

1. Proposed Research—60 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).

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.

c. The proposed project schedule, including clearly established and obtainable project objectives for which progress toward attainment can and will be measured.

d. The proposed mechanism to be utilized as a resource to address community concerns and opinion, and create lines of communication.

e. The proposed method to disseminate the study results to State and local public health officials, tribal governments, Indian Health Service, community residents, and to other concerned individuals and organizations.

f. 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.

2. Program Personnel—30 percent

The extent to which the proposal has described:

a. The qualifications, experience, and commitment of the Principal Investigator, and his/her ability to devote adequate time and effort to provide effective leadership.

b. The competence of associate investigators to accomplish the proposed study, their commitment, and time devoted to the study.

3. Applicant Capability—10 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? 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.

I. Other Requirements*Technical Reporting Requirements*

Provide CDC with original plus two copies of:

(a) An Interim progress report, due June 15th. The progress report will serve as your non-competing continuation application, and must contain the following elements:

(1) Current Budget Period Activities Objectives.

(2) Current Budget Period Financial Progress.

(3) New Budget Period Program Proposed Activity Objectives.

(4) Detailed Line-Item Budget and Justification.

(5) Additional Requested Information.

(b) Financial status report, due no later than 90 days, after the end of the budget period.

(c) Final financial and performance reports, due no later 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.

AR-1 Human Subjects Requirements
AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR-3 Animal Subjects Requirements

AR-7 Executive Order 12372 Review

AR-9 Paperwork Reduction Act Requirements *

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

For a complete description of each, see Attachment I of the program announcement, as posted on the CDC Web site.

* OMB Clearance under the Paperwork Reduction Act is not required for this program.

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 Road, Atlanta, GA 30341-4146, Telephone: 770-488-2700.

For business management and budget assistance, contact: Ms. Edna Green, Grant 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: ECG4@cdc.gov.

For program technical assistance, contact: Dr. Heraline E. Hicks, Research Implementation Branch, Division of Toxicology, 1600 Clifton Road, NE., Mail Stop E29, Atlanta, Georgia 30333, Telephone: (404) 498-0717, E-mail address: HEH2@cdc.gov.

Dated: May 30, 2003.

Edward Schultz,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Agency for Toxic Substances and Disease Registry**

[Program Announcement 03079]

Exposure to Tremolite Asbestos in Vermiculite Ore; Notice of Availability of Funds

Application Deadline: July 21, 2003.

A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 104(i)(1)(E), (6), (7), (14) and (15) of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980 as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986 (42 U.S.C. 9604 (i)(1)(e), (6), (7), (14) and (15)). The Catalog of Federal Domestic Assistance number is 93.161.

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 site-specific health activities due to exposure to tremolite asbestos in vermiculite ore. This program addresses the "Healthy People 2010" focus area of Environmental Health. The purpose of the program is to conduct site-specific health activities related to human exposure to contaminated vermiculite ore at sites identified by the Environmental Protection Agency (EPA) as receiving and/or processing ore from the mine in Libby, Montana.

Measurable outcomes of the program will be in alignment with the following performance goals for ATSDR:

1. Evaluate human health risks from toxic sites and take action in a timely and responsive public health manner.
2. Ascertain the relationship between exposure to toxic substances and disease.

C. Eligible Applicants

Assistance will be provided only to the health departments of States or their bona fide agents or instrumentalities. State organizations, including State universities, must establish that they meet their respective State legislature's definition of a State entity or political subdivision to be considered an eligible applicant.

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

D. Funding

Availability of Funds

Approximately \$250,000 is available in FY 2003 to fund approximately one to four awards. It is expected that the awards will range from \$10,000 to \$250,000 (\$10,000 per site evaluated for the conduct of health statistics reviews; \$100,000 for mesothelioma surveillance; and a maximum of \$250,000 for

epidemiologic investigations.) It is expected that the awards will begin on or about September 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 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. Funds may not be used to purchase equipment.

Recipient Financial Participation

Matching funds are not required for this program.

