

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: 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 NIP. 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.

Applications that are complete and responsive to the PA will be evaluated for scientific and technical merit by an appropriate peer review group or charter study section convened by NIP in accordance with the review criteria listed above. As part of the initial merit review, all applications may:

- Undergo 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 and assigned a priority score.

- Receive a written critique.
- Receive a second level programmatic review by a NIP panel.

Award Criteria: Criteria that will be used to make award decisions include:

- Scientific merit (as determined by peer review)
- Availability of funds
- Programmatic priorities

V.3. Anticipated Announcement and Award Dates

Anticipated Application Deadline Date: May 2004.

Anticipated Award Date: August 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 Review
- AR-10, Smoke-Free Workplace Requirements
- AR-11, Healthy People 2010
- AR-12, Lobbying Restrictions
- AR-15, Proof of Non-Profit Status (if applicable)
- AR-22, Research Integrity
- AR-24, Health Insurance Portability and Accountability Act Requirements

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 scientific/research issues, contact:

Mr. Gary Edgar, Extramural Project Officer, CDC, National Immunization Program, 1600 Clifton Road NE., Mailstop E-52, Atlanta, GA 30333, Phone: (404) 639-8787, E-mail: GWE1@CDC.GOV.

For questions about peer review, contact:

Ms. Beth Gardner, Scientific Review Administrator, CDC, National Immunization Program, 1600 Clifton Road NE., Mailstop E-05, Atlanta, GA 30333, Phone: (404) 639-6101, E-mail: BGardner@CDC.GOV.

For financial, grants management, or budget assistance, contact:

Jesse L. Robertson, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: (770) 488-2747, E-mail: jtr4@CDC.GOV.

VIII. Other Information

National Immunization Program, Centers for Disease Control and Prevention, Internet address: <http://www.cdc.gov/nip>.

Dated: March 24, 2004.

Edward J. Schultz,

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

[FR Doc. 04-7015 Filed 3-25-04; 1:52 pm]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Economic Studies of Vaccines and Immunization Policies, Programs, and Practices

Announcement Type: New.
Funding Opportunity Number: 04092.
Catalog of Federal Domestic Assistance Number: 93.185.

Key Dates:

Letter of Intent Deadline: April 29, 2004.

Application Deadline: June 1, 2004.

SPOC Notification Deadline: April 29, 2004. For more information, see section "IV.4. Intergovernmental Review of Applications."

I. Funding Opportunity Description

Authority: Public Health Services Act, Section 317(k)(1), 42 U.S.C. 247b(k)(1), as amended.

Purpose: The purpose of the program is to provide important economic information about vaccines and immunization policies, programs, and practices. As new vaccines or vaccine combinations are developed, economic studies provide increasingly valuable data about the costs of program implementation and maintenance, the medical costs that can be averted by vaccine use, the costs of adverse events associated with vaccines, and the changes in health utilities resulting from their use. These data assist decision makers as they balance the health burden and economic costs of disease against vaccination costs when they make immunization recommendations.

This program addresses the "Healthy People 2010" focus area of Immunization and Infectious Diseases.

Measurable outcomes of the program will be in alignment with performance goal of the Centers for Disease Control and Prevention's (CDC) National Immunization Program (NIP) to reduce the number of indigenous cases of vaccine-preventable diseases.

Research Objectives: To generate economic information needed to inform and guide immunization policy, program, and practice decisions.

Activities: Awardee activities for this program are as follows:

1. Assemble a research team with demonstrated experience in conducting health economic studies of vaccine preventable diseases from multiple perspectives. To produce research results compatible with other CDC economic research, this team must be able to conduct quantitative research in the areas of cost-effectiveness, cost-utility, and cost-benefit analysis.

2. Conduct activities addressing (a) and (b) below. The subject of activity (a) is a varicella vaccine to prevent zoster infection in adults and the elderly. Clinical trials of the vaccine are now underway. The purpose of the study is to provide important health economic information useful to the immunization decision making process once the clinical trials are completed. There is currently little information about the health values and utilities associated with herpes zoster infection, prevention of infection, and possible adverse events associated with a potential vaccine. Hence CDC's interest in innovative approaches to valuation of the benefits associated with this vaccine. Additional studies will be conducted as described in (b) below. Specific protocols for

activities conducted under (1) and (2) must be developed collaboratively by the awardee and CDC.

