

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

Community/Tribal Subcommittee and the Board of Scientific Counselors, Agency for Toxic Substances and Disease Registry: Meetings

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) announces the following subcommittee and committee meetings.

Name: Community/Tribal Subcommittee.

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

Place: The Westin Peachtree Plaza Hotel, 210 Peachtree Street, N.W., Atlanta, Georgia 30303.

Status: Open to the public, limited by the available space. The meeting room accommodates approximately 60 people.

Purpose: This subcommittee will bring to the Board of Scientific Counselors advice and citizen input, as well as recommendations on community and tribal programs, practices, and policies of the Agency. The subcommittee will report directly to the Board of Scientific Counselors.

Matters To Be Discussed: Issues and concerns of the Community/Tribal Subcommittee relates to ATSDR's community and tribal programs. ATSDR will present issues and concerns on which it wishes community/tribal input. Policies and activities will be identified and recommendations for the Agency will be developed. The subcommittee will discuss CTS procedures; ways and means of outreach to communities affected by hazardous substances in the environment; possibilities for providing funding to communities to obtain their own health study expertise; the specific problems with Federal facilities and community access to health services. A report will be prepared and presented to the Board of Scientific Counselors.

Name: Board of Scientific Counselors, Agency for Toxic Substances and Disease Registry.

Times and Dates: 8:30 a.m.-5:30 p.m., May 6, 1999; 8:30 a.m.-2:00 p.m., May 7, 1999.

Place: The Westin Peachtree Plaza Hotel, 210 Peachtree Street, N.W., Atlanta, Georgia 30303.

Status: Open to the public, limited by the available space. The meeting room accommodates approximately 60 people.

Purpose: The Board of Scientific Counselors, ATSDR, advises the Secretary; the Assistant Secretary for Health; and the Administrator, ATSDR, on ATSDR programs to ensure scientific quality, timeliness, utility, and dissemination of results. Specifically, the Board advises on the adequacy of the science in ATSDR-supported research, emerging problems that require scientific investigation, accuracy and currency of the science in ATSDR reports,

and program areas to emphasize and/or to de-emphasize. In addition, the Board recommends research programs and conference support for which the Agency seeks to make grants to universities, colleges, research institutions, hospitals, and other public and private organizations.

Matters To Be Discussed: Agenda items will include an overview and panel discussions of ATSDR's plans, approaches, and time schedule for developing, with BSC collaboration and input, a five-year environmental public health research agenda; a report to the Board of Scientific Counselors from the Community/Tribal Subcommittee on issues and concerns related to hazardous waste sites; a presentation on an ATSDR/Department of Energy (DOE) coordinated research and public health activities plan for selected DOE sites; and brief ATSDR presentations on translating science to service, counter-terrorism activities, and international health.

Written comments are welcome and should be received by the contact person listed below prior to the opening of the meeting.

Agenda items are subject to change as priorities dictate.

Due to administrative delays, this notice has not been published fifteen days prior to the start of the meeting.

Contact Person for More Information:

Robert F. Spengler, Sc.D., Executive Secretary, BSC, ATSDR, M/S E-28, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/639-0708.

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 CDC and ATSDR.

Dated: April 13, 1999.

Carolyn J. Russell

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

[FR Doc. 99-9823 Filed 4-19-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99070]

Pregnancy Risk Assessment Monitoring System; 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 a Pregnancy Risk Assessment Monitoring System (PRAMS) program. This program addresses the "Healthy People 2000 Objectives" priority area of Maternal and Infant Health. The purpose of the

program is to assist State public health agencies to: (1) Establish and maintain State-specific, population-based surveillance of selected maternal behaviors and experiences that occur around the time of pregnancy and early infancy, and (2) to generate State-specific data for informing perinatal health programs and policies.

B. Eligible Applicants

Assistance will be provided only to the official State and territorial public health agencies designated as registration areas for vital statistics, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau.

The following are excluded:

1. States funded in September 1996, under Program Announcement 659, entitled "Pregnancy Risk Assessment Monitoring System": Alabama, Alaska, Arkansas, Colorado, Florida, Georgia, Illinois, Maine, New Mexico, New York, North Carolina, Oklahoma, South Carolina, Washington, and West Virginia.

2. District and States which have previously received funds from CDC for PRAMS: District of Columbia, Indiana, and Michigan.

In addition, all applicants must provide the following evidence of support:

1. Written assurance, signed by the head of the State's Vital Statistics unit, that the recipient PRAMS program will have timely (i.e., able to draw a sample from birth certificates within 2 to 4 months after delivery) access to edited birth certificate information needed for sampling and data collection. In addition, written assurance that a final birth tape will be available to CDC by December 1 of the following data year for the purpose of weighting the annual dataset.

2. A letter of commitment from the Directors of the Maternal and Child Health (MCH), the Vital Statistics, the Data Processing units, that they will work collaboratively to support the PRAMS program.

Applicants who do not provide these assurances and letters of commitment will not be eligible for funding, and their applications will be returned.

C. Availability of Funds

Approximately \$600,000 is available in FY 1999 to fund approximately 5 awards. It is expected that the average award will be \$100,000 ranging from \$60,000 to \$120,000. It is expected that

the awards will begin on or about September 30, 1999, and will be made for a 12-month budget period within a project period of up to 2 years. 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 on the availability of funds.

Use of Funds

Supplantation of existing program efforts funded through other Federal or non-Federal sources is not allowable.

Recipient Financial Participation

CDC funding usually is sufficient to cover some operational costs for PRAMS, but it is not intended to fully support all aspects of the program. States currently receiving cooperative agreement funds contribute their own resources to PRAMS—mostly in the form of operational resources and in-kind staff support. Recipients of awards under this announcement are expected to commit a minimum of two full-time staff to the project.

Funding Preferences

Funding preferences will be given to states which have not implemented PRAMS through a Memorandum of Understanding with CDC.

D. Program Requirements

Recipients must identify and obtain review and approval from a NIH-approved Institutional Review Board (IRB). No data collection may begin until the provisions of 45 CFR 46, Protection of Human Subjects, have been met (See "Other Requirements" section below).

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. (Recipient Activities), and CDC will be responsible for conducting activities under 2. (CDC Activities).

1. Recipient Activities

a. Adopt the standard PRAMS written protocol.

b. Identify, at a minimum, a program coordinator and a data manager dedicated to overall coordination and operations of PRAMS.

c. Form a Steering Committee consisting of representatives from the organizational units housing and collaborating on PRAMS, as well as other public and private health community representatives. The committee should provide oversight and set directions for the program and, at a minimum, meet at least once per year.

d. Assure active cooperation and collaboration among the participating

organizational units such as MCH, Vital Records, and Data Processing units.

e. Design a State-wide PRAMS program that assures access to needed vital record information. Timely (i.e., able to draw a sample from birth certificates within 2 to 4 months after delivery) access to birth certificates is essential.

f. Prepare State-specific questions and their rationale and pretest, if needed, the questionnaire. With other participating States, revise the common questions at agreed upon intervals.

g. Define the study population and design and maintain a representative PRAMS sample.

h. Develop a cycle of sampling and data collection in accordance with the protocol and CDC developed PRAMS software.

i. Individual interviewers used by the State to conduct telephone interviewing must follow the standard PRAMS protocol and should be trained in accordance with PRAMS standards for phone interviewing.

j. Develop, maintain, and make available to CDC, using the standardized PRAMS protocol, electronic files on birth certificate information of the sampling frame, and of sampled women, data collection activities, and questionnaire data on a timely basis for data management (i.e., sampling, cleaning, and weighting).

k. Monitor, at least, monthly the quality of data collected and its management (i.e., through verification and validation efforts).

l. Develop and implement an analysis plan.

m. Collaborate with CDC on multi-State analyses combining or comparing data across PRAMS States.

n. Disseminate PRAMS findings through presentations and publications to health departments, professional societies, voluntary agencies, universities, other PRAMS States, and other interested individuals and organizations.

o. Participate with other States in training, workshops, and meetings at least once per year.

p. Assure that CDC has a final birth tape by December 1 of the following data year. The birth tape is needed by CDC for the weighting of the annual dataset which is returned to the State for analyses.

