

- Provide evidence of successful studies in pediatric settings such as day care centers or pediatric clinics.

- Demonstrate that the proposed population under study has a high prevalence of community-associated methicillin-resistant *Staphylococcus aureus* among pediatric population.

- Demonstrate a working collaboration with microbiology laboratories, such as a laboratory network for identifying CA-MRSA cases in different geographic and demographic settings.

- Demonstrate existing close collaboration with a large healthcare provider to ensure successful collection of case-patient data and appropriate identification and handling of *Staphylococcus aureus* isolates.

### V.3. Anticipated Announcement and Award Dates

Anticipated award date is July 1, 2004.

## VI. Award Administration Information

### VI.1. Award Notices

Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

### VI.2. Administrative and National Policy Requirements

45 CFR Part 74 and Part 92

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.

The following additional requirements apply to this project:

- 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-9 Paperwork Reduction Act Requirements.
- AR-10 Smoke-Free Workplace Requirements.
- AR-11 Healthy People 2010.
- AR-12 Lobbying Restrictions.
- AR-22 Research Integrity.
- AR-25 Release and Sharing of Data.

Additional information on these requirements can be found on the CDC Web site at the following Internet address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

### VI.3. Reporting

You must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, (use form PHS 2590, OMB Number 0925-0001, rev. 5/2001 as posted on the CDC website) 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. Budget.
- e. Additional Requested Information.
- f. Measures of Effectiveness.

2. Financial status report and annual progress 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.

These reports must be mailed to the Grants Management Specialist listed in the "Agency Contacts" section of this announcement.

## VII. Agency Contacts

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

For program technical assistance, contact: Dan Jernigan, M.D., Division of Healthcare Quality Promotion, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop A-35, Atlanta, GA 30333, Telephone: 404-639-2621, E-mail: [DJernigan@cdc.gov](mailto:DJernigan@cdc.gov).

For financial, grants management, or budget assistance, contact: Jeff Napier, Grants Management Officer, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: (770) 488-2628, E-mail: [JNapier@cdc.gov](mailto:JNapier@cdc.gov).

Dated: April 19, 2004.

**William P. Nichols,**

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

[FR Doc. 04-9373 Filed 4-23-04; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Food Safety: Discovering Novel Causes of Foodborne Illness

*Announcement Type:* New.

*Funding Opportunity Number:* 04103.

*Catalog of Federal Domestic Assistance Number:* 93.283.

*Key Dates: Letter of Intent Deadline:* May 26, 2004.

*Application Deadline:* June 25, 2004.

### I. Funding Opportunity Description

**Authority:** This program is authorized under section 317(k)(2) of the Public Health Service Act, (42 U.S.C. 247(k)(2)), as amended.

**Purpose:** The purpose of the program is to better define the burden of foodborne, infectious diarrheal diseases among a broad array of known and potential pathogens, to test for novel pathogens and evaluate new diagnostic tests where the results will advance our knowledge of relative frequency of foodborne pathogens and improve disease surveillance and prevention efforts. This program addresses the "Healthy People 2010" focus area of Food Safety. See Attachment II of this announcement as posted on the CDC Web site for more background information.

Measurable outcomes of the program will be in alignment with the following performance goals for the National Center for Infectious Diseases (NCID): Protect Americans from infectious diseases and reduce the spread of antimicrobial resistance.

**Research Objectives:**

- Develop a collaborative multisite study within Foodborne Diseases Active Surveillance Network (FoodNet) (see attachment II for FoodNet description) to expand activities into microbiologic research of potentially important foodborne etiologies of infectious diarrhea.

- Enroll persons with and without diarrhea in a study to determine the potential infectious etiologies of diarrheal illness.

- Determine the demographic and clinical characteristics of infectious etiologies of diarrheal illness.

- Determine major risk factors for the acquisition of diarrheagenic pathogens or antibiotic resistance among enteric pathogens or normal enteric flora.

- Develop and assess culture and non-culture techniques to identify and characterize potential foodborne diarrheal pathogens.

