

Dated: March 16, 2001.

William F. Raub,

Acting Assistant Secretary for Planning and Evaluation.

Dated: March 16, 2001.

John M. Eisenberg,

Director, Agency for HealthCare Research and Quality, Cochairpersons, HHS Data Council.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01035]

Grants for Education Programs in Occupational Safety and Health: Training Project Grant for Cross-Cultural Training in the Pacific Rim Basin Region; Notice of Availability of Funds for Fiscal Year 2001

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2001 funds for an institutional training project grant (TPG) in occupational safety and health. This program will support the development of a Pacific Rim Basin focus in occupational safety and health. For the purposes of this announcement, the areas include Hawaii, the Marshall Islands, the Federated States of Micronesia, Palau, Samoa and the Northern Marianas with collaborative activities in countries, such as, Singapore and Taiwan. This program addresses the "Healthy People 2010" focus area of occupational safety and health. The goal of the program is to provide an adequate supply of qualified personnel to carry out the purposes of the Occupational Safety and Health Act. The specific program objective of this grant is to provide financial assistance to an eligible institution to assist in providing an adequate supply of qualified professional occupational safety and health personnel to address occupational and environmental exposure to toxins in the Pacific Rim Basin. This project will be supported as a Long-Term Training Project Grant (TPG).

B. Eligible Applicants

Any public or private educational or training agency or institution with disciplines relevant to the field of occupational safety and health and which is located in a state, the District

of Columbia, or U. S. Territory, is eligible to apply for a training grant.

Preference will be given to academic institutions in the Pacific Rim Basin dealing with transitional economies which expose workers to a multitude of new occupational and environmental exposures in a large minority population. Transitional economies can be defined as those which are moving from traditional types of industries and products to newer and diverse industries dominating the marketplace.

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

C. Availability of Funds and Types of Training Awards

Approximately \$250,000 is available in 2001 to fund one award. It is expected that the award will begin on or about August 1, 2001 and will be made for a 12-month budget period within a project period of up to five years. Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

D. Program Requirements

The following are intended to serve as applicant requirements:

1. The applicant must document that the program(s) cover an occupational safety and health discipline in critical need or meets specific regional workforce needs in the Pacific Rim Basin Region. There shall be a minimum of three full-time students or full-time equivalent students in each academic program. Applicants should address the importance of providing training and education content related to special populations at risk, including minority and disadvantaged workers and multicultural populations. Justification should be provided in support of the degree levels proposed for financial assistance.

2. The types of training currently eligible for support are:

a. Undergraduate and other pre-baccalaureate training for disciplines, such as nursing and psychology, which provide trainees with capabilities for positions in business, industry, community agencies, government and labor organizations.

b. Special technical or other programs, such as short-term training programs for interdisciplinary training in occupational safety and health.

3. Curriculum content should focus on occupational health of workers in

multicultural populations. The focus should be on occupational/environmental exposures and illness in tropical regions, including pesticides and environmental toxins found in farming and fisheries. Content should also include the behavioral and social aspects of work and work organization. Field experiences should be provided, including direct hands on work with exposures and environmental agents found in the region. Training plans and curricula should be structured and clearly identified for each level of training as well as the number of full and part-time students proposed.

4. Collaborative relationships should be established within the university and with external institutions and agencies that work with the culturally diverse community to serve as resources for the program and to promote education in the occupational health of multicultural populations. Examples of collaborating groups could include:

a. The disciplines of medicine, engineering, safety, nursing, business, psychology and others in the behavioral and social sciences.

b. Industry, labor, the public sector and worker organizations.

5. The Program Director shall be a full-time faculty member, preferably with education and experience in the occupational safety and health field. Consultants and adjunct faculty should be available and provide needed expertise in the field of occupational safety and health.

6. Key faculty should be full-time faculty with documented experience and education in their appropriate fields.

7. The applicant should include a plan for student recruitment, including entrance requirements.

8. The applicant shall include a plan for evaluation of the program, including placement of graduates, tracking of graduates, and contributions that graduates are making in providing programs for workers and meeting the occupational health and safety needs of populations in the region.

