

provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel ZDK1 GRB-1(M2)P.  
*Date:* April 8-9, 1999.

*Time:* April 8, 1999, 7:30 pm to Adjournment.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

*Contact Person:* Carolyn Miles, Scientific Research Administrator, Review Branch, DEA, NIDDK, Natcher Building, Room 6AS-37, National Institutes of Health, Bethesda, MD 20892, (301) 594-7791.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, ZDK1 GRB-8(M1)P.  
*Date:* April 14-16, 1999.

*Time:* April 14, 1999, 8:30 am to adjournment.

*Agenda:* To review and evaluate grant applications.

*Place:* Crowne Plaza Hotel, 14th & K Streets, NW., Washington, DC 20005.

*Contact Person:* Roberta J. Haber, Scientific Research Administrator, Review Branch, DEA, NIDDK, Natcher Building, Room 6AS-25N, National Institutes of Health, Bethesda, MD 20892, (301) 594-8898.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: March 2, 1999.

**LaVerne Y. Stringfield,**

*Committee Management Officer, NIH.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Program Announcement 99018]

#### Water Intervention Studies To Determine the Fraction of Gastrointestinal Illness Attributable to Drinking Water; Notice of Availability of Funds

##### A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the

availability of fiscal year (FY) 1999 funds for a cooperative agreement program for water intervention studies to determine the amount of gastrointestinal illness attributable to drinking water. This program addresses the "Healthy People 2000" priority area(s) of Immunization and Infectious Diseases. The purpose of the program is to provide assistance for conducting two studies: one in a municipality receiving drinking water from a conventionally treated, surface water source and a second in a municipality with a ground water source. Since the amount of waterborne disease in a population can most directly be estimated by determining the rate of gastrointestinal illness in the community and multiplying this by an estimate of the percentage of illness that is attributable to water, these studies will involve measuring both of these parameters in a population.

##### B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

**Note:** Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

##### C. Availability of Funds

Approximately \$1,800,000 is available in FY 1999 to fund approximately two awards. It is expected that the average award will be \$900,000 ranging from \$900,000 to \$1,800,000. It is expected that the awards will begin on or about April 15, 1999, and will be made for a 12-month budget period within a project period of up to two years. The funding estimate 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.

##### D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient shall be responsible for the activities under "Recipient Activities" below and CDC shall be responsible for the activities under "CDC Activities" below:

##### Recipient Activities

1. Develop a study design and protocol.
2. Identify a community where residences are served by a single water utility.
3. Conduct a household intervention trial that allows determination of what proportion of illness is attributable to drinking water. For example, studies have been conducted using intervention devices installed in household plumbing to eliminate viable pathogens. Investigators may want to consider conducting a randomized, blinded trial in which control households receive a sham device.
4. Measure disease outcomes among study participants. Examples of such outcomes could include: (a) clinically defined diarrhea, (b) vomiting, (c) laboratory studies of stool from cooperative, ill participants that would be tested broadly for bacterial, parasitic, and viral pathogens, and (d) antibody response to specific pathogens such as *Cryptosporidium* and caliciviruses in study participants willing to give serum.
5. Collaborate with the water utility, the American Water Works Research Foundation (AAWRF) and its collaborators, and others as appropriate to evaluate the relationship between health outcomes and physical and microbial water quality data.
6. The recipient(s) will develop a Quality Assurance Project Plan (QAPP) and will coordinate the plan with EPA to ensure that the results are of high quality.
7. Determine rates of relevant outcomes in the community in which the intervention study is being conducted. For example, this could be done through ongoing, cross-sectional, random telephone surveys of the population served by the water utility during the study period. Examples of outcomes that could be measured include signs and symptoms of gastrointestinal illness, water consumption patterns, days of work or school missed, etc.
8. Publish the results of the study.

##### CDC Activities

1. CDC and EPA are available to provide technical assistance in the design and conduct of the research. If needed, this may include:
  - a. providing technical consultation in the design and conduct of the project, including data collection, evaluation, and analytic approach;
  - b. facilitating exchange of information among collaborators;
  - c. performing selected laboratory tests;

d. participating in analysis of research data and the interpretation and dissemination of research findings; and

e. providing educational materials, including working with grantees to develop new materials that might be needed.

