

applicants will be asked to provide proof of mailing by the deadline date. When proof is not provided, an application will not be considered for funding. Private metered postmarks are not acceptable as proof of timely mailing.

Hand-delivered applications will be accepted Monday through Friday prior to and on August 28, 1995 during the hours of 9:00 a.m. to 4:30 p.m. in the lobby of the Hubert H. Humphrey building located at 200 Independence Avenue, SW., in Washington, D.C. when hand delivering an application, call 690-8794 from the lobby for pickup. A staff person will be available to receive applications. Applications which do not meet the August 28, 1995 deadline will not be considered or reviewed. HHS will send a letter to this effect to each late applicant.

HHS reserves the right to extend the deadline for all applications if there is widespread disruption of the mail because of extreme weather conditions or natural disasters or if HHS determines an extension to be in the best interest of the Government. However, HHS will not waive or extend the deadline for any applicant unless the deadline is waived or extended for all applicants.

#### *Selection Process and Evaluation Criteria*

Selection of the successful applicants will be based on the technical criteria laid out in this announcement. Reviewers will determine the strengths and weaknesses of each application in terms of the evaluation criteria listed below, provide comments and assign numerical scores. The review panel will prepare a summary of all applicant scores, strengths, weaknesses and recommendations.

The point value following each criterion heading indicates the maximum numerical weight that each section will be given in the review process. An unacceptable rating on any individual criterion may render the application unacceptable. Consequently, applicants should take care to ensure that all criteria are fully addressed in the applications. Applications will be reviewed as follows:

#### *Evaluation Criteria*

1. *Goals, Objectives, and Potential Usefulness of the Analyses.* (25 points). The potential usefulness of the objectives and how the anticipated results of the proposed project will advance scientific knowledge and policy development.
2. *Methodology and Design.* (35 points). The appropriateness,

soundness, and cost-effectiveness of the methodology, including the research design, statistical techniques, analytical strategies, the selection of existing data sets, and other procedures.

3. *Qualifications of Personnel and Organizational Capability.* (25 points). The qualifications of the project personnel for conducting the proposed research as evidenced by professional training and experience, and the capacity of the organization to provide the infrastructure and support necessary for the project.

4. *Work Plan and Budget.* (15 points). Is the plan reasonable? Are the activities sufficiently detailed to ensure successful, timely implementation? Do they demonstrate an adequate level of understanding by the applicant of the practical problems of conducting such a project? Is the proposed budget reasonable and sufficient to ensure completion of the study?

#### *Disposition of Applications*

1. *Approval, disapproval, or deferral.* On the basis of the review of an application, the ASPE will either (a) approve the application in whole, as revised, or in part for an amount of funds and subject to such conditions as are deemed necessary or desirable for the research project; or (b) disapprove the application; or defer action on the application for such reasons as a lack of funds or a need for further review.

2. *Notification of disposition.* The ASPE will notify the applicants of the disposition of their application. A signed notification of the award will be issued to notify the applicant of the approved application.

3. *The Assistant Secretary's Discretion.* Nothing in this announcement should be construed as to obligate the Assistant Secretary for Planning and Evaluation to make any awards whatsoever. Awards and the distribution of awards among the priority areas are contingent on the needs of the Department at any point in time and the quality of the applications which are received.

*Components of a Complete Application.* A complete application consists of the following items in this order:

1. Application for Federal Assistance (Standard Form 424, Revised 4-88);
2. Budget Information—Non-construction Programs (Standard Form 424A, Revised 4-88);
3. Assurances—Non-construction Programs (Standard Form 424B, Revised 4-88);
4. A table of Contents;
5. Budget Justification for Section B—Budget Categories;

6. Proof of nonprofit status, if appropriate;

7. A copy of the applicant's approved indirect cost rate agreement if necessary;

8. Project Narrative Statement, organized in five sections addressing the following topics:

- (a) Abstract,
- (b) Goals, Objectives and Usefulness of the Project,
- (c) Methodology and design,
- (d) Background of the Personnel and Organizational Capabilities and
- (e) Work plan (timetable);

9. Any appendices/attachments;
10. Certification Regarding Drug-Free Work place;

11. Certification Regarding Debarment, Suspension and Other Responsibility Matters;

12. Certification and, if necessary, Disclosure Regarding Lobbying;

*Reports.* The grantee must submit quarterly progress reports and a final report. The specific format and content for these reports will be provided by the project officer.

*State Single Point of Contact (E.O. No. 12372).* The Department of Health and Human Services has determined that this program is not subject to Executive Order No. 12372, Intergovernmental Review of Federal Programs, because it is a program that is national in scope and does not directly affect State and local governments. Applicants are not required to seek intergovernmental review of their applications within the constraints of E.O. No. 12372.

Dated: June 21, 1995.

**David T. Ellwood,**

*Assistant Secretary for Planning and Evaluation.*

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BILLING CODE 4151-04-M

## **Agency for Toxic Substances and Disease Registry**

[Announcement 530]

### **The Great Lakes Human Health Effects Research Program**

#### **Introduction**

The Agency for Toxic Substances and Disease Registry (ATSDR) announces that grant applications will be accepted to conduct research on the impact on human health of fish consumption from the Great Lakes. ATSDR's mission includes the prevention of adverse health effects resulting from human exposure to hazardous substances in the environment. The ATSDR Great Lakes Human Health Effects Research Program will focus on identified populations that have a potentially higher risk of long-

term adverse health effects from exposure to contaminants in Great Lakes fish, i.e., Native Americans, sport anglers, urban poor, the elderly, Asian Americans and other racial/ethnic minority populations, and fetuses and nursing infants of mothers who consume contaminated Great Lakes fish.

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 improve the quality of life. This announcement is related to the priority area of Environmental Health. (For ordering a copy of "Healthy People 2000," see the Section **Where to Obtain Additional Information.**)

#### Authority

This 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)].

#### Smoke-Free Workplace

PHS 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.

#### Eligible Applicants

Eligible applicants are the Great Lakes States and political subdivisions thereof, including federally-recognized Indian tribal governments. State organizations, including State universities, State colleges, and State research institutions, must affirmatively establish that they meet their respective State's legislative definition of a State entity or political subdivision to be considered an eligible applicant. The Great Lakes States include Illinois, Indiana, Michigan, Minnesota, Ohio, Pennsylvania, New York, and Wisconsin, consistent with section 106, subsection 118(e) of the Great Lakes Critical Programs Act of 1990 [33 U.S.C. 1268(e)]. ATSDR encourages collaborative efforts among these potential applicants.

#### Availability of Funds

Approximately \$4 million is available in fiscal year (FY) 1995 to fund approximately 9 re-competing and 1 to 2 new awards. It is expected that the average award will be \$250,000 ranging from \$200,000 to \$300,000. It is expected that the awards will be made on or about September 30, 1995. It is anticipated that the new as well as the re-competing awards will be for a 12-month budget period with a proposed project period of 3 years. Funding estimates may vary and are subject to change.

The continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

#### Use of Funds

Funds may be expended for reasonable program purposes, such as personnel, travel, supplies and services. Funds for contractual services may be requested; however, the grantee, as the direct and primary recipient of PHS grant funds, must perform a substantive role in carrying out project activities and not merely serve as a conduit for an award to another party or provide funds to an ineligible party. Equipment may be purchased with grant funds; however, the equipment must be appropriate and reasonable for the research activity to be conducted. Property may be acquired only when authorized in the grant. The grantee, as part of the application process, should provide a justification of need to acquire property, the description, and the cost of purchase versus lease.

#### Purpose

The purpose of this announcement is to solicit scientific proposals designed to investigate and characterize the association between the consumption of contaminated Great Lakes fish and potential long-term adverse health effects. The research objectives of this 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, the concerned public and their medical health care professionals; and (5) in concert with State and local health 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.

#### Program Requirements

ATSDR will provide financial assistance to applicants in conducting studies on potential human health effects which result from human consumption of contaminated fish from the Great Lakes basin, particularly in the 31 areas of concern within the U.S. boundaries identified by the International Joint Commission. ATSDR encourages the submission of applications that emphasize research that will extend existing studies. ATSDR is also interested in funding applicant programs that identify populations which have a higher risk of short- and long-term adverse health effects from exposure to Great Lakes contaminants in fish, i.e., Native Americans, sport anglers, urban poor, the elderly, Asian Americans, racial/ethnic minority populations, and fetuses and nursing infants of mothers who consume contaminated Great Lakes fish. Priority areas of research for this program include:

1. Characterizing exposure and determining the profiles and levels of Great Lakes contaminants in biological tissues and fluids in high-risk populations;
2. Identifying sensitive and specific human health endpoints, i.e., reproductive/developmental, behavioral, endocrinologic, and immunologic effects and correlating them to exposure to Great Lakes contaminants; and
3. Determining the short- and long-term risk(s) of adverse health effects in children which result from parental exposure to Great Lakes contaminants.

Proposed projects covering these priority areas should include strategies (risk communication) to inform susceptible populations about the potential human health impact of consuming contaminated fish from the Great Lakes.

Based upon research findings, longer term priority areas may include, but are not limited to:

1. Investigating the feasibility of, or establishing, registries and/or surveillance cohorts in the Great Lakes region; and
2. Establishing a chemical mixtures database with emphasis on tissue and blood levels to identify new cohorts, conduct surveillance and health effects studies, and establish registries and/or surveillance cohorts.

In awarding grants pursuant to the ATSDR Great Lakes Human Health Effects Research Program, ATSDR shall consider proposed projects that will help fill information gaps and address research needs regarding the human health impact of consumption of contaminated fish from the Great Lakes. ATSDR encourages collaborative efforts among potential applicants in pursuing these research needs.

#### Evaluation Criteria

New and re-competing applications will be reviewed and evaluated according to the following criteria:

##### 1. *Scientific and Technical Review Criteria of New and Re-competing Continuation Applications*

- a. PROPOSED PROGRAM—60%  
The extent to which the applicant's proposal addresses:
  - (1) the scientific merit of the hypothesis of the proposed project, including the originality of the approach and the feasibility, adequacy, and rationale of the design (the design of the study should ensure statistical validity for comparison with other research projects);
  - (2) the technical merit of the methods and procedures for the proposed project (analytic procedures should be state of the art, including quality assurance and quality control methods for comparison with other research projects; additionally, the applicant is expected to participate in a tissue bank as part of the quality assurance quality control program) including the degree to which the project can be expected to yield results that meet the program objective as described in the Purpose section of this announcement;
  - (3) the proposed project schedule, including clearly established and obtainable project objectives for which progress toward attainment can and will be measured;
  - (4) the proposed mechanism to be utilized to address community concerns and opinion, and create lines of communication; and
  - (5) the proposed method to disseminate the study results to State and local public health officials, tribal governments, and the other Federal agencies, community residents, and

other concerned individuals and organizations.

- b. PROGRAM PERSONNEL—30%  
The extent to which the proposal describes:
  - (1) the qualifications, experience, and commitment of the Principal Investigator, and his/her ability to devote adequate time and effort to provide effective leadership; and
  - (2) the competence of associate investigators to accomplish the proposed study; their commitment and time devoted to the study.
- c. APPLICANT CAPABILITY—10%  
Description of the adequacy and commitment of the institutional resources to administer the program and the adequacy of the facilities as they impact on performance of the proposed study.
- d. PROGRAM BUDGET—(NOT SCORED)

The extent to which the budget is reasonable, clearly justified, and consistent with intended use of grant funds.

##### 2. *Review of Continuation Applications*

Continuation awards within the project period will be made on the basis of the following criteria:

- a. Satisfactory progress in meeting project objectives;
- b. Realistic, specific, and measurable objectives for the new budget period;
- c. Applicability and feasibility of proposed changes in meeting long-term objectives; methods of operation, need for grant support, and/or evaluation procedures to achieve project objectives; and
- d. Budget request is clearly justified and consistent with the intended use of grant funds.

#### Funding Preferences

ATSDR will give funding preference to the nine competitive continuation grants funded during FY 1994 on the basis of satisfactory progress.

#### Executive Order 12372

The applications submitted under this announcement are not subject to the Intergovernmental Review of Federal Programs as governed by Executive Order 12372.

#### 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 number is 93.161, Health Programs for Toxic Substances and Disease Registry.

#### Other Requirements

##### 1. *Protection of Human Subjects*

If the proposed project involves research on human subjects, the applicants must comply with Department of Health and Human Services Regulations (45 CFR Part 46) regarding the protection of human subjects. Assurances must be provided that the project will be subject to initial and continuing review by the appropriate institutional review committees. 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. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and forms provided in the application kit.

##### 2. *Cost Recovery*

The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), provides for the recovery of costs incurred for health-related activities at each Superfund site from potentially responsible parties. The recipient will agree to maintain an accounting system that will keep an accurate, complete, and current accounting of all financial transactions on a site-specific basis, i.e., individual time, travel, and associated costs, including indirect cost, as appropriate for the site. The recipient will retain the documents and records to support these financial transactions for possible use in a cost recovery case for a minimum of ten (10) years after submission of a final financial status report, unless there is a litigation, claim, negotiation, audit, or other action involving the specific site. The records will then be maintained until resolution of all issues on the specific site. Note: Recipients of awards must maintain all records for 10 years following submission of the final Financial Status Report unless otherwise directed by the Cost Recovery Activity, OPOM, ATSDR, and must obtain written approval from the Cost Recovery Activity Official before destroying any records.

##### 3. *Third Party Agreements*

Project activities which are approved for contracting pursuant to the prior approval provisions shall be formalized in a written agreement that clearly

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.*

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[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