L. 104–13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Increasing Donor Awareness on College Campuses; New

Despite apparent widespread public support for organ donation and transplantation, few individuals in the United States declare intent to be organ and tissue donors. Innovative interventions are necessary to help individuals move from positive attitudes about organ donation to the behaviors of declaring intent and informing family of that intent. The goal of the current project is to develop, implement and evaluate a donor awareness program on college and university campuses. The specific aim of the study is to evaluate the effect of a 6-month college-wide intervention program on organ donation intentions. An experimental design will be used consisting of two pairs of colleges matched on variables including freshman class size, geographic region, and cultural diversity of the student body. The design is a 2 (Intervention × Control) by 2 (School pair 1 × School pair 2). To increase donor awareness, intervention schools will receive a ''how-to-kit'' to aid them in implementing a campus-wide donor campaign. This kit will provide materials and activities, and serve as a guide for initiating an organ and tissue donor awareness campaign. The kits will be standardized across schools. Donation intentions and other variables of interest will be assessed by means of self-administered questionnaires completed by a sample of students at each university at two time periods, prior to and following the 6-month intervention period. The frequency of students declaring intent to donate organs and documenting that intent via college student identification cards or donor cards is the primary outcome measure. The frequency of students reporting that they have informed family members of their donation intent also will be evaluated. In addition, secondary and process outcomes (e.g., levels of readiness to become an organ donor) will be assessed.

The estimated respondent burden is as follows:

Survey phase	Number of respondents	Responses per respondent	Hours per response	Total hour burden
Baseline	4,000	1	0.3	1,200
Follow-up	4,000	1	0.3	1,200
Total	4,000	2	0.3	2,400

Send comments to Patricia Royston, HRSA Reports Clearance Officer, Room 14–36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: March 10, 1998.

Jane Harrison,

Acting Director, Division of Policy Review and Coordination.

[FR Doc. 98–6778 Filed 3–16–98; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Institutes of Health

[Announcement 98044]

Implementation of the National Occupational Research Agenda; Notice of Availability of Funds for Fiscal Year 1998

Introduction

The Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) announce that grant applications are being accepted for research related to some of the priority areas identified in the National Occupational Research Agenda (NORA) that is described in the Background section. Three types of grants will be supported: traditional research projects, demonstration projects, and pilot studies (see MECHANISMS OF SUPPORT section).

CDC and NIH are committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2000,'' a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority areas of ''Occupational Safety and Health'' and ''Unintentional Injuries.'' (For ordering a copy of ''Healthy People 2000,'' see the section Where To Obtain Additional Information.)

This announcement is jointly sponsored by (1) the National Institute for Occupational Safety and Health (NIOSH) in CDC, (2) the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) in the National Institutes of Health (NIH), (3) the National Institute of Environmental Health Sciences (NIEHS) in NIH, and (4) the National Heart, Lung, and Blood Institute (NHLBI) in NIH. The portion of this initiative dealing with older workers is also of interest to the National Institute on Aging (NIA) in NIH.

Authority

This program is authorized under the Public Health Service Act, as amended,

Section 301(a) [42 U.S.C. 241(a)], and the Occupational Safety and Health Act of 1970, Section 20(a) [29 U.S.C. 669(a)]. The applicable program regulation is 42 CFR Part 52.

Smoke-Free Workplace

CDC and NIH strongly encourage all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products, and 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, and early childhood development services are provided to children.

Eligible Applicants

Eligible applicants include domestic and foreign non-profit and for-profit organizations, universities, colleges, research institutions, and other public and private organizations, including State and local governments, and small, minority and/or woman-owned businesses.

Note: Effective January 1, 1986, Public Law 104–65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 which engages in lobbying activities shall not be eligible to receive Federal funds constituting an award, grant (cooperative agreement), contract, loan, or any other form.

Availability of Funds

Approximately $8.0 million is available in fiscal year (FY) 1998 to fund approximately 45–50 grants. The approximate amounts that are expected to be available by each Institute are: NIOSH—$5.0 million, NIAMS—$1.0 million, NIEHS—$1.0 million, NHLBI—$1.0 million.