- Serve to evaluate stool samples for infectious etiologies from foodborne outbreaks of unknown etiology among FoodNet sites.

- Characterize antibiotic resistance determinants among pathogens and normal human fecal flora.
- Transfer new diagnostic technology to public health and clinical laboratories.

*Activities:* Awardee activities of this program are as follows:

- Conduct all activities and studies in a collaborative network of investigators from the study sites, collaborating FoodNet sites, and the Centers for Diseases Control and Prevention (CDC). Study results from individual study sites will be combined for analyses, presentation and manuscripts.

- Develop a study protocol, standard questionnaires, medical chart data abstraction forms and databases in collaboration with study investigators from other FoodNet study sites and CDC.

- Establish clinic-based pediatric and adult patient enrollment in emergency departments and clinics to enroll case-patients presenting with diarrhea and persons without diarrhea (controls). Case-patient enrollment, with the collection of bulk stool specimens, should exceed a minimum of 250 per year. An approximately equal number of control-patients, with bulk stool specimens collected, should be enrolled annually.

- Collect bulk stool specimens from all case- and control-patients and appropriately transport and store them for testing.

- Conduct interviews with case- and control-patients using standardized questionnaires.

- Conduct standardized medical chart abstractions.

- Determine a broad array of bacterial, parasitic, and viral etiologies for diarrhea in all collected stool specimens. An example of a possible testing scheme is demonstrated in Attachment III. Tests proposed by applicants may or may not include, and are not limited to those in the example testing scheme.

- Seek heretofore unknown pathogens in select populations and circumstances.

- Establish a bank of frozen whole stool specimens, isolated pathogens, and nucleic acid extracts from stool specimens collected as part of this study.

- Determine antimicrobial drug susceptibilities for bacterial pathogens and selected normal fecal flora.

- Develop and/or evaluate new diagnostic tests for infectious diarrhea.

- Maintain a database of results using software and database structure which will allow merging data with that from other sites for combined analyses.

- Obtain and maintain all local approvals for human subjects' protection.

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC Activities for this program are as follows:

- Organize and host initial and yearly investigator's meeting.

- Collaborate with recipients in the consensus development of the study protocols, questionnaires, medical chart abstraction forms and study databases.

- Provide coordination and technical assistance in carrying out project activities, including data analyses, presentations and manuscripts.

- If a proposed project involves research with human subjects and CDC scientists will be co-investigators in that research, assist in the development of a research protocol for IRB review by all institutions participating in the research project. The CDC IRB will review and approve the project initially and on, at least, an annual basis until the research project is completed.

- Making site visits to review progress.

## II. Award Information

*Type of Award:* Cooperative Agreement.

CDC involvement in this program is listed in the Activities Section above.

*Fiscal Year Funds:* 2004.

*Approximate Total Funding:* \$700,000.

*Approximate Number of Awards:* Two.

*Approximate Average Award:* \$350,000.

*Floor of Award Range:* None.

*Ceiling of Award Range:* \$700,000.

*Anticipated Award Date:* September 1, 2004.

*Budget Period Length:* 12 months.

*Project Period Length:* Three years.

Throughout the project period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government.

## III. Eligibility Information

### III.1. Eligible Applicants

Applications may be submitted by public and private nonprofit

organizations and by governments and their agencies, such as:

- Public nonprofit organizations.
- Private nonprofit organizations.
- Universities.
- Colleges.
- Research institutions.
- Hospitals.
- Community-based organizations.
- Faith-based organizations.
- Federally recognized Indian tribal governments.
- 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).

A Bona Fide Agent is an agency/organization identified by the State as eligible to submit an application under the State eligibility in lieu of a State application. If you are applying as a bona fide agent of a State or local government, you must provide a letter from the State or local government as documentation of your status. Place this documentation behind the first page of your application form.

### III.2. Cost Sharing or Matching

Matching funds are not required for this program.

### III.3. Other

If you request a funding amount greater than the ceiling of the award range, your application will be considered non-responsive, and will not be entered into the review process. You will be notified that your application did not meet the submission requirements.

