

interventions; specific objectives that are realistic, measurable and time phased; and clear definition of both process and outcome measures for the evaluation of implementation activities.

#### 6. Management and Staffing for Intervention Activities (15 points)

The current functioning of asthma staff (program and surveillance) within the health agency; the description of staff to be hired or contracts to be developed; the link of staff to program objectives; and the continued role of the statewide partnership group.

#### 7. Budget (Not scored)

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

### H. Other Requirements

#### Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Semi-annual progress reports (The progress report will include a data requirement that demonstrates measures of effectiveness.) The progress reports shall include the following items:

- a. A brief project description.
- b. A comparison of actual accomplishments to the goals and objectives established for the period.
- c. In the case that established goals and objectives may not be accomplished or are delayed; documentation of both the reason for the deviation and the anticipated corrective action or a request for deletion of the activity for the project.
- d. A financial summary of obligated dollars to date as a percentage of total available dollars.
- e. Other pertinent information (i.e. curriculum vitae for new key personnel).

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.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment III of the application kit.

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

### I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301 and 317 of the Public Health Service Act, [42 U.S.C. section 241 and 247b], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

### J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications and associated forms can be found on the CDC home page Internet address—<http://www.cdc.gov> Click on "Funding" then "Grants and Cooperative Agreements."

For business management assistance, contact:

Sonia V. Rowell, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, Program Announcement 02085, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146.

Telephone number: (770) 488-2724.

Email address: [SRowell@cdc.gov](mailto:SRowell@cdc.gov).

For program technical assistance, contact:

Daniel J. Burrows, M.S., Public Health Advisor, Air Pollution and Respiratory Health Branch, National Center for Environmental Health, Centers for Disease Control and Prevention, Mailstop E-17, 1600 Clifton Rd., NE, Atlanta, GA 30333.

Telephone number: (404) 498-1004.

Email address: [DBurrows@cdc.gov](mailto:DBurrows@cdc.gov).

Dated: May 4, 2002.

**Sandra R. Manning,**

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

[FR Doc. 02-11564 Filed 5-8-02; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### [Program Announcement 02167]

### "Phase I Study To Assess The Safety, Tolerability, Immunogenicity, And Shedding Of Attenuated Measles Vaccine Administered As A Single Intranasal Dose To Healthy Adults"; Notice of Availability of Funds

#### A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2002 funds for a cooperative agreement

program for "Phase I Study to Assess the Safety, Tolerability, Immunogenicity, and Shedding of Attenuated Measles Vaccine Administered as a Single Intranasal Dose to Healthy Adults." This program addresses the "Healthy People 2010" focus area "Immunization and Infectious Diseases" and "Medical Product Safety".

The purpose of the program is to conduct a double blinded, randomized, placebo controlled, 2-step, single-center study of intranasal administration of attenuated measles vaccine in healthy adults to assess safety and immunogenicity of vaccine, tolerability of vaccination, and shedding of vaccine virus.

#### Research Objectives

##### Primary

1. To determine the safety and tolerability of live attenuated measles vaccine administered intranasally (IN) to healthy adults.

2. To compare the serum antibody responses elicited following IN versus subcutaneous (SC) administration of live attenuated measles vaccine, using standard methods (plaque-reduction neutralization titers and ELISAs).

##### Secondary

1. To measure the incidence of measles vaccine viral shedding following vaccination.

2. To explore the utility of mucosal antibody measurements in evaluating responses to measles immunization.

#### Background

Measles continues to be a major source of morbidity and mortality in developing countries despite the availability of an effective vaccine. Expanded immunization programs are hampered by the fact that until now there has only been a parenteral vaccine available. Inappropriate vaccination procedures can lead to injection site infections, nerve damage or transmission of blood-borne pathogens.

Mucosal immunization has proven to be an effective and non-invasive manner by which to induce a local and systemic immune response. Measles immunization via aerosol has been studied extensively and has been found to be safe and effective. Previous studies of IN measles vaccination have yielded variable results attributable to varied doses and methods of administration plus interference by concomitant upper respiratory infections, making it difficult to determine if this is an effective vaccination route. No serious adverse events have been reported. Currently, the only Food and Drug

Administration (FDA) approved method for giving Measles-Mumps-Rubella (MMR) vaccination is by subcutaneous injection.