2. CDC Activities

a. Provide model protocol and assist with development of State-specific written protocols.

b. Assist the recipient agencies with development and revisions of State-

specific questions and core questions for new States.

c. Provide program software, training, and ongoing technical support for operations management, questionnaire data entry, and development of the PRAMS analysis database.

d. Assist with the specification of variable descriptions and format layouts of all data files.

e. Provide technical assistance for data editing.

f. Assist with the development of computer programs for sampling.

g. Provide technical assistance to resolve problems regarding data collection procedures, response rates, sampling procedures (unbiased sampling and estimate omissions), and database files (completeness).

h. Assist in the development of annual weighted analysis datasets for recipient agencies, including developing statistical weights.

i. Assist recipient agency staff in obtaining training in sample survey analysis software.

j. Provide recipients with epidemiological and statistical technical assistance.

k. Conduct multi-State and single-State analyses, in collaboration with the State, and facilitate dissemination and translation of findings.

l. Participate with recipient agencies in workshops, training, and meetings to exchange information among States.

m. Conduct site visits to monitor the program operations and to provide technical assistance as needed.

n. Assist in the development of a research protocol for IRB review by all cooperating institutions participating in the research project.

o. 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 30 double-spaced pages, printed on one side, with one inch margins, and un-reduced font.

The applicant must submit the following:

1. Background and Need

a. Describe the rates of low birth weight and infant mortality on a Statewide basis and for high-risk sub-populations and geographical areas of

special interest and describe their relationship to relevant national rates for the "Healthy People 2000 Objectives".

b. Identify gaps in needed information concerning adverse pregnancy and infant outcomes, pregnancy and infant risk factors, and provide a description of how PRAMS data may be used to fill these gaps.

c. Describe pregnancy-related information that State programs need to develop and direct intervention policies and activities; and identify priorities for information on risk factors.

d. Describe how analyses of linked birth and infant death certificates have been used to identify infant health problems. The applicant should describe how data from PRAMS will complement the analyses of vital records by increasing understanding of previously identified infant health problems and identifying new problems.

2. Profile of State Birth Registration Process

a. Describe, in detail, State process for registering births, to include each step from collection of information at the birth site, having an initial computerized file (the sampling frame from which the PRAMS sample will be drawn), and having a clean, edited file from which other information can be drawn. Documentation should be provided that the sample could be drawn from birth certificate information within 2 to 4 months after the date of birth. The description should indicate whether development of the file requires linkage of medical and legal portions of the birth certificate. If so, this process should be described, along with the length of time needed to complete the linkage.

b. Describe the schedule on which vital records information (frame files and end-of-year birth files, such as NCHS standard birth files) will be available to CDC. CDC uses these files for assisting the state with evaluation of the sample and weighting the data.

c. Describe the current methods of processing birth certificates in the State: whether electronic birth certificate (EBC) registration is in place, and if so, for how long; if not, how long the current system has been in place; and any anticipated changes to the process.

d. Describe the extent to which applicant can link birth certificate data to other data sources (e.g., infant deaths, Supplemental Nutrition Program for Women, Infants, and Children (WIC), Medicaid).

3. Plan of Operation

a. Describe how and when the major project components (such as sampling, mail and telephone operations, data analysis, staffing plan, protocol development, steering committee) will be developed and implemented.

b. Provide any available data that describe the extent to which the data collection approach is likely to produce adequate response rates among the sampled population, including high-risk sub-populations. Applicant should provide examples of previous surveys, including past experiences with PRAMS and other data collection activities, and their response rates in the proposed populations. Describe and provide for the inclusion of women, racial and ethnic minority populations in the proposed research to include:

i. The proposed plan for the inclusion of women, racial and ethnic minority populations for appropriate representations.

ii. The proposed justification when representation is limited or absent.

iii. A statement whether the design of the study is adequate to measure differences when warranted.

iv. A statement whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

c. Describe the roles, responsibilities, and supervision of key personnel who will be contributing to the PRAMS program during the next budget period.

d. Document the relevant expertise and experience of proposed personnel involved in PRAMS program direction, operational management, and data analysis and dissemination, and their placement within the organization. It is strongly recommended that a minimum of two full-time equivalents at the State level be committed to working on daily operations and coordination of PRAMS.

e. Thoroughly describe the specific roles and responsibilities of participating organizational units, such as MCH, vital records, and data processing units.

f. Describe a plan for data analysis and dissemination of findings through various channels, including steering committee members, health policy makers, and health providers. Applicant should provide a description of existing partnerships and how findings from previous studies have been disseminated.

g. Provide an organizational chart that shows the proposed location of units that participate in PRAMS.

4. Timetable

Provide a general time-line of major milestones for the project period and a schedule of activities for the first 12 months of the project period.

