

literature search; (2) combinability of results of separate studies; (3) control and measurement of potential bias; (4) statistical analysis including significance tests and point and interval estimation; (5) sensitivity analysis to confirm final results; and (6) application of results which provides perspective of pooled results.

Pooled data analyses attempt to analyze and combine the results of individual subject level data across studies. Pooled data analyses can facilitate the study of rare exposures as well as confounding and interactions between established and suspected risk factors. Common definitions, coding, cutpoints for variables, and adjustment for the same confounders can be accomplished in pooled data analyses. Consistency of findings and previously unrecognized errors, inconsistencies, and associations may also be examined. However, pooled data analyses are more difficult to conduct because they are labor- and time-intensive. In addition, important methodologic issues remain regarding the influence of study populations and methods on the results of the pooled data analyses, and the integration of qualitative assessments of research studies with quantitative estimates of the results. Guidelines for a systematic methodology for the pooled analysis of subject level data from previously conducted epidemiologic studies focus on eight critical areas. Proposed pooled data analyses for ATSDR studies will be conducted according to a predetermined protocol which will address the eight critical areas as follows: (1) location of all studies conducted on the topic of interest; (2) selection of the studies for the pooling project; (3) obtaining the primary data from original investigators and preparing the data for the pooled analysis; (4) estimation of study-specific effects; (5) examination of heterogeneity of these study-specific effects and how they should be pooled; (6) estimation of the pooled effects with the appropriate statistical model; (7) examination of heterogeneity between studies if this exists; and (8) conduct of a sensitivity analysis.

Dated: June 20, 1995.

Claire V. Broome,

Deputy Administrator, Agency for Toxic Substances and Disease Registry.

[FR Doc. 95-15659 Filed 6-26-95; 8:45 am]

BILLING CODE 4163-70-P

Centers for Disease Control and Prevention

[Announcement No. 563]

Cooperative Agreements for Investigational Consortium for Research in Laboratory Medicine

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1995 funds for the establishment of an Investigational Consortium for Research in Laboratory Medicine to pursue new and evolving frontiers in laboratory quality research.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity to reduce morbidity and mortality, and to improve quality of life. This announcement is related to the priority area of Surveillance and Data Systems. In December 1991, an institute was convened by CDC and the Association of State and Territorial Public Health Laboratory Directors (ASTPHLD) entitled "Laboratory Initiatives for the Year 2000 (LIFT 2000)" to develop consensus on laboratory components which are essential to achieving the "Healthy People 2000" national health objectives. (For ordering a copy of "Healthy People 2000" and "LIFT 2000," see the section **Where to Obtain Additional Information.**)

Authority

This program is authorized under section 317(k)(2) [42 U.S.C., 247(k)(2)] of the Public Health Service Act, as amended.

Smoke-Free Workplace

PHS 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

Applications may be submitted by public and private nonprofit organizations and government and their agencies. Thus, universities, colleges, research institutions, hospitals, other public and private organizations, State and local governments or their bona fide agents, federally recognized Indian tribal organizations, and small,

minority- and/or women-owned businesses are eligible to apply.

Availability of Funds

Approximately \$600,000 is available in FY 1995 to fund up to three cooperative agreements. It is expected that the award will begin on or about September 29, 1995, and will be made for a 12-month budget period within a project period of up to two years. Funding estimates may vary and are subject to change. Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

Purpose

The principal purposes of these cooperative agreements are a) to provide assistance in developing an Investigative Consortium for Research in Laboratory Medicine, and b) to increase the capability of laboratorians and clinicians interested in laboratory medicine to engage in outcome-based laboratory research. The results of the research conducted by such a laboratory-based consortium will include increased knowledge of:

1. Improved methods for measuring patient outcome and performance of laboratory services.
2. The relationship between performance of laboratory services and patient outcome.
3. More comprehensive and improved assessment of the impact that changes in analytical technologies and test site locations have on patient outcome and laboratory practice.
4. Improved methods for defining required and desirable analytical goals that would have medical relevance for patient care.

Applications should explore new or evolving areas of critical research about quality measurements and components influencing quality in laboratory medicine. Also sought are applications from professional organizations interested in conducting outcome-based research in laboratory medicine. Applications dealing with clinical utility of specific tests are not sought unless they show direct relevance to specific areas of laboratory quality, and especially those enumerated above.