#### Research Plan

This is a request for proposals to conduct a phase 1, double blinded, randomly assigned, study comparing the safety, tolerability and immunogenicity of IN vs. SC administration of measles vaccine. The study must be done under an Investigational New Drug application from the FDA, as the goal is to eventually obtain FDA approval for IN vaccination with MMR vaccine. In order to maximize participant safety this request is for proposals to study only measles vaccination, and to begin with immune and semi-immune adults. The first step should include healthy measles-immune adults, the second, partially immune adults. Immune adults are those having a plaque-reduction neutralization titer of 1:120 or higher; partially immune adults are those with detectable titers that fall under 1:120. An Independent Safety Monitor (ISM) should review safety data from step 1 and determine that it is safe to continue before additional work begins with step 2. Before actually doing so, however, the grantee and researchers from the CDC should discuss the report of the ISM and the data, and agree whether or not to proceed with step 2.

Measurable outcomes of the program will be in alignment with the "Government Performance Results Act" (GPRA) performance goals for the National Immunization Program (NIP):

1. Reduce the number of indigenous cases of vaccine-preventable diseases.
2. Ensure that 2 year-olds are appropriately vaccinated.
3. Work with global partners to reduce the cumulative global measles related mortality rate.

#### B. Eligible Applicants

Applications may be submitted by public and private nonprofit and for-profit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit and for-profit organizations, faith-based organizations, State and local governments or their bona fide agents, including 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, federally recognized Indian tribal governments, Indian tribes, or Indian

tribal organizations, and small, minority, women-owned businesses.

**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.

#### C. Availability of Funds

Approximately \$192,000 is available in FY 2002 to fund one (1) award. It is expected that the award will be begin on or about September 30, 2002 and will be made for a 12-month budget period within a project period of up to two years. Funding estimates may change. Continuation awards within an approved project period will be made on the basis of satisfactory progress, as evidenced by required reports, and the availability of funds.

#### Use of Funds

Funds cannot be used for construction or renovation, to purchase or lease vehicles or vans, to purchase a facility to house project staff or carry out project activities, or to supplant existing support.

#### D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. (Recipient Activities), and CDC will be responsible for the activities listed under 2. (CDC Activities). The intention is for the Recipient and the CDC to work jointly and in collaboration in developing, executing and reporting on this project.

##### 1. Recipient Activities

The following section describes the expected activities of the recipient:

- a. Develop the study protocol, determining the approaches to take in addressing the specific aims in the program announcement.
- b. Plan the analytic approach to be taken to understand and interpret the principal findings from the study.
- c. Obtain IRB approval for the protocol.
- d. Develop, submit and obtain an Investigational New Drug Application from the FDA for intranasal administration of measles vaccine.
- e. With assistance from and in collaboration with CDC staff, develop a plan of studies for phase I/II trials of intranasal rubella and mumps vaccines, as well as further studies of intranasal measles vaccine and phase I/II trials of combined MMR vaccine.
- f. Provide research pharmacist and facilities for filling nasal spray device with reconstituted measles vaccine.

g. Hire, manage and train research staff to provide clinical assessments, administer vaccine, collect samples and perform laboratory tests in compliance with Good Clinical Practice.

h. Implement the study protocol, conducting the study according to the protocol and resolving problems in study implementation as they arise.

i. Arrange for an Independent Safety Monitor to review the progress of the study and to determine if it is safe to proceed from step 1 to step 2. Before actually doing so, however, the grantee and researchers from the CDC should discuss the report of the ISM and the data, and agree whether or not to proceed with step 2.

j. Report serious and unexpected adverse events to CDC and FDA in a timely manner.

k. Perform standard measles immunogenicity assays, including ELISAs and plaque-reduction neutralization titers.

l. Perform tests of mucosal immunity.

m. Participate as authors in the preparation of manuscripts describing the results of the research.

n. Prepare reports for regulatory agencies and grantee Institutional Review Board (IRB), as necessary.

o. Applicants are required to provide Measures of Effectiveness that will demonstrate the accomplishment of the various identified objectives of the grant. Measures must be objective/quantitative and must measure the intended outcome. These Measures of Effectiveness shall be submitted with the application and shall be an element of the evaluation.