Funding Preference

For the mesothelioma surveillance, preference will be given to states with at least 100 cases of mesothelioma per year and at least eight sites that received the asbestos contaminated ore.

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. Health Statistics Reviews

Analyze existing health outcome data of select asbestos-related diseases. Mortality data will be the most readily available data for asbestos-related diseases such as mesothelioma, lung cancer, and asbestosis, although cancer registry data should be utilized where available. Using disease rates by site, determine if there is any excess in disease that would require additional follow-up in years two and three.

b. Epidemiologic Investigations

After demonstrating an increase of asbestos related disease at a specific site (e.g. through a health statistics review), develop a protocol, conduct the investigation and prepare a final report of the study. This protocol and report will undergo scientific peer review as required by ATSDR.

c. Mesothelioma Surveillance

Determine if a particular site which received Libby ore is contributing to the

mesothelioma burden in the state. (Please see Attachment 1 of this announcement as posted on the CDC Web site for information about vermiculite ore from Libby, Montana). Identify cases of mesothelioma in the State and interview the cases and next-of-kin. Provide information to ATSDR to combine with other State information. Prepare a final report of the project. This report will undergo scientific peer review as required by ATSDR.

d. Provide proof, by citing a State code or regulation or other State pronouncement under authority of law, that medical information obtained pursuant to the agreement will be protected from disclosure when the consent of the individual to release identifying information is not obtained.

e. If a demonstrated excess of disease is found, develop a mechanism for ongoing interaction with, and education of the affected community.

2. ATSDR Activities

a. Health Statistics Review

(1) Provide a standard protocol to use to analyze existing health outcome data of select asbestos-related diseases.

(2) Provide scientific and epidemiologic assistance.

b. Epidemiologic Investigations

Provide consultation and assist in monitoring the data; participate in the study analysis and collaborate in interpreting the study findings.

c. Mesothelioma Surveillance

(1) Provide a standard protocol and questionnaire to be used to trace and interview cases of mesothelioma, and analyze the risk of environmental exposure to asbestos contaminated vermiculite ore from Libby, MT, and link it to the cases of mesothelioma.

(2) Provide scientific and epidemiologic assistance.

d. Conduct technical and peer review

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 30 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 Plan, Objectives, Methods, Evaluation and Budget.

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 July 21, 2003. Submit the application to: Technical Information Management—PA#03079, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341-4146.

Applications may not be submitted electronically.

CDC Acknowledgement 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

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 stated in the purpose section of this announcement. Measures must be objective and quantitative and

must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

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

1. Proposed Program (50 percent)

The criteria will include the extent to which the application addresses (a) the approach, feasibility, adequacy, and rationale of the proposed project design; (b) the technical merit of the proposed project, including the degree to which the project can be expected to yield results that meet the program objective, and the technical merit of the methods and procedures (including quality assurance and quality control procedures) for the proposed project; (c) the proposed project timeline, including clearly established project objectives towards which progress can and will be measured; (d) the proposed community involvement strategy; (e) the proposed method to disseminate the results to State and local public health officials, community residents, and other concerned individuals and organizations; and (f) 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 the proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

2. Program Personnel (30 percent)

The criteria will include the extent to which the application has described (a) the qualifications, experience, and commitment of the principal investigator (or project director) and his/her ability to devote adequate time and effort to provide effective leadership; and (b) the competence of associates to accomplish the proposed activity, their commitment, and the time they will devote.

3. Applicant Capability and Coordination Efforts (20 percent)

The extent to which the application has described (a) the capability of the applicant's administrative structure to foster successful scientific and administrative management of a study and (b) the capability of the applicant to demonstrate an appropriate plan for interaction with the community.

4. Program Budget—(not scored)

The extent to which the budget is reasonable, clearly justified, and consistent with intended use of cooperative agreement 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? 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.

I. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. 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 II of the program announcement, as posted on the CDC web site.

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 2010

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

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 Road, 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, Room 3000, Atlanta, GA 30341-4146, Telephone: (770) 488-2743, E-mail Address: ecg4@cdc.gov.

