

violations of standards of conduct and other investigative matters within the jurisdiction of the OIG. They coordinate investigations and confer with HHS operating divisions, staff divisions, OIG counterparts and other investigative and law enforcement agencies. They prepare investigative and management improvement reports.

*C. Investigations Policy and Oversight.* This office is directed by the Assistant Inspector General for Investigations Policy and Oversight who leads outreach activities to State and local investigative agencies, and the general management functions of the Office of Investigations.

1. The office oversees State Medicaid fraud control units and is responsible for certifying and recertifying these units and for auditing their Federal funding. The office provides pertinent information from HHS records to assist Federal, State and local investigative agencies to detect, investigate and prosecute fraud. It manages the HHS Hotline to receive complaints and allegations of fraud, waste and abuse, and to refer the information for investigation, audit, program review, or other appropriate action. It coordinates with the GAO hotline and hotlines from other agencies.

2. The office maintains an automated data and management information system used by all OI managers and investigators. It provides technical expertise on computer applications for investigations and coordinates and approves investigative computer matches with other agencies.

3. The office develops general management policy for the OI. It develops and issues instructional media on detecting wrongdoing and on investigating and processing cases. The office reviews proposed legislation, regulations, policies and procedures to identify vulnerabilities and recommends modification where appropriate. It reviews investigative files in response to Privacy and Freedom of Information Act requests. It plans, develops, implements and evaluates all levels of employee training for investigations, management, support skills and other functions, and serves as OIG liaison to the Office of the Secretary for Freedom of Information and Privacy Act requests. It coordinates general management processes, e.g., compiles reports on the budget, on awards and on other personnel matters for OI as a whole; implements policies and procedures published in the OIG Administrative Manual; and processes procurement requests and other service related actions.

Dated: May 15, 1997.

**June Gibbs Brown**

*Inspector General.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Toxic Substances and Disease Registry

[Announcement Number 747]

#### Research Programs for the Development of Methods for the Toxicity Assessment of Environmental Chemical Mixtures

##### Introduction

The Agency for Toxic Substances and Disease Registry (ATSDR) announces the availability of fiscal year (FY) 1997 funds for a cooperative agreement based research program to develop methods to determine the health effects of hazardous substances in combination with other substances with which they are commonly found at National Priorities List (NPL) sites and facilities. Such combinations are referred to as "chemical mixtures." The objective of this program is to develop methods of toxicity assessment of chemical mixtures so as to promote public health practices based on current scientific understanding and to evaluate exposure to environmental chemicals of populations living in the vicinity of hazardous waste sites.

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 Healthy People 2000 priority areas of Environmental Health, Surveillance and Data Systems, and Occupational Safety and Health. (For ordering a copy of "Healthy People 2000," see the Section WHERE TO OBTAIN ADDITIONAL INFORMATION.)

##### Authority

This program is authorized under sections 104(i)(5)(A) and (15) 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)(5)(A) and (15)).

##### 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.

Funding preference will be given to the three applicants that are currently funded under this cooperative agreement program.

##### Smoke-Free Workplace

ATSDR strongly encourages all cooperative agreement recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. 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.

##### Availability of Funds

Approximately \$400,000 will be available in FY 1997 to fund up to 3 cooperative agreement awards. It is expected that the average award will be approximately \$125,000, ranging from \$50,000 to \$250,000. The awards are expected to begin on or about September 30, 1997, for a 12-month budget period within a project period of 5 years. Continuation awards within the project period will be made on the basis of satisfactory progress and availability of funds. The funding estimate above may vary and is subject to change.

##### Purpose

The purpose of this program to develop methods for the assessment of health effects of chemical mixtures found at hazardous waste sites. Specific areas of funded research may include to: (1) Identify hazards associated with chemical mixtures found in the environment that impact public health; (2) evaluate potential toxicity to human populations from exposure to chemical mixtures; (3) study the pharmacokinetic behavior of chemical mixtures; (4) study the various endpoints that would be affected and the target organs that would be impacted; (5) study the mechanisms of action, progression and repair of the injury caused by chemical

mixtures; (6) identify biomarkers (specific and generic) that would allow the determination of the health of an organism; (7) develop qualitative and quantitative health assessment methods for chemical mixtures; and (8) develop methods for assessments of multiple health effects.

#### Program Requirements

ATSDR will provide financial assistance for developing assessment methods and/or conduct of experimental animal research. The objective of the assessment component is to solve the immediate problems posed to the Agency while the research component allows the development of generic guidance for chemical mixtures through a long term plan. Both of these activities are necessary and complementary for the successful development of a viable research program. This research program for chemical mixtures would improve the knowledge base on the linkage between the uptake of hazardous substances and their health consequences, and reduce the uncertainties in the public health assessments performed at hazardous substance releases and facilities.

In conducting activities to achieve the objectives of this program, the recipient will be responsible for the activities listed under A., below, and ATSDR will be responsible for conducting activities listed under B., below:

##### A. Recipient Activities

1. Develop a detailed program of research to investigate toxicity of chemical mixtures found at hazardous waste sites and facilities based on the specific objectives listed in the **Purpose** section of this announcement.

2. Establish and maintain a research plan and system for collecting information.

3. Provide technical and research updates to ATSDR on a quarterly basis. Also, provide a formal annual report of research and financial status of the project.

4. Conduct workshops or symposia (periodically) to exchange current information, opinions and research findings on mixtures.

5. Develop and implement mechanisms to assure the publication of research supported through this cooperative agreement.

6. Demonstrate the potential application of research findings to public health assessment at hazardous waste sites.

##### B. ATSDR Activities

1. Provide consultative, administrative and technical assistance,

as needed, in the development of the program of research activities.

2. Conduct technical peer review of protocols, studies and results according to ATSDR established policies.

3. Collaborate with the recipient in the establishment of a research plan and system for collecting/monitoring data and developing periodic reports on activity.

4. Collaborate on the preparation of reports and briefing materials on a timely basis to assist recipient in presenting and writing publications including abstracts, and journal articles.

5. Participate and collaborate with the applicant in planning workshops or symposia to exchange current information, opinions, and research findings on mixtures.

#### Application Content

In a narrative form, the applicant shall submit sufficient supporting evidence to satisfy all items in the EVALUATION CRITERIA section of this announcement. The applications submitted under this cooperative agreement will contain a testing program to distinguish health effects posed by exposure to mixtures of hazardous chemicals. It is anticipated that the application received will contain technical proposal(s) that may cover up to a five-year period.

#### Evaluation Criteria

Applications will be reviewed and evaluated for scientific and technical merit according to the following criteria:

##### A. Scientific and Technical Review Criteria of New Applications

###### 1. Appropriateness and Knowledge of Study Design—25%

The extent to which the applicant's proposal addresses: (a) Rationale for the proposed study design; (b) a plan for exposure assessment and/or a plan for evaluating adverse health outcomes; and (c) a detailed plan for analysis of the data.

###### 2. Proposed Study—25%

The adequacy of the proposal relevant to: (a) The study purpose, objectives, and rationale; (b) the quality of program objectives in terms of specificity, measurability, and feasibility; (c) the specificity and feasibility of the applicant's timetable for implementing program activities and timely completion of the study; (d) the likelihood of the applicant completing proposed program activities and attaining proposed objectives based on the thoroughness and clarity of the overall program; and (e) the degree to which the applicant has met the CDC

Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed project. This includes, (1) the proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation; (2) the proposed justification when representation is limited or absent; (3) a statement as to whether the design of the study is adequate to measure the differences when warranted; and (4) a statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

###### 3. Relationship to Initiative—15%

The extent to which the application addresses the areas of investigation outlined by ATSDR. (See examples under PURPOSE section of this announcement).

###### 4. Quality of Data Collection—15%

The extent to which: (a) The study ascertains the information necessary to meet the objectives, including (but not limited to) information on pathways of exposure, confounding factors, and biomedical testing; (b) the quality control and quality assurance of questionnaire data are provided, including (but not limited to) interviewer training and consistency checks of data; (c) the laboratory tests (if applicable) are sensitive and specific for the chemical or disease outcome of interest; and (d) the quality control, quality assurance, precision and accuracy of information for the proposed tests are provided and acceptable.

###### 5. Applicant Capability and Coordination Efforts—10%

The extent to which the proposal has described: (a) The capability of the applicant's administrative structure to foster successful scientific and administrative management of a study; (b) the capability of the applicant to demonstrate an appropriate plan for interaction with the community; and (c) the suitability of facilities and equipment available.

###### 6. Program Personnel—10%

The extent to which the proposed program staff is qualified and appropriate, and the time allocated for them to accomplish program activities is adequate.

###### 7. Program Budget—(NOT SCORED)

The extent to which the budget is reasonable, clearly justified, and

consistent with intended use of cooperative agreement/grant funds.

#### 8. *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.

#### *B. Review of Continuation Applications*

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

1. Satisfactory progress has been made in meeting project objectives;
2. Objectives for the new budget period are realistic, specific, and measurable;
3. 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
4. The budget request is clearly justified and consistent with the intended use of grant funds.

#### **Technical Reporting Requirements**

Quarterly progress reports are required. An annual progress report is due with submission of the application for continuation. Annual Financial Status Reports (FSRs) are due 90 days after the end of each budget period. The final financial status and performance reports are required 90 days after the end of the project period.

