DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Enhanced Surveillance for New Vaccine Preventable Diseases

Announcement Type: New.

Funding Opportunity Number: 04117.

Catalog of Federal Domestic Assistance Number: 93.185.

Key Dates:

Letter of Intent Deadline: March 29, 2004.

Application Deadline: May 12, 2004.

Executive Summary: The program will provide funding for approximately two grantees for five years (initially $550,000 per award in year one) to establish surveillance and evaluation sites that will collaborate with a larger network (the New Vaccine Surveillance Network (NVSN)) to conduct multi-site and individual projects to assess the impact of new vaccines and vaccine policies for diseases that are currently vaccine-preventable and those that are potentially vaccine preventable in the future. The current network consists of a total of three sites, one located in each New York, Tennessee, and Ohio. Two sites are in year five of a five-year project period, and one site is in year two of a five year project period. Currently, these sites conduct population-based surveillance of hospitalizations for ferbrile and acute viral respiratory illness (ARI) among children aged less than five years, surveillance for medically attended outpatient visits in community practices and emergency departments for ARIs among children aged less than five years, health service evaluation and research projects of knowledge, attitudes, and practices regarding vaccine use (including provider surveys, chart abstraction for vaccine use in community-wide provider practices, evaluation of vaccine effectiveness, and other projects.) The activities have included data collection on vaccine use, disease burden, and other variables in order to assess the impact of vaccines and related policies in populations. Although the current focus is on young children, the program is not restricted to the younger age group.

I. Funding Opportunity Description

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

Purpose: The purpose of the program is to support a network of sites that provide surveillance and data collection on new vaccine use, the impact of the new vaccines, and new vaccine policies through enhanced inpatient and outpatient surveillance, applied epidemiologic research, and investigator-initiated investigations. This program addresses the ''Healthy People 2010'' focus area(s) of Immunization and Infectious Diseases.

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 vaccine-preventable diseases (VPD).

Research Objectives: 1. To evaluate the impact of new vaccines or new vaccine policies on disease in site populations. 2. To evaluate the impact of new vaccines or new vaccine policies on administration of other vaccines. 3. To understand the burden of VPD in the population.

Activities: Awardee activities for this program are as follows:

A. Establish and operate an NVSN site. The site must be able to conduct the following activities:

(1) Establish a site with a defined catchment population, which could include either an entire state or a geographically defined area (or areas) within a state, *e.g.,* counties, in order to conduct population-based surveillance. A minimum population base of approximately 500,000 persons of all ages will be necessary to accomplish the objectives of certain NVSN activities (*e.g.,* obtaining population-based estimates of influenza and respiratory syncytial virus (RSV) in children less than five years of age.)

(2) Simultaneously conduct multiple surveillance activities and other studies *e.g.,* population-based inpatient surveillance for ARI among children less than five years old, outpatient ARI surveillance in a representative sample of children, other joint projects with one or more of the other NVSN sites (current or past projects include influenza vaccine effectiveness studies among inpatients and outpatients using case-cohort or screening method, and chart reviews from a broad sample of pediatric care providers in the community to assess uptake of pneumococcal conjugate vaccine (PCV) and its clinical impact and impact on vaccination practices (including timeliness in administering other vaccines, number of injections per vaccination visit, etc.)).

(3) Accommodate changes in specific projects and priorities as the public health system's need for information changes or new vaccines are licensed and implemented into the vaccination program.

(4) Develop projects and protocols collaboratively as part of a multi-site network with investigators at other NVSN sites and CDC. Site data will have to be integrated with data from the other sites for most projects. The ARI surveillance data from hospitals and outpatient clinics must be merged with data from other sites. Some local databases of vaccination or disease burden (*e.g.,* registries or insurance company data) may be proprietary; however, for joint NVSN projects, the data can be analyzed locally and presented together in joint publications. This requires that variables be available and defined in a way that is compatible with data from other sites. Sites must make every effort to ensure that data can be integrated with those of other NVSN sites.

(5) Conduct surveillance and other studies (*e.g.,* influenza vaccine effectiveness) with pediatric care providers in both inpatient and outpatient facilities during the first year of participation. Activities include promoting vaccination following ACIP recommendations and accurately estimating vaccination coverage in the surveillance area by conducting chart reviews in providers practices, as well as other methods deemed appropriate for particular study designs (*e.g.,* vaccine effectiveness using case-cohort or screening method).