Target amounts for the NORA priority areas are as follows:

1. Occupational irritant contact dermatitis (approximately $1.0M).

2. Work-related musculoskeletal disorders, traumatic injuries, indoor environment, and asthma and chronic obstructive pulmonary disease (COPD) (approximately $3.0M).

3. Special populations at risk—nature and magnitude of the special risk factors experienced by older and/or minority workers (approximately $1.0M).

4. Social and economic consequences of workplace illness and injury and health services research (approximately $1.0M).

5. Intervention effectiveness research—the evaluation of existing or new interventions for work-related musculoskeletal disorders, traumatic injuries, asthma and COPD and other occupational risks via changes in work organization factors, through the implementation of control technology or other worker protection techniques (approximately $2.0M).

Awards are anticipated to range up to $250,000 in total costs (direct and indirect) per year for traditional research and demonstration projects, and up to $50,000 in direct costs for pilot studies.

Only applications that are found to be of high scientific merit will be considered for funding and not all of the funds will be spent if there are not enough highly meritorious applications.

The amount of funding available may vary and is subject to availability of funds. Awards are expected to begin in September 1998, although some awards may not begin until FY 99. Awards will be made for a 12-month budget period within a project period not to exceed 3 years for traditional research and demonstration projects, and 2 years for pilot studies.

Continuation awards within the project period will be made on the basis of satisfactory progress and availability of funds.

Use of Funds

Restrictions on Lobbying

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. 1352 (which has been in effect since December 23, 1989), 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, the FY 1998 Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act (Pub. L. 105–78) states in Section 503 (a) and (b) that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relations, 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 legislature, except in presentation to the Congress or any State legislature itself. No part of any appropriation contained in this Act 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 legislature.

Background

In 1970, Congress passed the Occupational Safety and Health Act ''to assure so far as possible every working man and woman in the Nation safe and healthful working conditions.'' In the years since then, substantial progress has been made in improving worker protection. Much of this progress has been based on actions guided by occupational safety and health research. However, workplace hazards continue to inflict a tremendous toll in both human and economic costs. Employers reported 6.3 million work injuries and 515,000 cases of occupational illnesses in 1994. In 1995, occupational injuries alone cost $119 billion in lost wages and lost productivity, administrative expenses, health care, and other costs. This figure does not include the costs of occupational diseases. Research is needed to advance the scientific base of knowledge necessary to define optimal strategies for ensuring the safety and health of all workers.

In 1996, the National Institute for Occupational Safety & Health (NIOSH) and its partners in the public and private sectors developed the National Occupational Research Agenda (NORA) to provide a framework to guide occupational safety and health research into the next decade—not only for NIOSH, but also for the entire occupational safety and health community. The Agenda identifies 21 research priorities and reflects consideration of both current and emerging needs. The priority areas are not ranked because each is considered to be of equal importance. Because the funding resources available for this special announcement are limited, both internal and external partners have recommended that only a subset of the priority areas be targeted as initial areas of emphasis in order to have a meaningful impact in any area. It is expected that, in future years, the remaining NORA priorities will receive similar, much-deserved attention.

Purpose

The purpose of this grant program is to develop knowledge that can be used in preventing occupational diseases and injuries and to better understand their underlying pathophysiology. Thus, the following types of applied research

projects will be supported: Causal research to identify and investigate the relationships between hazardous working conditions and associated occupational disease and injury; the nature and magnitude of special risk factors experienced by older and/or minority workers; methods research to develop more sensitive means of evaluating hazards at work sites; and evaluations of the effectiveness of prevention and intervention programs, including new approaches or combinations of techniques such as control technologies, personal protective equipment and changes in work organization factors, which have been developed and implemented in workplaces.

Mechanisms of Support

The types of grants supported under this announcement are as follow:

1. Research Project Grants (R01)

A research project grant application should be designed to establish, discover, develop, elucidate, or confirm information relating to occupational safety and health, including innovative methods, techniques, and approaches for addressing problems. These studies may generate information that is readily available to solve problems or contribute to a better understanding of the causes of work-related diseases and injuries.

