individuals given such a diagnosis may undergo prospective treatment for surgical procedures or even lifelong anticoagulation. The reasons that some individuals with a particular gene defect experience symptoms while others with the same defect do not is poorly understood. An understanding of additional risk factors involved would result in more appropriate targeting of therapy and reduce unnecessary treatment with blood products or drugs with significant side effects.

The primary objective of this study is to identify risk factors related to intra-familial differences in manifestations of hemostatic diseases, including bleeding disorders, such as von Willebrand disease and platelet storage pool disease, and thrombotic disorders, such as protein C deficiency and protein S deficiency.

This is a descriptive study of families with bleeding or thrombotic disorders. The goal is to identify families with 5–10 members affected with a bleeding or thrombotic disorder. Family members who have the same abnormal gene will be compared as to their clinical symptoms or lack thereof and differences in physiologic and genetic markers which may be related to the disorder under study. Data will be collected for at least five years for descriptive and hypothesis generating purposes.

Ten families a year will qualify for this study; up to 100 members will be enrolled. Participants will be asked to be interviewed by a trained interviewer with questions on demographics, medical history, behavioral and lifestyle factors, and family history; have 35 milliliters (about 2.5 tablespoons) of blood drawn from a vein in the arm. The blood will undergo testing of appropriate coagulation parameters and physiologic variables such as blood groups. The tests chosen will depend upon the disorder present in the family. Participants will also be asked to give study staff access to previous laboratory results collected at other institutions or at CDC, provide contact information for family members thought to have symptoms of bleeding or clotting, and allow his or her diagnosis to be disclosed to family members. There is no cost to the respondents.

Respondents	No. of respondents	No. of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Male	50	2	30/60	50
Female	50	2	30/60	50
Total	.....	.....	.....	100

Thomas A. Bartenfeld,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 03–16676 Filed 7–1–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 03032]

Addressing Asthma From a Public Health Perspective; Notice of Availability of Funds Amendment

A notice announcing the availability of fiscal year (FY) 2003 funds for cooperative agreements for ''Addressing Asthma From a Public Health Perspective'' published in the **Federal Register** on May 28, 2003, Volume 68, Number 102, pages 31707–31720. The notice is amended as follows:

On page 31707, third column, at the end of the first paragraph, insert the following, ''If the applicant is not the State health department, but is another department responsible for the State asthma program, or a *bona fide* agent of the State health department, they must include documentation to indicate their status. This documentation should include: (1) A letter from the State health department designating the applicant organization as their *bona fide* agent, or as the organization responsible for asthma programs within the State; and/or (2) any official documentation showing that the applicant organization maintains responsibility for the State asthma program. The documentation must be placed directly behind the face page of the application form.''

Dated: June 26, 2003.

Edward Schultz,

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

[FR Doc. 03–16681 Filed 7–1–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 03102]

Expanding Existing Surveillance Systems To Include Pfiesteria, Other Harmful Algal Blooms, and Marine Toxins; Notice of Availability of Funds

Application Deadline: August 1, 2003

A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301 of the Public Health Service Act, [42 U.S.C. section 241], 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) 2003 funds for a cooperative agreement program for Expanding Existing Surveillance Systems to Include Pfiesteria, Other Harmful Algal Blooms, and Marine Toxins. This program addresses the ''Healthy People 2010'' focus area Environmental Health.

The purpose of the program is to assist state and local public health departments with expanding surveillance activities for adverse human health outcomes and exposure to waters contaminated with not only Pfiesteria, but also other harmful algae, their toxins, or other marine toxins.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Center for Environmental Health (NCEH): Increase the capacity of state and local health departments to deliver environmental health services in their communities.

C. Eligible Applicants

Applications may be submitted by: state and local governments or their bona fide agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the

Marshall Islands, and the Republic of Palau), and political subdivisions of states (in consultation with states).

To be eligible, applicants must:

1. Provide evidence of an existing surveillance system(s) for Pfiesteria or other harmful algae, their toxins, or other marine toxins. This may be demonstrated through a letter from your organization's leadership and a copy of a recent surveillance report print out.

2. Demonstrate your organization has capacity and experience providing surveillance activities for adverse human health outcomes and exposure to waters contaminated with Pfiesteria, other harmful algae, their toxins, or other marine toxins. This may be demonstrated through letters of support.

This information should be placed directly behind the face page (first page) of your application. Applications that fail to submit evidence requested above will be considered non-responsive and 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 $3,000,000 is available in FY 2003 to fund approximately six to eight awards. It is expected that the average award will be $500,000, ranging from $250,000 to $750,000. 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.