9. An Advisory Committee should be established representing stakeholders in occupational safety and health in the Pacific Rim Basin region, and should comprise members representing industry, the business community, professional groups, the public sector and labor groups.

E. Application Content

Competing Applications

Applications will be evaluated on the basis of the Program Requirements, Other Requirements, and Evaluation

Criteria sections listed, so it is important to follow them in laying out the program plan. The narrative should be no more than 15 pages per program. Prepare the application single-sided, staying within margin limitations indicated on the form and continuation pages. The print must be clear and legible. Use standard size, black letters that can be clearly copied. Do not use photo reduction. Prepare all graphs, diagrams, tables and charts in black ink. The application must contain only material that can be photocopied. Do not include course catalogues and course brochures. When additional space is needed to complete any of the items, use plain white paper (8 1/2 x 11 inches), leave 1/2-inch margin on each side, identify each item by its title, and type the name of the program director and the grant number in the upper right corner of each page. All pages, including Appendices should be numbered consecutively at least 1/2 in from the bottom of the page.

Note: Please consult the detailed Recommended Outline for a Training Project Grant for Cross-Cultural Training in the Pacific Rim Basin Region On the CDC website at www.cdc.gov/od/pgof/forminfo.htm

F. Submission and Deadline

Applications should be clearly identified as an application for a TPG Training Grant.

Application

Submit the original and two copies of CDC 2.145 A-TPG (OMB Number 0920-00261). Forms are in the application kit. Forms and instructions are also available on the CDC home page <http://www.cdc.gov>. On or before May 11, 2001 submit the application to the Grants Management Specialist identified in Section J of this announcement, "Where to Obtain Additional Information".

Deadline: Applications shall 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 independent review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late Applications: Applications which do not meet the criteria in (a) or (b) above are considered late applications, will not be considered, and will be returned to the applicant.

G. Evaluation Criteria

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC:

1. The extent of the occupational health and safety needs of populations in the Pacific Rim Basin area based on factors such as, a transitional economy, the nature of the workforce and workplaces, the composition of the population with respect to diverse cultures, and unique exposures in tropical climates. Documentation shall be provided of the need for training in the program area(s) outlined by the application and the contribution this project will make toward meeting the need for specialized training in occupational safety and health in the region.

2. Evidence of a plan describing the training program(s) that are proposed. Should include a plan for student recruitment, projected enrollment, job opportunities, and regional need for programs addressing the under-representation of minorities in the occupational safety and health field. The goals, elements of the program, faculty and amount of effort, facilities and equipment and methods for implementing and evaluating the program shall be documented.

3. Curriculum content and design which should include formalized program objectives, minimal course content to achieve degrees, course sequence, related courses open to students, time devoted to lecture, laboratory and field experience, nature and the interrelationship of these educational approaches. Field experiences shall include ongoing supervised hands-on experiences as part of the program of study.

4. Previous records of training in this or related areas, including placement of graduates.

5. The extent to which the program has initiated collaborative relationships with internal and external agencies and institutions to strengthen its training capabilities.

6. Methods in use or proposed to evaluate effectiveness of the training, including the use of feedback mechanisms from graduates and employers, placement of graduates, and reports from cooperative activities with other schools and institutions.

7. Degree of institutional commitment: Is grant support necessary for program initiation or continuation? Will support gradually be assumed? Is there related instruction that will go on with or without the grant?

8. Adequacy of facilities (classrooms, laboratories, library services, books, and

journal holdings relevant to the program, and access to appropriate occupational settings).

9. Evidence of a plan for establishment of an Advisory Committee, including meeting times, members, roles and responsibilities. The Committee should meet at least annually to provide advice and periodic evaluation of TPG activities.

10. Evidence of a plan to develop a strategy for evaluating the impact that the program has had on the region. Examples could include a workforce needs survey, consultation programs provided to address regional occupational safety and health problems, a program data base to track the contributions of graduates to the occupational safety and health field.