##### 2. CDC Activities

CDC staff will participate as a partner in the activities of the study, providing technical and laboratory assistance, where needed, as well as scientific collaboration.

a. Provide technical assistance and programmatic information relevant to the project.

b. Assist in the development of a research protocol for IRB review by all cooperating institutions participating in the research project. The CDC IRB will review and approve the protocol initially and on an annual basis until the research project is completed.

c. Assist in the performance of the study and participate, with recipient staff members, in the progression from step 1 to step 2 of the research plan (as per "i." of Recipient's Activities).

d. Participate in the development of the plan for future studies (as per "e." of Recipient's Activities).

e. Perform nucleic acid detection (RT-PCR methods) and/or viral cultures to

detect measles vaccine virus in clinical samples.

f. Participate in the analysis and interpretation of data from the study and in presentation and publication of the findings of the research.

#### E. Content

The Program Announcement title and number must appear in the applications. Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Applications will be evaluated on the criteria listed, so it is important to address them when describing the program plan. The narrative should be no more than 20 single-spaced pages and be printed on one side, with one-inch margins and a 12-point unreduced font.

The narrative should consist of, at a minimum, a Plan, Objectives, Methods, Evaluation and Budget.

#### F. Submission and Deadline

Submit the original application and five copies of PHS 398 (OMB Number 0925-0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398). Forms are available in the application kit and at the following Internet address: [www.cdc.gov/od/pgo/forminfo.htm](http://www.cdc.gov/od/pgo/forminfo.htm) Application forms must be submitted in the following order:

Cover Letter  
Table of Contents  
Application  
Budget Information Form  
Budget Justification  
Checklist  
Assurances  
Certifications  
Disclosure Form  
Human Subjects Certification (if applicable)  
Indirect Cost Rate Agreement (if applicable)  
Narrative

On or before 5 p.m. Eastern Time July 15, 2002, submit the application to the Technical Information Management Section, PA# 02167, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146.

**Deadline:** Applications shall be considered as meeting the deadline if they are received before 5 p.m. Eastern Time on the deadline date. Applicants sending applications 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.

Applications which do not meet the above criteria will not be eligible for competition and will be discarded. Applicants will be notified of their failure to meet the submission requirements.

#### G. Evaluation Criteria

Applicants are required to provide Measures of Effectiveness that will demonstrate the accomplishment of the various identified objectives of the grant or cooperative agreement. Measures of Effectiveness must relate to the performance goal (or goals) as stated in section "A. Purpose" 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.

Applications will be evaluated against the following criteria by an independent review group appointed by CDC:

##### 1. Understanding the Project Objectives (10 points)

The extent to which the applicant possesses an understanding of the needs and purpose of the project as demonstrated through knowledge and understanding of current research and activities being performed in this area, past studies, existing literature and the clarity and practicality of the proposed project plan.

##### 2. Research Objectives (10 points)

The extent to which the research proposal addresses the research objectives provided in this announcement, provides a clear description of the methods to be used, and demonstrates adherence to accepted research practices as well as Good Clinical Practice. The applicant should also demonstrate that the applicant's research proposal is clear, feasible and practical.

##### 3. Research Methods (30 points)

The adequacy of the proposed research design, approaches and methodology to carry out the research, including quality assurance procedures and plans for data management and statistical analyses:

- a. Recruitment procedures, screening tests and eligibility/exclusion criteria.
- b. Method for allocation of subjects to IN vs. SC immunization.

c. Method for masking investigators and participants as to vaccination group.

d. Quality assurance procedures, plans for data analysis, statistical analysis methods and study endpoints.

e. Safety assessments and reporting of adverse events.

f. Methods for testing immunogenicity of vaccine, both in serum and mucosal fluids; these should be consistent with any methods described in the research objectives of this announcement.

g. Criteria for suspending the trial or for moving from step 1 to step 2.

h. A statistical analysis plan appropriate to the primary and secondary objectives.

i. The project time line.

j. Informed consent procedures.

k. Measures of Effectiveness. The Peer Review Panel shall assure that measures set forth in the application are in accordance with CDC's performance plans. (See CDC's Performance plans at website [www.cdc.gov/od/perfplan/2001perfplan.pdf](http://www.cdc.gov/od/perfplan/2001perfplan.pdf)).

##### 4. Research Population (5 points)

The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes:

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.

d. 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.

##### 5. Management Plan (20 points)

The soundness and feasibility of the applicant's proposed management plan for accomplishing the work expectations outlined in section D to include identification of applicant's key personnel to be assigned to the study and clear identification of their respective roles in the management and operations of the program.

