

| Respondents | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|--|-----------------------|------------------------------------|--|-------------------------|
| Men, all races aged 50–70 years (validation study) | 200 | 1 | 90/60 | 300 |
| African-American men aged 40–70 years (validation study) | 200 | 1 | 90/60 | 300 |
| Primary care physicians | 250 | 2 | 15/60 | 125 |
| Men, all races aged 50–70 years (intervention group) | 300 | 1 | 90/60 | 450 |
| Men, all races aged 50–70 years (control group) | 300 | 1 | 1 | 300 |
| Total | | | | 1,475 |

Dated: April 29, 2003.
Thomas Bartenfeld,
Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 03120]

Applied Research on Antimicrobial Resistance: Characterization of Strains of Community-Associated Methicillin-Resistant Staphylococcus Aureus; Notice of Availability of Funds

Application Deadline: June 19, 2003.

A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301(a) and 317(k)(2) of the Public Health Service Act, [42 U.S.C. Sections 241(a) and 247b(k)(2)], 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 grant program for Applied Research on Antimicrobial Resistance (AR): Characterization of Strains of Community-Associated Methicillin-Resistant Staphylococcus Aureus (MRSA). This program addresses the “Healthy People 2010” focus area of immunization and infectious diseases.

The purpose of the program is to provide assistance for applied research aimed at prevention and control of the emergence and spread of AR in the United States. This grant will focus on characterization of strains of community-associated MRSA.

This program’s design will implement Part 1 of “A Public Health Action Plan to Combat Antimicrobial Resistance, Domestic Issues.” Visit the internet site:

<http://www.cdc.gov/drugresistance/actionplan/index.htm> for more information on the Action Plan. See Attachments II and III on the CDC Web site (<http://www.cdc.gov>) for information related to this grant.

This research includes three components that will provide information needed to prevent and control AR: (1) Identification and access to a defined population of persons within which community-associated MRSA disease and data appear to be sufficiently prevalent to allow appropriate analyses; (2) obtaining strains of Staphylococcus aureus (S. aureus) causing disease in this population with appropriate, linked epidemiologic and clinical data; and (3) characterizing MRSA strains using a variety of molecular and biochemical techniques.

Measurable outcomes of the program will be in alignment with one or more of the following performance goals for the National Center for Infectious Diseases (NCID): Reduce the spread of AR, and protect Americans from infectious diseases.

C. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies; that is:

- Universities
- Colleges
- Technical schools
- Research Institutions
- Hospitals
- Community-based organizations
- Faith-based organizations
- Federally recognized Indian tribal governments
- Indian Tribes
 - Indian tribal organizations
 - 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 Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau)

- Political subdivisions of States (in consultation with States)

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 \$600,000 is available in FY 2003 to fund approximately three awards. It is expected that the average award will be \$200,000, ranging from \$150,000 to \$250,000. It is expected that the awards will begin on or about August 30, 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

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 all of the following activities:

1. Assemble a network of partners (a consortium) to accomplish the objectives of the program announcement, including identification and access to a defined population of persons within which there is community-associated MRSA disease and data sufficiently prevalent to allow appropriate analyses.
2. Obtain strains of *S. aureus* causing disease in this population with appropriate epidemiologic and clinical data to make findings generalizable to similar populations from diverse geographic areas. Ensure that the variety and quantity of distinguishable strain types included allow for valid comparisons between strain types.

3. Characterize strains and/or the relationship between these strains using a variety of molecular and biochemical techniques, including, Pulsed Field Gel Electrophoresis (PFGE), Multi Locus Sub Typing (MLST), and Polymerase Chain Reaction (PCR) for virulence genes. Studies could include demonstrating the correlation of host response to disease and strain characteristics, or relative impact strain characteristics have on colonization or invasive disease.

F. Content

Letter of Intent (LOI)

An LOI is optional for this program. The Program Announcement title and number must appear in the LOI. The narrative should be no more than five pages, double-spaced, printed on one side, with one-inch margins, and un-reduced 12-point font. Your letter of intent will be used to estimate the potential reviewer workload and to avoid conflicts of interest during the peer review. It should include the following information: name, address, telephone number, and e-mail address of the Principal Investigator, the identities of other key personnel and participating institutions, and a narrative description of the proposed research project.

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

The narrative should consist of, at a minimum, a detailed Research Plan, Objectives, Methods, an Evaluation Plan and Budget. The Research Plan should include activities to be conducted over the entire three year project period.

G. Submission and Deadline

Letter of Intent (LOI) Submission

On or before June 4, 2003, submit the LOI to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Application Forms

Submit the signed original and two copies of PHS-398 (OMB Number 0925-0001) Adhere to the instructions on the

Errata Instruction Sheet (posted on the CDC Web site) for PHS 398. 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 on or before 4 p.m. Eastern Time, June 19, 2003. Submit the application to: Technical Information Management—PA03120, CDC Procurement and Grants Office, 2920 Brandywine Road, 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

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 submission requirements.

H. Evaluation Criteria

Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the grant. Measures of effectiveness must relate to the performance goals as stated in 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 and shall be an element of evaluation.

Upon receipt, applications will be reviewed for completeness and responsiveness jointly by PGO-TIM and the NCID Office of Extramural Research. Incomplete and/or non-responsive applications will be returned to the applicant without further consideration.

Dual-Level Peer Review: As part of the initial merit review, all applicants will receive a written critique based on the comments and recommendations of the scientific (peer) review group. The review of most research applications will also include a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed, assigned a priority score, and receive a second level review. The second level of review will be performed by either CDC senior staff or the NCID Board of Scientific Counselors. Senior staff or Board recommendations are based not only on considerations of scientific merit, as judged by the scientific (peer) review group, but also on the relevance of the proposed study to the Center's programs and priorities.

Review Criteria

The goal of this research is to prevent and control the emergence and spread of AR in the United States. In the written comments, reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals:

- Significance
- Approach
- Innovation
- Investigator
- Environment

The peer review group will address and consider each of these criteria in assigning the application's overall score, weighting them as appropriate for each application. The application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

Approach: Are the conceptual framework, design, methods, and

analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

Innovation: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)? Are the investigators committed to collaborative and cooperative nature of this program?

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

Additional Review Criteria: In addition to the above criteria, the following items will be considered in the determination of scientific merit and the priority score:

Protection of Human Subjects from Research Risk: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed. (See criteria included in Attachment I).

Inclusion of Women, Minorities and Children in Research: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated. (See criteria included in Attachment I).

Public Health Importance: Does the applicant justify the proposed project as important to the prevention of community-associated MRSA?

Measures of Effectiveness: Does the applicant provide Measures of Effectiveness that will demonstrate the accomplishment of the purpose of the grant? Are the measures objective/quantitative and do they adequately measure the intended outcome.

Additional Considerations

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research. (not scored)

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 Activity 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 for Inclusion of Women and Racial and Ethnic

Minorities in Research

AR-7—Executive Order 12372

AR-10—Smoke Free Work Place Requirements

AR-11—Healthy People 2010

AR-12—Lobbying Restrictions

AR-15—Proof of Non-Profit Status

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

For business management and budget assistance, contact: Merlin Williams, Grants Management Specialist,

Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone: 770-488-2765, E-mail Address: mqw6@cdc.gov.

For business management and budget assistance in the Territories, contact: Steward Nichols, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone: 770-488-2788, E-mail address: shn8@cdc.gov.

For program technical assistance, contact: Barbara Stewart, Program Analyst, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Atlanta, GA 30333, Telephone: 404-639-0045, E-mail address: bstewart@cdc.gov.

Dated: April 29, 2003.

Sandra R. Manning,

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 03081]

Using Private Provider Partnerships To Strengthen the Immunization Message; Notice of Availability of Funds

A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 317(k)(1) of the Public Health Service Act (42 U.S.C. 247b(k)(1)), as amended. The Catalog of Federal Domestic Assistance number is 93.185.

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 national private health care provider organizations to inform their constituency on immunization issues, identify best practices and successful immunization programs, promote the improvement of immunization coverage in primary care settings, and enhance and create partnerships with state and local health departments, non-governmental organizations, and other professional organizations to collaborate on immunization programs around the country. This program addresses the "Healthy People 2010" focus area of Immunization and Infectious Diseases.

The purposes of the program are to: