Contracts,'' Vol. 23, No. 18. Like the original PORTs, PORT IIs are pragmatic, methodologically sophisticated, multidisciplinary projects that focus on patient outcomes for common clinical problems. They differ from the original PORTs by their individualized research strategies and are also distinguished by their expected impact on clinical practice, patient outcomes, and health care policy. PORT IIs focus on the establishment of direct linkages between practice and outcomes and on research methods that facilitate direct comparisons of two or more distinct clinical strategies. Clinical conditions addressed to date by the AHCPR PORT II program include:

- Localized Breast Cancer
- Cardiac Arrhythmia
- End-stage Renal Disease
- Depression
- Prostate Disease
- Infant Dehydration
- Cataract: Preoperative Testing
- Pelvic Inflammatory Disease

In addition to PORTs and PORT IIs, AHCPR has funded approximately 130 other outcomes and effectiveness research clinical studies. For clinical subjects as diverse as AIDS, dental disease, emergency medicine, and cancer, these studies document patterns of practice, describe the natural history of diseases, synthesize the evidence for various clinical strategies, or answer relatively discrete effectiveness questions. Major ongoing program areas focus on pharmaceutical therapy, minority health, and primary care.

AHCPR Process for Determining Priority Topics

Topic selection for the original PORT projects was guided by work of the Institute of Medicine (IOM) which was described in the 1990 IOM publication entitled ''National Priorities for the Assessment of Clinical Conditions and Medical Technologies.'' A new process to identify priorities for future outcomes research was discussed at a November, 1995 expert panel meeting. During this meeting, the AHCPR conferred with health services and effectiveness experts, representing multiple disciplines, specialties, and institutions. Alternative approaches for prioritizing topic areas and identification of populations whose major health conditions have not yet been adequately addressed (e.g., young children, the very elderly, women, and ethnic minorities) were considered.

Based on the IOM work and expert discussions, AHCPR has initiated a three stage process for identifying topics:

1. Develop a preliminary list of priority topics and reasons for importance, representing the views of health care providers, insurers, medical and health specialty societies, consumers, and the general public;

2. Convene an expert panel to review and assess the preliminary research priorities and suggested criteria; and

3. Identify which topic areas can be most appropriately addressed using outcomes and effectiveness research methods.

This Notice initiates the first step, that is, a solicitation of topics from health care providers, insurers, health-related societies, consumers, and the public. Written suggestions for research topics that fit within the parameters of AHCPR's outcomes and effectiveness research program are invited.

For each suggestion, the nominee should provide a clear rationale and supporting evidence for the topic's importance and clinical relevance. Responses should be submitted by July 29, 1996 to: Carolyn Clancy, M.D., Acting Director, Center for Outcomes and Effectiveness Research, Agency for Health Care Policy and Research, Suite 605, 2101 East Jefferson Street, Rockville, Maryland 20852. All responses will be available for public inspection at the Center for Outcomes and Effectiveness Research, Telephone (301) 594–1485, weekdays between 8:30 a.m. and 5 p.m. The AHCPR will not reply to individual responses, but will consider all submissions in developing the research priorities.

For further information on the outcomes and effectiveness research program, contact: Carolyn Clancy, M.D., Acting Director, Center for Outcomes and Effectiveness Research, Agency for Health Care Policy and Research, Suite 605, 2101 East Jefferson Street, Rockville, Maryland 20852; Telephone (301) 594–1485.

Dated: May 16, 1996.

Clifton R. Gaus,

Administrator.

[FR Doc. 96–13195 Filed 5–24–96; 8:45 am]

BILLING CODE 4160–90–M

Centers for Disease Control and Prevention

[ANNOUNCEMENT 648]

National Institute for Occupational Safety and Health; Fatality Surveillance and Field Investigations at the State Level Using the NIOSH Fatality Assessment and Control Evaluation (FACE) Model

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1996 funds for cooperative agreements to build State capacity for conducting traumatic occupational fatality surveillance, investigation, and intervention activities through the National Institute for Occupational Safety and Health (NIOSH) Fatality Assessment and Control Evaluation (FACE) Model.

The 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 areas of Occupational Safety and Health, and Surveillance and Data Systems. (To order a copy of Healthy People 2000, see the section Where to Obtain Additional Information.)

Authority

This program is authorized under section 20(a) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 669(a)) and sections 301 (42 U.S.C. 241) and 317 (42 U.S.C. 247b) of the Public Health Service Act, as amended.

