The Great Lakes Human Health Effects Research Program Notice of Availability of Funds for Fiscal Year 1998

Introduction

The Agency for Toxic Substances and Disease Registry (ATSDR) announces the availability of fiscal year (FY) 1998 funds for the continuation of a grant program to conduct research on the impact on human health of fish consumption from the Great Lakes. Congressionally mandated funds are provided to the ATSDR to conduct studies of the human health impact of consuming contaminated fish from the Great Lakes, as amended and authorized by the Great Lakes Critical Programs Act of 1990. 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 non-English speaking populations, and fetuses and nursing infants of mothers who consume contaminated Great Lakes fish.

ATSDR is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Environmental Health. (For ordering a copy of Healthy People 2000, see the Section WHERE TO OBTAIN ADDITIONAL INFORMATION.)

Availability of Funds

Approximately $2.4 million is available in FY 1998 to fund approximately 10 re-competing awards. It is expected that the average award will be $250,000, ranging from $200,000 to $300,000. It is expected that the re-competing awards will be made on about September 30, 1998, for a 12-month budget period and a project period of up to 3 years. Funding estimates may vary and are subject to change. This program is available only to the ten currently funded grantees. 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 ATSDR 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 proposed should 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.

Background

The Great Lakes basin comprises one-fifth of the total freshwater on the earth’s surface and is the historical heartland for American industrial and agricultural activity. The physical nature of the basin and the long retention time of the chemicals in the Lakes combine to make this huge freshwater resource a repository for chemical byproducts of these production activities. Through the process of bioaccumulation, these pollutants are taken up by aquatic life and become especially concentrated in Great Lakes game fish, and other wildlife. The presence of toxic substances in the Great Lakes continues to be a significant concern in the 1990s. Eleven of the most persistent and widespread toxic substances were identified as “critical Great Lakes pollutants” by the International Joint Commission (IJC). The critical pollutants are polychlorinated biphenyls (PCBs), dichlorodiphenyl trichloroethane (DDT and its metabolites), dieldrin, toxaphene, mirex, methylmercury, benz[a]pyrene, hexachlorobenzene, furans, dioxins, and alkylated lead. Associations between the consumption of contaminated Great Lakes fish and long-term adverse health effects have been demonstrated in certain susceptible populations.

Research conducted as part of this program may also serve to fill priority data needs identified in ATSDR’s Substance-Specific Applied Research Program. PCB’s, DDT, dieldrin, mercury, PAHs and lead are members of the first set of 38 substances selected by ATSDR for initiation of this Superfund mandated program (56 FR 52178). This research may also provide information for the assessment of human risk from simultaneous exposure to chemical mixtures in the Great Lakes basin; and...
extend the knowledge of the effects of Great Lakes contaminants on human reproductive/developmental, behavioral, neurologic, endocrinologic, and immunologic health effects. Finally, ATSDR anticipates that the findings generated from this research program can be utilized on a national level by providing a “model” for other ecosystem level studies intended to determine potential human health impacts of hazardous wastes.

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 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 research programs and activities of other agencies, 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 and other non-English speaking 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 (several of these contaminants have been identified as endocrine disruptors); 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.

All applicants should also participate in the ATSDR Great Lakes research quality assurance and quality control (QA/QC) and tissue bank programs.

Proposed projects covering these priority areas should include strategies (risk communication and health intervention) 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. Establishing the chemical etiology between exposure, body burden levels, and adverse health effects;
2. Investigating the feasibility of, or establishing, registries and/or surveillance cohorts in the Great Lakes region; and
3. Establishing a chemical mixtures database with emphasis on tissue and blood levels in order 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.

Technical Reporting Requirements
1. Progress and Financial Reports
An original and two copies of an annual progress report and financial status report are required no later than 90 days after the end of the budget period. Final financial and performance reports are required no later than 90 days after the end of the project period. All reports are submitted to Ron Van Duyne, Grants Management Officer, Grants Management Branch, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, Mailstop E-13, Atlanta, GA 30305.

The progress report must include the following for the program, function, or activity involved: (1) a comparison of actual accomplishments to the goals established for the period; (2) the reasons for slippage if established goals are not met; and (3) other pertinent information.

