rev. 9/2004 as posted on the CDC Web site) no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following additional elements:

a. Progress Toward Measures of Effectiveness.

b. Additional Information Requested by Program.

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

3. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management Specialist listed in the ''Agency Contacts'' section of this announcement.

**VII. Agency Contacts**

We encourage inquiries concerning this announcement.

For general questions, 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: Susan Chu, PhD, MSPH, Extramural Program Official, Centers for Disease Control and Prevention, National Immunization Program, MS E–05, 1600 Clifton Road NE, Atlanta, GA 30333. Telephone: (404) 639–8727. E-mail: *SChu@cdc.gov.*

For questions about peer review, contact: Mary Lerchen, DrPH, Scientific Review Administrator, CDC/Office of Public Health Research, One West Court Square, Suite 7000, MS D–72, Telephone: 404–371–5277. Fax: 404–371–5215. E-mail: *MLerchencdc.gov.*

For financial, grants management, or budget assistance, contact: Sharron Orum, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341. Telephone: (770) 488–2716. E-mail: *spo2@cdc.gov.*

**VIII. Other Information**

This and other CDC funding opportunity announcements can be found on the CDC Web site, Internet address: *http://www.cdc.gov.* Click on ''Funding'' then ''Grants and Cooperative Agreements.''

Dated: May 5, 2005.

**William P. Nichols,**

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

[FR Doc. 05–9372 Filed 5–10–05; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Developing Methods and Strategies To Increase Use of Immunization Registries by Private Providers

*Announcement Type:* New.

*Funding Opportunity Number:* RFA IP05–096.

*Catalog of Federal Domestic Assistance Number:* 93.185.

*Letter of Intent Deadline:* June 10, 2005.

*Application Deadline:* June 27, 2005.

**I. Funding Opportunity Description**

**Authority:** Section 311 [42 U.S.C. 243] and 317 (k)(1) [42 U.S.C. 247b (k)(1)] of the Public Health Service Act, as amended.

*Background*

Immunization registries are confidential, computerized information systems that collect vaccination histories and help ensure correct and timely immunizations, especially for children. Even though the United States currently enjoys the highest immunization rates and lowest disease levels ever, the growing complexity of the childhood vaccination schedule, as well as the need to vaccinate a new birth cohort of four million infants each year, makes such recordkeeping imperative. Inaccurate vaccination histories could lead to unnecessary immunization or missed opportunities for immunization. Because about 20 percent of children see a second provider during the second year of life and the paper records from the first provider may not be available, there is some risk that toddlers may receive an unnecessary vaccination. This waste increases the cost of medical care and results in an unnecessary injection for the young child. On the other hand, if a provider who sees a child for some but not all immunizations relies on the parent's hand-held vaccination records, a missed opportunity for immunization may occur if the parent forgets to bring in the child's records. The provider may then either (1) remind the parent verbally at the time to bring in the record for review at the next visit, or (2) attempt to obtain all immunization records from other known immunization providers, a time-intensive function. Instead, by electronically combining such records, registries can reduce both the possibility of extra immunizations as well as missed opportunities, as well as enhance other aspects of an immunization program by identifying at-risk and high-risk persons.

Presently 44 states have statewide or regional registries. Nationwide, although about 75 percent of public vaccination providers use them, only an estimated 31 percent of private providers do so. Only seven states have a majority (75 percent) of providers using their central registry. Although studies indicate that providers in general support registry use, several barriers persist. Many providers are not aware of the existence of a registry, despite significant promotion. Many are concerned that the registry available to them is not easily integrated into their other data systems (*e.g.*, appointments, billing, electronic medical records), lacks accuracy compared with hard copy records, or does not already contain the immunization history of patients sufficient to make real-time decisions in the office. Fees and other costs are perceived as a barrier as well. However, published research has refuted the basis of many of these perceptions. CDC has found that the median cost per child younger than six years is $4.71; another recent study estimated the per-shot additional cost at 56¢. Further, where a strong computer record system was put into place, registries were found to be 78 percent sensitive, compared with only 55 percent sensitivity for parental vaccination cards.

Given the presently low use of registries in private office practices, coupled with the high proportion of children (greater than 60 percent according to the 2003 National Immunization Survey) who receive at least some immunizations by private practitioners, a high degree of acceptance and use of registries by private providers is critical to its long-term success.

*Purpose*

This study is designed to determine methods and strategies to overcome obstacles to full, active participation of a state or county-based immunization registry (''central registry'') by private practitioners. The methods and strategies developed and applied will seek to change procedures in those private practice offices in which county or state based immunization registries are not fully and actively used.