Benefits of the Cooperative Agreement

Individual participants in this investigational consortium are expected to benefit from the collaboration, communication and information exchange among themselves, the recipients of these cooperative agreements, and CDC. The recipients of these cooperative agreements are

expected to benefit by initiating research programs that may lead to future research efforts and similar consortia on their own. The public will benefit from CDC-established additional linkages to frontier research efforts dealing with quality of laboratory services impacting patient outcome and the increased knowledge gained in evaluating and improving the critical components of laboratory testing that impact public health.

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 will be responsible for the activities under B. (CDC Activities).

A. Recipient Activities

1. Either alone or through their constituents, carry out the research projects that were developed as stated in the application for assistance and as evaluated and prioritized by both CDC and the recipient.

2. Provide leadership in the design and implementation of research methodologies and protocols used to assess quality of laboratory testing and patient outcome.

3. Provide leadership in optimal data collection and analysis using the best epidemiological, statistical, and mathematical approaches available. Participant identification information may be omitted from these data if the consortium manager or research director is able to respond to questions concerning the validity of the data without providing participant information.

4. Use a mechanism for the sharing of the raw and analyzed data both within the consortium and with CDC.

5. Prepare manuscripts, along with the principal investigators of the individual projects if appropriate, for peer-reviewed publications that describe the results of some or all of the activities listed above. Manuscripts should benefit the public; the papers must also note the source of the funding for the project.

B. CDC Activities

1. Assist in the selection of projects that have the greatest public health concerns and in the evaluation of the detailed projects after their solicitation.

2. Provide technical input in the refinement of research protocol and methodologies proposed by the recipients and individual researchers including data collection, statistical analyses, and epidemiological approaches.

3. Collaborate in the development of a mutually defined data set standard for transmission of raw data, analyzed data, and reports within the consortium and with CDC.

4. Provide technical input and participate in the presentation of data at professional forums, meetings, and conferences as needed.

5. Provide technical assistance and input in the preparation of manuscripts related to the activities of the funded projects.

Evaluation Criteria

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

1. Responsiveness of the overall application and its constituent projects to the objectives of the cooperative agreement including: a) applicant's understanding of the objectives of the proposed cooperative agreement and each proposed project; b) relevance of the projects to the stated objectives; c) public health benefits of the proposed research projects; and d) relationship to previous studies if applicable. (25 points)

2. Ability to provide staff, knowledge, and other resources required to provide oversight of the investigators—responsibilities in the individual projects. Of paramount importance are the assessed quality of the individual projects and ability of the individual investigators to carry out the functions as stated in their projects. The qualifications and time allocations of key personnel to be assigned to the cooperative agreement as well as the facilities, equipment, and other resources available to provide oversight of the constituent projects. (30 points)

3. The methods to be used in carrying out the responsibilities of the cooperative agreement and the projects contained therein and the steps to be taken in the planning and implementation of the projects. Scope of the studies in addition to the statistical and epidemiological methods to be used if applicable. (35 points)

4. Schedule for the activities of the cooperative agreement and the individual projects therein and methods for evaluating the accomplishments including detailed research plan to meet the objectives of the projects. (10 points)

5. In addition, consideration will be given to the extent to which the budget is reasonable, clearly justified, and consistent with the intended use of the funds. (Not scored)

Executive Order 12372 Review

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

Public Health 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 is 93.283.

Other Requirements

Paperwork Reduction Act

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

Human Subjects

If any of the proposed projects involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations, 45 CFR part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate 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. In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved or will support the research. If any Native American community is involved, its tribal government must also approve that portion of the project applicable to it.

Application Submission and Deadline

The original and two copies of the application Form PHS 5161-1 (OMB Control Number 0937-0189) must be submitted to Henry S. Cassell III, Acting Chief, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Atlanta, Georgia 30305, Attention: Marsha D. Driggans, Grants Management Specialist, Mailstop E16, on or before August 7, 1995.

1. *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 objective 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.)

2. *Late Application:* Applications which do not meet the criteria in 1.(a) or 1.(b) above are considered late applications. Late applications will not be considered and will be returned to the applicant.

