mailto:dw47y@nih.gov>

## SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). Applications must have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number can be obtained by calling (866) 705-5711 or through the web site at <http://www.dunandbradstreet.com/>. The DUNS number should be entered on line 11 of the face page of the PHS 398 form. The PHS 398 is available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov).

The title and number of this program announcement must be typed on line 2 of the application form and the YES box must be checked.

**APPLICATION RECEIPT DATES:** Applications submitted in response to this program announcement will be accepted at the standard application deadlines, which are available at <http://grants.nih.gov/grants/dates.htm>. Application deadlines are also indicated in the PHS 398 application kit.

**SPECIFIC INSTRUCTIONS FOR MODULAR GRANT APPLICATIONS:** Applications requesting up to \$250,000 per year in direct costs must be submitted in a modular grant format. The modular grant format simplifies the preparation of the budget in these applications by limiting the level of budgetary detail. Applicants request direct costs in \$25,000 modules. Section C of the research grant application instructions for the PHS 398 (rev. 5/2001) at <http://grants.nih.gov/grants/funding/phs398/phs398.html> includes step-by-step guidance for preparing modular grants. Additional information on modular grants is available at <http://grants.nih.gov/grants/funding/modular/modular.htm>.

**SPECIFIC INSTRUCTIONS FOR APPLICATIONS REQUESTING \$500,000 OR MORE PER YEAR:** Applications requesting \$500,000 or more in direct costs for any year must include a cover letter identifying the NIOSH or NIH staff member (as appropriate) within NIOSH or one of NIH institutes or centers who has agreed to accept assignment of the application. Applicants requesting more than \$500,000 must carry out the following steps:

(1) Contact the IC program staff at least six weeks before submitting the application, i.e., while you are developing plans for the study;

(2) Obtain agreement from the IC staff that the IC will accept your application for consideration for award; and,

(3) Identify, in a cover letter sent with the application, the staff member and IC who agreed to accept assignment of the application.

This policy applies to all investigator-initiated new (type 1), competing continuation (type 2), competing supplement, or any amended or revised version of these grant application types. Additional information on this policy is available in the NIH Guide for Grants and Contracts, October 19, 2001 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html>.

**SENDING AN APPLICATION TO THE NIH:** Applications may not be submitted electronically. Submit a signed, typewritten original of the application, including the checklist, and five signed photocopies in one package to:

Center for Scientific Review (CSR)  
National Institutes of Health  
6701 Rockledge Drive, Room 1040, MSC 7710  
Bethesda, MD 20892-7710  
Bethesda, MD 20817 (for express/courier service)

**APPLICATION PROCESSING:** Applications must be received by or mailed on or before the receipt dates described at <http://grants.nih.gov/grants/dates.htm>. The CSR will not accept any application in response to this PA that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of a substantial revision of an application already reviewed, but such application must include an Introduction addressing the previous critique.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within 8 weeks.

## PEER REVIEW PROCESS

Applications submitted for this PA will be assigned on the basis of established PHS referral guidelines. An appropriate scientific review group convened in accordance with the standard NIH peer review procedures <http://www.csr.nih.gov/refrev.htm> will evaluate applications for scientific and technical merit.

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

- o 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
- o Receive a written critique
- o Receive a second level review by the appropriate national advisory council or board

## REVIEW CRITERIA

The goals of NIOSH and NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to discuss the following aspects of your application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. The scientific review group will address and consider each of the following criteria in assigning the application's overall score, weighting them as appropriate for each application.

- o Significance
- o Approach
- o Innovation
- o Investigator
- o Environment

The 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 your study address an important problem? If the aims of your application are achieved, how do they advance scientific knowledge? What will be the effect of these studies on the concepts or methods that drive this field?

**APPROACH:** Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Do you acknowledge potential problem areas and consider alternative tactics?

**INNOVATION:** Does your project employ novel concepts, approaches or methods? Are the aims original and innovative? Does your project challenge existing paradigms or develop new methodologies or technologies?

**INVESTIGATOR:** Are you appropriately trained and well suited to carry out this work? Is the work proposed appropriate to your experience level as the principal investigator and to that of other researchers (if any)?

**ENVIRONMENT:** Does the scientific environment in which your work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

**ADDITIONAL REVIEW CRITERIA:** In addition to the above criteria, your application will also be reviewed with respect to the following. **New wording:** 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:** The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed (See criteria included in the section on Federal Citations, below).

**INCLUSION OF WOMEN, MINORITIES AND CHILDREN IN RESEARCH:** The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria in the sections on Federal Citations, below).

**CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH:** If vertebrate animals are to be used in the project, the five items described under Section f of the PHS 398 research grant application instructions (rev. 5/2001) will be assessed.

## **ADDITIONAL REVIEW CONSIDERATIONS**

### **Sharing Research Data**

Applicants requesting more than \$500,000 in direct costs in any year of the proposed research are expected to include a data sharing plan in their application. 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 priority score.

BUDGET: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

#### AWARD CRITERIA

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

- o Scientific merit of the proposed project as determined by peer review
- o Availability of funds
- o Relevance to program priorities

#### REQUIRED FEDERAL CITATIONS

HUMAN SUBJECTS PROTECTION: Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks of 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://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>

DATA AND SAFETY MONITORING PLAN: Data and safety monitoring is required for all types of clinical trials, including physiologic, toxicity, and dose-finding studies (phase I), efficacy studies (phase II), efficacy, effectiveness and comparative trials (phase III). The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risk to the participants. NIH Policy for Data Safety and Monitoring, NIH Guide for Grants and Contracts, June 12, 1998:

<http://grants.nih.gov/grants/guide/notice-files/not98-084.html>.

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>);

a complete copy of the updated Guidelines are available at

[http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm)

The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

**INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS:** The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998. NIOSH has adopted this policy for this announcement.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at <http://grants.nih.gov/grants/funding/children/children.htm>.

**REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS:** NIOSH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

**PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT:** The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at [http://grants.nih.gov/grants/policy/a110/a110\\_guidance\\_dec1999.htm](http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm).

Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

**STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION:** The Department of Health and Human Services (DHHS) issued final modification to the “Standards for Privacy of Individually Identifiable Health Information”, the “Privacy Rule,” on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as “covered entities”) must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (<http://www.hhs.gov/ocr/>) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on “Am I a covered entity?” Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

**URLs IN NIOSH GRANT APPLICATIONS OR APPENDICES:** All applications and proposals for NIOSH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

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

HEALTHY PEOPLE 2010: CDC is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a national activity for reducing morbidity and mortality, and to improve the quality of life.

This RFA is related to one or more focus areas. Potential applicants may obtain a copy of "Healthy People 2010" <http://www.healthypeople.gov>.

**AUTHORITY AND REGULATIONS:** This program is described in the Catalog of Federal Domestic Assistance at <http://www.cfda.gov/> and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284 and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. And under the Occupational Safety and Health Act of 1970, Section 20(a) (29 USC 669(a)).

All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm>

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

#### References

USDOL, 2001. Workplace injuries and illnesses in 2000. News Release 12/18/01; Bureau of Labor Statistics

USDOL, 2001. National census of fatal occupational injuries in 2000. News Release 8/14/01; Bureau of Labor Statistics

National Safety Council, 2000. Injury Facts, 2000 Edition.

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[Return to Volume Index](#)

[Return to NIH Guide Main Index](#)



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