2. Demonstration Project Grants (R18)

A demonstration project grant application should address the technical or economic feasibility of implementing a new/improved innovative procedure, method, technique, or system for preventing occupational safety or health problems. The project should be conducted in an actual workplace where a baseline measure of the problem will be defined, the new/improved approach will be implemented, a follow-up measure of the problem will be documented, and an evaluation of the benefits will be conducted.

3. Pilot Study Grants (R03)

A pilot study is a preliminary evaluation for the purpose of developing the foundation for a future, more comprehensive study. Thus, a pilot study might test feasibility, collect initial data, refine methodology, or evaluate critical factors that would influence the ability to conduct a larger study. An application should contain a clear description of how the pilot study could form the basis for preparing a research proposal that would be submitted for competitive review, in the future, if the results of the pilot study are promising. The application should include only the following sections of the PHS 398 application form: face page (in item 2, place ''NORA Pilot Study''), abstract, budget, key person biosketches, aims, background, study plan, and human or animal subject matters. There is a 15 page limit for the aims, background, and study plan, not including references. The budget for an entire pilot study is limited to $50,000 in direct costs for a period of up to two years.

Programmatic Interest

The research needs identified in this announcement are consistent with the NORA developed by NIOSH and partners in the public and private sectors to provide a framework to guide occupational safety and health research in the next decade towards topics which are most pressing and most likely to yield gains to the worker and the nation. The Agenda identifies 21 research priorities. The NORA document is available through the NIOSH Home Page at http://www.cdc.gov/niosh/nora.html.

Potential applicants with questions concerning the acceptability of their proposed work are strongly encouraged to contact the technical information personnel listed in this announcement in the section WHERE TO OBTAIN ADDITIONAL INFORMATION.

Applications responding to this announcement will be reviewed by staff for their responsiveness to the following program interests and their potential for developing knowledge that can be used in preventing occupational diseases and injuries.

Targeted NORA Priority Areas for this announcement are as follow:

1. *Occupational Irritant Contact Dermatitis.* This announcement targets a part of the NORA priority area, Allergic and Irritant Dermatitis. In 1993, the Bureau of Labor Statistics (BLS) data estimated an incidence of 76 cases of occupational skin disorders (OSDs) per 100,000 U.S. workers, making OSDs the most common non-trauma-related occupational disease affecting workers in many different occupations. Irritant contact dermatitis (ICD) is the most common form of dermatitis, usually resulting from reactions to chemical irritants such as solvents and cutting fluids. The goal of the ''Healthy People 2000'' is to reduce OSDs to an incidence of not more than 55 per 100,000. To aid in achieving this national health objective, further research in ICD is needed.

Research applications are sought in the following areas: (1) methods for identifying irritants prior to introduction into the workplace; (2) pathophysiology of ICD; (3) the genetic basis of susceptibility; (4) the influence of environmental factors on ICD; (5) the relationship of ICD to allergic contact dermatitis; (6) methods to identify skin changes that precede overt clinical disease; (7) risk factors for initiation and/or chronicity of ICD; (8) methods for measuring skin exposure and skin deposition; (9) methods for assessing percutaneous penetration and evaluating skin barrier function; (10) intervention design and evaluation; (11) enhanced membrane/film development for skin protection; (12) improved procedures for testing chemical protective clothing (CPC) field performance; and, (13) the effectiveness of CPC and/or barrier creams. The ultimate goal is the primary, secondary, and tertiary prevention of ICD.

2a. Work-Related Musculoskeletal Disorders. Thirty-two percent of the injuries and illnesses recorded in the BLS survey in 1994 involved musculoskeletal (MS) injuries or disorders and resulted from over-exertion or repetitive motion. In the United States (U.S.), back disorders account for 27 percent of all nonfatal occupational injuries and illnesses involving days away from work. Musculoskeletal disorders of the upper extremities (such as carpal tunnel syndrome and rotator cuff tendinitis) due to work factors are common and occur in nearly all sectors of the economy. More than $2 billion in workers' compensation costs are spent annually on these work-related problems.

Research applications are sought in the following areas: (1) Development and validation of models of nonspecific or specific musculoskeletal disorders which predict biomechanical, biochemical or structural changes in soft tissues resulting from repetitive exposure to physical loads. (An example of this type of research would be to develop an animal model for investigating the effects of repetitive use of tendons, ligaments, and synovium); (2) age and gender differences in the biochemistry and/or biomechanical responses of musculoskeletal soft tissues to injury and repair; (3) development and validation of exposure-assessment methods directed toward existing prevention activities in the private sector, State or local government agencies and for future epidemiologic studies of work-related musculoskeletal disorders; (4) epidemiological studies to determine exposure-response (injury/disorder) relationships between work-related musculoskeletal disorders and physical exposures as well as work organization

factors. These studies should include both work and non-work exposure and modifying factors; (5) evaluation of existing or new interventions directed at either primary, secondary, or tertiary prevention of common work-related musculoskeletal disorders. (Projects directed at secondary or tertiary prevention should focus on reducing lost work time and preventing future injuries or disorders, or their recurrence); and (6) evaluation of the effectiveness and outcomes of preventive, diagnostic and medical treatments (includes non-operative, operative, rehabilitative and alternative medicine treatments) for work injuries and illnesses of the musculoskeletal system.

2b. *Traumatic Injuries.* Injury exacts a huge toll in U.S. workplaces. On an average day, 16 workers are killed and more than 17,000 are injured. The leading causes of occupational injury fatalities over the period 1980 to 1992 were motor vehicles, machines, homicides, falls, electrocutions, and falling objects. The leading causes of the nonfatal injuries were overexertion, contact with objects or equipment, and falls.

Relatively good information is available on the overall burden of work injuries including the industries and occupations where they occur most frequently and with greatest severity. The challenge is to move beyond this broad understanding to specific strategies that address the complex interplay between machines, tools, and behavioral and environmental factors that cause injuries at a worksite. Research applications are sought which will: (1) Conduct etiological research into risk factors or contributors to occupational injuries; (2) advance knowledge of the interactions between human performance/human limitations and workplace, machine and equipment design to remove the possibility of unsafe actions; (3) develop models and simulations for the safe design, operation and maintenance of workplaces and equipment; (4) develop cost/benefit analysis models of various prevention strategies; and, (5) develop simple cost-effective injury prevention models and guidelines for application by safety and health practitioners in the field.

2c. Indoor Environment. Traditionally, indoor nonindustrial occupational environments have been considered clean and relatively free of exposures to substances which pose a health hazard. In the last 20 years, however, reports of symptoms and other health complaints related to these indoor environments have been increasing. More than half of the U.S. workforce is employed indoors, and estimates of the proportion of indoor workers affected by these problems range up to 30 percent. Among the requests received annually by NIOSH for occupational health investigations, the proportion related to indoor nonindustrial environments has increased dramatically, from 2 percent in 1980 to 40 percent in recent years.

Research applications are sought in the following areas: (1) Causes or prevention of health effects from indoor work environments, including the transmission of communicable respiratory diseases, asthma or other allergic diseases, or acute symptoms from unknown causes or multiple chemical sensitivities. (Strategies of particular interest include intervention designs to evaluate the effectiveness of environmental controls or of following current practice standards for building operation and improving relevant exposure (microbiological or chemical) assessments); (2) creating practical tools to help the building sector create healthier indoor environments, such as new or improved measurement tools for exposure assessment, and scientifically-validated guidelines to help assure healthy indoor environments (e.g., for design, operation, and maintenance actions, or through building performance); and (3) estimating health and other social and economic consequences (such as health care costs, absenteeism, and productivity losses) resulting from adverse effects of indoor environments, as well as potential benefits of improved indoor environments.

2d. Asthma and Chronic Pulmonary Obstructive Disease. Asthma and Chronic Obstructive Pulmonary Disease (COPD) are leading respiratory diseases in the U.S. and major causes of morbidity and mortality. Although both diseases have nonoccupational causes, workplace exposures also contribute to their development, persistence, and exacerbation. More research is needed to guide efforts to prevent and reduce the occupational contribution to these diseases.