- (a) Conduct a utility analysis of vaccinating adults against zoster infection, including the associated adverse events. Primary data collection methods will be employed to obtain stated-preferences and utilities about willingness to avoid zoster infection and adverse events. Study focus will be on survey design and implementation, measurement of health state values and utilities, and translation into quality-adjusted life-years. The study will be designed so that the resulting data will be compatible with data that are obtained through the vaccine clinical trials. The analysis will complement other economic studies of vaccines being conducted at CDC.

- (b) Develop and conduct as many as three additional applied studies in vaccine economics to be decided upon in collaboration with CDC staff. The awardee must have the flexibility to accommodate changes in specific studies and priorities as CDC's need for information changes.

Examples of potential areas of interest for future studies include:

- (1) Evaluation of coverage rates, costs, and implementation barriers for new or modified childhood, adolescent, and adult vaccines.

- (2) Evaluation of coverage rates and costs of vaccine delivery to children, adolescents, and adults in traditional and non-traditional health care settings or other alternative settings

- (3) Development and application of innovative, quantitative epidemiologic and economic methods to provide data to support decisions about vaccine policies, programs, and practices.

- (4) Routinely evaluate progress in achieving the purpose of this program.

- (5) Analyze and interpret data from the program studies, and publish and disseminate findings in collaboration with CDC.

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:

1. Provide CDC investigator(s) to monitor the cooperative agreement as project officer(s).

2. Participate as active project team members in the development, implementation and conduct of the research project and as coauthors of all scientific publications that result from the project.

3. Provide technical assistance on the selection and evaluation of data

collection and data collection instruments.

4. Assist in the development of research protocols for Institutional Review Boards (IRB) review. The CDC IRB will review and approve the project protocol initially and on at least an annual basis until the research project is completed.

5. Provide subject matter expertise in the areas of epidemiologic methods and statistical analysis, health economics, and survey research consultation

6. Participate in the analysis and dissemination of information, data and findings from the project, facilitating dissemination of results.

7. Serve as liaisons between the recipients of the project award and other administrative units within the CDC.

8. Facilitate an annual meeting between awardee and CDC to coordinate planned efforts and review progress.

9. Analyze and interpret data from studies, and publish and disseminate findings in collaboration with CDC.

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: \$400,000.

Approximate Number of Awards: One.

Approximate Average Award: \$400,000 (This amount is for the first 12-month budget period, and includes both direct and indirect costs).

Floor of Award Range: None.

Ceiling of Award Range: \$400,000.

Anticipated Award Date: August 15, 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

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.

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: 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 LOI is required and must be written in the following format:

- Maximum number of pages: Three
- Font size: 12-point un-reduced
- 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, telephone number, and fax number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Number and title of this Program Announcement (PA)
- Summary of proposed activities and description of study design, methods, and analyses

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.

The Program Announcement Title and number must appear in the application.

You must include a research plan with your application. The research plan should be double spaced and be no more than 25 pages.

Your application will be evaluated on the criteria listed under Section V. Application Review Information, so it is important to follow them, as well as the Research Objectives and the Administrative and National Policy Requirements (AR's), in laying out your research plan.

Your research plan should address activities to be conducted over the entire project period. The research plan should consist of the following information:

1. **Abstract.** It is especially important to include an abstract that reflects the project's focus, because the abstract will be used to help determine the responsiveness of the application.

2. **Program Goals and Objectives.** Describe the goals and objectives the proposed research is designed to achieve in the short and long term. Specific research questions and hypotheses should be included.

3. **Methods.** Provide detailed methods of completing activity (a) described in Section I, including the collection of data to develop utilities associated with vaccination, and recruitment of participants if appropriate. Provide information to demonstrate how these data will be compatible with data obtained through relevant vaccine clinical trials. If any materials are not extant, the methods and timeframe for measure development and pilot testing should be given. Describe approach and

any past experience relevant to completing activity (b) described in Section I.

