

scheduled for the meeting; or you may contact the Board's Web site at <http://www.federalreserve.gov> for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Board of Governors of the Federal Reserve System, March 5, 2004.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 04-5448 Filed 3-8-04; 11:03 am]

BILLING CODE 6210-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on HIV/AIDS

AGENCY: Office of the Secretary, Office of Public Health and Science, HHS.

ACTION: Notice of meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (DHHS) is hereby giving notice that the Presidential Advisory Council on HIV/AIDS (PACHA) will hold a meeting. This meeting is open to the public. A description of the Council's functions is included also with this notice.

DATE AND TIME: March 29, 2004, 9 a.m. to 5 p.m., and March 30, 2004, 9 a.m. to 4 p.m.

ADDRESSES: Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201. Conference Room 800 on March 29 and Conference Room 705A on March 30, 2004.

FOR FURTHER INFORMATION CONTACT: Josephine Robinson, Acting, Executive Director, Presidential Advisory Council on HIV/AIDS, U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, SW., 7th Floor, Room 701H, Washington, DC 20201; (202) 690-7440 or visit the Council's Web site at www.pacha.gov.

SUPPLEMENTARY INFORMATION: PACHA was established by Executive Order 12963, dated June 14, 1995, as amended by Executive Order 13009, dated June 14, 1996. PACHA was established to provide advice, information, and recommendations to the President regarding programs and policies intended to (a) promote effective prevention of HIV disease, (b) advance research on HIV and AIDS, and (c) promote quality services to persons living with HIV disease and AIDS. PACHA was established to serve solely

as an advisory body to the President and the Secretary of Health and Human Services. PACHA is composed of not more than 35 members. PACHA membership is determined by the Secretary from individuals who are considered authorities with particular expertise in, or knowledge of, matters concerning HIV/AIDS.

The agenda for this meeting includes the following topics: HIV/AIDS prevention, care and treatment, and global HIV/AIDS issues. Time will be allotted during the meeting for public comment.

Public attendance is limited to space available and pre-registration is required for both attendance and public comment. Any individual who wishes to attend and/or comment must call (202) 690-5560 to register. Individuals must provide a government issued photo ID for entry into the meeting. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the registrar.

Members of the public will have the opportunity to provide comments at the meeting. Public comment will be limited to three (3) minutes per speaker and to time available. Written testimony, not exceed five (5) pages, will be accepted by mail or facsimile at 202/690-7425. Written testimony will not be accepted after 5 p.m., Wednesday, March 24, 2004

Dated: February 27, 2004.

Josephine Bias Robinson,

Executive Director (Acting), Presidential Advisory Council on HIV/AIDS.

[FR Doc. 04-5344 Filed 3-9-04; 8:45 am]

BILLING CODE 4150-28-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Varicella and Viral Vaccine Preventable Disease Surveillance and Epidemiologic Studies

Announcement Type: New.

Funding Opportunity Number: PA 04116.

Catalog of Federal Domestic Assistance Number: 93.185.

Key Dates:

Letter of Intent Deadline: March 22, 2004.

Application Deadline: May 12, 2004.

I. Funding Opportunity Description

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

Purpose: The purpose of the program is to support population-based active surveillance for varicella, herpes zoster, and other viral Vaccine Preventable Diseases (VPD), to assess vaccination coverage by age group and to conduct applied epidemiological research on the above mentioned viral VPD. This program addresses the "Healthy People 2010" focus area(s) of priority 20.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Immunization Program (NIP): Reduce the number of indigenous cases of varicella and other viral VPDs.

Research Objectives: 1. To evaluate the impact of varicella vaccination program on varicella disease and herpes zoster, including the impact of disease control and prevention activities.

2. To conduct applied epidemiological research related to varicella, herpes zoster, varicella vaccine policy and/or other viral VPD.

3. To conduct a study to assess immunity against varicella among vaccinated health care workers. For those who lack detectable antibodies, measure anamnestic response after receiving a third dose.

4. To evaluate the burden of disease of one or more current VPD, like influenza, or that may be vaccine preventable in the future like rotavirus, human papillomavirus (HPV), herpes simplex virus type 2 (HSV2), respiratory syncytial virus (RSV), or CMV cytomegalovirus (CMV).

Applicants may apply for objective 1, 2, 3, and 4 alone, or any or all combination of the four components. Separate budgets are required for each program component.