If your application is incomplete or non-responsive to the requirements listed in this section, it will not be entered into the review process. You will be notified that your application did not meet submission requirements:

This program is designed and intended to support research, therefore only research will be supported under this cooperative agreement. Any applications proposing anything other than research will be considered non-responsive.

An LOI is required for this program. Any application received without the prior submission of an LOI will be considered non-responsive.

Applications from principal participants of the FoodNet must

include a letter of collaboration and support from the research institution responsible for conducting advanced microbiologic testing.

Applications from research institutions conducting advanced microbiologic testing must include a letter of collaboration and support from principal participants of the collaborating FoodNet site.

This research study is intended as an expansion of activities among FoodNet collaborative partners. Other proposed studies within FoodNet will interface with this project. For example, FoodNet investigations into the etiology of outbreaks of unknown etiology will use the laboratory capacity established under this cooperative agreement to conduct advanced microbiologic testing.

*Individuals Eligible to Become Principal Investigators:* Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for CDC programs.

**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.

#### IV. Application and Submission Information

##### IV.1. Address To Request Application Package

To apply for this funding opportunity, use application form PHS 398 (OMB number 0925-0001 rev. 5/2001). Forms and instructions are available in an interactive format on the CDC Web site, at the following Internet address: <http://www.cdc.gov/od/pgo/forminfo.htm>.

Forms and instructions are also available in an interactive format on the National Institutes of Health (NIH) Web site at the following Internet address: <http://grants.nih.gov/grants/funding/phs398/phs398.html>.

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

##### IV.2. Content and Form of Application Submission

*Letter of Intent (LOI):* A Letter of Intent is required for this Program Announcement and must be written in the following format:

- Maximum number of pages: Two.
  - Font size: 12-point unreduced.
  - Single spaced.
  - Paper size: 8.5 by 11 inches.
  - Page margin size: One inch.
  - Printed only on one side of page.
  - Written in plain language, avoid jargon.
- Your LOI must contain the following information:
- Descriptive title of the proposed research.
  - Name, address, E-mail address, and telephone number of the Principal Investigator.
  - Names of other key personnel.
  - Participating institutions.
  - Number and title of this Program Announcement (PA).

*Application:* Follow the PHS 398 application instructions for content and formatting of your application. For further assistance with the PHS 398 application form, contact PGO-TIM staff at (770) 488-2700, or contact GrantsInfo, Telephone (301) 435-0714, e-mail: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov).

Your research plan should be single spaced and address activities to be conducted over the entire project period.

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. Your DUNS number must be entered on line 11 of the face page of the PHS 398 application form. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access <http://www.dunandbradstreet.com> or call 1-866-705-5711. For more information, see the CDC Web site at: <http://www.cdc.gov/od/pgo/funding/pubcommt.htm>.

Additional requirements that may require you to submit additional documentation with your application are listed in section "VI.2. Administrative and National Policy Requirements."

##### IV.3. Submission Dates and Times

*LOI Deadline Date:* May 26, 2004. Submission of an LOI is required if you intend to apply for this program. The LOI will not be evaluated or scored. It will be used to gauge the level of

interest in this program and to allow CDC to plan the application review. If you do not submit an LOI, you will not be allowed to submit an application.

*Application Deadline Date:* June 25, 2004.

*Explanation of Deadlines:* Applications must be received in the CDC Procurement and Grants Office by 4 p.m. Eastern Time on the deadline date. If you send your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If CDC receives your application 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, you will be given the opportunity to submit documentation of the carrier's guarantee. If the documentation verifies a carrier problem, CDC will consider the application as having been received by the deadline.

This announcement is the definitive guide on application submission address and deadline. It supersedes information provided in the application instructions. If your application does not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that your application did not meet the submission requirements.

CDC will not notify you upon receipt of your application. If you have a question about the receipt of your application, first contact your courier. If you still have a question, contact the PGO-TIM staff at: (770) 488-2700. Before calling, please wait two to three days after the application deadline. This will allow time for applications to be processed and logged.

##### IV.4. Intergovernmental Review of Applications

Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order (EO) 12372. This order sets up a system for State and local governmental review of proposed federal assistance applications. You should contact your state single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your State's process. Click on the following link to get the current SPOC list: <http://www.whitehouse.gov/omb/grants/spoc.html>.

#### IV.5. Funding Restrictions

Restrictions, which must be taken into account while writing your budget, are as follows:

- Construction is not allowable.

If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement should be less than 12 months of age.

#### IV.6. Other Submission Requirements

**LOI Submission Address:** Submit your LOI by express mail, delivery service, fax, or e-mail to: Ken Fortune, Extramural Program Coordinator, Centers for Disease Control and Prevention, National Center for Infectious Diseases, 1600 Clifton Road, NE., Mailstop C-19, Atlanta, GA 30333, Telephone Number: (404) 639-0890, Fax: (404) 639-4195, E-mail: [kef2@cdc.gov](mailto:kef2@cdc.gov).

**Application Submission Address:** Submit the original and five hard copies of your application by mail or express delivery service to: Technical Information Management-PA#04103, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

Applications may not be submitted electronically at this time.

### V. Application Review Information

#### V.1. Criteria

You 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.

The goals of CDC-supported research are to advance the understanding of biological systems, improve the control and prevention of disease and injury, and enhance health. In the written comments, reviewers will be asked to evaluate the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals.

Your application will be evaluated against the following criteria:

#### Operational Plan (40 Points)

Does the applicant propose clear operational plan(s) for the various study components addressed? Collectively, how well do the applicant's proposed

activities address the stated objectives and suggested activities outlined in the Activities section? Does the applicant describe the essential collaboration between FoodNet site investigators and research site investigators? Does the plan for case-patient and control-patient enrollment, with whole stool specimen collection, indicate probable success in achieving the stated enrollment goals? Does the plan include adequate personnel to carry out the proposed enrollment, consent, patient interviews, chart reviews, specimen collection and microbiologic testing? Are letters of collaboration and support from collaborating investigators or institutions included?

#### Experimental Plan (40 Points)

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, specifically concerning case-patient and control-patient enrollment and specimen collection? Does the proposed testing include a broad array of bacterial, parasitic, and viral pathogens? Does the proposed testing include proposals to identify novel agents? Does the proposal include the identification and characterization of antibiotic resistance determinants in pathogens and select normal stool flora? Does the proposal include diagnostic test development and/or evaluation?

#### Facilities and Personnel (10 Points)

Do the proposed investigators and personnel have the background and experience to carry out the proposed activities? Do they have experience in related research? Are the facilities described and are they appropriate?

#### Understanding the Problem (10 Points)

Does the applicant demonstrate a clear understanding of the surveillance, epidemiologic and microbiologic issues in determining the burden of foodborne illness among enteric pathogens, particularly for pathogens for which routine surveillance does not exist and for pathogens yet to be discovered?

#### Protection of Human Subjects From Research Risks (No Score)

Does the application adequately address the requirements of Title 45 CFR part 46 for the protection of human subjects? This will not be 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.

#### Inclusion of Women and Minorities in Research (No Score)

Does the application adequately address 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; and (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.

#### Budget (No Score)

The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

#### V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO), and for responsiveness by NCID. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

An objective review panel will evaluate complete and responsive applications according to the criteria listed in the "V.1. Criteria" section above.

In addition, the following factors may affect the funding decision:

- Although new programs are encouraged, a funding preference will be given to current FoodNet participants or current or newly established collaborative university medical center partners of FoodNet sites (located in the States of Maryland, Connecticut, New York, Minnesota, California, Colorado, New Mexico, Georgia, Tennessee, and Oregon) over applications not already receiving support under the program. Current FoodNet sites have implemented networks that require continued support to become fully developed and to realize the benefits of the network activities.

### V.3. Anticipated Announcement and Award Dates

Anticipated Award Date: September 1, 2004.