Recipient Financial Participation

No matching funds are 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

All proposed activities should be planned and conducted in collaboration and coordination with CDC by state/local health departments, and where appropriate, in consultation with:

- Appropriate state and local professional associations.
- Health care providers and institutions serving, diagnosing, or providing treatment and care for persons having symptoms related to exposure to Pfiesteria, harmful algal blooms, or marine toxins, including laboratories conducting testing.
- Relevant community groups and organizations.
- Universities and health research agencies.

Surveillance activities should:

a. Target individuals with high risk of exposure to waters containing harmful algae, including Pfiesteria piscicida.

b. Conduct investigations of all cases of Pfiesteria-related illnesses meeting the set of exposure conditions and clinical signs and symptoms previously agreed upon by State and Federal partners to determine risk factors for illness, and to consider banking clinical materials for future laboratory confirmation of exposure.

c. Conduct investigations of illnesses associated with harmful algae to determine risk factors for illness and to consider banking clinical materials for future laboratory confirmation of exposure.

d. Develop and conduct surveillance activities to identify potential sources of exposure to harmful algae, including P. piscicida and Pfiesteria-like organisms, and bank clinical samples for future analysis.

e. Regularly report information collected using the pre-existing PEAS (Possible Estuary Associated Syndrome) surveillance software to the aggregate database that is housed at CDC.

f. Assess clinical data on people with illnesses related to exposure to harmful algae.

g. Develop and implement appropriate preventive strategies and develop information materials for use by health professionals and the public to aid in prevention and control of illnesses associated with P. piscicida and other harmful algae.

Applicants may include several research activity projects within their proposal. If applying for the research funding, suggested examples of the specific areas of research activities may include:

a. Laboratory studies to further define the biological impacts associated with the presence of P. piscicida, other harmful algae, and the toxins they produce.

b. Further characterization of the environmental impact on estuarine waters associated with the presence of P. piscicida, other harmful algae, and the toxins they produce.

c. Exploring the impact of anthropogenic nutrient sources on the composition of phytoplankton communities in drinking water sources and recreational waters.

d. Examining the potential for human health effects from chronic low-level exposures to toxins produced by similar organisms.

2. CDC Activities

a. Provide consultation and scientific and technical assistance and training, surveillance, epidemiologic research, laboratory and prevention activities.

b. As needed, assist in refining the format for reporting surveillance data including case report forms, database, and maintaining the reporting system.

c. Participate with states to reach mutually agreed upon standardized study protocols and, where appropriate, data collection instruments for projects or studies.

d. Assist in preparing standard data collection forms, questionnaires, etc., as needed in surveillance activities and special epidemiologic investigations.

e. Assist in the evaluation of the overall effectiveness of program operations, including the impact of surveillance data on the development of public policy, and on targeting and evaluating prevention activities.

f. Participate in the analysis of information and data gathered from program activities and facilitate the transfer of information and technology among all states and communities.

g. Assist in the development of 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.

F. Content

Letter of Intent (LOI)

A LOI is required for this program. The Program Announcement title and number must appear in the LOI. The narrative should be no more than 5 pages, double-spaced, printed on one side, with one-inch margins, and unreduced 12-point font. Your letter of intent will be used to enable CDC to determine the level of interest in the announcement, and should include the following information:

a. Organization name and address.

b. Project Director and telephone number.

c. An abstract briefly summarizing the surveillance program for which funds are requested, including the activities to be undertaken and an estimated budget.

d. If also applying for funding for research activities, a brief description of the activities to be undertaken for each research project/activity and an estimated budget for each.

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 25 pages, double-spaced, printed on one side, with one-inch margins, and unreduced 12-point font.

The narrative should consist of a description of the planned first year activities, and clearly lay out future year objectives and activities to be conducted over the entire three-year project period. The criteria listed in the Evaluation Criteria section will serve as the basis for evaluating the application; therefore, the narrative of the application should address the following:

a. Applicant's understanding of the problem.

b. Applicant's ability to carry out the project.

c. Technical and program personnel capability.

d. Budget justification.

e. Human Subjects review.

G. Submission and Deadline

Letter of Intent (LOI) Submission:

The LOI must be received by 4 p.m. Eastern Time, July 16, 2003. Submit the LOI to the Grants Management Specialist identified in the ''Where To Obtain Additional Information'' section of this announcement. The LOI may not be submitted electronically.