B. Have plans for obtaining additional programmatic support to supplement assistance from CDC.

C. Utilize existing relationships with state and local health departments, and other public and private organizations to facilitate the ability to interact with health care providers and others in addressing study needs and public health issues relating to new vaccines and vaccine policies.

D. Conduct activities addressing (1) through (7) below. Specific protocols for activities conducted at more than one surveillance site must be developed collaboratively by investigators at those sites and CDC. Specific protocols for activities conducted at a single site must be approved in advance by CDC.

(1) Conduct year-round enhanced surveillance consistent with NVSN protocol (applicants can refer to NVSN publications, conference proceedings/ abstracts, etc., that can be found in the literature or on websites), for selected current and prospective vaccine-preventable diseases by performing the following activities in all surveillance area hospitals that admit children less than five years old: Provide staff to screen admissions year-round and enroll children with ARI; collect information on demographics, insurance

coverage, medical history, influenza vaccination, risk factors, hospital course, admission and discharge diagnoses, and laboratory results from parents and medical records; collect nasal and throat swabs from all enrolled children; demonstrate ability to perform timely, sensitive and specific viral culture and polymerase chain reaction (PCR) testing for influenza, RSV, and parainfluenza on a large volume of collected samples; conduct quality assurance checks of the data including laboratory assays in accordance with NVSN procedures; and enter data and send it to CDC using the NVSN web-based data collection system. Site must be able to begin inpatient surveillance in the first year of participation. Have the flexibility and capability of extending surveillance to other vaccine-preventable diseases, which may require the conduct of other laboratory tests. Collect influenza vaccination data on inpatients enrolled during surveillance, including accurate vaccination data from the primary care providers and other settings where vaccine is administered. Access hospital databases for hospital admission data for periodic enrollment audits.

(2) Depending on funding and priorities, conduct surveillance similar to that described in (1) above among a population-based or representative sample of children less than five years old seen at outpatient practices in the surveillance area. Viral culture and/or PCR would be used to test specimens from outpatients. Collect influenza vaccination data on outpatients enrolled during surveillance, including accurate vaccination data from the primary care providers and other settings where vaccine is administered.

(3) As needed, and depending on funding and priorities, study the impact of incorporating new vaccines on provider policies, practices, and utilization. Collect data from pediatric outpatient care providers to document the impact of new vaccines recommended for routine use among children, potentially including combination vaccines. Applicants may include, but are not limited to, a description of the number of vaccine and injections offered at visits during the first two years of life; vaccine-specific coverage rates of all recommended vaccines at specified ages, both before and after incorporating new vaccines; the number of visits used to complete administration of all recommended vaccine by ages one and two; and revenues and costs associated with incorporating new vaccines in practice.

(4) As needed, and depending on priorities, access hospital, clinic and other databases that will provide important administrative and patient level data for surveillance and other studies.

(5) Depending on funding and priorities, in addition and as a related or separate effort to influenza vaccination data collection under D(1) and D(2) activities, immunization data should be collected using methods that enable the NVSN to estimate accurately vaccine coverage and uptake for the defined site population, overall and for important subgroups. Applicants must have sufficiently extensive and established collaboration with pediatric provider practices in the catchment area in order to be able to estimate coverage in the first year of site's participation.

(6) As needed, possibly on an annual basis (including the first year of participation), and depending of funding and priorities, evaluate influenza vaccine effectiveness/efficacy. Examples of current ongoing evaluation of vaccine effectiveness using NVSN inpatient and outpatient surveillance cases include case-cohort (screening method) studies that obtain vaccination coverage by conducting chart reviews in provider practices throughout the catchment counties, and also by county-wide random digit dial telephone household surveys with provider validation of vaccination. In order to obtain accurate estimates, applicants must have sufficiently extensive and established collaboration with pediatric provider practices in the catchment area such that all could be considered for inclusion in chart reviews. Other childhood vaccinations would also be collected during the chart reviews.

(7) Depending on funding and priorities, develop and conduct other applied epidemiologic and/or health services research projects related to new vaccine introduction. Examples of completed or current projects include: cost effectiveness of influenza vaccination; analyses of Medicaid and private insurance databases to assess the impact of PCV on the burden of pneumococcal disease-related outcomes; survey of provider attitudes and practices regarding PCV; a feasibility study of implementing a recommendation for universal influenza vaccination of young children 6–35 months old through focus groups, national provider survey, time and motion study in seven provider practices, and a database analysis.