## VI. Award Administration Information

### VI.1. Award Notices

Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

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### VI.2. Administrative and National Policy Requirements

45 CFR Part 74 and Part 92

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.

The following additional requirements apply to this project:

- 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-9 Paperwork Reduction Act Requirements.
- AR-10 Smoke-Free Workplace Requirements.
- AR-11 Healthy People 2010.
- AR-12 Lobbying Restrictions.
- AR-15 Proof of Non-Profit Status.
- AR-22 Research Integrity.
- AR-23 States and Faith-Based Organizations.
- AR-25 Release and sharing of Data.

Additional information on these requirements can be found on the CDC Web site at the following Internet address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

### VI.3. Reporting

You must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, (use form PHS 2590, OMB Number 0925-0001, rev. 5/2001 as posted on the CDC Web site) 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. Budget.
  - e. Additional Requested Information.
  - f. Measures of Effectiveness.
2. Financial status report and annual progress 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.

These reports must be mailed to the Grants Management Specialist listed in the "Agency Contacts" section of this announcement.

## VII. Agency Contacts

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

For scientific/research issues, contact: Chris Braden, Program Official, Centers for Disease Control and Prevention, National Center for Infectious Diseases, 1600 Clifton Road, NE., Atlanta, GA 30333, Telephone: (404) 639-2206, E-mail: [crb5@cdc.gov](mailto:crb5@cdc.gov).

For financial, grants management, or budget assistance, contact: Theresa Routh-Murphy, Contract Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: (770) 488-2648, E-mail: [tnr3@cdc.gov](mailto:tnr3@cdc.gov).

Dated: April 20, 2004.

**William P. Nichols,**

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

[FR Doc. 04-9374 Filed 4-23-04; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Annual Influenza Vaccine Effectiveness Estimates in Healthy and High-risk Populations

*Announcement Type:* New.  
*Funding Opportunity Number:* 04109.  
*Catalog of Federal Domestic Assistance Number:* 93.283.

*Key Dates:*

*Letter of Intent Deadline:* May 11, 2004.

*Application Deadline:* June 10, 2004.

*Executive Summary:* Annual estimates of influenza vaccine

effectiveness are important to assess the protection against influenza provided by vaccination. These studies will help determine the degree of protective immunity provided by the vaccine in years when the vaccine contains a virus that is antigenically different from the predominantly circulating strain as well as in years where the vaccine and circulating viruses are well-matched. The results will provide information that is beneficial to future vaccine strain decisions and help guide policy development for influenza vaccination recommendations. This cooperative agreement seeks to support researchers with access to pediatric and adult populations to conduct vaccine efficacy studies each year beginning in the fall of 2004.

## I. Funding Opportunity Description

**Authority:** This program is authorized under sections 301(a) and 317(k)(1) of the Public Health Service Act, [42 U.S.C. sections 241(a) and 247b(k)(1)], as amended.

**Purpose:** Each year, on average, influenza results in 36,000 deaths in the United States. Influenza vaccination is the best way to prevent influenza and its severe complications. Each year the Advisory Committee for Immunization Practices (ACIP) reviews the annual recommendations for influenza vaccination and uses new studies or other evidence gained over the previous years to decide if there should be new target groups for immunization. The current target groups for immunization include groups that are at increased risk for influenza related complications, such as the elderly (*i.e.*, persons 65 years of age and older) and persons with certain chronic medical conditions. Persons aged 50 to 64, because of the likelihood of chronic medical conditions, and caretakers (health-care workers and household contacts) who have frequent contact with people who have high-risk conditions are also recommended for vaccination to reduce the likelihood of transmitting influenza to high-risk groups.

Over the years, the results from studies on the effectiveness and efficacy of influenza vaccination in preventing influenza-like illness or laboratory-confirmed influenza infection have varied. In addition, vaccine effectiveness or efficacy is dependent on the age group and health care status of the group being studied. Vaccine effectiveness and efficacy estimates tend to be higher in healthy, immunocompetent people, whereas, studies have shown lower effectiveness in the elderly. In years when the vaccine match is suboptimal, estimates of