2. Peer and Technical Reviews
   A. CERCLA, as amended by SARA, Section 104(i)(13), and (42 U.S.C. 9604 (l)) requires all studies and results of research (other than public health assessments) that ATSDR carries out or funds in whole or in part will be peer reviewed by ATSDR. The ATSDR peer review process for final reports requires that:
      1. Studies must be reported or adopted only after appropriate peer review.
      2. Studies shall be peer reviewed within a period of 60 days to the maximum extent practical.
      3. Studies shall be reviewed by no fewer than three or more than seven reviewers who (1) are selected by the Administrator, ATSDR; (2) are disinterested Scientific experts; (3) have a reputation for scientific objectivity; and (4) who lack institutional ties with any person involved in the conduct of the study or research under review.
   B. ATSDR encourages the rapid reporting and interpretation of laboratory results and references back to individual participants. However, if summary tables or distribution of laboratory results are prepared using the study data, this is considered a preliminary finding and will require ATSDR technical and peer review prior to release.
   C. When, in the opinion of the investigator(s), a public health concern exists requiring the release of summary study statistics prior to the completion of the study, the investigator must obtain concurrence from ATSDR prior to releasing the summary statistics. A request for ATSDR concurrence for the release of information must be
documented in a letter to ATSDR and should outline the public health concern, and recommended response, and the draft document proposed for release by the investigator. ATSDR will provide a technical review and peer review within ten (10) working days to the maximum extent possible. Summary statistics may be released only after peer review. The release of summary statistics does not preclude the requirement for a final report.

D. By statute, the reporting of preliminary studies and preliminary research results to the public is not acceptable without prior review by ATSDR. This includes manuscripts prepared for publication, presentations at scientific meetings, and reporting of preliminary findings to the community or the media.

E. The final report for every study should include a detailed description of the problem, hypothesis, methods, results, conclusions, and recommendations that constitute a complete performance record of the study.

F. ATSDR is responsible for the technical and peer review of draft final reports of any study that it funds prior to the submission of the final report. This will allow for the recipient to incorporate all technical and peer review comments into the final report. Responses to all ATSDR required technical and peer review comments should be summarized in a letter to ATSDR. This letter should also include the investigator’s response to each comment and a rationale for those responses. Based upon the comments of the technical and peer reviewers, modifications in the study report may result. The modified study report should accompany the letter to ATSDR.

G. ATSDR will make available assistance to investigators in formatting and copy editing draft final reports, should the investigator request this assistance. Editing will be conducted by ATSDR staff and an edited copy of the draft final report will be supplied to the investigator for review and concurrence. Editing will occur DURING the conduct of the peer review. It is requested that the report be furnished in WordPerfect 5.1 on a disk with the hard copy double-spaced, with clearly numbered pages, unbound and unstapled, and printed on one side only. All appendices, including maps and reproduced forms used in this study, should be furnished to ATSDR by the investigator.

H. Following the steps outlined above, a final report of all studies and results of research carried out or supported by ATSDR must be submitted to the Procurement and Grants Office with a copy furnished to ATSDR.

I. If assistance in printing the final report is needed, the Principal Investigator can submit a hard copy of the final report to the Procurement and Grants Office with a copy furnished to the Division of Toxicology, ATSDR.

Application Content

The application must be developed in accordance with PHS Form 5161-1 (OMB Number 0937-0189) information. In a narrative form, the application should include a discussion of areas listed under the “Evaluation Criteria” section of this announcement as they relate to the proposed program. Because these criteria serve as the basis for evaluating the application, omissions or incomplete information may affect the rating of the application. Although this program does not require in-kind support or matching funds, the applicant should describe any in-kind support in the application. For example, if the in-kind support includes personnel, the applicant should provide the qualifying experience of the personnel and clearly state the type of activity to be performed.

An original application and two copies should be submitted. The application pages must be clearly numbered, and a complete index to the application and its appendices must be included. The original and each copy of the application must be submitted unstapled and unbound. All material must be typed single-spaced, with un-reduced type on a 8 ½” by 11” paper, with at least 1” margins, and printed on one side only.