Activities: Awardee activities for this program are as follows: Under objective 1:

- Implement, conduct, maintain, and evaluate active population based surveillance systems with the capacity to monitor varicella and/or herpes zoster disease. To ensure statistical validity, these surveillance areas must have populations of at least 300,000 for varicella and at least 500,000 for herpes zoster to provide a sufficient number of varicella and herpes zoster cases each year.

- Perform case investigations for varicella and/or herpes zoster, for all ages, and collect, analyze, and disseminate information using these data.

- Collect and report information on vaccine coverage by age group. For varicella age group: less than 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 greater than 20 years.

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

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

- Function as part of a network of surveillance sites. Submit data to CDC according to project procedures.

Under Objective 2:

- Conduct applied epidemiological research for varicella and/or herpes zoster. Examples of such projects include but are not limited to the following: evaluation of risk factors for varicella vaccine failure; evaluation of completeness of reporting by age group; risk factors for severe varicella disease and hospitalization; evaluation of vaccine effectiveness; measurement of reliability of physician diagnosis of breakthrough disease; assessment of duration of immunity to varicella among vaccinees in low-varicella incidence settings; virus strain identification for herpes zoster in vaccinees; assessment of herpes zoster hospitalizations and trend of herpes zoster over time.

And/or

- Conduct applied epidemiological research for other viral VPD. Examples of such projects include but are not limited to the following: risk factors for severe influenza disease and hospitalization; studies of vaccine effectiveness; planning and implementation of community based demonstration/interventions to increase vaccination; impact evaluation of implemented demonstration/interventions on disease incidence and prevalence; evaluation of cost effectiveness of suggested demonstration/interventions as well as illness and severity.

Under objective 3:

- The study is going to assess the need for a third dose of varicella vaccine among health care workers (HCW) who are seronegative after having received two doses. To ensure statistical power, the study site should demonstrate ability to enroll at least 200 HCW who

have previously received two doses of varicella vaccine (based on assumption of 15 percent susceptibility among vaccinated HCW).

- Identify HCW who have previously received two doses of varicella vaccine. Obtain blood samples and send them to CDC for serologic and cellular immunity testing. Through interviews and using standardized forms, collect data on potential risk factors (demographics, varicella vaccination and disease history, time since vaccination, work place/type (pediatrics, infectious disease, etc), children at home, underlying disease, and exposure to varicella cases since vaccination) for susceptibility following two doses. Administer a third dose of varicella vaccine to HCW who are seronegative as measured by IgG gpELISA and collect blood samples seven to ten days and four to six weeks after vaccination for testing humoral and cellular immunity. Calculate the proportion of HCW who are protected by showing an anamnestic response as measured by antibody levels and correlate it to their cell mediated immunity (CMI) response prior to third dose. Examine risk factors for not having antibodies following two doses.

Under Objective 4:

- Implement, maintain, and evaluate a surveillance system with the capacity to monitor one or more viral VPD (other than varicella and herpes zoster) like influenza, rotavirus, HPV, HSV2, RSV, or CMV. To ensure statistical validity, these surveillance areas must have populations of at least 500,000 to provide a sufficient number of cases each year and include child care centers and schools among the sites under surveillance.

- Develop, implement and evaluate influenza and/or other viral VPD prevention and control strategies among children.

- Provide laboratory specimens such as disease-causing isolates to appropriate organizations (which may include CDC) for laboratory evaluation needed for influenza and/or other viral VPD surveillance or as part of epidemiological studies on influenza and/or other viral VPD, *e.g.* virus strain identification and molecular epidemiological studies.

For those choosing influenza, activities may consider:

- Collect and report information on vaccine coverage by age group. For influenza age groups: 6–23 months and their household contacts; at risk children 2–7 years, 8–19 years and their household contacts.

- Evaluate the feasibility of pediatric hospital-based influenza virologic data

for following trends in the impact of influenza in children 6–23 months old.

- Conduct applied epidemiological research for influenza. Examples of such projects include but are not limited to the following: risk factors for severe influenza disease and hospitalization; studies of vaccine effectiveness; planning and implementation of community based demonstration/interventions to increase influenza vaccination; measure impact and monitor implementation of the Advisory Committee on Immunization Practices (ACIP) recommendations for influenza vaccination of 6–23 month old children, at-risk children, and their household contacts: offering influenza vaccination at obstetrics and gynecology clinics, public health clinics, private providers, day care facilities, school based vaccination, and others; evaluation of cost effectiveness of suggested demonstration/interventions.

General Activities (for all objectives):

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

- Participate in planning meetings to coordinate varicella, herpes zoster, other viral VPD, and influenza project activities.

