

assistance may be obtained from: Victoria Sepe, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99121, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, NE, Room 3000, Atlanta, GA 30341 telephone (770) 488-2721, Email address vxw1@cdc.gov.

For program technical assistance, contact: Mr. Art Robinson, Public Health Educator, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention, 4770 Buford Highway, NE, Chamblee, Georgia 30341, Telephone: (770) 488-7040, E-mail address: ajr3@cdc.gov

Dated: May 5, 1999.

John L. Williams,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99132]

**Notice of Availability of Funds;
Varicella Surveillance and
Epidemiologic Studies**

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1999 funds for a cooperative agreement program to conduct surveillance and case investigations for varicella disease (chickenpox). This program will supplement existing local, State and national surveillance efforts and will facilitate research on impact of varicella vaccine on disease. Funds will be provided to conduct active surveillance and epidemiologic studies to monitor disease trends related to vaccine coverage. This program addresses the "Healthy People 2000" priority area 20, Immunization and Infectious Diseases.

The purpose of this program is:

1. To maintain a surveillance system to accurately monitor trends in varicella incidence by age group.
2. To monitor varicella vaccine coverage by age group.
3. To develop, implement, and evaluate strategies for the prevention and control of varicella.
4. To conduct other applied epidemiological research related to varicella disease and varicella vaccine.

B. Eligible Applicants

Assistance will be provided only to official State and local public health agencies 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, federally-recognized Indian tribal governments the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau.

C. Availability of Funds

1. Approximately \$665,000 is available in FY 1999 to fund two to three awards. The average award will be about \$200,000, ranging from \$150,000 to \$250,000. It is expected that awards will begin on or about September 30, 1999, and will be made for a 12-month budget period within a project period of up to 5 years. Funding estimates may vary and are subject to change. Continuation awards within the project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds. Funds awarded under this cooperative agreement cannot be used to supplant existing state expenditures in this area.

D. Program Requirements

In conducting the activities to achieve the purpose of this program, the recipient will be responsible for the activities listed under (1.) Recipient Activities and CDC will be responsible for the activities listed under (2.) CDC Activities.

1. Recipient Activities

a. Establish, maintain, and evaluate a surveillance system with the capacity to monitor varicella disease trends by age group in a well-defined population. To ensure statistical validity, these surveillance areas must have populations of at least 300,000 to provide a sufficient number of varicella cases each year as varicella incidence declines with increasing use of the vaccine in children.

b. Perform case investigations and collect, analyze, and disseminate information using this information.

c. Collect and verify with health care providers the immunization status of all reported cases of breakthrough disease, including age of vaccination and other vaccines administered simultaneously or within 30 days.

d. Collect and report information on vaccine coverage by age group (age groups <1 year, 1 year, 2 years, 3 years, 4 years, 5 years, 6 years, 7 years, 8-9

years, 10-12 years, 13-14 years, 15-19 years and >20 years).

e. Develop, implement and evaluate varicella prevention and control strategies including outbreak control.

f. Conduct applied epidemiological research. Examples of such projects include but are not limited to the following: evaluation of risk factors for vaccine failure; evaluation of completeness of reporting by age group; risk factors for severe varicella disease and hospitalization; studies of vaccine effectiveness; reliability of physician diagnosis of breakthrough disease and reliability of parental history of varicella among children less than 10 years.

g. Provide laboratory specimens such as disease-causing isolates to appropriate organizations (which may include CDC) for laboratory evaluation needed for varicella surveillance or as part of epidemiological studies, e.g. virus strain identification, confirmation of breakthrough disease, and molecular epidemiological studies.

h. Manage, analyze and interpret data and present and publish important public health findings.

i. Participate in planning meetings to coordinate varicella surveillance project activities.

j. Function as part of a network of varicella surveillance sites.

3. CDC Activities

a. Provide consultation, scientific and technical assistance in general operation of the project and in the design and conduct of applied research projects.

b. Provide assistance to recipients regarding development and implementation of all surveillance activities, data collection methods including a standard case investigation form, and analysis of data.

c. Assist in the development and implementation of a standard data management process, including development of computer programs for data entry and interim analyses.

d. Assist in monitoring and evaluating scientific and operational accomplishments of the varicella surveillance project and progress in achieving the purpose and overall goals of this program.

e. Participate in analysis and interpretation of data and in presentation and publication of findings.

E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. The program narrative should include the following sections: background, objectives,

methods, plan of operation, and plan of evaluation. The narrative should describe:

1. The demographic characteristics of the general population upon which the surveillance system will focus.

2. The epidemiology of varicella in the surveillance population during the period 1995–1999 and varicella vaccine coverage among specified age groups during the period 1995–1999. The availability of historical data for baseline disease trends by age group prior to, and following, implementation of a vaccination program is required. These data should be comparable to that proposed for collection through this project in order to monitor trends.

3. The sources of reporting within the reporting area under study. Appropriate reporting and sources for surveillance should be identified and described in detail. If sampling is proposed, it must be described in detail including how it will be performed and how validity will be assured.

4. The operation of the surveillance system. This should include details of reporting, type and format of data to be obtained, mechanism for monitoring the system, and personnel requirements for obtaining, managing and analyzing data. The proposed surveillance system should provide the basis for epidemiological studies of the impact of varicella vaccine, identify cases occurring in vaccinated individuals, document the severity of disease and facilitate public health action.

5. A brief proposal for implementing and evaluating a disease prevention and/or control strategy.

6. A brief proposal for an applied epidemiological research study (addressing issues other than disease prevention and control strategies).

7. Background information and other data to demonstrate that the applicant has the appropriate organizational structure, administrative support, and ability to access appropriate target populations or study subjects.

8. The qualifications, including training and experience, of project personnel, and projected level of effort by each toward accomplishment of the proposed activities.

Budget Instructions

For each line item (as identified on the Form 424a of the application), show both Federal and non-Federal (e.g., State funding) shares of total cost for the varicella surveillance project. For each staff member listed under the Personnel line item, indicate their specific responsibilities relative to each of the proposed projects. Include provisions for travel of the principal investigator

and one varicella surveillance project participant to two meetings at CDC in Atlanta during the first year of the program.

A budget justification is required for all budget items, consistent with the purpose and objectives of the project. Letters of support should be included if applicants anticipate the participation of other organizations in conducting proposed activities.

The application narrative (excluding budget, appendices, and required forms) must not exceed 30 single-spaced pages, printed on one side, with one-inch margins, and un-reduced font. Only the following information should be presented in appendices: Letters of support, documentation of bona fide agent status, curricula vitae, and budget. All other materials or information that should be included in the narrative will not be accepted if placed in the appendices.

F. Submission and Deadline

Letter of Intent

In order to enable CDC to determine the level of interest in the program announcement, a non-binding letter-of-intent to apply is requested from potential applicants. The letter-of-intent should include: (1) Name and address of institution, and (2) name, address, and telephone number of contact person. The letter-of-intent should be submitted to the Grants Management Specialist identified in Section J "Where to Obtain Additional Information on or before June 11, 1999."

Application

Submit the original and two copies of PHS 5161-1 (OMB Number 0937-0189). Forms are provided in the application kit. On or before July 12, 1999, submit the application to: Mattie Jackson, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99132, 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 either:

(a) Received on or before the deadline; or

(b) Sent on or before the deadline date and received in time for submission to the review panel. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier of U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing).

Late Applications: Applications which do not meet the criteria (a) or (b) above a considered late applications, will not be considered, and will be returned to the applicant.

G. Evaluation Criteria

Each application will be evaluated individually by an independent review group appointed by CDC according to the following criteria:

(1) Understanding the objectives of the varicella surveillance project (5 points).

(a) Demonstration of a clear understanding of the background and objectives of this cooperative agreement program and the feasibility of accomplishing the outcomes described.

(2) Description of the population base and the vaccine providers in the varicella surveillance project site (5 points)

(a) Clear definition of the geographic area and population base in which the varicella surveillance site will operate. Detailed description of the demographics of the proposed population base including the extent to which the population base is diverse in terms of demographics and special populations.

(b) Description of vaccination providers in both the private and public sectors within the varicella surveillance site.

(3) Adequacy of baseline data for varicella surveillance; availability of trend data for varicella surveillance from 1995–1999 and comparability of these data to the proposed surveillance system (20 points).

(4) Description of existing capacity to perform surveillance for varicella, to assess vaccine impact, and to perform other applied epidemiological research (40 points).

(a) Adequacy of plan for performing and maintaining varicella surveillance that will cover all age groups. Description of methods for monitoring varicella disease in all age groups including the adequacy of an appropriate plan, and the extent to which the proposed sources of case reports will ensure an adequate sample size and representativeness of populations and all age groups at risk for varicella to ensure that the epidemiological analysis of the impact of varicella vaccine will be appropriate and statistically valid. If sampling is proposed, provide a detailed description of how sampling will be performed and how validity will be assured.