2. Assist in the development of a research protocol for IRB review by all institutions participating in the research project. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

### 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. The narrative should be no more than 25 double-spaced pages, printed on one side, with one inch margins, and un-reduced font.

### F. Submission and Deadline

#### *Letter of Intent (LOI)*

In order to assist CDC in planning and executing the evaluation of applications submitted under this Program Announcement, all parties intending to submit application(s) are requested to inform CDC of their intention to do so as soon as possible but not later than 30 business days prior to the application due date. Notification should include (1) name and address of institution, (2) name, address, and phone number of contact person, and (3) the name and address of the water utility the applicant intends to collaborate with if awarded this cooperative agreement, and (4) information regarding whether the source water for the households the applicant intends to study is from a ground water source or a surface water source. Notification can be provided by facsimile, postal mail, or electronic mail (E-mail) to Deborah Levy, Ph.D., National Center for Infectious Diseases, 4770 Buford Highway, N.E., Mailstop F-22, Atlanta, Georgia 30341. Facsimile: (770) 488-7761. E-mail address: DEL7@cdc.gov.

### Application

Submit the original and five copies of PHS-398 (OMB Number 0925-0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398). Forms are in the application kit. On or before May 14, 1999, submit the application to: Andrea Wooddall, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office,

Announcement 99018, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, Georgia 30341

If your application does not arrive in time for submission to the independent review group, it will not be considered in the current competition unless you can provide proof that you mailed it on or before the deadline (i.e., receipt from U.S. Postal Service or a commercial carrier; private metered postmarks are not acceptable).

The application should identify a water utility that:

1. For surface water sites: (a) serves a population of  $\geq 50,000$  persons, (b) has a surface water source known to be challenged with highly variable water quality which at times has evidence of substantial fecal contamination, (c) is served by only one water treatment plant and that plant employs standard, conventional treatment (i.e. coagulation, sedimentation, filtration, and chlorine disinfection), (d) has source water that is difficult to treat (e.g. average finished water turbidity  $\geq 0.1$  NTU and/or occasional spikes of finished water turbidity or particle counts), and (e) generally does not place treated water in a reservoir for more than 24 hours prior to entering the distribution system; or

2. For ground water sites: (a) serves a population of  $\geq 25,000$  persons, (b) is served solely by ground water, (c) is not under the direct influence of surface water, and (d) has information available that will allow inference on likelihood of microbial source water contamination, e.g. multiyear records of microbial source water quality and/or well characterized hydrogeology (such as knowledge of recharge area<sup>1</sup> and sources of fecal contamination), (e) is disinfected, and (f) is not subject to membrane filtration or softening; and

3. Contain written assurance from the water utility that it will collaborate with the grantee, CDC, EPA, AWWARF and its cooperators in the collection and analysis of physical and microbial water quality data. The reason for this requirement is that it will be useful to examine the relationship between water quality indicators and health outcomes. AWWARF will be simultaneously issuing requests for proposals (RFPs) for the collection and analysis of physical and microbiological water quality data from the utilities participating in the studies funded through this CDC cooperative agreement. One of these

<sup>1</sup>The recharge area of a well is the land surface from which water that is drawn into the well originated. Typical sources of human fecal contamination include septic systems, sewers (which invariably leak), and rivers subject to sewage treatment plant discharges.

RFPs will be for the surface water site (RFP 2850) and the other for the ground water site (RFP 2851). These AWWARF RFPs can be found on the World Wide Web at: <http://www.awwarf.com/newprojects/rfps/98rfps.htm>. The types of water quality data collected will be determined by AWWARF, EPA, and the grantee in collaboration with the utility. It would be advantageous if the water utility continuously monitors turbidity or particle counts of water coming from each individual filter bed. Such monitoring would need to be accompanied by frequent equipment calibration for quality assurance and quality control; and

4. Provide information regarding the number of households the applicant anticipates recruiting into the study and the anticipated drop out rate. The study should have power to detect an attributable fraction of gastrointestinal illness due to drinking water that is less than 15 percent. It would be advantageous to be able to detect an attributable fraction of gastrointestinal illness due to drinking water that is less than or equal to 10 percent.

### G. Evaluation Criteria

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

#### 1. Background and Need (10 points)

Extent to which applicant's discussion of the background for the proposed project demonstrates a clear understanding of the purpose and objectives of this cooperative agreement program.

