

of the Agency to enhance the quality, appropriateness, and effectiveness of health care services, and access to such services through scientific research, the promotion of improvements in clinical practice and in the organization, financing, and delivery of health care services. Six current members' terms will expire in 1997 and there is one vacancy for a term expiring in 1998. Nominations to fill these vacancies should be received on or before June 20. All nominations for membership should be submitted to Ms. Pat Longus, AHCP, 2101 East Jefferson Street, Suite 603, Rockville, Maryland 20852. Nominations also may be faxed to (301) 443-0251.

FOR FURTHER INFORMATION CONTACT: Ms. Nancy Foster, AHCP, at (301) 594-1349.

SUPPLEMENTARY INFORMATION: 42 U.S.C. 299c, section 921 of the PHS Act, provides that the National Advisory Council for Health Care Policy, Research, and Evaluation shall consist of 17 appropriately qualified representatives of the public appointed by the Secretary of Health and Human Services and five ex officio representatives from Federal agencies conducting or supporting health care research. The Council meets in the Washington, D.C., metropolitan area approximately three times a year to provide broad guidance to the Secretary and AHCP's Administrator on the direction and programs of the Agency.

To ensure broad representation, individuals serving on AHCP's Advisory Council reflect a variety of disciplines and perspectives. The seven positions for which nominations are being sought require representatives with expertise in health services research (two members); and in law, ethics, economics or public policy or business (two members); and representatives of the practice of medicine (one member); other health professions (one member); and the interests of health care consumers (one member).

Members generally serve 3-year terms. Appointments are staggered to permit an orderly rotation of membership. Individuals selected by the Secretary to serve on the Council will be expected to attend their first meeting in the fall of this year.

Interested persons may nominate one or more qualified persons for membership on the Council. Nominations shall include a copy of the nominee's resume or curriculum vitae, and state that the nominee is willing to serve as a member of the Council. Potential candidates will be asked to

provide detailed information concerning their financial interests, consultant positions, and research grants and contracts, to permit evaluation of possible sources of conflict of interest.

The Department is seeking a broad geographic representation and has special interest in assuring that women, minority groups, and the physically handicapped are adequately represented on advisory bodies and, therefore, extends particular encouragement to nominations for appropriately qualified female, minority, and/or physically handicapped candidates.

Dated: May 23, 1997.

John M. Eisenberg,
Administrator.

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BILLING CODE 4160-90-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement 754]

National Institute for Occupational Safety and Health; Development of Graduate Training Programs in Occupational Health Psychology

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1997 funds for a cooperative agreement to oversee the development and implementation of graduate-level training programs in university settings in the area of work organization, stress and health.

CDC is 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 area of Occupational Safety and Health. (For ordering Healthy People 2000, see 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 of 1970 [29 U.S.C. 669(a) and 671(e)(7)].

Smoke-Free Workplace

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 organizations, associations or groups representing relevant behavioral/social science professions, or universities, colleges, and training institutions offering professional (postdoctoral) development programs in cogent areas and in a position to affect the leadership, coordination, and other actions needed to implement the requirements of the cooperative agreement.

Note: Public Law 104-65, dated December 19, 1995, prohibits an organization described in section 501(c)(4) of the IRS Code of 1986, that engages in lobbying activities to influence the Federal Government, from receiving Federal funds.

Availability of Funds

Approximately \$100,000 will be available in Fiscal Year 1997 to fund one cooperative agreement. This award is expected to begin on or about September 30, 1997, for a 12-month budget period within a project period not to exceed 5 years.

Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds. Funding estimates are subject to change.

Student or faculty research, except for training and research methods, is not covered under this announcement.

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. Section 1352 (which has been in effect since December 23, 1989), recipients (and their sub-tier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying Congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition, the FY 1997 HHS Appropriations Act, which became effective October 1, 1996, expressly

prohibits the use of 1997 appropriated funds for indirect or "grass roots" lobbying efforts that are designed to support or defeat legislation pending before State legislatures. This new law, Section 503 of Pub. L. No. 104-208, provides as follows:

Sec. 503(a) No part of any appropriation contained in this Act 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, * * * except in presentation to the Congress or any State legislative body itself.

(b) 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.

Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1997, as enacted by the Omnibus Consolidated Appropriations Act, 1997, Division A, Title I, Section 101(e), Pub. L. No. 104-208 (September 30, 1996).

Background

The concept of work organization refers broadly to the way work processes are structured and managed, and addresses conditions such as the scheduling of work, design of tasks, interpersonal relationships at work, career and employment concerns, management style, and organizational characteristics such as climate and culture. These elements are commonly referred to as workplace psychosocial factors. They are known risk factors for job stress and are increasingly linked to health and safety outcomes such as traumatic injury, work-related musculoskeletal disorders, psychological disorders, and cardiovascular disease. The National Occupational Research Agenda, a collaborative effort between NIOSH and its stakeholders to identify key research needs in occupational safety and health, recognizes work organization as one of 21 top research priorities. (For ordering the National Occupational Research Agenda, see section Where to Obtain Additional Information.)

Research and interventions addressing work organization and associated health and safety risks hinge critically on the availability of appropriately trained professionals to

guide such efforts. However, professional training programs in work organization and health are uncommon in the United States, and these fields of study are often mutually exclusive. For example, organizational psychology is an expansive area of training in behavioral science, equipping professionals with valuable knowledge and skills in work organization. However, this area of training and practice rarely addresses the occupational safety and health implications of work organization. Presently, there are few ready programs of study in the U.S. in which work organization and health are integrated.

In 1992, NIOSH recognized the need for specialized training in work organization and health, and supported a program to provide postdoctoral training in occupational health psychology in an effort to bridge this training gap. A main objective of this earlier program was to provide supplemental training of Doctoral-level psychologists to better equip them for practice in the field of occupational health.

Purpose

The purpose of this program is to develop and implement a plan to establish specialized graduate-level training at multiple universities in the area of work organization, stress and health.

Examples of appropriate training activities under this program would include, but are not limited to: (1) Expansion of curricula in organizational psychology to provide a focus on organizational risk factors for stress, illness and injury at work, and on intervention strategies; (2) expansion of curricula and practica in clinical psychology to improve the recognition of job stress and its organizational sources; and, (3) increased exposure of behavioral scientists to the methods and practice of epidemiology.

Vehicles for this training could include new courses or clusters of courses, graduate minor or masters/doctoral degree programs, or practica or internship experiences at the predoctoral level. Because training in work organization, stress and health is an inherently multidisciplinary area, these training experiences should draw upon and integrate knowledge and faculty from several relevant areas, such as psychology, management, public health, occupational medicine, epidemiology.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient

shall be responsible for conducting activities under A. (Recipient Activities), below, and CDC/NIOSH will be responsible for conducting activities under B. (CDC/NIOSH Activities), below:

A. Recipient Activities

1. Implement a plan of action to promote and establish 5-year graduate-level training opportunities in work organization, stress and health, acknowledging the needs for integrating knowledge in the behavioral and social sciences with knowledge in occupational medicine, public health, and other relevant disciplines.

2. Incorporate this type of training as a recognized specialty area in the behavioral and occupational health sciences.

3. Collaborate with established professional groups in the behavioral and social sciences, and professional groups representing occupational medicine, public health and other relevant disciplines to obtain necessary support and input to curricula/program development.

4. Implement mechanisms for soliciting qualified university-based sites for graduate level training in work organization, stress and health.

5. In cooperation with CDC, develop criteria and procedures for selection of the training sites.

6. Implement program evaluation and quality assurance mechanisms.

7. Publicizing the program, including participating sites and training activities.

B. CDC/NIOSH Activities

1. Provide technical assistance and consultation, through site visits and correspondence, in the areas of program development and implementation.

2. Provide technical support for training including lecturers (if requested) and materials, i.e., NIOSH technical reports, research publications, etc.

3. Assist with collaboration between the recipient and traditional NIOSH-supported professional training institutions to assist in developing training opportunities.

Technical Reporting Requirements

An original and two copies of semi-annual progress reports are required. Timelines for the semi-annual reports will be established at the time of award. Final financial status and performance reports are required no later than 90 days after the end of the project period. All reports are submitted to the Grants Management Branch, Procurement and Grants Office, CDC.

Semi-annual progress report should include:

- A. A brief program description.
- B. A listing of program goals and objectives accompanied by a comparison of the actual accomplishments related to the goals and objectives established for the period.
- C. If established goals and objectives to be accomplished were delayed, describe both the reason for the deviation and anticipated corrective action or deletion of the activity from the project.

D. Other pertinent information, including the status of completeness, timeliness and quality of data.

All reports should be submitted to the Grants Management Branch, Procurement and Grants Office, CDC.

Applicant Content

The entire application, including appendices, should not exceed 40 pages and the Proposal Narrative section contained therein should not exceed 25 pages. Pages should be clearly numbered and a complete index to the application and any appendices included. The original and each copy of the application must be submitted unstapled and unbound. All materials must be typewritten, double-spaced, with unreduced type (font size 12 point) on 8 1/2" by 11" paper, with at least 1" margins, headers, and footers, and printed on one side only. Do not include any spiral or bound materials or pamphlets.

The applicant should provide a detailed description of first-year activities and briefly describe future-year objectives and activities.

A. Title Page

The heading should include the title of grant program, project title, organization, the project director's name, address, and telephone number.

B. Abstract

A one page, singled-spaced, typed abstract must be submitted with the application. The heading should include the title of grant program, project title, organization, name and address, project director and telephone number. This abstract should include a work plan identifying activities to be developed, specific activities to be completed, and a timeframes for completion of these activities.

C. Proposal Narrative

The narrative of each application must:

- 1. Briefly state the applicant's understanding of the need or problem to

be addressed, the purpose, and goals over the 5 year period of the cooperative agreement.

2. Describe the project plan including objectives, timelines, and all steps to be taken in developing, implementing and evaluating the project.

3. Describe mechanisms for soliciting qualified university-based sites for graduate level training in work organization, stress and health.

4. Document the applicant's expertise and prior involvement in overseeing specialized training in the area of work organization, stress and health at multiple universities.

5. Document the applicant's ability to: provide staff, knowledge, financial and other resources necessary to perform this project. Provide the name, qualifications, and proposed time allocation of the Project Director who will be responsible for administering the project. Describe staff, equipment available for performance of this project, and other resources that define the applicant's capacity or potential to accomplish the requirements. List the names (if known), qualifications, and time allocations of the existing professional staff to be assigned to (or recruited for) this project, the support staff available for performance of this project, and the available facilities including space.

6. Provide letters of support from professional organizations, affiliate groups and agencies essential to program development and success.

D. Budget

Provide a detailed budget which indicates anticipated costs for personnel, equipment, travel, communications, supplies, postage, and the sources of funds to meet these needs. The applicant should be precise about the program purpose of each budget item. For contracts described within the application budget, applicants should name the contractor, if known; describe the services to be performed; and provide an itemized breakdown and justification for the estimated costs of the contract; the kind of organizations or parties to be selected; the period of performance; and the method of selection. Place the budget narrative pages showing, in detail, how funds in each object class will be spent, directly behind form 424A. Do not put these pages in the body of the application. CDC may not approve or fund all proposed activities.

Evaluation Criteria

Applications will be reviewed and evaluated according to the following criteria:

A. Responsiveness to the objectives of the cooperative agreement including:

- 1. The applicant's understanding of the objectives of the proposed cooperative agreement; and
- 2. The relevance of the proposal to the objectives. (10%)

B. The extent to which the applicant documents experience and/or unique qualities to accomplish this program, and documents experience in evaluating or accrediting academic programs of this nature. (30%)

C. Feasibility of the proposed plan, including objectives, time lines and resources to accomplish this project within the stated budget. (30%)

D. Training, experience, and special capabilities of the Program Director and key staff members to perform this proposed activity. This includes previous experience in training professionals in occupational health psychology. (30%)

E. 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.

Application Submission and Deadline

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 Branch, CDC at the address listed in this section. It should be postmarked no later than June 20, 1997. The letter should identify announcement number 754, name of principal investigator. 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.

B. Application

The original and two copies of the application PHS Form 5161-1 (Revised 7/92, OMB Number 0937-0189) must be submitted Victoria Sepe, Grants Management Specialist, 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 15, 1997.

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 NIOSH Announcement Number 754. You will receive a complete program description, information on application procedures, and application forms. If you have any questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Victoria Sepe, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 321, Mailstop E-13, Atlanta, GA 30305, telephone (404) 842-6804, Internet: vxw1.cdc.gov.

Programmatic technical assistance may be obtained from Steven L. Sauter, Ph.D., Chief, 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) 533-8157, Internet: sls4.cdc.gov; or from Michael Colligan, Ph.D., Director Scientist, Training Evaluation Team, Education and Information Division, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC), Mailstop C-11, 4676 Columbia Parkway, Cincinnati, OH 45226-1998, telephone (513) 533-8222, Internet: mlc4.cdc.gov.

Please refer to Announcement Number 754 when requesting information on this program.

This and other CDC announcements are available through the CDC homepage on the Internet. The address for the CDC homepage is: <http://www.cdc.gov>.

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.

The National Occupational Research Agenda: copies of this publication may be obtained from The National Institute for Occupational Safety and Health, Publications Office, 4676 Columbia Parkway, Cincinnati, OH 45226-1998 or telephone 1-800-356-4674.

Dated: May 23, 1997.

Diane D. Porter,

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

[FR Doc. 97-14182 Filed 5-29-97; 8:45 am]

BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0182]

Agency Information Collection

Activities: Proposed Collections; Comment Request; Reinstatements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collections of certain information by the agency. Under the

Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection provisions relating to the regulation that samples and protocols of biological products may be required to be submitted to the agency, and Transmittal of Labels and Circulars, Form FDA 2657.

DATES: Submit written comments on the collections of information by July 29, 1997.

ADDRESSES: Submit written comments on the collections of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B-19, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collections of information listed below.

With respect to each of the following collections of information, FDA invites comments on: (1) Whether the proposed collections of information are necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimates of the burdens of the proposed collections of information, including the validity of the methodology and assumptions used;