(b) Adequacy of plan for monitoring vaccine coverage. Description of plan for obtaining information on vaccine

coverage by age group on an ongoing basis.

(c) Adequacy of plans for data management. Description of plans for data management and analysis.

(d) Quality of proposals submitted for:

(i) Implementing and evaluating a disease prevention and/or control strategy.

(ii) An applied epidemiological research study (addressing an issue other than disease prevention and control strategies).

(5) Operational plan (15 points).

(a) The plan should identify the proposed organizational and operating structure/procedures including the roles and responsibilities of all participating agencies, organizations, institutions, and individuals. Description of applicant's partnerships with necessary and appropriate organizations for establishing and operating the proposed varicella surveillance including appropriate public health action in response to outbreaks.

(b) Ability to function as part of a surveillance network. The extent to which the applicant describes plans for collaboration with other varicella surveillance sites in the establishment and operation of the varicella surveillance and individual varicella surveillance projects, including project design/development (e.g., protocols) and synthesis and dissemination of findings.

(c) Quality of the proposed projects (as requested in the Application Content section above) regarding consistency with public health needs, intent of this program, feasibility, methodology/approach, and collaboration/participation of partner organizations. 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: (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.

(d) Demonstration of support from non-applicant participating agencies, institutions, organizations, etc. indicated in applicant's operational plan. Applicant should provide (in an appendix) letters of support which

clearly indicate collaborators willingness to be participants in the varicella surveillance activities. Do not include letters of support from CDC personnel.

(6) Personnel qualifications and management plan (10 points).

(a) Identification of applicant's key professional personnel to be assigned to the varicella surveillance site and varicella surveillance projects (provide curriculum vitae for each in an appendix). Clear identification of their respective roles in the management and operation of the varicella surveillance site. Descriptions of their experience in conducting work similar to that proposed in this announcement.

(b) Description of all support staff and services to be assigned to the varicella surveillance project.

(7) Evaluation (5 points).

(a) Quality of plan for monitoring and evaluating the completeness of surveillance, the quality of vaccine coverage data, and the scientific and operational accomplishments of the varicella surveillance site and of individual varicella surveillance projects.

(b) Quality of plan for monitoring and evaluating progress in achieving the purpose and overall goals of this cooperative agreement program.

(8) Budget (not scored).

Extent to which the line item budget is detailed, clearly justified, and consistent with the purpose and objectives of this program.

If requesting funds for any contracts, provide the following information for each proposed contract: (1) Name of proposed contractor, (2) breakdown and justification for estimated costs, (3) description and scope of activities to be performed by contractor, (4) period of performance, and (5) method of contractor selection (e.g., sole-source or competitive solicitation).

(9) Human Subjects (not scored).

Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects?

H. Other Requirements

Technical Reporting Requirements

Provide CDC with the original plus two copies of:

1. Semiannual progress reports
2. Financial status report, no more than 90 days after the end of the budget period.
3. 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

Section J "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 I in the application kit.

- AR98-1 Human Subjects Requirements
- AR98-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR98-7 Executive Order 12372 Review
- AR98-9 Paperwork Reduction Act Requirements
- AR98-10 Smoke-Free Workplace Requirements
- AR98-11 Healthy People 2000
- AR98-12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under Sections 301(a) and 317(k)(1), (2) of the Public Health Service Act [42 U.S.C. sections 241(a) and 247b(k)(1), (2)], as amended. The Catalog of Federal Domestic Assistance number is 93.185.

J. Where To Obtain Additional Information

Copies of this announcement and application forms can be downloaded by using the CDC homepage address on the Internet: <http://www.cdc.gov> (click on funding).

To receive additional written information and to request an application kit, call 1-888-GRANTS4 (1-888-472-6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

To obtain additional information contact: Mattie Jackson, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office Announcement 99132, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000 Atlanta, GA 30341-4146, Telephone (770) 488-2718 E-mail: mij3@cdc.gov.

For programmatic technical assistance, contact: Jane Seward, MBBS, MPH, Medical Epidemiologist, Varicella Activity, VPDB, National Immunization Program, Centers for Disease Control and Prevention (CDC), MS E-61, Atlanta, GA 30333, Telephone (404) 639-8230, E-mail: jfs2@cdc.gov.

Dated: May 5, 1999.

John L. Williams,

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

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