For program technical assistance, contact Kevin Horton, Epidemiologist, Division of Health Studies, Agency for Toxic Substances and Disease Registry, Executive Park, Building 4, Suite 2300, MS E-31, Atlanta, GA 30305, Telephone: (404) 498-0571, E-mail Address: Dhorton@cdc.gov. Or: Maggie Warren, Public Health Advisor, Division of Health Studies, Agency for Toxic Substances and Disease Registry, 1600 Clifton Rd., NE., MS E-31, Atlanta, GA 30333, Telephone (404) 498-0546, E-mail Address: mcs9@cdc.gov.

Dated: May 30, 2003.

Edward Schultz,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 04002]

Cooperative Agreement for Assessing Folic Acid Knowledge and Behaviors; Notice of Availability of Funds

Application Deadline: August 4, 2003.

A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301 and 317C of the Public Health Service Act, (2 U.S.C. 241 and 247b-4 of the PHS Act, as amended). The Catalog of Federal Domestic Assistance number is 93.283.

B. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2004 funds for a cooperative agreement

program for the assessment of knowledge of the relationship between folic acid consumption and the prevention of spina bifida and anencephaly and the broad dissemination of findings for educational purposes. This program addresses the "Healthy People 2010" focus area of Maternal, Infant, and Child Health.

The purpose of this program is to provide for the evaluation of the effectiveness of public health programs to prevent birth defects through (1) an assessment of the current state of knowledge among reproductive-age women and their health care providers relative to folic acid consumption and the prevention of spina bifida and anencephaly; and, (2) the broad dissemination of findings to audiences who can use the findings for educational purposes.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Center on Birth Defects and Developmental Disabilities (NCBDDD): Increase the consumption of folic acid among women of reproductive age to prevent serious birth defects.

C. Eligible Applicants

Assistance will be provided only to applicants that are well-established national, non-profit organizations with experience in: (1) Conducting birth defects prevention research; (2) conducting science-based educational outreach activities; and, (3) communicating research findings effectively to national, regional, state, and local level media outlets in coordination with partners.

To be eligible, applicants must:

1. Demonstrate that the organization's mission is explicitly committed to the prevention of birth defects. This may be demonstrated by submission of the charter, articles of incorporation, or other governing documents.

2. Demonstrate that the organization is a nonprofit and recognized as tax exempt under Section 501(C)(3) of the Internal Revenue Code. This may be demonstrated through inclusion of your Internal Revenue Service determination letter.

3. Demonstrate the organization has the capacity and experience providing health education to women who are at risk of having a Neural Tube Defects (NTD)-affected pregnancy. This may be demonstrated through letters of support.

4. Demonstrate that the organization has a national membership and a national network of local organizations. This may be done through a letter from

the organization's leadership which describes the national network.

This information should be placed directly behind the face page (first page) of your application. Applications that do not include the above information will be determined as non responsive and will be returned without review.

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.

D. Funding

Availability of Funds

Approximately \$180,000 is available in FY 04 to fund approximately one award. It is expected that the award will begin on or about December 1, 2003, and will be made for a 12-month budget period within a project period of up to five 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.

Recipient Financial Participation

Matching funds are not required for this program.

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 CDC will be responsible for the activities listed in 2. CDC Activities.

1. Recipient Activities

a. Conduct studies of women of reproductive age (18 to 45) to measure their awareness, knowledge, and behaviors related to folic acid, pregnancy, and birth defects' prevention.

b. Conduct studies to measure the awareness, knowledge, and practices of health care professionals and others who interact with women of reproductive age in health care/health education settings related to their knowledge of folic acid and birth defects prevention.

c. Develop surveys/studies of women of reproductive age.

d. Evaluate the results of surveys to determine if changes are occurring.

e. Publish the results of each survey and comparison analyses of the surveys in peer reviewed publications such as *Teratology, Morbidity and Mortality Weekly Report (MMWR)*, etc.

f. Coordinate and collaborate with partners, including the National Center