

29. Turtle Mountain Community College,  
Belcourt, North Dakota  
30. United Tribes Technical College  
Bismarck, North Dakota  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Toxic Substances and Disease Registry

[Program Announcement 99076]

#### Human Health Studies—Applied Research and Development; Notice of Availability of Funds

##### A. Purpose

The Agency for Toxic Substances and Disease Registry (ATSDR) announces the availability of fiscal year (FY) 1999 funds for a grant program entitled Human Health Studies—Applied Research and Development. This program addresses the “Healthy People 2000” priority area of Environmental Health.

The purpose of this program is to fill gaps in knowledge regarding human health effects of hazardous substances focusing on those health conditions prioritized by ATSDR. The ATSDR Priority Health Conditions are (in alphabetical order): (1) Birth defects and reproductive disorders; (2) cancers (selected anatomic sites); (3) immune function disorders; (4) kidney dysfunction; (5) liver dysfunction; (6) lung and respiratory diseases; and (7) neurotoxic disorders. The program will focus upon sensitive human populations (women, children and elderly), the use of innovative methodologies to fill data gaps identified through ATSDR’s public health assessments and consultations at hazardous waste sites, ecologic studies using data from multiple sites to assess the health status of several communities, and analytical studies, including meta-analysis of existing sets of human data.

Research activities may include, but not be limited to the following: (1) Epidemiological studies, (2) health outcomes studies, (3) further analysis of existing human data sets, (4) identification, validation, and development of biomarkers of exposure, susceptibility, and effect, and (5) further evaluating the link or lack of linkage between specific hazardous substances and specific health effects.

##### B. Eligible Applicants

Assistance will be provided only to official public health agencies of 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 establish that they meet their respective state’s definition of a state entity or political subdivision to be considered an eligible applicant.

##### C. Availability of Funds

Approximately \$350,000 is available in FY 1999 to fund one or two awards. The award(s) is expected to begin on or about September 30, 1999, and will be made for a 12-month budget period within a project period of up to three years. Funding estimates are subject to 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 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, justification must be provided which should include a cost comparison of purchase versus lease, and title will be retained by ATSDR.

This program does not require in-kind support or matching funds, however, the applicant should describe any in-kind support in the application.

##### Funding Priorities

Priority will be given for studies which address one or more of the following areas of investigation:

1. Evaluate the occurrence of adverse health effects in sensitive populations. This will include the evaluation of the incidence or prevalence of a disease, disease symptoms, self-reported health concerns, or biological markers of disease, susceptibility, or exposure. Sensitive populations are persons who are more susceptible to developing adverse health effects resulting from exposures to hazardous substances [e.g.,

extremes in age (children and the elderly), other medical conditions, genetic factors, dietary or nutritional deficiencies, poverty, or racial injustice].

2. Identify risk factors for adverse health effects in populations. This will include hypothesis generating cohort or case-control studies on potentially impacted populations to identify linkages between exposure to hazardous substances and adverse health effects and those risk factors which may be impacted by prevention actions.

##### D. Application Content

Use the information in the 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.

The application should be presented in a manner that demonstrates the applicant’s ability to address environmental health problems.

The applicant’s protocol should contain (when applicable) consent forms and questionnaires, baseline morbidity and mortality information, procedures for collecting biological and environmental specimens and for conducting laboratory analysis and evaluation of the test results of biological specimens, statistical and epidemiological analysis of study information, and a description of the safeguards for protecting the confidentiality of individuals on whom data are collected.

The application pages must be clearly numbered, and a complete index to the application and its appendices must be included. A less than 200 word abstract of the proposed project should be supplied with the application. The original and two copies of the application must be submitted unstapled and unbound. All material must be typed single-spaced, with un-reduced font on 8½” by 11” paper, printed on one side, and with one inch margins.

##### E. Submission and Deadline

###### Application

Submit the original and two copies of PHS 5161-1 (OMB Number 0937-0189). Forms are in the application kit. On or before June 18, 1999, submit the application to:

Nelda Godfrey, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99076, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Suite 3000, Atlanta, GA 30341-4146.

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 orderly processing. (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 (a) or (b) above are considered late applications, will not be considered, and will be returned to the applicant.

## F. Evaluation Criteria

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

### Review Criteria

#### 1. Appropriateness and Knowledge of Study Design (25 percent)

Extent to which the applicant's proposal addresses: (a) The scientific merit of the proposed project, including the novelty, originality and feasibility of the approach and the adequacy of the design; (b) the technical merit of the proposed project, including the degree to which the project can be expected to yield or demonstrate results that will be useful and desirable in furthering the program objectives; and (c) the proposed project schedule, including clearly established and obtainable project objectives for which progress toward attainment can and will be measured.

#### 2. Proposed Study (25 percent)

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 agency 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 research. 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 differences when warranted.

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 percent)

Extent to which the application addresses the areas of investigation outlined.

#### 4. Quality of Data Collection (15 percent)

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 analyte 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. Capability and Coordination Efforts (10 percent)

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 or to be purchased for the project.

#### 6. Program Personnel (10 percent)

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

#### 7. Budget (Not scored)

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

#### 8. Human Subjects (Not scored)

Does the application adequately address the requirements of 45 CFR part 46 for the protection of human subjects? Are procedures adequate for the

protection of human subjects?