Evaluation Criteria

Re-Competing applications will be reviewed and evaluated according to the following criteria:

1. Scientific and Technical Review

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. Budget should reflect funds for participation in the QA/QC program.

E. Human Subjects—(Not Scored)

The extent to which the applicant complies with the Department of Health and Human Services Regulations (45 CFR Part 46) regarding the protection of human subjects.

2. Review of Continuation Applications

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

A. Satisfactory progress has been made in meeting project objectives;

B. Objectives for the new budget period are realistic, specific, and measurable;

C. Proposed changes in described long-term objectives, methods of operation, need for grant support, and/
or evaluation procedures will lead to achievement of project objectives; and D. Budget request is clearly justified and consistent with the intended use of grant funds.

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.

Other Requirements

Paperwork Reduction Act

Projects that involve the collection of information from 10 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

The applicant must comply with the Department of Health and Human Services Regulations, 45 CFR Part 46, regarding the protection of human subjects. Assurances must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and forms provided in the application kit.

Women, Racial and Ethnic Minorities

It is the policy of the CDC to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, and Native Hawaiian or other Pacific Islander. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exists that inclusion is inappropriate or not reasonable, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the Federal Register, Vol. 60, No. 179, Friday, September 15, 1995, pages 47947-47951 (a copy is included in the application kit).

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 would 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; then the records will 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.

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:

(A) 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;

(B) State that any copyrighted or copyrightable works shall be subject to a royalty-free, 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;

(C) 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

(D) 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 shall not relieve the grantee of any part of its responsibility or accountability to ATSDR under the grant. The agreement shall therefore retain sufficient rights and control to the grantee to enable it to fulfill this responsibility and accountability.

Application Submission and Deadline Dates

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, Attn: Patrick A. Smith, 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 on or before July 31, 1998. (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. (Applications 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.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[Program Announcement 98027]

Research Program for Exposure-Dose Reconstruction

Introduction

The Agency for Toxic Substances and Disease Registry (ATSDR) announces the availability of fiscal year (FY) 1998 funds for a continuation of a cooperative agreement research program for exposure-dose reconstruction. The purpose of the program is to reconstruct, estimate, predict, and evaluate exposures to widely varying contaminant concentrations, exposure frequencies, and exposure durations, with widely varying emission characteristics that can be found at National Priorities List (NPL) sites, Resource Conservation and Recovery Act (RCRA) facilities, and other sites or facilities where a hazardous substance has been released into the environment.

ATSDR is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Environmental Health. (For ordering a copy of Healthy People 2000, see the section Where To Obtain Additional Information.)

Authority

This program is authorized under section 104(i)(1)(E) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986 [42 U.S.C. 9604(i)(1)(E)] and section 3019(b) (c) of the Resource Conservation and Recovery Act (RCRA), as amended (Hazardous and Solid Waste Amendments of 1984) [42 U.S.C. 6939a(b) and (c)].

Smoke-Free Workplace

ATSDR strongly encourages all grant and cooperative agreement 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 official public health agencies of the States or their bona fide agents or instrumentalities. This includes the District of Columbia, American Samoa, the Commonwealth of Puerto Rico, the Virgin Islands, the Federated States of Micronesia, Guam, the Northern Mariana Islands, the Republic of the Marshall Islands, the Republic of Palau, and 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.

Availability of Funds

Approximately $300,000 is available in FY 1998 to fund one award. It is expected that the award will begin on or about September 30, 1998, for a 12-month budget period and a project period of up to 5 years. The funding estimate may vary and is subject to change.

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 awardee, as the direct and primary recipient of ATSDR cooperative agreement 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. If contractors are proposed, justification must be provided along with the following: (1) Name of contractor, (2) method of selection, (3) period of performance, (4) detailed budget, (5) justification for use of contractor, and (6) assurance of non-conflict of interest.

Equipment may be purchased with cooperative agreement funds. However, the equipment proposed should be appropriate and reasonable for the activity to be conducted. The applicant, as part of the application process, should provide: (1) a justification for the need to acquire the equipment, (2) the description of the equipment, (3) the intended use of the equipment, and (4) the advantages/disadvantages of purchase versus lease of the equipment (if applicable). Requests for equipment...