Where to Obtain Additional Information

A complete program description, information on application procedures, application package and business management technical assistance may be obtained from Marsha D. Driggans, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 305, Mailstop E16, Atlanta, Georgia 30305, telephone (404) 842-6523, facsimile (404) 842-6513, or via Internet: mdd2@opspgo1.em.cdc.gov.

Programmatic technical assistance may be obtained from Dr. Shahram Shahangian, Supervisory Health Scientist, Division of Laboratory Systems, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop G23, Atlanta, Georgia 30341, telephone (404) 488-7680, facsimile (404) 488-7693, or via Internet: sns9@phpdls1.em.cdc.gov.

Please refer to Announcement Number 563 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) referenced in the INTRODUCTION through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800. A copy of "Laboratory Initiatives for the Year 2000" may be obtained through Division of Laboratory Systems, CDC, Mailstop G25, Atlanta, Georgia 30341-3724, telephone (404) 488-7660.

Dated: June 21, 1995.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95-15660 Filed 6-26-95; 8:45 am]

BILLING CODE 4163-18-P

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Occupational Radiation and Energy-Related Health Research Grants—Program Announcement 521: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Disease, Disability, and Injury Prevention and Control SEP: Occupational Radiation and Energy-Related Health Research Grants—Program Announcement 521.

Time and Dates: 8 a.m.–5 p.m., July 20, 1995.

Place: Executive Park Courtyard by Marriott, Meeting Room A, 1236 Executive Park Drive, Atlanta, Georgia 30329

Status: Closed.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement 521, entitled Occupational Radiation and Energy-Related Health Research Grants.

The meeting will be closed to the public in accordance with provisions set forth in section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92-463.

Contact Person for More Information: Pervis C. Major, Ph.D., Health Science Administrator, Office of Extramural Coordination and Special Projects; Office of the Director, NIOSH, CDC, 1095 Willowdale Road, Morgantown, West Virginia 26505.

Dated: June 21, 1995.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95-15661 Filed 6-26-95; 8:45 am]

BILLING CODE 4163-19-M

Health Care Financing Administration

[ORD-076-N]

New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: April 1995

AGENCY: Health Care Financing Administration (HCFA).

ACTION: Notice.

SUMMARY: This notice lists new proposals for Medicaid demonstration projects submitted to the Department of Health and Human Services during the month of April 1995 under the authority of section 1115 of the Social Security Act. This notice also lists proposals that were approved, disapproved, pending,

or withdrawn during this time period. (This notice can also be accessed on the Internet at [HTTP://WWW.SSA.GOV/HCFA/HCFAHP2.HTML](http://WWW.SSA.GOV/HCFA/HCFAHP2.HTML).)

COMMENTS: We will accept written comments on these proposals. We will, if feasible, acknowledge receipt of all comments, but we will not provide written responses to comments. We will, however, neither approve nor disapprove any new proposal for at least 30 days after the date of this notice to allow time to receive and consider comments. Direct comments as indicated below.

ADDRESSES: Mail correspondence to: Susan Anderson, Office of Research and Demonstrations, Health Care Financing Administration, 2230 Oak Meadows, 6325 Security Boulevard, Baltimore, MD 21207.

FOR FURTHER INFORMATION CONTACT: Susan Anderson (410) 966-3996.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 1115 of the Social Security Act (the Act), the Department of Health and Human Services (HHS) may consider and approve research and demonstration proposals with a broad range of policy objectives. These demonstrations can lead to improvements in achieving the purposes of the Act.

In exercising her discretionary authority, the Secretary has developed a number of policies and procedures for reviewing proposals. On September 27, 1994, we published a notice in the **Federal Register** (59 FR 49249) that specified (1) the principles that we ordinarily will consider when approving or disapproving demonstration projects under the authority in section 1115(a) of the Act; (2) the procedures we expect States to use in involving the public in the development of proposed demonstration projects under section 1115; and (3) the procedures we ordinarily will follow in reviewing demonstration proposals. We are committed to a thorough and expeditious review of State requests to conduct such demonstrations.

II. Listing of New, Pending, Approved, and Withdrawn Proposals for the Month of April 1995

As part of our procedures, we publish a notice in the **Federal Register** with a monthly listing of all new submissions, pending proposals, approvals, disapprovals, and withdrawn proposals. Proposals submitted in response to a grant solicitation or other competitive process are reported as received during the month that such grant or bid is