Recommendations on the adequacy of protections include: (1) Protections appear adequate and there are no comments to make or concerns to raise, or (2) protections appear adequate, but there are comments regarding the protocol, or (3) protections appear inadequate and the Objective Review Group (ORG) has concerns related to human subjects; or (4) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are inadequate as to make the entire application unacceptable.

## G. Other Requirements

### Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Progress reports (annual);
2. Financial status report, no more than 90 days after the end of the budget period; and
3. Final financial status and performance reports, no more than 90 days after the end of the project period.

Send all reports to: Nelda Y. Godfrey, Grants Management Specialist Grants Management Branch Procurement and Grants, Office, Grant Number: \_\_\_, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Suite 3000, Atlanta, GA 30341-4146.

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

AR-1—Human Subjects Requirements

AR-2—Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR-7—Executive Order 12372 Review

AR-9—Paperwork Reduction Act

AR-10—Smoke-Free Workplace Requirements

AR-11—Healthy People 2000

AR-12—Lobbying 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

ATSDR

AR-18—Cost Recovery—ATSDR

AR-19—Third Party Agreements—ATSDR

## H. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 104(i)(1)(E), (7), 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)(1)(E), (7), and (15)). The

Catalog of Federal Domestic Assistance number is 93.161.

### **I. Where To Obtain Additional Information**

To receive additional written 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.

See also the CDC home page on the Internet for a complete copy of the announcement: <http://www.cdc.gov>.

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, Announcement 99076, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Suite 3000, Atlanta, GA 30341-4146, telephone (770) 488-2722, E-mail address [NAG9@cdc.gov](mailto:NAG9@cdc.gov).

For program technical assistance, contact: Jeffrey A. Lybarger, M.D., Director, Division of Health Studies, Agency for Toxic Substances and Disease Registry, Executive Park, Building 4 Suite 2300, Atlanta, GA 30305, telephone (404) 639-6200, E-mail address [JAL2@cdc.gov](mailto:JAL2@cdc.gov).

Dated: March 26, 1999.

**Georgi Jones,**

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

### **Background**

Since 1993, ATSDR has applied this paradigm to the evaluation of seven priority health conditions. This purpose of these evaluations was to support the development of a body of knowledge about the interrelationships of the model parameters and thus the relationship between exposures to hazardous substances and adverse health effects. Health studies were conducted and supported predominantly evaluating a cross-section of the general public living near waste sites. It is possible, however, that the occurrence of adverse health effects and subclinical toxic effects are more common among a small number of sensitive people. People may be more likely to experience adverse health effects resulting from exposures to hazardous substances if they have underlying illnesses, suffer effects of poverty such as poor diet or education about health seeking behaviors, have limited physiological reserve of organ function due to being very young or very old, or are limited by environmental injustices. The application of this paradigm to selected groups of persons with hypothesized sensitivities would assist in identifying

affected people and evaluating risk modifying factors.

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

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

#### **Inter-Tribal Council on Hanford Health Projects; Notice of Meeting**

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 (HHES).

The Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC) announce the following meeting.

*Name:* Public meeting of the ICHHP in association with the Citizens Advisory Committee on PHS Activities and Research at DOE Sites: HHES.

*Time and Date:* 9 a.m.-4 p.m., May 12, 1999.

*Place:* Tamastslikt Cultural Institute, Umatilla Indian Reservation, 72777 Highway 331, Pendleton, Oregon 97801.

*Status:* Open to the public, limited only by the space available. The meeting room accommodates approximately 35 people.

*Background:* Under a Memorandum of Understanding (MOU) signed in October 1990 and renewed in November 1992 between ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or "Superfund"). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

In addition, under an MOU signed in December 1990 with DOE and replaced by an MOU signed in 1996, the Department of Health and Human Services (HHS) has been given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production and use. HHS has delegated program responsibility to CDC.

Community Involvement is a critical part of ATSDR's and CDC's energy-related research and activities and input from members of the ICHHP is part of these efforts. The ICHHP will work with the HHES to provide input on American Indian health effects at the Hanford, Washington site.

*Purpose:* The purpose of this meeting is to address issues that are unique to tribal involvement with the HHES, including discussion on Hanford Thyroid Disease Study results, update on tribal cooperative agreements, and development of a National Research Agenda with tribal input.

*Matters to Be Discussed:* Agenda items will include a dialogue on issues that are unique to tribal involvement with the HHES. This will include updating tribal members of the cooperative agreement activities in environmental health capacity building and providing support for tribal involvement in and representation on the HHES.

Agenda items are subject to change as priorities dictate.

*Contact Persons for More Information:*

Leslie C. Campbell, Executive Secretary HHES, or Marilyn Palmer, Committee Management Specialist, Division of Health Assessment and Consultation, ATSDR, 1600 Clifton Road, NE, M/S E-56, Atlanta, Georgia 30333, telephone 1-888/42-ATSDR (28737), fax 404/639-6075.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: March 25, 1999.

**Carolyn J. Russell,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).*

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

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

#### **Citizens Advisory Committee on Public Health Service (PHS) Activities and Research at Department of Energy (DOE) Sites: Hanford Health Effects Subcommittee**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC) announce the following meeting.

*Name:* Citizens Advisory Committee on PHS Activities and Research at DOE Sites: Hanford Health Effects Subcommittee (HHES).

*Times and Dates:* 8:30 a.m.-5 p.m., May 13, 1999; 8:30 a.m.-4 p.m., May 14, 1999.