Application Forms

If applying for surveillance funding, submit the signed original and two copies of PHS 5161–1 (OMB Number 0920–0428). If applying for research funding, submit the signed original and two copies of PHS 398 should be utilized. Forms are available at the following Internet address: *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, August 1, 2003. Submit the application to: Technical Information Management–PA#03102, 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

Letters of intent and 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 CDC will evaluate each application against the following criteria:

a. Understanding of the Problem (25 Points):

The extent to which the applicant understands the purpose and requirements of the program. This includes the extent of the applicant's identification and description of the problem, the realistic presentation of objectives to maintain effective surveillance systems and prevention programs, and evaluation criteria established to assess surveillance, epidemiologic research, and prevention activities.

b. Ability to Carry Out the Project (25 Points):

Degree to which the applicant provides evidence of the ability to carry out the proposed project and the extent to which the applicant documents demonstrated capability to achieve the objectives of the proposed program. This may include plans, approaches, methods, and evaluations to be used in conducting and evaluating surveillance, epidemiologic research, and prevention programs, and may include collaborating with universities or other health research agencies.

c. Technical Approach (20 Points):

Degree to which proposed objectives are clearly stated, realistic, measurable, time-phased, and related to the stated purpose of this project. Also, the adequacy of the proposed surveillance, epidemiologic research, and prevention plans to achieve the objectives. The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed project. 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; and (d) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with communities and recognition of mutual benefits will be documented.

d. Personnel (20 Points):

Extent to which professional personnel involved in this project are qualified, including evidence of experience similar to this project.

e. Plans for Administration (10 Points):

Adequacy of the plans submitted for administering the project.

f. Budget Justification (Reviewed, but Not Scored):

Itemized budget for conducting the project, along with justification, is provided and is reasonable. The applicant should include the costs for one person to travel in Atlanta, GA, to attend the 6th National Environmental Health Conference December 3–5, 2003. Review the CDC/NCEH web site for

additional information concerning this conference: *http://www.cdc.gov/nceh/default.htm*

g. Human Subjects (Reviewed, but Not Scored)

The extent to which the applicant complies with the Department of Health and Human Services Regulations (45 CFR Part 46) regarding 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. 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.

Projects that involve the collection of information from 10 or more individuals and funded by cooperative agreement will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

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 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

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: Sharron Orum, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2716, E-mail address: *spo2@cdc.gov*.

For program technical assistance, contact: Dennis Christianson, Project Officer, Health Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop: E23, Atlanta, GA 30333, Telephone: 404–498–1340, E-mail address: *djc2@cdc.gov*.

Dated: June 26, 2003.

Edward Schultz,

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

[FR Doc. 03–16678 Filed 7–1–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 03157]

Public Health Research Accreditation Project; Notice of Availability of Funds

Application Deadline: August 1, 2003.

A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301 and 317(k)(2) of the Public Health Service Act, [42 U.S.C. 241 and 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.993.

B. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2003 funds for a grant to assess the role of accreditation in enhancing the protection of participants in public health research. This program addresses the ''Healthy People 2010'' focus area 23 Public Health Infrastructure.

The purpose of the program is to assess the role of accreditation of human research protection programs to enhance protections afforded to persons involved in the full range of public health research programs, *e.g.*, epidemiologic research, health services research, and social and behavioral intervention research, as well as traditional biomedical research and clinical trials. Voluntary accreditation is one component of a national oversight system for protection of human subjects. The National Bioethics Advisory Commission (2001) and the Institute of Medicine (2001, 2002) recommended that a voluntary system for accreditation of human research protection programs be initiated and evaluated over the next several years.

This project will result in the development of pilot measures that can be used to assess the improvement of the ability of the public health infrastructure (such as state and local public health departments, schools of public health, and other public health research partners) to assess and monitor research involving human subjects. In year two, the pilot measures will be implemented in several locations, such as state or local health departments, schools of public health, or community-based organizations that engage in public health research, and will be evaluated for utility and feasibility in the public health setting. In year three, the measures will be refined and made available to public health research partners to document and evaluate the impact of accreditation as a process to improve protection of human subjects in public health research.

Measurable outcomes of the program will be in alignment with the performance goals for the CDC Office of Science Policy and Technology Transfer.

C. Eligible Applicants

Limited Eligibility

Assistance will be provided only to a public, private, for-profit, or non-profit organization that is currently actively engaged in the process of accrediting human research protection programs that represent the full range of activities,