DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of National AIDS Policy; Notice of Meeting of the Presidential Advisory Council on HIV/AIDS and its Subcommittees

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Presidential Advisory Council on HIV/AIDS on April 5–8, 1997, at the Madison Hotel, Washington, D.C. The meeting of the Presidential Advisory Council on HIV/AIDS will take place on Saturday, April 5, Sunday April 6, Monday, April 7 and Tuesday, April 8 from 8:30 am to 5:30 pm at the Madison Hotel, 1177 15th Street, N.W., Washington, D.C. 20005. The meetings will be open to the public.

The purpose of the subcommittee meetings will be to finalize recommendations and assess the status of previous recommendations made to the Administration. The agenda of the Presidential Advisory Council on HIV/AIDS will include presentations from the Council's five committees, Research, Services, Prevention, Discrimination and Prison Issues.

Daniel C. Montoya, Office of National AIDS Policy, 750 17th Street, N.W., Washington, D.C. 20503, Phone (202) 632–1090, Fax (202) 632–1096, will furnish the meeting agenda and roster of committee members upon request. Any individual who requires special assistance, such as sign language interpretation or other reasonable accommodations, should contact Kimberly Farrell at (301) 986–4870 no later than March 28.

Dated: February 5, 1997.

Daniel C. Montoya,

Office of National AIDS Policy.

[FR Doc. 97–3825 Filed 2–14–97; 8:45 am]

BILLING CODE 3195–01–M

Meeting of the National Bioethics Advisory Commission (NBAC), Human Subjects Subcommittee

SUMMARY: Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is given of the third meeting of the subcommittee on the protection of human subjects of the National Bioethics Advisory Commission. The subcommittee members will continue addressing the protection of the rights and welfare of human subjects in research. The meeting is open to the public and opportunities for statements by the public will be provided.

DATE: Monday, February 24, 1997, 8:00 a.m. to 4:30 p.m.

LOCATION: The subcommittee will meet at the Holiday Inn Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814, in the Versailles I Room, at the Mezzanine level.

SUPPLEMENTARY INFORMATION: The President established the National Bioethics Advisory Commission (NBAC) by Executive Order 12975 on October 3, 1995. The mission of the NBAC is to advise and make recommendations to the National Science and Technology Council and other entities on bioethical issues arising from the research on human biology and behavior, and in the applications of that research including clinical applications.

Tentative Agenda

The subcommittee will continue discussion of current approaches to the protection of human subjects by Federal agencies; special protections in research on cognitively impaired subjects; possible topics for further analysis, including the concept of vulnerability, community, and the changing context and paradigm of research; and other related issues.

Public Participation

The meeting is open to the public with attendance limited by the availability of space. Members of the public who wish to present oral statements should contact the Deputy Executive Director of the NBAC by telephone, fax machine, or mail as shown below as soon as possible, prior to the meeting. The Chair of the subcommittee will reserve time for presentations by persons requesting an opportunity to speak. The order of speakers will be assigned on a first come, first serve basis. Individuals unable to make oral presentations are encouraged to mail or fax their comments to the NBAC at least two business days prior to the meeting for distribution to the subcommittee members and inclusion in the record.

Persons needing special assistance, such as sign language interpretation or other special accommodations, should contact NBAC staff at the address or telephone number listed below as soon as possible.

FOR FURTHER INFORMATION CONTACT: Ms. Henrietta D. Hyatt-Knorr, National Bioethics Advisory Commission, MSC–7508, 6100 Executive Boulevard, Suite 3C01, Rockville, Maryland 20892–7508, telephone 301–402–4242, fax number 301–480–6900.

Dated: February 11, 1997.

Henrietta D. Hyatt-Knorr,

Deputy Executive Director, National Bioethics Advisory Commission.

[FR Doc. 97–3862 Filed 2–14–97; 8:45 am]

BILLING CODE 4160–17–P

Agency for Health Care Policy and Research

Nominations of Topics for Evidence-based Practice Centers (EPCs); Extension for Submission of Topic Nominations

The Agency for Health Care Policy and Research is extending the time of submission for nominations of topics to March 24, 1997. This notice was published in the Federal Register on December 23, 1996 (61 FR 67554–67556).

Dated: February 10, 1997.

Clifton R. Gaus,

Administrator.

[FR Doc. 97–3920 Filed 2–14–97; 8:45 am]

BILLING CODE 4160–90–M

Centers for Disease Control and Prevention

[Announcement Number 722]

Intervention Studies for Construction Safety and Health; Availability of Funds for Fiscal Year 1997

Introduction

The Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), announces that applications are being accepted for intervention projects relating to occupational safety and health in the construction industry. Such projects are intended to develop and evaluate the effectiveness of methods or approaches for preventing illnesses and injuries among construction workers. Thus, this announcement is not intended for traditional hypothesis-testing research projects to identify and investigate the relationships between health outcomes and occupational exposures to hazardous agents.

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 a copy of ''Healthy People 2000,'' see the section

WHERE TO OBTAIN ADDITIONAL INFORMATION.)

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.

Eligible Applicants

Eligible applicants include 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: 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, contract, loan, or any other form.

Smoke-Free Workplace

CDC strongly encourages 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.

Avalibility of Funds

About $500,000 is available in fiscal year (FY) 1997 to fund approximately 3 project grants. The amount of funding available may vary and is subject to change. Awards are anticipated to range from $150,000 to $200,000 in total costs (direct and indirect) per year. Awards are expected to begin on or about September 30, 1997. Awards will be made for a 12-month budget period within a project period not to exceed 3 years. Continuation awards within the project period will be made on the basis of satisfactory progress and availability of funds.

Background

The Bureau of Labor Statistics reported five million employees in the construction sector in 1994 (Undercounting in this sector may be significant because of self-employment). The construction industry is considered one of the most hazardous industries in the nation. For example, there were only 3.3 deaths per 100,000 construction workers in the Netherlands in 1992 compared to 14 deaths per 100,000 construction workers in the United States. More fatalities occur in the construction industry than in any other industry. The construction industry also experiences a higher incidence rate of nonfatal injuries and illnesses than workers in other industries. These injuries and illnesses can also contribute to project delays and lost productivity.

Some construction groups are able to achieve substantially lower injury rates than the national average, which may be the result of interventions that are not widely known. The lost-time injury rate of the National Constructors Association, which consists of several large construction contractors in the United States, was less than 1 per 100 full-time workers in 1993 compared to the national average in construction of 5.1 per 100 full-time workers in 1993. In addition, the average lost-time injury rate from 1988 to 1994 for Army Corps of Engineers construction projects was also less than 1 per 100 full-time workers. The average workers' compensation insurance premiums for all workplaces are 2.4% of payrolls. In contrast, workers' compensation insurance premiums in construction workplaces range upwards to over 100% of payrolls such as in very hazardous iron work at high elevations. All of these problems are influenced by the complexity of the construction work place: Multiemployer work sites, a mobile workforce (multiple employers each year), a continually changing work site for each worker in both location and the kind of work, episodic and potentially high exposures, and work in inclement weather.

For the purposes of this announcement, NIOSH has placed a priority on intervention and control technology research in the construction industry. NIOSH is encouraging intervention research to assess the effectiveness of policies, regulations, education and training, government and private outreach programs, and new technology in preventing disease and injury. Control technology research, a form of intervention research, seeks to prevent work-related diseases and injuries by designing, implementing, and evaluating measures to reduce occupational hazards at their source. In reviewing its National Program for Occupational Safety and Health in Construction, NIOSH has found that solutions to problems often exist (tools, technology, and best safety practices), but they are not adopted at the work place. Effective interventions can lead to reduced injury and death rates.

Purpose

NIOSH seeks to prevent work-related diseases and injuries in the construction industry by designing, implementing, and evaluating measures to reduce occupational hazards. If prevention measures are not currently available, new technologies should be developed for controlling hazardous exposures. Such new technologies must be evaluated to determine that the prevention measures are feasible, even for smaller businesses. Intervention research, of which control technology is a part, examines the utility and impact of new and existing preventive measures in the workplace.

Programmatic Interest

The focus of these grants is to facilitate progress in preventing adverse effects among construction workers. A project that is proposed to develop or test the efficacy of an intervention should be designed to establish, discover, develop, elucidate, or confirm information relating to occupational safety and health, including innovative methods, techniques, and approaches for solving occupational safety and health problems. A project that is proposed to demonstrate the effectiveness of an intervention should address, either on a pilot or full-scale basis, the technical or economic feasibility of implementing a new/improved innovative procedure, method, technique, or system for preventing occupational safety or health problems. A demonstration project should be conducted in an actual workplace where a baseline measure of the occupational 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.

The overall NIOSH program priorities, including those related to the construction industry, were developed by NIOSH with input from 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 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.

Consistent with NORA, the following are high priority directions for research under this announcement. Investigators may also apply in other areas related to construction safety and health, but the rationale for the significance of the research and demonstrations to construction must be developed in the application.

1. Understand how economic issues impact the acceptance of best safety practices.
2. Understand the aspects of changing the safety culture in organizations, including residential and other small contractors.
3. Improve the health and safety aspects of construction tools and of general technology development/utilization.
4. Identify effective ways to obtain information and conduct research on non-union workers and contractors.
5. Identify training techniques that are effective in causing safe work practices to be adopted.
6. Investigate mechanisms that lead to nongovernmental support/funding for regional training and safety and health services.
7. Investigate new concepts for job-site improvement (such as scheduling of deliveries, material location and transport in vehicular worker traffic patterns, etc.).
8. Identify causes of dramatic differences in regional injury rates for both small and large firms, as well as union and non-union operations.
9. Select focus areas that will be of perceived immediate benefit to the customers. (Based upon achievable benchmarks in construction safety and health, the NIOSH program priorities applicable to this Program Announcement are to reduce construction-related deaths, lost-time injuries and illnesses, back injuries, eye injuries, skin disorders or diseases, lead poisonings, hearing loss, silicosis, and asbestosis.)

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

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. 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 for completeness and responsiveness. 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 in which applications will be determined to be competitive or non-competitive based on their technical merit 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.

Review criteria for technical 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 industry, unions, or other participants 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 Objective Review Group (ORG) 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.

Secondary review criteria for programmatic importance are as follows:

1. Results of the initial review.
2. Magnitude of the problem in terms of numbers of workers affected.
3. Severity of the disease or injury in the worker population.
4. Usefulness to applied technical knowledge in the evaluation, or control of construction safety and health hazards.
5. Degree to which the project can be expected to yield or demonstrate results that will be useful on a national or regional basis.

Applicants will compete for available funds with all other approved applications. The following will be considered in making funding decisions:

1. Quality of the proposed project as determined by peer review.
2. Availability of funds.
3. Program balance among priority areas of the announcement.

Executive Order 12372 Review

Applications are not subject to the review requirements of Executive Order 12372, entitled Intergovernmental Review of Federal Programs.

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 number is 93.262.

Other Requirements

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 to ensure that women and racial and ethnic groups will be included in CDC 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 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.

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 March 14, 1997. 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.

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 May 14, 1997 to: Ron Van Duyne, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, (CDC), 255 East Paces Ferry Road, NE., Room 321, MS-E13, 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 (404) 332–4561. You will be asked your name, address, and telephone number and will need to refer to Announcement 722. You will receive a complete program description, information on application procedures, and application forms. In addition, this announcement is also available through the CDC Home Page on the Internet. The address for the CDC Home Page is http://www.cdc.gov. If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Georgia Jang, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., MS–E13, Atlanta, GA 30305, telephone (404) 842–6796; fax: 404–842–6513; internet: glj2@cdc.gov. Programmatic technical assistance may be obtained from Roy M. Fleming, Sc.D., Associate Director for Grants, 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.

Please Refer to Announcement Number 722 When Requesting Information and Submitting an Application.

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.

Dated: February 11, 1997.

Diane D. Porter,

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

[FR Doc. 97–3909 Filed 2–14–97; 8:45 am]

BILLING CODE 4163–19–P

Food and Drug Administration

Advisory Committees; Tentative Schedule of Meetings for 1997

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a tentative schedule of forthcoming meetings of its public advisory committees for 1997. At the request of the Commissioner of Food and Drugs (the Commissioner), the Institute of Medicine (the IOM) conducted a study of the use of FDA's advisory committees. The IOM recommended that the agency publish an annual tentative schedule of its meetings in the Federal Register. In response to that recommendation, FDA is publishing its