Research applications are sought in the following areas: (1) Estimation of the proportions of COPD and/or asthma in the adult general population that are attributable to occupational causes, including industry- and agent-specific attributable fractions; (2) risk factors for developing asthma or COPD in response to occupational agents, which might include attention to exposure-response relationships, novel means of characterizing exposure or exposure kinetics, host factors, modifying factors (such as smoking or impaired lung function), and conditions necessary for occupational asthma to completely resolve; (3) methods for identifying substances that may cause asthma prior to their introduction into the workplace; (4) application of methodological approaches to assessing the burden of occupational asthma/COPD with attention to healthy worker effect; (5) mechanisms and pathophysiology of asthma or COPD caused by occupational exposures; and (6) approaches useful for effective screening and surveillance of worker populations at risk for airways diseases caused by occupational exposure.

3. Special Populations at Risk. Occupational hazards are known to be distributed differentially, and workers with specific biologic, social and/or economic characteristics are more likely to have increased risks of work-related diseases and injuries. This announcement targets a subset—older workers and racial ethnic minorities—of the special populations included in the NORA priority area. The relative proportions of these special populations within the workforce is increasing. It is estimated that, by the year 2000, approximately 39 percent of the projected U.S. population of 275 million will be a member of a minority population (American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and Hispanic or Latino.) The median age of the U.S. workforce is rising as a result of the aging of the ''baby boom'' generation, an increasing percentage of older workers remaining in the workforce, as well as an increasing number of older workers reentering the workforce after retirement. As a result, between 1992 and 2005, the number of workers aged 55 and older is projected to increase by 38 percent.

Research applications are sought in the following areas: (1) The nature and magnitude of risks to minority and older workers, including the social and biologic factors (e.g., biochemical susceptibility) that may influence a worker's risk for injury or disease; (2) the incidence and mechanisms of diseases and injuries in minority and older worker populations; (3) the interdependence between work organizations and individuals and the consequences of adapting work (flex-place, flex-time, job sharing, retraining, reengineering, etc.) to the needs and capacities of these special populations; and, (4) the characteristics of the work/workplace that facilitate or impede the productivity of older workers and the

ability of older workers to stay in the workforce.

4a. Social and Economic Consequences of Workplace Illness and Injury. Occupational injuries and illnesses remain a leading cause of morbidity, mortality, and economic loss in the United States. The annual costs to employers for workers' compensation increased from $2.1 billion in 1960 to $60 billion by 1992. In addition to the direct costs such as those for health care, employers also incur numerous indirect costs including those for additional hiring and training and disruption of work processes. Other costs are borne by injured workers and their families through reduced income, depletion of savings and increased expenditures and by the community through increased use of social services and cost shifting between health and social service agencies. Leigh, *et al.* (Leigh, J.P. *et al.*, Occupational Injury and Illnesses in the United States, Arch. Intern. Med., 157, 1557–68, 1997) estimated that, for 1992, the total direct and indirect costs associated with occupational injuries and diseases were $171 billion annually, but noted that these estimates were likely to be low in part due to the lack of data for a number of the associated indirect costs.

Research applications are sought in the following areas: (1) Measures of total economic costs (direct and indirect) and non-economic costs borne by injured workers and their families, by employers; and by non-occupational community, State and local government services; and (2) evaluation of the economic benefit of interventions (e.g., ergonomic work system and task redesign) including occupational health service interventions, and assessment of their contribution to the cost of work-related illness and injury at both the service system level (e.g., managed care in compensation services) and service component level (e.g., cost-effectiveness of different clinical treatments for back pain).

4b. Health Services Research. Despite the large burden and cost of work-related morbidity and mortality, relatively little is known about the structure and functioning of occupational health services. Occupational health services (OHS) research includes evaluation of both service components and delivery systems, including distribution and coverage, access, appropriateness, acceptability, utilization, equity, quality, organization, policy and planning, management, financing, productivity, effectiveness and efficiency, and impacts on health needs, health status and occupational hazards.

Research applications are sought in the following areas: (1) Descriptions of the state, the distribution of types, and the prevailing trends in the provision of OHS for the prevention, treatment and rehabilitation of work-related illness and injury, and the interactions of OHS with other parts of the health care system; (2) evaluation, in terms of health and vocational outcomes (e.g., return to work), of different occupational health services and systems (e.g., managed care versus fee-for-service compensation services), and service interventions (e.g., different treatments for back pain); and (3) evaluation of the effectiveness (through clinical trials, observational research, and clinical trials) of the effectiveness and efficiency of clinical therapeutic interventions and rehabilitation modalities for occupational diseases and injuries.

5. Intervention Effectiveness Research. Many workplace prevention and intervention programs have been developed and implemented in workplaces, yet few have undergone systematic evaluation to determine their impact on health and safety outcomes. Evaluations of the effectiveness of intervention efforts can provide crucial guidance and corrective feedback for current and future occupational health and safety (OSH) intervention efforts. Evaluation research, whether descriptive or experimental, can provide a firm base of evidence for what works, what does not, and why, and assure better use of limited resources in workplace implementations of preventive and control strategies. This announcement targets intervention efforts addressing work-related traumatic injuries, musculoskeletal disorders, asthma and COPD as well as the implementation of engineering controls, use of personal protective equipment (PPE) and/or changes in the organization of work systems or tasks.

Research applications are sought which focus on the systematic evaluation of (1) the effectiveness of intervention efforts addressing musculoskeletal disorders, traumatic injuries, and work-related asthma and COPD; (2) the practicality and usability of specific control strategies, technologies and/or PPE in the elimination or reduction of hazards; (3) the identification of critical factors for implementing and conducting effective OSH programs; (4) the components of effective OSH programs, including worker participation programs, training or other organizational and administrative aspects, as well as engineering solutions; and (5) identification and elimination of barriers to the implementation of interventions, such as a lack of acceptance due to practicality, perception that cost is prohibitive, etc.

Applications are encouraged that will evaluate interventions in real work settings, assessment of cost-effectiveness and identification of adverse or unexpected outcomes of interventions.

Reporting Requirements

Progress reports are required annually as part of the continuation application (75 days prior to the start of the next budget period). The annual progress reports must contain information on accomplishments during the previous budget period and plans for each remaining year of the project. Depending upon funding entity, financial status reports (FSR) are required no later than 90 days after the end of the budget period.

The final performance and financial status reports are required 90 days after the end of the project period. The final performance report should include, at a minimum, a statement of original objectives, a summary of research methodology, a summary of positive and negative findings, and a list of publications resulting from the project. Research papers, project reports, or theses are acceptable items to include in the final report. The final report should stand alone rather than citing the original application. Three copies of reprints of publications prepared under the grant should accompany the report.

Evaluation Criteria

Upon receipt, applications will be reviewed by CDC and NIH for completeness and responsiveness and will be assigned to the appropriate Institute. Applications determined to be incomplete or unresponsive to this announcement will be returned to the applicant without further consideration. If the proposed project involves organizations or persons other than those affiliated with the applicant organization, letters of support and/or cooperation must be included.

Applications that are complete and responsive to the announcement will be reviewed by an initial review group and determined to be competitive or non-competitive, based on the review criteria relative to other applications received. Applications determined to be non-competitive will be withdrawn from further consideration and the principal investigator/program director and the official signing for the applicant organization will be promptly notified. Applications judged to be competitive will be discussed and assigned a priority score. Following initial review

for scientific merit, the applications will receive a secondary review for programmatic importance (for applications assigned to NIH Institutes, the review will be conducted by the appropriate Council).

Review criteria for scientific merit are as follows:

1. Technical significance and originality of proposed project.
2. Appropriateness and adequacy of the study design and methodology proposed to carry out the project.
3. Qualifications and research experience of the principal investigator and staff, particularly but not exclusively in the area of the proposed project.
4. Availability of resources necessary to perform the project.
5. Documentation of cooperation from collaborators in the project, where applicable.
6. Adequacy of plans to include both sexes and minorities and their subgroups as appropriate for the scientific goals of the project. (Plans for the recruitment and retention of subjects will also be evaluated.)
7. Appropriateness of budget and period of support.
8. Human Subjects. Procedures adequate for the protection of human subjects must be documented. Recommendations on the adequacy of protections include: (1) Protections appear adequate and there are no comments to make or concerns to raise, (2) protections appear adequate, but there are comments regarding the protocol, (3) protections appear inadequate and the Initial Review Group has concerns related to human subjects, or (4) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are inadequate as to make the entire application unacceptable.

Review criteria for programmatic importance are as follows:

1. Magnitude of the problem in terms of numbers of workers affected.
2. Severity of the injury or disease in the population.
3. Usefulness to applied technical knowledge in the identification, evaluation, or control of occupational safety and health hazards on a national or regional basis.
4. Propensity to improve understanding of the pathophysiology (includes biomechanics), diagnosis, treatment, and prevention of occupational irritant dermatitis, work-related musculoskeletal disorders and asthma or COPD caused by occupational exposures.

The following will be considered in making funding decisions:

1. Merit of the proposed project as determined by the initial peer review.
2. Programmatic importance of the project as determined by secondary review.
3. Availability of funds.
4. Program balance among priority areas of this announcement.

Executive Order 12372 Review

Applications are not subject to the review requirements of Executive Order 12372.

Public Health System Reporting Requirement

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance numbers are:

93.262 for the National Institute for Occupational Safety and Health (NIOSH) in CDC
93.846 for the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) in NIH
93.113 and 93.115 for the National Institute of Environmental Health Sciences (NIEHS) in NIH
93.837, 93.838, and 93.839 for the National Heart, Lung, and Blood Institute (NHLBI) in NIH
93.866 for the National Institute on Aging (NIA) in NIH

Other Requirements

Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations, 45 CFR Part 46, regarding the protection of human subjects. Assurances must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

Women and Racial and Ethnic Minorities

It is the policy of the CDC and the NIH to ensure that women and racial and ethnic groups will be included in CDC- or NIH-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, Native Hawaiian or Other Pacific Islander, and Hispanic or Latino. Applicants shall ensure that women and racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is not feasible, this situation must be explained as part of the application. In conducting the review of applications for scientific merit, review groups will evaluate proposed plans for inclusion of minorities and both sexes as part of the scientific assessment and assigned score. 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, Friday, September 15, 1995, pages 47947–47951 and/or in the ''NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research'' **Federal Resister** of March 28, 1994 [FR 59, 14508–14513], and reprinted in the NIH Guide for Grants and Contracts, Vol. 23, No. 11, March 18, 1994.

Application Submission and Deadlines

A. Preapplication Letter of Intent

Although not a prerequisite of application, a non-binding letter of intent-to-apply is requested from potential applicants. The letter should be submitted to the Grants Management Officer (whose address is reflected in section B, ''Applications''). It should be postmarked no later than May 1, 1998. The letter should identify the announcement number, name of principal investigator, and specify the priority area to be addressed by the proposed project. The letter of intent does not influence review or funding decisions, but it will enable CDC and NIH to plan the review more efficiently, and will ensure that each applicant receives timely and relevant information prior to application submission.

B. Applications

Applicants should use Form PHS–398 (OMB Number 0925–0001) and adhere to the ERRATA Instruction Sheet for Form PHS–398 contained in the Grant Application Kit. Please submit an original and five copies on or before June 23, 1998 to: Ron Van Duyne, Grants Management Officer, ATTN: Joanne Wojcik, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry

Road, NE., Room 300, MS E–13, Atlanta, GA 30305.

C. Deadlines

1. Applications shall be considered as meeting a deadline if they are either:

a. Received at the above address on or before the deadline date, or

b. Sent on or before the deadline date to the above address, and received in time for the review process.

Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be accepted as proof of timely mailings.

2. Applications which do not meet the criteria above are considered late applications and will be returned to the applicant.

Where To Obtain Additional Information

To receive additional written information call 1–888–GRANTS4. You will be asked your name and address and will need to refer to Announcement 98044. You will receive a complete program description, information on application procedures, and application forms. Also, this and other CDC Announcements can be found on the CDC homepage (http://www.cdc.gov) under the ''Funding'' section, as well as on the NIOSH homepage (http://www.cdc.gov/niosh/homepage.html) under ''Extramural Programs.'' For your convenience, you may be able to retrieve a copy of the PHS Form 398 from (http://www.nih.gov/grants/funding/phs398/phs398.html).