- Provide surveillance data on a quarterly basis and provide semiannual progress reports for varicella, herpes zoster, and other viral VPD and provide timely progress reports for influenza during influenza season and the recommended influenza vaccination period (September–May).

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:

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

- 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.

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

- Assist in monitoring and evaluating scientific and operational accomplishments of the varicella, herpes zoster, other viral VPD, and influenza projects and progress in achieving the purpose and overall goals of this program.

- Participate in analysis and interpretation of data and in presentation and publication of findings.
- In addition, for Objective 3, conduct serologic and CMI testing on the samples collected.

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: \$932,600.

Approximate Number of Awards: Two to five.

Approximate Average Award: \$460,000 (This amount is for the first 12-month budget period, and includes both direct and indirect costs).

Floor of Award Range: \$100,000.

Ceiling of Award Range: \$603,000.

1. Varicella and/or herpes zoster surveillance (objective 1): Varicella/herpes zoster surveillance: \$200,000; varicella surveillance alone: \$150,000; herpes zoster surveillance alone: \$100,000

2. Varicella-herpes zoster, other viral VPD epidemiological research (objective 2): \$150,000

3. Varicella HCW study (objective 3): \$102,600

4. Influenza and/or other viral VPD surveillance (objective 4): \$150,000

Anticipated Award Date: August, 2004.

Budget Period Length: 12 Months.

Project Period Length: Five Years. For Objective 3, project period is 12 months.

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 tribes
- Indian tribal organizations
- State and local governments or their Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau)

- Political subdivisions of States (in consultation with States)

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

CDC will accept and review applications with budgets greater than the ceiling of the award range.

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): Your LOI must be written in the following format:

- Maximum number of pages: two
- Font size: 12-point unredacted
- 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 phone 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.

You must submit a research plan narrative with your application forms. The narrative must be submitted in the following format:

- Maximum number of pages: 30. If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.
- Font size: 12 point unredacted
- Double spaced
- Paper size: 8.5 by 11 inches
- Page margin size: One inch
- Single spaced, printed only on one side of page
- Held together only by rubber bands or metal clips; not bound in any other way.

Your research plan narrative should address the activities listed for the objectives/program components you are responding to, and which will be conducted over the entire project period, and must include the following items in the order listed: Background, Objectives, Methods, Plan of Operation, Plan of Evaluation and a separate Budget for each submitted program component. The Budget will not be counted as part of the stated page limit.

For each one of the program components you are responding to, the narrative should describe (where pertinent):

- The demographic characteristics of the general population which the surveillance system will cover.
- The epidemiology of varicella, herpes zoster, other viral VPD, and influenza. For varicella baseline epidemiological data, the time period in the surveillance population should be 1995–2003 and varicella vaccine coverage among specified age groups during the period 1995–2003. The availability of historical data for baseline disease trends for varicella by age group prior to, and following, implementation of a varicella vaccination program is required. These data should be comparable to that proposed for collection through this project in order to monitor trends. For other viral VPD and influenza, the time period would be two to three years of baseline data in 2000–2003. If available, for other viral VPD and influenza, vaccine coverage among specified age groups during the same period should be presented.
- 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.
- The operation of the varicella, herpes zoster, and other viral VPD surveillance system and monitoring of influenza impact in children: 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 systems should provide the basis for epidemiological studies of the impact of varicella, other viral VPD, and influenza vaccine, identify cases occurring in vaccinated individuals, document the severity of disease and facilitate public health action.
- A brief proposal for implementing and evaluating a disease prevention and/or control strategy for varicella, other viral VPD, and influenza.
- A brief proposal for applied epidemiological research studies (addressing issues other than disease prevention and control strategies) for varicella, herpes zoster, other viral VPD, and influenza. It would be advantageous to indicate the existence or the proposed establishment of collaboration with a state/city health department for outbreak response/prevention/control

activities under applied epidemiological research.

- 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.

Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit. This additional information includes:

- The qualifications, including training and experience, of project personnel, and projected level of effort by each toward accomplishment of the proposed activities.
- Letters of support.
- Documentation of bona fide agent status.
- Curricular vitas.

Budget—Budget section should have separate line items for (1) Varicella and/or herpes zoster surveillance; (2) epidemiologic studies of varicella, herpes zoster, and/or other viral VPD; (3) Varicella HCW study; (4) Other viral VPD surveillance. For each line item show both Federal and non-Federal (e.g., State funding) shares of total cost. A budget justification is required for all budget items, consistent with the purpose and objectives of the program. Letters of support should be included if applicants anticipate the participation of other organizations in conducting proposed activities.