#### 2. Capacity and Personnel (35 points total)

a. Extent to which applicant describes adequate resources and facilities (both technical and administrative) for conducting the project. (10 points)

b. Extent to which applicant documents that professional personnel involved in the project are qualified and have past experience and achievements in research related to that proposed as evidenced by curriculum vitae, publications, etc. (10 points)

c. Extent to which applicant includes letters of support from the proposed water utility, non-applicant organizations, individuals, etc. Extent to which the letters clearly indicate commitment to participate as described in the operational plan, which must include the water utility's intent to provide specific water quality data and collaborate with others involved in the study. If appropriate, the extent to which letters from non-participating local and State health departments express their support of the operational

plan (15 points). Do not include letters of support from CDC or EPA personnel.

3. Objectives and Technical Approach (55 points total)

a. Extent to which applicant adequately describes specific objectives of the proposed project which are consistent with the purpose and goals of this cooperative agreement program and which are measurable and time-phased. (10 points)

b. Extent to which applicant presents a detailed operational plan for initiating and conducting the project, which clearly and appropriately addresses all "Recipient Activities." Extent to which applicant clearly identifies specific assigned responsibilities for all key professional personnel. Extent to which the plan clearly describes applicant's technical approach/methods for conducting the proposed studies and extent to which the plan is adequate to accomplish the objectives. Extent to which the described cohort and water supply will be appropriate for achieving the goals of this request for assistance. Extent to which applicant describes specific study protocols or plans for the development of study protocols that are appropriate for achieving project objectives. If there is a laboratory component to the proposal, the extent to which plans for ensuring quality of measurements are included. If the proposed project involves human subjects, whether or not exempt from the DHHS regulations, the extent to which adequate procedures are described for the protection of human subjects. This specifically includes working with CDC and EPA to obtain human subjects clearances and approval for data collection activities.

**Note:** Objective Review Group (ORG) 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 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. Extent 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 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, 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. (25 points)

c. Extent to which the applicant describes adequate and appropriate collaboration with CDC, EPA and/or others (e.g. water utilities and health departments) during various phases of the project. (10 points)

d. Extent to which the applicant provides a detailed and adequate plan for evaluating study results and for evaluating study results for evaluating progress toward achieving project objectives. (10 points)

4. Budget (not scored)

Extent to which the proposed budget is reasonable, clearly justifiable, and consistent with the intended use of grant/cooperative agreement funds.

#### H. 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: Andrea Wooddall, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment 1, 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 Requirements.
- AR-10 .... Smoke-Free Workplace Requirements.
- AR-11 .... Healthy People 2000.
- AR-12 .... Lobbying Restrictions.
- AR-14 .... Accounting System Requirements.
- AR-15 .... Proof of Non-Profit Status.

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

This program is authorized under the Public Health Service Act Sections 301(a)[42 U.S.C. 241(a)], 317(k)(1)(2), [42 U.S.C. 247b (k)(1)] and [247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

#### J. Where To Obtain Additional Information

Please refer to Program Announcement 99018 when you request information. For a complete program description, information on application procedures, an application package, and business management technical assistance, contact: Andrea Wooddall, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99018, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341, telephone (770) 488-2751, E-mail address ayw3@cdc.gov.

See also the CDC home page on the Internet: <http://www.cdc.gov>.

For program technical assistance, contact Deborah Levy, Ph.D., Division of Parasitic Diseases, National Center for Infectious Diseases, Center for Disease Control and Prevention, 4770 Buford Highway, Mail Stop F22, Atlanta, GA 30341, telephone (770) 488-7760, E-mail address DEL7@cdc.gov.

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.

Dated: March 2, 1999.

**John L. Williams,**

*Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Substance Abuse and Mental Health Services Administration

##### Fiscal Year (FY) 1999 Funding Opportunities

**AGENCY:** Substance Abuse and Mental Health Services Administration, HHS.

**ACTION:** Notice of funding availability.

**SUMMARY:** The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Treatment (CSAT) and the Center for Mental Health Services (CMHS) announce the availability of FY 1999 funds for the following activities. These activities are discussed in more detail under Section 4 of this notice. This notice is not a complete description of the activities; potential applicants *must* obtain a copy of the Guidance for