11. The establishment of new and innovative programs and approaches to training and education relevant to the occupational safety and health field and based on documentation that the program meets specific regional and cultural needs. In reviewing such proposed programs, consideration shall be given to the developing nature of the program and its capability to produce graduates who will meet such workforce needs.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. progress reports (annual and may be incorporated as component of non-competing continuation applications);

2. financial status report, no more than 90 days after the end of the budget period; and

3. final financial status and progress reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in Section J of this announcement, "Where to Obtain Additional Information".

The following additional requirements are applicable to this program. For a complete description of each, see Attachment 1 available with the application from the Grants Management Specialist.

AR-10 Smoke-Free Workplace Requirements

AR-11 Healthy People 2010

AR-12 Lobbying Restrictions

Data collection initiated under this training grant program has been approved by the Office of Management and Budget under Number 0920-0261. "Training Grants, Application and Regulations—42 CFR Part 86," Expiration Date 01/31/2004.

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 21(a) of the Occupational Safety and Health Act [29 U.S.C. 670(a)]. Regulations applicable to this Program are in 42 CFR 86, "Grants for Education Programs in Occupational Safety and Health". The Catalog of Federal Domestic Assistance number is 93.263.

J. Where To Obtain Additional Information

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

Please refer to Program Announcement 01035 when you request information. To receive additional written information and to request application materials call 1-888-GRANTS4 (1-888-472-6874). You will be asked to leave your name and address and will be instructed to identify the announcement number of interest. If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Sonia Rowell, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 01035, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone: (770) 488-2724, Email address: svp1@cdc.gov.

For program technical assistance, contact: Bernadine Kuchinski, Occupational Health Consultant, Office of Extramural Programs, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, N.E., Mailstop D-40, Atlanta, Georgia 30341, Telephone (404) 639-3342, Email address: bbk1@cdc.gov

Dated: March 21, 2001.

Diane D. Porter,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

The Fourth Annual Educational Workshop—Current Topics in Regulatory Affairs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA), in cosponsorship with the Orange County Regulatory Affairs (OCRA) discussion group, is announcing its Fourth Annual Educational Workshop intended to give the drugs, devices, and biologics industries an opportunity to interact with FDA's reviewers and compliance officers from FDA's centers and district offices. The main focus of this interactive workshop is to provide regulatory updates, guidances, and recommendations regarding new product submissions, postapproval changes, and postmarketing issues.

Date and Time: The meeting will be held on May 21 and 22, 2001, 7:30 a.m. to 5 p.m.

Location: The meeting will be held at The Irvine Marriott, 18000 Von Karman Ave., Irvine, CA.

Contact: Ramlah I. Oma, Food and Drug Administration, 19900 MacArthur Blvd., suite 300, Irvine, CA 92612, 949-798-7611, FAX: 949-798-7656, or Peri Ann DiRocco, OCRA discussion group, PMB 624, 5405 Alton Pkwy., suite 5A, Irvine, CA 92604, voice/FAX: 949-348-9141, e-mail: sdirocco@aol.com, www.ocra-dg.org.

Registration and Requests for Oral Presentations: Space is limited. Preregistration and confirmation are required. Send registration information (including name, title, firm name, address, telephone, and fax number), written material, and requests to make oral presentations directly to the OCRA Web site.

If you need special accommodations due to a disability, please contact Ramlah I. Oma at least 10 days in advance.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: March 20, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-4396]

Guidance for Industry on Financial Disclosure by Clinical Investigators; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Financial Disclosure by Clinical Investigators." FDA published a final rule requiring anyone who submits a marketing application for any drug, biologic, or device to submit certain information concerning the compensation to, and financial interests of, any clinical investigator conducting clinical studies covered by the rule. These requirements took effect on February 2, 1999. This guidance is intended to provide clarification and respond to questions and comments concerning implementation of the final rule.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled "Financial Disclosure by Clinical Investigators" to Mary C. Gross, Office of International and Constituency Relations (HF-24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send a self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mary C. Gross, Office of International and Constituency Relations (HF-24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3450.

SUPPLEMENTARY INFORMATION:

I. Background

The financial disclosure by clinical investigators regulations require that financial interests and arrangements of clinical investigators that could affect the reliability of data submitted to FDA are identified and disclosed by the applicant. This requirement applies to any clinical study submitted in a marketing application that the applicant or FDA relies on to establish that the