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/pubcommnt.htm>.

This PA uses just-in-time concepts. 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: March 22, 2004. A Letter of Intent (LOI) is required for this Program Announcement. The LOI will not be evaluated or scored. Your LOI

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: May 12, 2004.

Explanation of Deadlines:

Applications must be received in the: Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1040, MSC 7710, Bethesda, MD 20892-7710.

Bethesda, MD 20817 (for express/courier service) 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.

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.

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
 - Real estate lease or purchase
 - Vehicle purchase
 - Vehicle lease, other than rental associated with travel for this project
- Awards will not allow reimbursement of pre-award costs. 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: Beth Gardner, National Immunization Program, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, MS E-05, Atlanta, GA 30333, Telephone: 404-639-6101, FAX: 404-639-0108, E-mail: BGardner@cdc.gov.

Application Submission Address: Submit the original and three hard copies of your application by mail or express delivery service to: Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1040, MSC 7710, Bethesda, MD 20892-7710, Bethesda, MD 20817 (for express/courier service).

At the time of submission, two additional copies of the application must be sent to: Scientific Review Administrator, Beth Gardner, Centers for Disease Control and Prevention, National Immunization Program, 1600 Clifton Road, MS E-05, Atlanta, GA 30333, Telephone Number: 404-639-6101, FAX: 404-639-0108. 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?

- Adequacy of baseline data and availability of trend data for the diseases under surveillance and the proposed viral VPD as indicated under activities; and comparability of these data to the proposed surveillance system where adequate.

- Clear definition of the geographic area and population base in which the surveillance and proposed activities 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.

- Understanding the objectives of the cooperative agreement by demonstrating a clear understanding of the background and objectives and the feasibility of accomplishing the outcomes described.

- Quality of the proposed activities under program objectives regarding consistency with public health needs, intent of this program, feasibility, methodology/approach, and collaboration/participation of partner organizations.

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?

For objective 1:

- Description of existing capacity to perform surveillance for varicella and/or herpes zoster and to assess vaccine impact.

- Adequacy of plan for performing and maintaining varicella and/or herpes zoster surveillance and the extent to which the proposed sources of case report will ensure adequate sample size and representativeness of populations under surveillance.

- Adequacy of plan for monitoring varicella vaccine coverage.

- Description of plan for obtaining information on varicella vaccine coverage by age group on an ongoing basis.

- Adequacy of plans for data management and analysis.

- Methodology for conducting population-based surveillance.

Under objectives 2 and 3:

- Description of existing capacity to perform applied epidemiological research on varicella, herpes zoster, and/or other viral VPD.

- Methodology for conducting applied epidemiological research on varicella, herpes zoster, and/or other viral VPD.

- Methodology for conducting vaccine effectiveness studies (Objective 2).

- Quality of the proposed applied epidemiological research projects, as requested under the Activities section above, regarding objectives, methodology/design, feasibility, and collaboration and participation with partner organizations like local and state health departments.

Under Objective 4:

- Description of existing capacity to perform surveillance for other viral VPD and to assess vaccine impact.

- Adequacy of plan for performing and maintaining other viral VPD surveillance and the extent to which the proposed sources of case report will ensure adequate sample size and representativeness of populations under surveillance.

- Description of plan for obtaining information on vaccine coverage by age group on an ongoing basis.

- Adequacy of plans for data management and analysis.

- Methodology for conducting population-based surveillance.

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)?

- Identification of applicant's key professional personnel to be assigned to manage/perform/implement activities under objectives 1-2-3-4 of the program (provide curriculum vitae for each in an appendix). Clear identification of their respective roles and responsibilities as well as management and operational plan.

- Descriptions of their experience in conducting work similar to that proposed in this announcement.

- Description of all support staff and services to be assigned to the different activities under program objectives.

- Proven record/publications of surveillance/research experience of key

investigator(s) (PI and main researchers) on the disease subjects considered under the applicant's response.

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?

- **Operational Plan:** 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, herpes zoster, and/or other viral VPD surveillance as well as applied epidemiological research including appropriate public health action in response to outbreaks.**

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

- **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.

- **Demonstration of support for 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 surveillance and applied epidemiological research activities. Do not include letters of support from CDC personnel.

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. In addition the application will be evaluated on the extent to which the line-item budget is detailed, clearly justified, consistent with the purpose and objectives of the program, and reflects both Federal and non-Federal (e.g., State funding) shares of total cost. If requesting funds for any contracts, provide the following information for each proposed contract: name of proposed contractor, breakdown and justification for estimated costs, description and scope of activities to be performed by contractor, period of performance, and method of contractor selection (e.g., sole-source or competitive solicitation).