##### 6. Experience and Capabilities (25 points)

The experience, qualifications, and technical abilities of the applicant and the proposed project staff relevant to:

- a. The content areas of immunizations and mucosal immunology.
- b. Conducting clinical research and publishing in peer-reviewed journals.

c. Ability to recruit suitable participants.

d. Demonstrable performance of measles serologies using ELISA and plaque-reduction neutralization methods.

e. Transmission of information in a timely, efficient, secure, and accurate manner.

f. Obtaining Investigational New Drug Applications from the FDA.

g. Receiving, storing and shipping biological specimens related to this project.

#### 7. Human Subjects (not scored)

The application should also adequately address the requirements of 45 CFR part 46 for the protection of human subjects. This should include the provision of the FWA number from the Office of Human Research Projection (OHRP).

#### 8. Budget (not scored)

The applicant shall describe their proposed plan for managing the resources necessary to comply with the requirements specified in Section D. This shall include a description of the proposed person hours for each key individual.

#### 9. GPRA Goals (not scored)

The applicant shall describe how their research plan meets the GPRA goals listed in Section A.

### H. Other Requirements

#### Technical Reporting Requirements

The grantee will provide CDC with the original plus two copies of:

1. Quarterly progress reports (the results of the Measures of Effectiveness shall be a data requirement to be submitted with or incorporated into the progress report);

2. Adverse event reports (within 24 hours of discovery of adverse event);

3. Financial status report, no more than 90 days after the end of the budget period;

4. Final financial report and performance report, 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.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment 1 of the announcement.

AR-1 Human Subjects Requirements

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

AR-10 Smoke-Free Workplace Requirements

AR-11 Healthy People 2010

AR-12 Lobbying Restrictions

AR-14 Accounting System Requirements

AR-21 Small, Minority, and Women-Owned Business

AR-22 Research Integrity

### I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301, 317 and 2102 of the Public Health Service Act, 42 U.S.C. 241, 247 and 30099-2(9), as amended. The Catalog of Federal Domestic Assistance number is 93.185.

### J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC home page Internet address—<http://www.cdc.gov> Click on "Funding" then "Grants and Cooperative Agreements."

For business management assistance contact: Peaches Brown, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146. *Telephone number:* (770) 488-2738. *Email address:* [PRB0@cdc.gov](mailto:PRB0@cdc.gov).

For program technical assistance, contact: Robert Perry, M.D., M.P.H., Epidemiology and Surveillance Division, National Immunization Program, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mailstop E-61, Atlanta, GA 30333. *Telephone number:* (404) 639-8224. *Email address:* [RMP9@cdc.gov](mailto:RMP9@cdc.gov).

Dated: May 4, 2002.

**Sandra R. Manning,**

*Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).*

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**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Program Announcement 02098]

### Expansion of HIV/AIDS Care Services in Côte d'Ivoire; Notice of Availability of Funds

#### A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the

availability of fiscal year (FY) 2002 funds for a cooperative agreement program for the expansion of HIV/AIDS care services in the Republic of Côte d'Ivoire.

The purpose of this cooperative agreement is to strengthen and expand the community response to Human Immunodeficiency Virus (HIV/AIDS) care services in the ten communities of Abidjan, the capital of Côte d'Ivoire, and selected secondary cities throughout the country.

#### B. Eligible Applicants

Applications may only be submitted by public and private non-profit and for profit-organizations, state and local governments or their bona fide agents, that currently conduct HIV/AIDS work in Côte d'Ivoire.

Applicants must have at least five years experience in HIV/AIDS work in Côte d'Ivoire including: Community mobilization for prevention of HIV/AIDS and promotion of voluntary counseling and testing; successful working relationships with both local and national government offices such as the mayors' office and the Ministries of Health and AIDS; establishment of support groups for people living with AIDS (PLWA); knowledge and understanding of resources available to create referral networks for clinical and psycho-social support for PLWA and families.

**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.

#### C. Availability of Funds

Approximately \$200,000 is available in FY 2002 to fund this award. It is expected that the average award will begin on or about September 30, 2002, and will be made for a 12-month budget period within a project period of up to three years. Annual funding estimates may change.

Continuation awards within the approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

#### 1. Use of Funds

Funds received from this announcement will not be used for the purchase of antiretroviral drugs for treatment of established HIV infection (with the exception nevirapine in Prevention of Mother to Child Transmission (PMTCT) cases and with prior written approval), occupational exposures, and non-occupational