

information and to request an application kit, call 1-888-GRANTS4 (1-888-472-6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Nelda Y. Godfrey, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone number: (770) 488-2722, email address: nag9@cdc.gov.

For program technical assistance, contact: Juan Reyes, Director, Office of Regional Operations, Agency for Toxic Substances and Disease Registry, 1600 Clifton Rd., NE, MS-E42, Atlanta, GA 30329, Telephone number: (404) 498-0537, email address: jur2@cdc.gov.

Dated: June 20, 2001.

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

Agency for Toxic Substances and Disease Registry

[Program Announcement 01165]

Thimerosal Pharmacokinetics: Assessment of the Distribution, Metabolism and Excretion; Notice of Availability of Funds

A. Purpose

The Agency for Toxic Substances and Disease Registry (ATSDR) announces the availability of fiscal year (FY) 2001 funds for a grant program for Thimerosal Studies as part of the applied research program. This program addresses the "Healthy People 2010" focus area(s) of Environmental Health.

The purpose of this program is to define and characterize the appropriate pharmacokinetics of both methyl mercury and thimerosal distribution, metabolism, and elimination that are needed to accurately characterize the comparative neurotoxicity of these substances and develop recommendations for future extrapolation of these results to possible human exposure scenarios.

B. Eligible Applicants

Applications may be submitted by official public health agencies of the States, or their bonafide agents. This includes the District of Columbia, American Samoa, Guam, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Federated States of Micronesia, the Virgin Islands, the Federated States of Marshall Island, the Republic of Palau, federally-recognized Indian tribal governments, public and private non-profit universities and colleges.

C. Availability of Funds

Approximately \$130,000 is available in FY 2001 to fund one award. It is expected that the award will begin on or about September 30, 2001, and will be made for a 12-month budget period within a project period of one year. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports 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. At the completion of the project, the equipment must be returned to ATSDR.

D. Program Requirements

The objectives of this program are to conduct research studies to achieve the following: (1) Animal Model and Dose Selection studies including literature search, determine appropriate in vitro tests, animal model and doses; (2) Thimerosal cleavage kinetics including investigating in vitro (serum or blood) reaction, determine the role of liver in metabolism of thimerosal; (3) Model dependent kinetic parameters including tissue partition coefficients of

thimerosal and ethyl mercury, time course studies for levels of thimerosal and ethyl mercury in blood, brain, fat, liver and muscle; (4) Model development and analysis including development of a pharmacokinetic model for thimerosal; and (5) Develop recommendations for extrapolating these results to human exposure scenarios.

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the following activities:

1. Identification and description of specific parameters that are necessary to accurately characterize the distribution, metabolism, and elimination associated with methyl mercury toxicity;
2. Identification and characterization of the metabolic pathways and sequences associated with conversion of thimerosal to the toxic inorganic mercury species (Hg⁺⁺);
3. Characterization of tissue levels and time-course for thimerosal, ethyl mercury, and Hg⁺⁺ following parenteral exposure to thimerosal; and
4. Publish the findings and results as journal article(s).

E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan.

F. Submission and Deadline

Submit the original and five copies of PHS 398 (OMB Number 0937-0189) on or before August 15, 2001. Submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

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 independent 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.)
- Late Applications:* Applications which do not meet the criteria in 1. or 2. above are considered late applications, will not be considered, and will be returned to the applicant.

G. Evaluation Criteria

Each application will be evaluated individually against the following criteria by an independent review group appointed by ATSDR:

1. Proposed Research—50 percent

The extent to which the applicant's project addresses:

- a. 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)(25 percent);
- b. The technical merit of the methods and procedures (analytic procedures should be state of the art), 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 (15 percent);
- c. The proposed project schedule, including clearly established obtainable project objectives for which progress toward attainment can and will be measured including plans for publishing research results in peer reviewed journals (10 percent); and

2. Program Personnel—45 percent

Because of the importance and potential impact of the outcome of this project on a number of public health programs:

- a. The Principal Investigator must be a recognized expert on organic and inorganic mercury (20 percent); and
- b. The Principal Investigator must have experience, validated by publication, in working with Thimerosal (10 percent); and
- c. Commitment and ability of the Principal Investigator and his/her Associates to devote adequate time and effort to provide effective leadership (15 percent).

3. Institutional Resources and Commitment—5 percent

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.

4. Program Budget—(NOT SCORED)

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

5. Human Subjects—(NOT SCORED)

Does the application adequately address the requirements of Title 45

CFR Part 46 for the protection of human subjects?

H. Other Requirements**Technical Reporting Requirements**

Provide CDC with original plus two copies of

1. annual progress reports;
2. financial status report, no more than 90 days after the end of the budget period; and
3. final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application kit.

- AR-3 Animal Subjects Requirements
- AR-7 Executive Order 12372 Review
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobby Restrictions
- AR-17 Peer and Technical Reviews of Final Reports of Health Studies—ATSDR
- AR-18 Cost Recovery—ATSDR
- AR-19 Third Party Agreements—ATSDR
- AR-22 Research Integrity

I. Authority and Catalog of Federal Domestic Assistance Number

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)]. The Catalog of Federal Domestic Assistance number is 93.161.

J. Where To Obtain Additional Information

This and other ATSDR announcements can be found on the CDC home page Internet address—<http://www.cdc.gov>. Click on "Funding" then "Grants and Cooperative Agreements."

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For program technical assistance, contact(s): Dr. Dennis Jones, Division of Toxicology, ATSDR, 1600 Clifton Road, N.E., Mail Stop E-29, Atlanta, Georgia 30333, Telephone number: 404-498-0160, Email address: dej2@cdc.gov or Dr. Moiz Mumtaz, Division of Toxicology, 1600 Clifton Road, N.E., Mail Stop E-29, Atlanta, Georgia 30333, Telephone number: 404-498-0727, Email address: mgm4@cdc.gov.

Dated: June 20, 2001.

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**Agency for Toxic Substances and Disease Registry****Public Meeting of the Inter-tribal Council on Hanford Health Projects (ICHHP) in Association With the Citizens Advisory Committee on Public Health Service (PHS) Activities and Research at Department of Energy (DOE) Sites: Hanford Health Effects Subcommittee**

Name: Public meeting of the Inter-tribal Council on Hanford Health Projects (ICHHP) in association with the Citizens Advisory Committee on PHS Activities and Research at DOE Sites: Hanford Health Effects Subcommittee (HHES).

Time and Date: 9 a.m.—4:30 p.m., July 25, 2001.

Place: Tamastlikt Cultural Institute, 72789 Highway 331, Pendleton, OR. Telephone: (541) 276-2323.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Background: A Memorandum of Understanding (MOU), signed in October 1990 and renewed in September 2000, between ATSDR and DOE delineates the responsibilities and procedures for ATSDR's public health