If you have questions after reviewing the contents of all the documents, business management information may be obtained from Joanne Wojcik, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., MS E–13, Atlanta, GA 30305, telephone (404) 842–6535; fax (404) 842–6513; internet jcw6@cdc.gov.

Programmatic technical assistance may be obtained from:

Roy M. Fleming, Sc.D., Research Grants Program, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Building 1, Room 3053, MS–D30, Atlanta, GA 30333, telephone 404–639–3343; fax 404–639–4616, internet rmf2@cdc.gov

Sidney M. Stahl, Ph.D., Behavioral and Social Research Program, National Institute on Aging, National Institutes of Health (NIH), Gateway Building #533, 7201 Wisconsin Avenue, Bethesda, MD 20892, telephone 301–402–4156, fax 301–402–0051, internet ss333h@nih.gov

Alan Moshell, M.D., Skin Diseases Branch, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health (NIH), Natcher Building, Room 5AS–25L, Bethesda, MD 20892–6500, telephone 301–594–5017, fax 301–480–4543, internet am40j@nih.gov

James S. Panagis, M.D., M.P.H., Musculoskeletal Diseases Branch, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health (NIH), 45 Center Drive, Room 5AS–37K, MSC 4500, Bethesda, MD 20892–6500, telephone 301–594–5055, fax 301–480–4543, internet jp149d@nih.gov

George S. Malindzak, Ph.D., Division of Extramural Research and Training, National Institute of Environmental Health Sciences, National Institutes of Health (NIH), 79 T.W. Alexander Drive, MD EC–23, Research Triangle Park, NC 27709, telephone 919–541–3289, fax 919–541–5064, internet malindzak@niehs.nih.gov

Gail Weinmann, M.D., Division of Lung Diseases, National Heart, Lung, and Blood Institute, National Institutes of Health (NIH), Two Rockledge Center, Suite 10018, 6701 Rockledge Drive, MSC 7952, Bethesda, MD 20892, telephone 301–594–0202, fax 301–480–3557, internet weinmanng@gwgate.nhlbi.nih.gov

Please Refer to Announcement Number 98044 When Requesting Information and Submitting an Application.

CDC will not send application kits by facsimile or express mail.

Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report, Stock No. 017–001–00474–0) or ''Healthy People 2000'' (Summary Report, Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

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. It is also available on the internet at ''http://www.cdc.gov/niosh/nora.html''.

Linda Rosenstock,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC).

Anthony L. Itteilag,

Deputy Director for Management, National Institutes of Health.

[FR Doc. 98–6869 Filed 3–16–98; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders (NIDCD); Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Development of a Vaccine Against Moraxella Catarrhalis Mediated Otitis Media

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: Moraxella catarrhalis is the third most common pathogen for otitis media, the most common cause of illness requiring medical treatment in children. The NIDCD is investigating candidate vaccines based on detoxified lipooligosaccharide-protein conjugates prepared from surface antigens of Moraxella catarrhalis.

The NIDCD, NIH, is seeking capability statements from parties interested in entering into a CRADA for the development of a candidate vaccine with the goal of conducting a Phase I clinical trial to determine the safety for most promising candidates. This project is with the Section on Experimental Immunology, Laboratory of Immunology, National Institute on Deafness and Other Communication Disorders, NIH. The goals are to use the respective strengths of both parties to achieve one or more of the following: (1) Establish an animal model to test experimental vaccines to provide protection against Moraxella catarrhalis mediated otitis media; (2) screen experimental vaccines for their relative efficacy; (3) determine the efficacy of the most promising vaccines; (4) prepare a sufficient quantity of vaccine to gain IND approval from the FDA and to conduct a Phase I clinical trial. Additional investigations may be undertaken when the efficacy of the candidate vaccines has been determined in an animal model and safety in humans has been assured.

It is anticipated that the commercial collaborator(s) will participate in