E. Routinely evaluate progress in achieving the purpose of this program.

F. Analyze and interpret data from NVSN projects, and publish and disseminate findings in collaboration with CDC.

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

CDC activities for this program are as follows:

- Provide CDC investigator(s) to monitor the NVSN cooperative agreement as protocol investigators and project officer(s). At least one CDC investigator will be assigned to each NVSN project.
- Provide consultation, scientific, and technical assistance in designing and conducting individual NVSN projects.
- Assist in the development of research protocols for Institutional Review Boards (IRB) review by all cooperating institutions participating in the research projects. For each protocol, the CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.
- As needed and arranged with investigators, perform laboratory evaluation of specimens or isolates (*e.g.,* molecular epidemiologic studies, evaluation of diagnostic tools) obtained in NVSN projects; and integrate results with data from other NVSN sites.
- Manage, maintain, and update the secure, encrypted CDC Web-based system which is used by the NVSN for data entry of ARI surveillance data at the sites, transfer of data from sites to CDC, merging of data from NVSN sites, and creation of data sets and data summaries which are accessible by each site. Each NVSN site will be able to download only its own site's raw data through the web-based system. Merged datasets will be shared among sites for approved analyses that require multi-site data.
- Analyze and interpret data from NVSN projects, and publish and disseminate findings in collaboration with NVSN site investigators.
- Participate as co-investigators on project activities including research design, methods, obtaining CDC IRB approval of protocols, data collection, data analysis, and co-authoring manuscripts.

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: $1,100,000.

Approximate Number of Awards: Two.

Approximate Average Award: $550,000 (This amount is for the first 12-month budget period, and includes both direct and indirect costs).

Floor of Award Range: None.

Ceiling of Award Range: $575,000 (This ceiling is for the first 12-month budget period.)

Anticipated Award Date: August, 2004.

Budget Period Length: 12 Months.

Project Period Length: Five years.

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

III. Eligibility Information

III.1. Eligible applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies, such as:

- Public nonprofit organizations
- Private nonprofit organizations
- Universities
- Colleges
- Research institutions
- Hospitals
- Community-based organizations
- Faith-based organizations
- Federally recognized Indian tribal governments
- 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 Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau)

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.

The existing site in Ohio, which is in Year 2 of 5, is based in Cincinnati with a Hamilton County catchment area. Applicants with catchment populations from this Cincinnati area will not be considered eligible to apply. New York and Tennessee sites are eligible.

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.

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

Applicants must demonstrate their capability and organizational ability to perform functions under Activities. In addition to describing inpatient and outpatient surveillance, applicants must describe activities listed under D(1) through D(4), describe proposed methods to accurately estimate vaccination coverage as listed in D(5), and propose at least one specific project from each of D(6) and D(7) under Activities. Each specific proposal for D(5)–D(7) activities must be clearly identified in a distinct portion of the Operational Plan and cannot exceed four pages.

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 925–0001 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 instruction 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 unreduced
- Single spaced
- Paper size: 8.5 by 11 inches
- Page margin size: One inch
- Printed only on one side of page
- Written in plain language, avoid jargon

Your LOI must contain the following information:

- Descriptive title of the proposed research
- Name, address, E-mail address, 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.*

Your research plan should be single spaced and address activities to be conducted over the entire project period. Also refer to III.3 Other, for description of required application content.

Descriptions of D(5)–D(7) activities must include objectives, methods, analytic approach, and illustrative sample size calculations and/or confidence intervals recognizing that data from two or more sites may be aggregated for analysis. Although the specific activities described address distinct issues and needs, they may be implemented in an integrated manner such that staff members work on more than one activity, and supplies and equipment are shared, etc. The specific project proposal(s) will be reviewed as a potential project that could be conducted under the award, but the NVSN may choose not to conduct the project depending on other NVSN interests, needs, and resources.

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. Your DUNS number must be entered on line 11 of

the face page of the PHS 398 application form. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access *www.dunandbradstreet.com* or call 1–866–705–5711. For more information, see the CDC Web site at: *http://www.cdc.gov/od/pgo/funding/pubcommt.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 29, 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 Deadline: 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, 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.

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

Awards will not allow reimbursement of pre-award costs.

IV.6. Other Submission Requirements

LOI Submission Address: Submit your LOI by express mail, delivery service, fax, or e-mail to: 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, 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, E-mail: *BGardner@cdc.gov*.