#### **Executive Order 12372**

Applications are subject to the Intergovernmental Review of Federal Programs as governed by Executive Order 12372. E.O. 12372 sets up a system for State and local government review of proposed Federal assistance applications. Applicants (other than federally recognized Indian tribal governments) should contact their State Single Point of Contact (SPOC) as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC for each affected State. A current list of SPOCs is included in the application kit. If SPOCs have any State process recommendations on applications submitted to CDC, they should forward them to Ron Van Duyne, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 321, Mailstop E-13, Atlanta, Georgia 30305, no later than 45 days after the

application deadline. The granting agency does not guarantee to "accommodate or explain" State process recommendations it receives after that date.

Indian tribes are strongly encouraged to request tribal government review of the proposed application. If tribal governments have any tribal process recommendations on applications submitted to CDC, they should forward them to Ron Van Duyne, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 321, Mailstop E-13, Atlanta, Georgia 30305, no later than 45 days after the application deadline. The granting agency does not guarantee to "accommodate or explain" for tribal process recommendations it receives after that date. (By formal agreement, the CDC Procurement and Grants Office will act on behalf of and for ATSDR on this matter.)

#### **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**

##### *A. Technical Review*

All protocols, studies, and results of research that ATSDR carries out or funds in whole or in part will be reviewed to meet the requirements of CERCLA section 104(i)(13). ATSDR funded or conducted studies must be:

1. Reported or adopted only after appropriate review;
2. Technically reviewed within a period of 60 days to the maximum extent practical; and
3. Reviewed by no fewer than three nor more than seven reviewers who are selected by the Administrator, ATSDR, are disinterested scientific experts, have a reputation for scientific objectivity, and lack institutional ties with any persons involved in the conduct of the study or research under review.

##### *B. Paperwork Reduction Act*

Projects that involve collection of information from 10 or more individuals and funded by cooperative agreements will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

OMB clearance will be requested, if required.

#### *C. Protection of Human Subjects*

If the proposal involves research on human subjects, the applicant must comply with 45 CFR part 46, regarding the protection of human subjects. Assurances must be provided that the project or activity will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing evidence of this assurance in accordance with the appropriate guidelines and forms 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 American Indian community is involved, its tribal government must also approve that portion of the project applicable to it.

#### *D. Women, Racial and Ethnic Minorities*

It is the policy of CDC and ATSDR to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-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, Alaskan Native, Asian, Pacific Islander, Black and Hispanic. 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 exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. In conducting review for scientific merit, review groups will evaluate proposed plans for inclusion of minorities and both sexes as part of the scientific assessment and scoring. 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, pages 47947-47951, Friday, September 15, 1995.

#### *E. Cost Recovery*

CERCLA, as amended by SARA, provides for the recovery of costs incurred for health assessments and health effects studies 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 cost 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 10 years after submission of a final Financial Status Report (FSR), 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.

#### *F. 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 technical review (ATSDR selected reviewers), release of data, 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-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.

3. State that whenever any work subject to this copyright policy may be developed in the course of a grant by a contractor under a 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.

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.

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

#### *G. Animal Subjects*

If the proposed project involves research on animal subjects, the applicant must comply with the "PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions." An applicant organization proposing to use vertebrate animals in DHHS-supported activities must file an Animal Welfare Assurance with the Office for Protection from Research Risks at the National Institutes of Health.

#### **Application Submission Deadline**

The original and two copies of the application Form PHS 5161-1 (Revised 7/92, OMB Number 0937-0189) must be submitted to Ron Van Duyne, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 321, Mail Stop E-13, Atlanta, Georgia 30305, on or before July 15, 1997. (By formal agreement, the CDC Procurement and Grants Office will act on behalf of and for ATSDR on this matter.)

#### *A. Deadline*

Applications shall be considered as meeting the deadline if they are either:

1. Received on or before the deadline date, or

2. 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.)

#### *B. Late Applications*

Applications which do not meet the criteria in A.1. or A.2. 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 an application kit, call (404) 332-4561. You will be asked your name, address, and telephone number and will need to refer to Announcement 747. In addition, this announcement is also available through the CDC Home Page on the Internet. The address for the CDC Home Page is <http://www.cdc.gov>. If you have questions after reviewing the contents of all the documents, business management assistance may be obtained from Kathy Raible, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers

for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mail Stop E-13, Atlanta, Georgia 30305, telephone (404) 842-6803.

Programmatic assistance may be obtained from Dr. Moiz Mumtaz, Project Officer, Division of Toxicology, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE., Mail Stop E-29, Atlanta, Georgia 30333, telephone (404) 639-6306.

Please refer to Announcement 747 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) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

Dated: May 29, 1997.

**Georgi Jones,**

*Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Disease Control and Prevention**

[INFO-97-12]

### **Proposed Data Collections Submitted for Public Comment and Recommendations**

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639-7090.

*Comments are invited on:* (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the