

18. **CURRENT ISSUES:** What would you do to develop national or regional guidelines or policies to enhance community involvement surrounding ATSDR activities?

19. **EXPECTATIONS:** What type of input, recommendations, and advice do you envision the Community/Tribal Subcommittee providing, and what type of outreach would you do in order to formulate your recommendations, via the CTS, to the Board of Scientific Counselors?

20. What is your ethnic origin/race?

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[Program Announcement Number 03087]

Polychlorinated Biphenyls Exposure and Adverse Health Effects in Anniston, Alabama; Notice of Availability of Funds

Application Deadline: June 30, 2003.

A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized in Sections 104(i)(1)(E), (7) and (15) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) as amended by the Superfund Amendments and Reauthorization Act (SARA) (42 U.S.C. 9604 (i)(1)(E), (7) and (15)). The Catalog of Federal Domestic Assistance number is 93.206.

B. Purpose

The Agency for Toxic Substances and Disease Registry (ATSDR) announces the availability of fiscal year (FY) 2003 funds for a cooperative agreement program to conduct research on the impact of polychlorinated biphenyls (PCBs) exposure on human health in Anniston, Alabama. This program addresses the "Healthy People 2010" focus area of Environmental Health.

The purpose of this program is to: (1) Collect baseline information and serum PCBs from a sample of Anniston residents; (2) study the relationship between exposure to PCBs and adverse health effects, such as cancer, neurobehavioral disorders, birth defects, and immune function; and (3) inform and educate residents about PCB exposure in their community.

Measurable outcomes of the program will be in alignment with one or more of the following performance goals for the ATSDR: (1) develop and provide reliable and understandable information for people in affected communities and tribes, and for stakeholders, and (2) ascertain the relationship between exposure to toxic substances and disease.

C. Eligible Applicants

Applications may be submitted by:

- Health departments of States or their *bona fide* agents, including the District of Columbia, 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.

- Federally recognized Indian tribal governments.
- State-based institutions (this includes universities, colleges, and research institutions).

Note: Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant or loan.

Special Requirements

Minimal Applicant Requirements

1. A documented link between the Anniston community and the applicant.
2. Experience with community outreach and health education to provide support and information.
3. The investigators should be prepared to work collaboratively with ATSDR and community leaders to achieve the goals of this solicitation.

4. The investigators should be prepared to meet on a periodic basis with community representatives.

D. Funding

Availability of Funds

Approximately \$1,500,000 is available in FY 2003 to fund up to two awards. It is expected that the average award will be \$750,000, ranging from \$600,000 to \$1,500,000. It is expected that the awards will begin on or about August 1, 2003, and will be made for a 12-month budget period within a project period of up to three 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 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 primary recipient of ATSDR 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 these funds; however, the equipment proposed should be appropriate and reasonable for the research activity to be conducted. Equipment may be acquired only when authorized and the application should provide a justification of the need to acquire equipment, the description, and the cost of purchase versus lease. To the greatest extent practicable, equipment and products purchased with ATSDR funds should be American made. ATSDR retains the right to request the return, at the completion of the project period, of all equipment in operable condition purchased with grant funds.

Recipient Financial Participation

Matching funds are not required for this program.

Funding Preferences

Preference will be given to the following: applicants who are located in the southeastern region of the United States, applicants who have support from the Anniston community as evidenced by letters of support, applicants who demonstrate collaborative effort with other institutions, or projects which avoid a duplication of study objectives.

E. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities listed in 1. Recipient Activities, and ATSDR will be responsible for the activities listed in 2. ATSDR Activities.

1. Recipient Activities

a. Develop a study proposal that examines the relationship between exposure to PCBs and an adverse health effect, such as cancer, neurobehavioral disorders, birth defects, and/or immune function. Protocol (study design and end point(s) under investigation) and data collection instruments will be developed by applicant, in consultation with ATSDR, and approved prior to project implementation. A recommended time line is available in Attachment IV. All attachments referenced in this announcement are posted with the announcement on the CDC Web site.

b. Meet in Anniston, Alabama, at least twice in the first year with ATSDR and Environmental Protection Agency Region IV staff to review available exposure data to help define the exposed population(s).

c. At the conclusion of the study, share all data collected through these activities with ATSDR. These data may be used by ATSDR to further characterize potential exposure pathways.

d. Through letters of support, provide evidence of on-going collaborative efforts with community representatives, local elected officials, state and local health departments, etc., to enhance communication and information exchange with the Anniston community (Attachment V).

e. Establish a mechanism to work with community leaders in Anniston, Alabama, on a periodic basis throughout the study period to gather input on study design issues, and receive feedback regarding outreach, participation, and education.

f. Meet annually with ATSDR and other awardee(s) in Atlanta, Georgia, to coordinate planned efforts and review progress.

g. Disseminate research results to community members, and publish in written format for distribution.