Smoke-Free Workplace

The CDC strongly encourages all grant recipients to provide a smoke-free workplace and to 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

Eligible applicants are State Departments of Health, Departments of Labor, Departments of Industry, etc., located within any State or territory of the United States. Program activities, however, may not be carried out by departmental divisions that are responsible for enforcement of occupational safety and health standards. Awards will be limited to

those organizations that can exercise public health authority for intervention into occupational safety and health problems. Only one application per State will be accepted under this announcement. Stronger consideration will be given to those States or territories submitting applications which demonstrate coordination among relevant State agencies.

Availability of Funds

Approximately $600,000 will be available in FY 1996 to fund five to seven awards. It is expected that the awards will range from $60,000 to $100,000 with an average award of $80,000. Individual awards may vary by State, and will be based upon the scope and nature of traumatic occupational fatalities documented by the respondent, and upon proposed personnel, administrative, and associated costs. The awards will be made on or about September 30, 1996, with 12-month budget periods within project periods of up to 5 years. Funding estimates may vary and are subject to change.

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

Purpose

The purpose of funding these cooperative agreements is to expand the State-based FACE project and significantly strengthen the occupational public health infrastructure. This will be accomplished by integrating resources for occupational safety and health research and public health prevention programs at the State and local levels. The ultimate goal of the project is to reduce traumatic occupational fatalities within the States. Over the past seven years, State level personnel have shown that the NIOSH FACE model for investigation of occupational fatalities can be successfully implemented in the States. The most immediate products of the State level FACE programs have been accurate and timely surveillance systems for detecting traumatic occupational fatalities occurring within the State, fatality investigations identifying causal factors, and recommendations for prevention strategies. This program will permit awardees to efficiently integrate resources for prevention of occupational fatalities at the State and local level. Additionally, States will be encouraged to target occupational traumatic injury research and prevention programs based on specific State priority areas. FACE data will be shared with all award recipients. The specific objectives for this cooperative agreement are as follows:

1. Develop a timely, comprehensive, multiple source State level surveillance system for identifying and recording basic epidemiologic data on all traumatic occupational fatalities occurring within the State.

2. Conduct on-site investigations of specific traumatic occupational fatalities using the NIOSH FACE investigative model.

3. Through case investigations, identify factors common to selected types of traumatic occupational fatalities, leading to development and prioritization of prevention strategies.

4. Develop and disseminate prevention recommendations to reduce the risk of fatal occupational injuries within the State.

5. Develop and implement prevention strategies and projects for reducing State incidence of traumatic occupational injuries and fatalities.

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 the activities under B. (CDC/NIOSH Activities).

A. Recipient Activities

1. Develop a comprehensive multiple-source, State-level surveillance system for prompt identification and reporting of epidemiologic data on all traumatic occupational fatalities occurring in the State.

2. Conduct in-depth site investigations of targeted occupational fatalities as determined by NIOSH. Currently, falls from elevations and machinery-related incidents are targeted fatality types. These are among the leading causes of work-place fatalities, as identified by national surveillance systems; however, they may change over the term of the agreement. Greatest emphasis must be placed on the determined targets; however, States may choose, in cooperation with NIOSH, to conduct in-depth investigations of other fatality types identified.

3. In specified format, develop and submit to NIOSH a narrative report of each in-depth fatality investigation which describes the fatal incident and includes recommendations for preventing future similar occurrences.

4. Submit first reports of fatalities, investigative narrative reports, and supplementary investigative data electronically to NIOSH through CDC's WONDER/PC system.

5. Evaluate surveillance data and investigative findings to identify specific worker populations to which prevention programs should be addressed.[1]

6. Identify entities such as employers, unions, and trade associations that can effect change in the workplace.

7. Communicate recommended preventions to those who can affect change in the workplace and to those at risk through targeted dissemination.

8. Prepare and submit periodic status reports of activities in designated format and an annual report that summarizes the activities and progress made by the State toward meeting the objectives for the State FACE program.

9. Participate in annual NIOSH-conducted FACE project workshop/conference in Morgantown, West Virginia, or other selected site.

B. CDC/NIOSH Activities

1. Provide formats for data reporting forms, coding formats, computer software, and State personnel training for electronic transmission of FACE surveillance and investigative data to the NIOSH data base.

2. Provide assistance to awardee staff in establishing traumatic occupational fatality notification networks.

3. Provide initial training in procedures and subsequent technical assistance for conducting on-site fatality investigations using the FACE investigative methodology (including the use of FACE investigative data collection instruments).