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:

Capability demonstration: The application will be evaluated based on response to all lettered and numbered items listed under Activities, and demonstration of capability of conducting these activities.

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? The application will be evaluated based on:

- Methodology for conducting population-based surveillance among patients at all surveillance area hospitals. Applicant must provide supporting evidence that surveillance would be population-based.
- Methodology for conducting surveillance among outpatients at a representative sample of outpatient practices.
- Methodology for conducting collection of influenza vaccination data and data for other vaccines that will enable accurate estimation of vaccine coverage in the population and for important subgroups.
- Methodology for conducting influenza vaccine effectiveness studies.
- Quality of the proposed additional research projects, as requested in IV.2 above, regarding objectives, methodology/design, feasibility, and collaboration and participation of partner organizations and CDC.

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)?

- The extent to which the applicant's plan for establishing and operating the NVSN site clearly describes the organizational structure and procedures and identifies all participating persons and groups including identifying key professional staff and their roles and responsibilities.
- Past experience of key professional staff in conducting work similar to that proposed in this announcement.
- Identifying key professional personnel from other collaborating organizations, agencies, etc. outside of the applicant's agency who will participate in NVSN activities, with roles described.
- Description of support staff and services to be assigned to the NVSN.
- Description of approach to flexible staffing to accommodate the changing requirements of NVSN projects that may occur due to changing public health needs and new vaccines or vaccine policies.

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.

- Past experience working with pediatric inpatient facilities and outpatient care providers in conducting epidemiologic and health services research of vaccines or other health care practices or interventions.
- The ability to develop and maintain strong cooperative relationships broadly with both public and private vaccine providers at the NVSN site, including public health agencies, academic centers, managed care organizations, and community organizations.
- Support from non-applicant participating agencies, institutions, organizations, laboratories, consultants, etc. indicated in applicant's operational plan. Applicant should provide (in an appendix) letters of support which clearly indicate collaborators' willingness to contribute to NVSN activities. Do not include letters of support from CDC personnel.
- Clear definition of the geographic area and population base in which the NVSN site will operate.
- Description of the demographics of the proposed population base including a description of various special populations as they relate to the proposed activities of the NVSN site.
- Description of vaccination providers within the NVSN site, and availability of or participation in a vaccination registry.

Additional Review Criteria: In addition to the above criteria, the following items will be considered in the determination of scientific merit and priority score: The extent to which the applicant demonstrates:

- A clear understanding of the background and objectives of this cooperative agreement program.
- A clear understanding of the requirements, responsibilities, problems, constraints, and complexities that may be encountered in establishing and operating the NVSN site.
- A clear understanding of the roles and responsibilities of participation in the NVSN network.
- Knowledge and understanding of current research and activities performed in this area, past studies, and existing literature.

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 for the NVSN site. 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 inpatient surveillance and outpatient surveillance and epidemiological and/or health services research studies, 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 NIP. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

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

- Undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority score.
- Receive a written critique.
- Receive a programmatic second level review by the NIP.

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 Woman and Racial and Ethnic Minorities in Research
- AR–6 Patient Care
- AR–7 Executive Order 12372
- AR–8 Public Health System Reporting 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, if applicable
- 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/pgo/funding/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 before 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: Carolyn Bridges, Centers for Disease Control and Prevention, National Immunization Program, ESD, 1600 Clifton Road, MS E–61, Atlanta, GA 30333, Telephone: 404–639–8689, E-mail: *CBridges@cdc.gov.*

Marika Iwane, Extramural Project Officer, Centers for Disease Control and Prevention, National Immunization Program, ESD, 1600 Clifton Road, MS E–61, Atlanta, GA 30333, Telephone: 404–639–8769, E-mail: *MIwane@cdc.gov.*

For questions about peer review, contact: Beth Gardner, Scientific Review Administrator, Centers for Disease Control and Prevention, National Immunization Program, OD, 1600 Clifton Road, MS E–05, Atlanta, GA 30333, Telephone: 404–639–6101, 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.

Sandra R. Manning, CGFM,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10082 OMB #0938–0898]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. The unanticipated lapse in the approval of this collection prior to implementation has resulted in the necessity to have the collection reinstated on an emergency basis. The information collection to be reinstated has not been modified from the version submitted to OMB under the regular PRA clearance process and approved on July 28, 2003.

CMS is requesting OMB review and approval of this collection within 15 days from the date of this publication, with an 180-day approval period.