establishes the relationship between the grantee and the third party.

The written agreement shall at a minimum:

1. State or incorporate by reference all applicable requirements imposed on the contractors under the grant by the terms of the grant, including requirements concerning peer review (ATSDR selected peer reviewers), ownership of data, and the arrangement for copyright when publications, data, or other copyrightable works are developed under or in the course of work under a PHS grant-supported project or activity;

2. State that any copyrighted or copyrightable works shall be subject to a royalty-fee, nonexclusive, and irrevocable license to the Government to reproduce, publish, or otherwise use them, and to authorize others to do so for Federal Government purposes;

3. State that whenever any work subject to this copyright policy may be developed in the course of a grant by a contractor under grant, the written agreement (contract) must require the contractor to comply with these requirements and can in no way diminish the Government's right in that work; and

4. State the activities to be performed, the time schedule for those activities, the policies and procedures to be followed in carrying out the agreement, and the maximum amount of money for which the grantee may become liable to the third party under the agreement.

The written agreement required shall not relieve the grantee of any part of its responsibility or accountability to PHS under the grant. The agreement shall therefore retain sufficient rights and control to enable the grantee to fulfill this responsibility and accountability.

Application Submission and Deadline Dates

The original and two copies of the application PHS Form 5161–1 (Revised 7/92, OMB Control Number 0937–0189) must be submitted to Henry S. Cassell, III, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–13, Atlanta, Georgia 30305 by August 10, 1995. (By formal agreement, the CDC Procurement and Grants Office will act for and on behalf of ATSDR on this matter.)

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 should 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 Applications:* Applications which 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 applicant.

Where To Obtain Additional Information

To receive additional written information call (404) 332–4561. You will be asked your name, address, and phone number and will need to refer to Announcement Number 530. You will receive a complete program description, information on application procedures, and application forms.

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., Room 300, Mail Stop E–13, Atlanta, Georgia 30305 or by calling (404) 842–6814. Programmatic technical assistance may be obtained from Dr. Heraline Hicks, Research Implementation Branch, or Michael Youson, Office of the Director, Division of Toxicology, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE., Mail Stop E–29, Atlanta, Georgia 30333 or by calling (404) 639–6306 or 6300.

Please refer to announcement number 530 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.

Dated: June 20, 1995.

Claire V. Broome,

Deputy Administrator, Agency for Toxic Substances and Disease Registry.

[FR Doc. 95–15658 Filed 6–26–95; 8:45 am]

BILLING CODE 4163–70–P

[ATSDR–95]

Proposed Procedures for Combined Analyses of Epidemiologic Studies as Part of the Great Lakes Human Health Effects Research Program

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Public Health Service (PHS), Department of Health and Human Services (HHS).

ACTION: This notice announces the procedures ATSDR will use for conducting combined research analyses as part of the ATSDR Great Lakes Human Health Effects Research Program.

SUMMARY: This notice describes the proposed procedures, meta- analyses and pooled data analyses, to be used by ATSDR to conduct combined analyses of epidemiologic studies supported by the ATSDR Great Lakes Human Health Effects Research Program. ATSDR may choose to utilize one or both procedures, depending on the data and the results of the future feasibility studies. The procedures will be used for both new and existing research investigations. Comments on this notice are requested. The procedures outlined herein will be used on an interim basis, subject to change based on comments received and experience gained during implementation of these procedures.

DATES: Public comments concerning this **Federal Register** notice must be received on or before December 26, 1995.

ADDRESSES: Comments on this notice should bear the docket control number ATSDR–95 and should be submitted to: Division of Toxicology, Research Implementation Branch, Agency for Toxic Substances and Disease Registry, Mailstop E–29, 1600 Clifton Road, NE, Atlanta, Georgia 30333.

Comments on this notice will be available for public inspection at the Agency for Toxic Substances and Disease Registry, Building 4, Suite 2400, Executive Park Drive, Atlanta, Georgia (not a mailing address), from 8 a.m. until 4:30 p.m., Monday through Friday, except for Federal legal holidays.

FOR FURTHER INFORMATION CONTACT: Dr. William Cibulas, Research Implementation Branch, Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E–29, 1600 Clifton Road NE., Atlanta, Georgia 30333, telephone (404) 639–6306.

SUPPLEMENTARY INFORMATION:

Background

The ATSDR Great Lakes Human Health Effects Research Program is

authorized in sections 104(I)(5)(A) and (15) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA) [42 U.S.C. 9604(I)(5)(A) and (15)]; and section 106, subsection 118(e) of the Great Lakes Critical Programs Act of 1990 [33 U.S.C. 1268(e)]. This research program is designed to investigate and characterize the association between the consumption of contaminated Great Lakes fish and associated short- and long-term harmful health effects. The research objectives of the program are to (1) build upon and amplify the results from past and ongoing research in the Great Lakes basin; (2) develop information databases and research methodology that will provide long-term benefit to human health effects research in the Great Lakes basin; (3) provide direction for future health effects research; (4) provide health information to State and local health officials, and to the concerned public and their medical health care professionals; and (5) in concert with State and local officials, increase the public awareness regarding the potential health implications of toxic pollution in the Great Lakes basin; and (6) coordinate as necessary with relevant Public Health Service (PHS) research programs and activities, including those of the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and the Indian Health Service (IHS), as well as the Environmental Protection Agency (EPA), and State and local health departments, to ameliorate adverse public health impacts of persistent toxic substances in the Great Lakes basin.

Toward this end, ATSDR has developed a Great Lakes Health Effects Research Strategy. The goals of this strategy are to identify human populations residing in the Great Lakes basin that may be at greater risk of exposure to chemical contaminants present in one or more of the Great Lakes, and to ameliorate or prevent any adverse health effects. This strategy is built upon the five traditional elements of disease prevention: identification, evaluation, control, dissemination, and infrastructure. This strategy has been endorsed by the Council of Great Lakes Research Managers and has been adopted by the International Joint Commission as a framework for the study of human health and other ecosystem effects in the Great Lakes basin.

In fiscal year 1992, ATSDR funded nine research grants to study the potential adverse human health effects of consuming contaminated fish. These studies include eight epidemiologic investigations in presumed susceptible populations, that is, Native Americans, sport anglers, the urban poor, pregnant women, fetuses and nursing infants of mothers who consume contaminated Great Lakes fish, infants and children, and the elderly. The ninth study focuses on developing more sensitive methods to detect persistent Great Lakes contaminants, such as polychlorinated biphenyls, dioxins, alkylated lead, mirex, and methylmercury, in human biologic tissues and fluids. In fiscal year 1993 ATSDR funded ten grants which included nine continuation awards for investigations funded in 1992 and one new award that established an interlaboratory-based, quality assurance/control program for the ATSDR research program. In fiscal year 1994, ATSDR funded continuation awards for all 10 research grants.

The impact of this research program will be felt most directly by the communities within the Great Lakes basin. Collectively, these 10 research projects will (1) build upon and extend six existing human health studies in the Great Lakes basin that include high-risk populations; (2) establish two new subpopulations that include African-American women, and men and women of reproductive age between 18 and 34; (3) improve analytical methodology for detecting low levels of Great Lakes contaminants in human biologic tissues and fluids and in environmental media; (4) characterize exposure to all 11 critical Great Lakes contaminants identified by the International Joint Commission, as well as other pollutants; (5) determine profiles and levels (body burden) of Great Lakes contaminants in high-risk populations; (6) identify sensitive human health end points from exposure to Great Lakes pollutants, i.e., behavioral, developmental, reproductive, neurologic, endocrinologic, and immunologic effects; (7) investigate paternal and maternal exposure to Great Lakes pollutants and assess the potential for related health effects in their children (transgenerational effects); (8) increase collaboration, cooperation, and communication between the researchers in the Great Lakes basin; and (9) provide public health information to the study populations, health care providers, and State and local health departments concerning human health effects that may result from exposure to Great Lakes pollutants by fish consumption.

Additionally, the research conducted by this program will help delineate the relationships among contaminant levels in the environment, exposure pathways, tissue levels, and potential human health effects; allow for evaluation and interpretation of data across human health studies to facilitate a basin-wide analysis of the pollution problem in the Great Lakes; and provide a ''model'' for other ecosystem-level studies intended to determine human health impacts of hazardous waste.

Rationale for Combined Analyses of ATSDR Research Investigations

Combined analyses of the research studies of the ATSDR Great Lakes Human Health Effects Research Program will provide qualitative and quantitative research synthesis of the ATSDR-supported investigations. It is expected that combined analyses of the studies will improve the science base for investigations of consumption of fish contaminated with persistent toxic compounds from the Great Lakes, strengthen the scientific foundation for informed decision-making regarding public policy, and improve coordination and linkages between research activities and public health practices.

Procedures for Combined Analyses of ATSDR Research Studies

The combined analyses (research synthesis) of epidemiologic investigations may be accomplished by meta-analysis of published results or pooled analysis of primary data. Both methods use explicit criteria, can be replicated, and provide a quantitative result. The following procedures will address key methodologic issues that are relevant to both methods of research synthesis, as well as their advantages and limitations.

Meta-analyses attempt to analyze and combine the results of previous independent studies of a given scientific issue. Meta- analyses can be used to increase the power of statistical tests for important end points and subgroups, to resolve uncertainty when studies have conflicting conclusions, and to improve estimates of effect size. Meta-analyses rely on the published reports of previous studies and are relatively easy and inexpensive to perform. However, they are also susceptible to many sources of bias and are influenced by statistical methods. Six major areas have been identified as critical elements of scientifically valid meta-analyses. Proposed meta-analyses of ATSDR studies will be conducted according to a predetermined protocol which will address the six major areas as follows: (1) study design, including protocol and

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