4. Provide assistance in identifying sentinel events resulting from industrial applications of new and emerging technologies.

5. Provide technical assistance in the dissemination of summary reports and other published findings to State and local health and labor officials, voluntary health groups, workers, unions, employers and professional organizations.

6. Provide technical assistance in identifying and evaluating effective intervention strategies.

7. CDC will provide funds to purchase one IBM-compatible, Pentium-based personal computer, printer, telecommunications equipment, and needed software for use on appropriate activities related to this cooperative agreement, if necessary.

[1] A Framework for Assessing the Effectiveness of Disease and Injury Prevention. Morbidity and Mortality Weekly Report (MMWR), March 27, 1992/Vol.41/Jn. The MMWR can be accessed through CDC's DocView, World-Wide Web (http://www.cdc.gov/epo/mmwr/mmwr.html).

Evaluation Criteria

Evaluation of the applications will be based on the following criteria:

1. Ability to communicate the scope and nature of traumatic occupational fatalities in the State as evidenced by the quality of the narrative and documented research and experience. (10%)

2. The qualifications and time commitment of proposed project staff (principal investigator, field investigator (if already identified), administrative and technical support staff). (30%—Total)

a. The existence of or potential for acquiring expertise in investigation of occupational fatalities. There should be a full-time field investigator dedicated to the project. (15%)

b. The existence of or potential for acquiring safety expertise relevant to formulation of injury prevention strategies. (15%)

3. Applicant's collaborative relationships with various relevant State or territorial agencies or organizations in addressing the problem of traumatic occupational fatality surveillance, investigation, and intervention. (30%—Total)

a. The existence of or potential for establishment of a multiple-source network for identification and reporting of traumatic occupational fatalities. (15%)

b. The existence of or potential for establishment of relationships with public safety departments, safety compliance agencies, and other entities that can provide background and supplementary data relating to specific fatality cases. (15%)

4. Demonstrated ability to communicate recommended preventions to those at risk through targeted dissemination. (25%)

5. Additional personnel/facilities/equipment already in place that can contribute to successful implementation of the project. (5%)

6. Human Subjects. (Not Scored)

Whether or not exempt from the DHHS regulations, are procedures adequate for 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.

7. Budget Justification. (Not Scored)

The budget will be evaluated to the extent that it is reasonable, clearly justified, and consistent with the intended use of funds.

Executive Order 12372 Review

Applications are subject to the Intergovernmental Review of Federal Programs as governed by Executive Order (E.O.) 12372. E.O. 12372 sets up a system for State and local government review of proposed Federal assistance applications. Applicants (other than federally recognized Indian tribal governments) should contact their State Single Point of Contact (SPOC) as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. Indian tribes are strongly encouraged to request tribal government review of the proposed application. For proposed projects serving more than one State, the applicant is advised to contact the SPOC for each affected State. A current list of SPOCs is included in the application kit.

If SPOCs or tribal governments have any State process recommendations on applications submitted to CDC, they should forward them to Ron Van Duyne, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Room 300, 255 East Paces Ferry Road, NE., Atlanta, GA 30305, no later than 60 days after the application deadline date. The granting agency does not guarantee to ''accommodate or explain'' State or tribal process recommendations it receives after that date.

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 for this program is 93.283.

Application Submission and Deadline

The original and two copies of the application PHS Form 5161–1 (OMB Number 0937–0189) must be submitted to Ron Van Duyne, 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 11, 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 Applications: 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 648. You will receive a complete program description and information on application procedures and forms.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Oppie M. Byrd, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Mailstop E–13, Room 300, 255 East Paces Ferry Road, NE., Atlanta, GA 30305, telephone (404) 842–6546, Internet: oxb3@opspgo1.em.cdc.gov.

Programmatic technical assistance may be obtained from Ted A. Pettit, State FACE Project Officer, Chief, Trauma Investigations Section, Surveillance and Field Investigations Branch, NIOSH/Division of Safety Research, Mailstop 180P, 1095 Willowdale Road, Morgantown, WV 26505–2888, telephone (304) 285–5972, Internet: TAP3@NIOSR1.EM.CDC.GOV, or Dr. Nancy Stout, Acting Chief, Surveillance and Field Investigations Branch, NIOSH/Division of Safety Research, Mailstop 180P, 1095 Willowdale Road, Morgantown, WV 26505–2888, telephone (304) 285–5916.