2. ATSDR Activities

a. Provide epidemiologic guidance and administrative support to achieve program goals.

b. In collaboration with the recipient, develop a research protocol for Institutional Review Board (IRB) review by all cooperating 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.

c. Develop and provide to recipient a number of baseline questions for data collection related to the participant's exposure history.

d. In collaboration with the Environmental Protection Agency Region IV and the recipient(s), coordinate meetings in Anniston, Alabama, at least twice in the first year to review available exposure data to better define exposed population(s).

e. Participate in periodic meetings with community leaders in Anniston, Alabama, to gather input on study design issues, and receive feedback regarding outreach, participation, and education throughout the study period.

f. Facilitate external peer review of the study protocol and the final report.

g. Provide assistance with the dissemination of information resulting from this project, including the review and publication of a final report.

h. Facilitate an annual meeting between awardee(s) in Atlanta, Georgia, to coordinate planned efforts and review progress.

F. Content

Applications

The Program Announcement title and number must appear in the application. 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 45 pages, double-spaced, printed on one side, with one-inch margins, and unreduced 12-point font. The narrative should consist of, at a minimum, a Proposed Research Plan, Objectives, Methods, Evaluation, Budget, and Time line. The program plan should address activities to be conducted over the entire three-year project period.

G. Submission and Deadline

Application Forms

Submit the signed original and two copies of PHS 5161-1 (OMB 0920-0428). Forms are available at the following Internet address: <http://www.cdc.gov/od/pgo/forminfo.htm>. If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management

Section (PGO-TIM) at: 770-488-2700. Application forms can be mailed to you.

Submission Date, Time, and Address

The application must be received by 4 p.m. eastern time June 30, 2003. Submit the application to: Technical Information Management—PA #03087, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Rd, Atlanta, GA 30341-4146.

Applications may not be submitted electronically.

CDC Acknowledgment of Application Receipt

A postcard will be mailed by PGO-TIM, notifying you that CDC has received your application.

Deadline

Applications shall be considered as meeting the deadline if they are received before 4 p.m. eastern time on the deadline date. Any applicant who sends their application by the United States Postal Service or commercial delivery services must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If an application is received after closing due to (1) carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, CDC will upon receipt of proper documentation, consider the application as having been received by the deadline.

Any application that does not meet the above criteria will not be eligible for competition, and will be discarded. The applicant will be notified of their failure to meet the submission requirements.

H. Evaluation Criteria

Application

An independent review group appointed by ATSDR will evaluate each application against the following criteria:

1. Goals and Objectives (20 percent)

The extent to which the applicant clearly identifies specific, measurable, and scientifically sound goals and objectives.

2. Study Design and Methods (20 percent)

a. Adequacy of the study design and methodology for accomplishing the stated goals and objectives.

b. The degree to which efficient and innovative approaches are proposed in collaboration with other institutions.

c. The extent to which the applicant's plans and schedule proposed for

accomplishing the activities to be carried out in this project are clearly stated, are realistic given the length of the funding period, and can be achieved within the proposed budget.

d. Applicant provides opportunities to collaborate with Anniston community leaders to develop final study protocol.

3. Community Involvement, Education, and Dissemination of Results (20 percent)

a. Adequacy of plan to address community concerns by establishing partnerships with community representatives, local environmental and health agencies, and other relevant public and private groups and organizations prior to project implementation.

b. Adequacy of plans to create formal lines of communication with Anniston leaders on a periodic basis, including representation from various disciplines and backgrounds.

c. The degree to which efficient and innovative approaches are proposed to educate the community about PCB exposure.

d. Adequacy of methods to work with the community to disseminate study results.