4. **Project Management.** Provide evidence of the expertise, capacity, and support necessary to successfully implement the project with an emphasis on team members with expertise necessary to conduct activities (a) and (b) described in Section 1. Each existing or proposed staff position for the project should be described by job title, function, general duties, level of effort, and allocation of time. Management operation principles, structure, and organization should also be noted.

5. **Collaborative Efforts.** List and describe any current and proposed collaborations with government or health agencies or other researchers that will impact this project. Include letters of support and memoranda of understanding that specify the nature of past, present, and proposed collaborations, and the products/services/activities that will be provided by and to the applicant.

6. **Data Sharing and release:** Describe plans for the sharing and release of data (See AR-25 for additional information).

7. **Project Budget:** Provide a detailed budget for each activity undertaken, with accompanying justification of all operating expenses that is consistent with the stated objectives and planned activities of the project.

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 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/pubcomm.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: April 29, 2004.

A letter of Intent (LOI) is required for this Program Announcement. The LOI will not be evaluated or scored. Your letter of intent will be used to estimate the potential reviewer workload and to avoid conflicts of interest during the review. If you do not submit a LOI, you

will not be allowed to submit an application.

Application Deadline Date: June 1, 2004.

Explanation of Deadlines:

Applications must be received in the CDC Procurement and Grants Office by 4:00 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 carriers 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

None.

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.

Awards will not allow reimbursement of pre-award costs.

IV.6. Other Submission Requirements

LOI Submission Address: Submit your LOI by express mail, delivery service, fax, or E-mail to:

Ms. Beth Gardner, Scientific Review Administrator, CDC, National Immunization Program, 1600 Clifton Road, NE., Mailstop E-05, Atlanta, GA 30333, Phone: 404-639-6101, Fax: 404-639-0108, E-mail: BGardner@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# 04092, 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.

The scientific review group will address and consider each of the following 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.

The criteria are as follows:

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)?

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 priority score:

(1) Ability to assemble a research team with demonstrated experience in conducting health economic studies of vaccine preventable diseases from multiple perspectives using the following approaches:

(a) modeling of epidemiologic and economic phenomena, (b) measuring health-related utilities associated with disease, disease prevention, and vaccine-associated adverse events, (c) estimating monetary values for reduced risk of disease and for reduced morbidity and mortality, (d) constructing decision-analytic models, and (e) conducting cost-effectiveness, cost-utility, and cost-benefit analyses.

(2) Demonstrated publication record using the types of analyses in (1) above and in the fields of epidemiology and vaccine economics.

Protection of Human Subjects from Research Risks: 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: 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: 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 National Immunization Program. 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.

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- Undergo 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 and assigned a priority score.

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Award Criteria: Criteria that will be used to make award decisions include:

- Scientific merit (as determined by peer review)
- Availability of funds
- Programmatic priorities

V.3. Anticipated Announcement and Award Dates

Anticipated Application Deadline Date: May 2004.

Anticipated Award Date: August 2004.

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- c. New Budget Period Program Proposed Activity Objectives.

- d. Budget.

- e. Additional Requested Information.

- f. Measures of Effectiveness.

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For scientific/research issues, contact:

Mark L. Messonnier, M.S., Ph.D., Project Officer, Lead Economist, CDC, National Immunization Program, 1600 Clifton Rd., NE., Mailstop E52, Atlanta, Georgia 30333, Telephone: (404) 639-8218, E-mail: MMessonnier@cdc.gov.

For questions about peer review, contact:

Ms. Beth Gardner, Scientific Review Administrator, CDC, National Immunization Program, 1600 Clifton Road, NE., Mailstop E-05, Atlanta, GA 30333, Phone: 404-639-6101, E-mail: BGardner@CDC.GOV.

For financial, grants management, or budget assistance, contact:

Jesse L. Robertson, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-27347, E-mail: jtr4@CDC.GOV.

VIII. Other Information

National Immunization Program, Centers for Disease Control and Prevention, Internet address: <http://www.cdc.gov/nip>.

Dated: March 24, 2004.

Edward J. Schultz,

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

[FR Doc. 04-7014 Filed 3-25-04; 1:52 pm]

BILLING CODE 4163-18-P