

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