4. Understanding of the Problem (10 percent)

a. The applicant's understanding of the problems facing the residents of Anniston, Alabama.

b. The applicant should demonstrate an understanding of scientific and epidemiologic issues when conducting environmental research.

c. Relevance of the proposed program to these and related problems.

5. Program Personnel (10 percent)

a. Applicant's technical experience and understanding in the areas of PCBs, environmental epidemiology, health education/community outreach, etc.

b. Qualifications and time allocation of the professional staff to be assigned to this project.

c. Extent to which the management staff and their working partners are clearly described.

6. Facilities and Resources (10 percent)

The adequacy of the applicant's facilities, equipment, and other resources available for performance of this project.

7. Measures of Effectiveness (10 percent)

Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the

cooperative agreement. Measures of effectiveness must relate to the performance goals as stated in the Purpose section of this announcement. Measures must be objective and quantitative and must measure the intended outcome. These measures of effectiveness shall be submitted with the application.

8. *Human Subjects*: does the application adequately address the requirements of 45 CFR part 46 for the protection of human subjects? (Not scored; however, an application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.)

9. Budget Justification (Not Scored)

The budget will be evaluated to the extent that it is reasonable, clearly justified, and consistent with the intended use of funds.

10. Does the application adequately address the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research? (Not scored.) This includes:

a. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

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

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

d. 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.

I. Other Requirements

Technical Reporting Requirements

1. Provide CDC with an original plus two copies of an interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Detailed Line-Item Budget and Justification.

e. Additional Requested Information.

2. Financial status report, no more than 90 days after the end of the budget period.

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.

Additional Requirements

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I of the program announcement as posted on the CDC Web site.

- AR-1 Human Subjects Requirements
- AR-2 Requirements of Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-7 Executive Order 12372 Review
- AR-9 Paper Work Reduction Act
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-17 Peer Review 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

J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC web site, Internet address: <http://www.cdc.gov>. Click on "Funding" then "Grants and Cooperative Agreements".

For general questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Rd, Atlanta, GA 30341-4146. Telephone: 770-488-2700.

For business management and budget assistance, contact: Edna Green, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341-4146. Telephone: 770-488-2743. e-mail address: EGreen@cdc.gov.

For program technical assistance, contact: Sherri Berger-Frank, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE., Mail Stop E-28, Atlanta, Georgia 30333. Telephone: (404) 498-0522. E-mail address: SBerger@cdc.gov; or Scott Bowen, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE., Mail Stop E-31, Atlanta, Georgia 30333. Telephone: (404) 498-3457. E-mail address: msb4@cdc.gov.

Dated: May 19, 2003.

Sandra R. Manning,

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Centers for Disease Control and Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

Centers for Medicare & Medicaid Services

[Program Announcement Nos. AoA-03-05 and CMS-2185-N]

Fiscal Year 2003 Program Announcement; Availability of Funds and Notice Regarding Applications

AGENCY: Administration on Aging, Centers for Medicare & Medicaid Services, HHS.

ACTION: Announcement of availability of funds and request for applications.

SUMMARY: The Administration on Aging (AoA) and the Centers for Medicare & Medicaid Services (CMS) announce that under this program announcement they will hold a competition for grant awards to be issued as cooperative agreements for up to sixteen (16) projects at a federal share of up to \$800,000 over 3 (three) years.

Legislative authority: AoA's authority for these grants is under the Older Americans Act, Public Law 106-501 (Catalog of Federal Domestic Assistance 93.048, Title IV and Title II, Discretionary Projects). CMS' legislative authority for these grants is under section 1110 of the Social Security Act. Funding to CMS and Congressional language was provided in the Consolidated Appropriations Resolution, 2003 (Pub. L. 108-7). AoA and CMS are the designated HHS agencies with administrative responsibility for their respective portion for funding this joint effort. See Supplementary Information below for additional discussion of CMS' authority under section 1110.

Purpose of grant awards: The awards are to be used by states to develop Aging and Disability Resource Center programs that will provide citizen-centered "one-stop shop" entry points into the long term support system and will be based in local communities accessible to people who may require long term support. Resource Centers will serve individuals who need long term support, their family caregivers, and those planning for future long term support needs. They will also serve as