Please refer to Announcement Number 648 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 through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: May 17, 1996.

Diane D. Porter,

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

[FR Doc. 96–13196 Filed 5–24–96; 8:45 am]

BILLING CODE 4163–19–P

Food and Drug Administration

[Docket No. 95N–0200]

Guidance on Applications for Products Comprised of Living Autologous Cells Manipulated Ex Vivo and Intended for Structural Repair or Reconstruction; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Guidance on Applications for Products Comprised of Living Autologous Cells Manipulated Ex Vivo and Intended for Structural Repair or Reconstruction.'' The guidance was prepared by the Center for Biologics Evaluation and Research (CBER) in consultation with the Center for Devices and Radiological Health. The document is intended to provide guidance on FDA's approach to the regulation of living autologous cells manipulated ex vivo and intended for structural repair or reconstruction (Manipulated Autologous cells or MAS cells). The agency is also inviting comments on the guidance.

DATES: Written comments by August 26, 1996.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Guidance on Applications for Products Comprised of Living Autologous Cells Manipulated Ex Vivo and Intended for Structural Repair or Reconstruction'' to the Division of Congressional and Public Affairs (HFM–44), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail or FAX by calling the CBER Voice Information System at 1–800–835–4709.

Persons with access to the INTERNET may obtain the document in several ways. Users of ''Web Browser'' software, such as Mosaic, Netscape, or Microsoft Internet Explorer may obtain this document via the World Wide Web by using the following Uniform Resource Locators:

http://www.fda.gov/cber/cberftp.html
ftp://ftp.fda.gov/CBER/

The document may also be obtained via File Transfer Protocol (FTP). Requestors should connect to FDA's FTP Server, FTP.FDA.GOV(192.73.61.21). CBER documents are maintained in a subdirectory called ''CBER'' on the server. Logins with the user name of anonymous are permitted, and the user's e-mail address should be sent as the password. The ''READ.ME'' file in that subdirectory describes the available documents that may be available as an ASCII text file (*.TXT), or a WordPerfect 5.1 or 6.x document (*.w51,wp6), or both. Finally, the guidance can be obtained by ''bounce-back e-mail''. A message should be sent to: GDEXV@al.cber.fda.gov''.

Submit written comments on the guidance to the Dockets Managements Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Sharon A. Carayiannis, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION:

FDA had recently become aware of the clinical use of MAS cell products. MAS cells are defined as cells derived from a patient's tissues, which are manipulated ex vivo, and then implanted locally into the same patient with the intent of providing repair or reconstruction of a structure. The repair and reconstruction does not involve systemic action by the MAS cell product. Examples of MAS cells include chondrocytes expanded ex vivo and implanted in focal cartilage defects (see 60 FR 36808 at 36809 for additional information and references). The commercialization and distribution of expanded cartilage cells to provide a potential solution to a relatively common medical injury suggested that numerous patients could be receiving these cells within a short period of time.

In light of the potential public health significance of the MAS cell products, the growth of a commercial industry potentially affecting a large number of patients, and the need to decide which existing regulatory authorities (e.g., device versus biologics) would be appropriate to apply or whether a new regulatory framework was required, the agency held a public hearing on November 16 and 17, 1995 (60 FR 36808). The intent of the meeting was to solicit information on the nature and diversity of these products, and to receive comments on the formulation and implementation of any new regulatory requirements. The public hearing had 8 panels with 24 speakers, and there was general consensus that the establishment, the production process, and the MAS cell products should be of the highest quality. The speakers and attendees also agreed that MAS cell products should benefit the patient, but there was little consensus on the appropriate mechanism that should be used to show this benefit.

In the Federal Register of March 7, 1996 (61 FR 9185), after reviewing the comments and further internal discussions, the agency published a notice announcing a Commissioner's roundtable to be held on March 15, 1996. The roundtable was held to present the elements of a planned regulatory framework intended to ensure patient safety and to demonstrate patient benefit, while accommodating the development of these therapies and the need for a flexible regulatory approach. Many of the concepts presented at the roundtable were derived from ongoing FDA Reinventing Government (REGO) initiatives. In the same Federal Register notice, FDA also invited the submission of written comments concerning FDA's draft plan for the regulation of MAS cells. Based on the discussions at the March 15, 1996, roundtable and on a review of all comments received, FDA has decided that, in light of the existing and increased flexibility provided by REGO initiatives, FDA will apply the regulatory framework as detailed and explained in the guidance. CBER is