Provide a separate detailed budget for each objective you are applying for, with accompanying justification of all operating expenses that is consistent with the stated objectives and planned activities of the project.

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Center for Scientific Review, and for responsiveness by the 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.

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 the National Immunization Program 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.
- Programmatic priorities receive a programmatic second level review by the National Immunization Program.

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

Announcement Date: March 2004.

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-6 Patient Care
- AR-7 Executive Order 12372
- AR-8 Public Health System Reporting Requirements
- AR-9 Paperwork Reduction Act Requirements

- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-14 Accounting System Requirements
- AR-15 Proof of Non-Profit Status
- AR-22 Research Integrity
- AR-23 States and Faith-Based Organizations
- 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/pgofunding/ARs.htm>.

VI.3. Reporting

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

1. Semi annual progress report, (use form PHS 2590, OMB Number 0925-0001, rev. 5/2001 as posted on the CDC Web site) no less than 30 days after the end of the first half 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: Dalya Guris, Extramural Project Officer, National Immunization Program, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, MS E-61, Atlanta, GA 30333, Telephone: 404-639-6205, E-mail: dhm5@cdc.gov.

For questions about peer review, contact: Beth Gardner, Scientific Review

Administrator, National Immunization Program, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, MS E-05, Atlanta, GA 30333, Telephone: 404-639-6101, FAX: 404-639-0108, E-mail: BGardner@cdc.gov.

For financial, grants management, or budget assistance, contact: Peaches Brown, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2738, E-mail: POBrown@cdc.gov.

VIII. Other Information

<http://www.cdc.gov/nip>.

Dated: March 4, 2004.

Edward Schultz,

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

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BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 69 FR 4302-4303, dated January 29, 2004) is amended to reflect the consolidation of administrative functions within the Office of the Director, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, into one single organizational component entitled the Administrative Services and Programs Office.

Section C-B, Organization and Functions, is hereby amended as follows:

Following the title and functional statement for the *Office of the Director (CAJ1)*, Office of the Chief Operating Officer (CAJ), insert the following:

Administrative Services and Programs Office (CAJ12). (1) Plans, coordinates, and provides administrative and management advice and guidance for the OD; (2) provides and coordinates OD-wide administrative, management, and support services in the areas of personnel, travel, procurement, facility management, and other administrative services; (3) plans, develops, and

implements OD-wide policies, procedures, and practices for administrative management, acquisition and assistance mechanisms, including contracts and memoranda of agreement, discretionary and block grants, and cooperative agreements; (4) coordinates OD requirements relating to small purchase procurements, VISA procurements, materiel management, and intra-agency agreements/reimbursable agreements; (5) coordinates facility management issues, problems and changes, physical security issues, and policies regarding telecommunications, office furniture and equipment; (6) maintains liaison with Centers, Institute and Offices, Staff Offices, Staff Service Offices, and OD staff; (7) provides guidance and coordination to the OD Offices on cross-divisional negotiated agreements; (8) facilitates and provides consultation on human resource management issues; (9) advocates the use of information technology to strengthen the communications among the divisions, field staff, and partners; (10) plans, coordinates, and implements training for the OD's Divisions' administrative personnel; (11) provides OD-wide management training to supervisors, managers and team leaders.

Delete the functional statement for the *Office of the Director (CAJ1)*, *Office of the Chief Operating Officer (CAJ)*, and insert the following:

(1) Manages and directs the activities and functions of the Office of the Chief Operating Officer; (2) provides guidance and support in the conduct and evaluation of program support, business services, and management activities performed for or by Centers/Institute/Offices; (3) participates in the development of CDC's goals and objectives; (4) advises and assists the Director, CDC, the Chief Operating Officer, and other key officials on all aspects of the mission, activities and functions of the Office of the Chief Operating Officer; (5) resolves and responds to external inquiries of current fiscal year funding expenditures; (6) plans and coordinates facility management issues, problems and changes, and physical security issues; and (7) plans and coordinates the implementation of various federal administrative, statutory, regulatory, and policy requirements.

Delete the functional statement for the *Office of the Director (CAJ31)*, *Facilities Planning and Management Office (CAJ3)*, and insert the following:

(1) Plans, directs, and coordinates the functions and activities of the Facilities Planning and Management Office (FPMO); (2) provides leadership and