5. Budget

Provide a detailed budget and line-item justification of all operating expenses that is consistent with the planned activities of the project. The budget should also address funds requested, as well as the applicant's in-kind or direct support. The budget should indicate if funds are already committed to PRAMS and the amount requested under this announcement should be adjusted accordingly.

F. Submission and Deadline

Application

Submit the original and two copies of CDC Form 0.1246(E). Forms are in the application kit. On or before June 18, 1999, submit the application to: Mildred S. Garner, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Announcement 99070, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, Georgia 30341.

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 prior to submission to the review panel. (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.

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 (30 Points)

a. The extent to which problems of poor pregnancy outcome exist, their severity, and whether they exist on a Statewide basis, within high-risk sub-populations, or defined geographical areas, and may be assessed in relationship to relevant national rates, the "Healthy People 2000 Objectives", and the Maternal and Child Health Bureau MCH indicators (5 points).

b. The programmatic relevance of the maternal and infant health program priorities (5 points).

c. The extent to which the applicant describes the surveillance information needed and how it may be used for health program planning and resource allocation (10 points).

d. The extent to which the applicant has used vital records data or other data sources, (e.g., infant deaths, WIC, Medicaid, or PRAMS) to identify and analyze infant health problems (10 points).

2. Profile of State Birth Registration Process (25 Points)

a. The extent to which the process is thorough; birth certificate information is computerized, edited, and available for sampling within 2 to 4 months after date of birth; and vital records information schedule provides timely access to CDC for sample evaluation and weighting (10 points).

b. The extent to which electronic birth certificate registration (EBC) or other methods for processing birth certificates are used, and whether any changes in the current process are anticipated along with a time frame for these changes (10 points).

c. The extent to which the applicant can link to other data sources (e.g., infant deaths, WIC, Medicaid) (5 points).

3. Plan of Operation (40 Points)

a. The extent to which the sampling method appears appropriate and likely to produce adequate response rates among the sampled populations. Applicants should provide evidence of previous experiences, including PRAMS, with the sampled populations (10 points).

b. The adequacy of the plan and timeline to carry out major project components (i.e., sampling, mail and telephone operations, data analysis) (5 points).

c. The extent to which the roles and responsibilities for organizational units, such as MCH, vital records, and data processing units; and key personnel and their expertise and experience, are documented and appear reasonable and appropriate; and whether two full-time equivalents are committed to working on PRAMS (10 points).

d. The extent to which the plan for data analysis assures dissemination of findings through multiple channels, to include steering committee members, health policy makers, and health providers and the extent to which previous study findings have been disseminated (10 points).

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 (5 points). This includes:

i. The proposed plan for the inclusion of women racial and ethnic minority populations for appropriate representation.

ii. The proposed justification when representation is limited or absent.

iii. A statement as to whether the design of the study is adequate to measure differences when warranted.

iv. 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.

4. Timetable (5 Points)

The extent to which the timetable incorporates major PRAMS activities and milestones and is specific, measurable, and realistic.

5. Budget (Not Scored)

The extent to which the budget is detailed, clear, justified, provides in-kind or direct project support, and is consistent with the proposed program activities.

6. Human Subjects: (Not Scored)

Does the application include a plan to adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects (see AR-1 below)?

___ Yes ___ No

Comments: _____

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. progress report, no more than 90 days after the end of the budget period;

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: Mildred S. Garner, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 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 I in the application kit.

AR98-1 Human Subjects Requirements

AR98-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR98-5 HIV Program Review Panel Requirements

AR98-7 Executive Order 12372 Review

AR98-9 Paperwork Reduction Act Requirements

AR98-10 Smoke-Free Workplace Requirements

AR98-11 Healthy People 2000

AR98-12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

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

J. Where To Obtain Additional Information

To obtain additional information, contact: Robert Hancock, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99070, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146 telephone (770) 488-2746, E-mail: RNH2@CDC.GOV.

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

For program technical assistance, contact: Mary M. Rogers, Dr.P.H., Project Officer, PRAMS, Program Services and Development Branch, Division of Reproductive Health, NCCDPHP 4770 Buford Highway, N.E., MS K-22, Atlanta, Georgia 31341, Phone: (770) 488-5220, E-Mail: MJR3@CDC.GOV.

Dated: April 14, 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

Centers for Disease Control and Prevention

Breast and Cervical Cancer Early Detection and Control Advisory Committee; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease