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#### [Announcement 624]

### **National Institute for Occupational Safety and Health Work Organization Interventions To Prevent Work-Related Musculoskeletal Disorders in Office and Video Display Terminal Work**

#### **Introduction**

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1996 funds for a cooperative agreement program to develop work organization interventions to prevent musculoskeletal disorders in office and video display terminal (VDT) workers.

The CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Occupational Safety and Health. (For ordering a copy of Healthy People 2000, see the section WHERE TO OBTAIN ADDITIONAL INFORMATION.)

#### **Authority**

This program is authorized under Sections 20(a) and 22(e)(7) of the Occupational Safety and Health Act [29 U.S.C. 669(a) and 671(e)(7)].

#### **Smoke-Free Workplace**

The CDC strongly encourages all grant recipients to provide a smoke-free workplace and promote the nonuse 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**

Applications may be submitted by public and private, non-profit and for-profit organizations and governments, and their agencies. Thus, universities, colleges, research institutions, hospitals, other public and private organizations, State and local health departments or their bona fide agents, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations, and small, minority- and/or women-owned businesses are eligible to apply.

#### **Availability of Funds**

Approximately \$140,000 is available in FY 1996 to fund one award. It is expected that the award will begin on or about September 30, 1996, and will be made for a 12-month budget period within a project period of one year. The funding estimate is subject to change.

Applications should be focused on the research priorities described in the section "FUNDING PRIORITIES" that includes new research priorities developed in a process which resulted in defining a National Occupational Research Agenda. Proposals in these areas will compete for the available funds as noted in the previous paragraph.

#### **Purpose**

The purpose of this cooperative agreement is to utilize the special resources of the extramural research community to conduct studies. The funded project will focus on worksite primary prevention efforts, replicating and extending the CDC/NIOSH interventions described in the BACKGROUND Section of the Program Announcement. This could include: (a) replication/validation of CDC/NIOSH findings on work-rest schedules and task rotation, (b) extension of these interventions to other types of VDT and office tasks, and (c) examination of other types of work organization interventions.

Prior studies have indicated that some types of VDT jobs may pose higher risk for stress and work-related musculoskeletal disorders (WRMD), particularly jobs involving highly repetitive and narrow tasks (e.g., data entry or teleoperator tasks). Such jobs are of particular interest for this project. Project results, in combination with NIOSH findings, will provide the basis for recommendations regarding effective work organization strategies for reducing WRMDs, and improving performance in repetitive VDT work. Project results will also improve our understanding of mechanisms mediating between work organization variables and musculoskeletal disorders in VDT work.

#### **Program Requirements**

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under A. (Recipient Activities) and CDC/NIOSH will be responsible for activities under B. (CDC/NIOSH Activities):

##### **A. Recipient Activities**

1. Evaluate the effectiveness of work organization interventions in reducing

WRMDs and in improving productivity among VDT workers. Both physical and psychological symptoms will be evaluated.

2. Develop a study protocol that reviews the pertinent literature on VDT-related musculoskeletal disorders and work organization, describes the study methodology, the data to be collected, and the proposed analysis of the data. Present the protocol to a panel of peer reviewers and revise the protocol as required for final approval.

3. Prepare necessary documentation for reviews and/or clearances required by CDC/NIOSH. (Depending on what is proposed, it may be necessary to obtain NIOSH peer review, Human Subjects Review Board, or OMB approvals on some protocols.)

4. Perform data collection and management. Data is to include measures of worker symptomatology and performance and can additionally include records data on factors such as absenteeism, health care utilization, etc. Symptomatology can include musculoskeletal discomfort, upper extremity musculoskeletal disorders, and indicators of negative mental health (e.g., depression, anxiety, tension). Performance indicators can include measures such as keystrokes/hour, forms/hour, and errors.

5. Prepare a final report summarizing the study methodology, results obtained, and conclusions reached. Develop recommendations regarding effective work organization interventions to reduce stress, fatigue, and WRMDs among VDT workers.

6. Report study results to the scientific community via presentations at professional conferences and articles in peer-reviewed journals.

##### **B. CDC/NIOSH Activities**

1. Provide scientific, epidemiologic, work organization, ergonomic, and medical collaboration for the successful completion of this project.

2. Identify reviews and/or clearances that must be fulfilled by the recipient, and identify and convene a Peer Review Panel to review draft study protocol.

3. Provide assistance in all stages of the study including study design, survey instrument design, collection, tabulation, and analysis of data, interpretation of the results and preparation of the written reports.

4. Provide electromyograph (EMG) or other instrumentation and data collection assistance in investigating physiological mechanisms in VDT WRMDs.

## Evaluation Criteria

The application will be reviewed and evaluated according to the following criteria:

### 1. Understanding of the Problem (25%)

Responsiveness to the objective of the cooperative agreement including: (a) applicant's understanding of the general objectives of the proposed cooperative agreement, and (b) evidence of ability to understand the problem and to conceive/design effective interventions.

### 2. Program Personnel (30%)

(a) Applicant's technical experience (e.g., in the areas of work organization, WRMDs and office and VDT ergonomics), (b) the qualifications (e.g., in the areas of industrial engineering, psychology and occupational safety and health) and time allocation of the professional staff to be assigned to this project, and, (c) the applicant's ability to describe the approach to be used in carrying out the responsibilities of the applicant.

### 3. Study Design (20%)

Steps proposed in planning and implementing this project and the respective responsibilities of the applicant for carrying out those steps. Also, the adequacy of the applicant's evidence of access to study populations. The degree to which the applicant has met the CDC policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes:

(a) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

(b) The proposed justification when representation is limited or absent.

(c) A statement as to whether the design of the study is adequate to measure differences when warranted.

(d) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits will be documented.

### 4. Project Planning (15%)

The applicant's schedule proposed for accomplishing the activities to be carried out in this project and for evaluating the accomplishments.

### 5. Facilities and Resources (10%)

The adequacy of the applicant's facilities, equipment, and other resources available for performance of this project.

### 6. Human Subjects

Whether or not exempt from the DHHS regulations, are procedures adequate for the protection of human subjects? 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 Objective 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. (NOT SCORED)

### 7. Budget Justification

The budget will be evaluated to the extent that it is reasonable, clearly justified, and consistent with the intended use of funds. (NOT SCORED)

### Executive Order 12372 Review

This program is not subject to the Executive Order 12372 review.

### Public Health System Reporting Requirements

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

### Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number for this project is 93.283.

### Other Requirements

#### *Paperwork Reduction Act*

Projects that involve the collection of information from ten or more individuals and funded by this cooperative agreement will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

#### *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. Assurance must be provided to demonstrate 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.

In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved or will support the research. If any

American Indian community is involved, its tribal government must also approve that portion of the project applicable to it.

### *Women, Racial and Ethnic Minorities*

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

### *Funding Priorities*

The NIOSH program priorities, listed below, were developed by NIOSH and its partners in the public and private sectors to provide a framework to guide occupational safety and health research in the next decade—not only for NIOSH but also for the entire occupational safety and health community. Approximately 500 organizations and individuals outside NIOSH provided input into the development of the National Occupational Research Agenda (NORA). This attempt to guide and coordinate research nationally is responsive to a broadly perceived need to address systematically those topics that are most pressing and most likely to yield gains to the worker and the nation. Fiscal constraints on occupational safety and health research are increasing, making even more compelling the need for a coordinated and focused research agenda. NIOSH intends to support projects that facilitate progress in understanding and preventing adverse effects among workers. The conditions or examples listed under each category are selected examples, not comprehensive definitions of the category. Investigators may also apply in other areas related to occupational safety and health, but the

rationale for the significance of the research to the field of occupational safety and health must be presented in the grant application.

The Agenda identifies 21 research priorities. These priorities reflect a remarkable degree of concurrence among a large number of stakeholders. The NORA priority research areas are grouped into three categories: Disease and Injury, Work Environment and Workforce, and Research Tools and Approaches. The NORA document is available through the NIOSH Home Page; <http://www.cdc.gov/niosh/nora.html>.

#### NORA Priority Research Areas

##### Disease and Injury

- Allergic and Irritant Dermatitis
- Asthma and Chronic Obstructive Pulmonary Disease
- Fertility and Pregnancy Abnormalities
- Hearing Loss
- Infectious Diseases
- Low Back Disorders
- Musculoskeletal Disorders of the Upper Extremities
- Traumatic Injuries

##### Work Environment and Workforce

- Emerging Technologies
- Indoor Environment
- Mixed Exposures
- Organization of Work
- Special Populations at Risk

##### Research Tools and Approaches

- Cancer Research Methods
- Control Technology and Personal Protective Equipment
- Exposure Assessment Methods
- Health Services Research
- Intervention Effectiveness Research
- Risk Assessment Methods
- Social and Economic Consequences of Workplace Illness and Injury
- Surveillance Research Methods

#### Application Submission and Deadline

##### 1. 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 Branch, CDC, at the address provided in this section. It should be postmarked no later than June 15, 1996. 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 to plan the review more efficiently and will ensure that each applicant receives timely and relevant information prior to application submission.

The original and two copies of the application PHS Form 5161-1 (Revised 7/92, OMB Number 0937-0189) must be submitted to Ron Van Dyne, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Mailstop E-13, 255 East Paces Ferry Road, NE., Room 300, Atlanta, GA 30305, on or before July 17, 1996.

1. Deadline: Applications will be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date, or

(b) Sent on or before the deadline date and received in time for submission to the objective review group. (The applicants must 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 will not be acceptable as proof of timely mailing.)

2. Late Applicants: Applications that do not meet the criteria in 1.(a) or 1.(b) above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicants.

#### Where To Obtain Additional Information

To receive additional written information call (404) 332-4561. You will be asked to leave your name, address, and telephone number and will need to refer to Announcement 624. You will receive a complete program description and information on application procedures and application forms. If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Oppie Byrd, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E-13, Atlanta, GA 30305, telephone (404) 842-6546; fax: (404) 842-6513; Internet: [oxb3@opspgo1.em.cdc.gov](mailto:oxb3@opspgo1.em.cdc.gov).

Programmatic technical assistance may be obtained from Naomi G. Swanson, Ph.D., Chief, Motivation and Stress Research Section, Applied Psychology and Ergonomics Branch, Division of Biomedical and Behavioral Science, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC), Mailstop C-24, 4676 Columbia Parkway, Cincinnati, OH 45226-1998, telephone (513) 533-8165; fax: (513)

533-8596; Internet: [nws3@niobbs1.em.cdc.gov](mailto:nws3@niobbs1.em.cdc.gov).

Please refer to Announcement 624 when requesting information and submitting an application.

There may be delays in mail delivery as well as difficulty in reaching the CDC Atlanta offices during the 1996 Summer Olympics (July 19-August 4). Therefore, CDC suggests the following to get more timely responses to any questions: use Internet/email, follow all instructions in this announcement, and leave messages on the contact person's voice 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) referenced in the Introduction section through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

Dated: May 30, 1996.

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#### Food and Drug Administration

##### Clinical Studies of Safety and Effectiveness of Orphan Products; Availability of Grants; Request for Applications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the following changes to its Orphan Products Development (OPD) grant program for fiscal year (FY) 1997. The previous announcement of this program, which was published in the Federal Register of August 15, 1994, is superseded by this announcement. In the future, a new announcement will be published annually. This and future announcements will provide the programmatic requirements and criteria, as well as the two dates for receipt of applications, the estimated amount of funds available, and the estimated number of awards to be made in each FY.

**DATES:** Application receipt dates are: October 15, 1996, and March 15, 1997. If the receipt date falls on a weekend, it will be extended to Monday; if the date falls on a holiday, it will be extended to the following workday.