Several definitions apply for the purpose of this Announcement. ''Community-based intervention'' is defined here as an intervention program provided to all primary care physicians (principally, pediatricians and family practice physicians) in the community. For example, a general education

program provided to all such physicians in a community concerning the value of using a registry in their practice would qualify. On the other hand, a study involving pre-selection and enrollment of only certain local physicians, followed by an intervention provided only to them, even if designed to provide them with skills or materials suitable to achieve the outcome desired, would not qualify.

Full, active registry use by a practice, for the purpose of this Announcement, is defined as: (a) The existence of a highly functional central registry to receive reports from providers; (b) submission of new records from practices to the central registry at least twice per month; and (c) submission of greater than 50 percent of all new immunizations given by a provider since his/her last report.

This program addresses the ''Healthy People 2010'' focus area of Immunization and Infectious Diseases, specifically Objective 14–26 of increasing to 95 percent the proportion of children aged greater than six years who are enrolled in a fully operational population-based immunization registry.

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

*Research Objective:* To develop and test the effectiveness of a community-based intervention to increase registry participation in private physician offices.

*Activities:* Awardee activities for this program are as follows: Awardees will develop, pilot-test, implement, and evaluate a strategy to convert at least ten private practices (or 20 percent of all practices in the intervention community, whichever is less) from non-use or partial use to full registry use. The individual steps (activities) needed to accomplish this are described below.

1. Identify two geographic separate communities (*e.g.* Memphis vs. Knoxville or Kansas City vs. St Louis) in which relatively few primary care providers fully and actively participate in their state or regional immunization registry. One will serve as the intervention community, the other as the control. The control community should be demographically similar to the intervention community, but will not be exposed to the intervention. The control and intervention communities must be evaluated at the same time intervals and in the same manner during the study. Providers from both communities must report to the same, single central registry site. The identity of the intervention and control communities and the justification for their selection should, if possible, be made explicit in the application. If one or both communities have not yet been identified, the applicant should specify their progress to date in identifying them.

2. In both communities, determine the knowledge, attitudes, and practices of local private providers and their staff concerning the use of registries in their office practices.

3. Within the intervention community, identify practice-based or physician-based barriers (and enablers) to the establishment and/or on-going full active use of registry programs.

4. Use these data to create, develop, and administer an intervention program designed to overcome identified barriers using education, non-cash incentives, and other, preferably novel methods. Program elements should be readily applicable to many types of practices, or alternatively, have the capacity to be easily tailored to each type of practice. The program may involve, for example, academic detailing, equipment purchase, train-the-trainer, management and training by the state or local health department or local immunization coalition, incentives by a local professional organization, or other methods. Multifaceted incentive programs are generally preferred over those with only one feature. This award is not intended to be used to develop or modify existing software already in use by the central registry. Justification should be shown to demonstrate that any motivators or (non-cash) reward system is low-cost and cost-efficient.

5. Assess the feasibility of providing the proposed intervention program to the entire intervention community before its full institution.

6. Provide the program throughout the intervention community over two years.

7. Measure the actual cost of the intervention program from the provider's perspective.

8. Measure the degree to which the intervention is associated with a change in the proportion of provider offices that become full active registry users. A successful outcome is defined as a practice that converts from non-use or partial use to full, active use of the registry, as defined above. The two-year goal is a 20 percent increase above the control community in the number of practices adopting full registry use by the 24th month. For relatively populous geographic areas, an alternate goal is a conversion of at least 10 practices during this period.

9. Develop an evaluation plan and conduct research that documents changes in knowledge and attitudes and any collateral benefits resulting from the intervention relative to the control community. In addition, document any unexpected or untoward (negative) outcomes that result. These data may require before-after survey(s) and measurements of provider registry participation in the two communities, among other potentially valuable methods.

10. Collaboratively disseminate research findings in peer-reviewed publications and for use in determining national policy.

11. Develop and institute a plan for sustaining registry use in the geographic area once the last funding cycle ends.

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

CDC activities for this program are as follows:

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

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

3. Provide technical assistance on site selection, data collection instruments, analysis, and evaluation plan and methods.

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

5. Contribute subject matter expertise in epidemiologic methods, statistical analysis, and survey methods.

6. Participate in the analysis and dissemination of project findings and facilitate dissemination of these results.

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

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

References

1. Glanzner JE, Beaty BL, Pearson KA et al. ''Using an immunization registry: effect on practice costs and time''. ''Ambulatory Pediatrics 2004''; 4:34–40

2. Ortega AN, Andrews SF, Katz SH et al. ''Comparing a computer-based childhood vaccination registry with

parental vaccination cards: a population-based study of Delaware children''. ''Clinical Pediatrics 1997''; 36:217–21.

**II. Award Information**

*Type of Award:* Cooperative Agreement.

CDC involvement in this program is listed in the Activities Section above.

*Mechanism of Support:* U01.

*Fiscal Year Funds:* 2005.

*Approximate Total Funding:* $200,000. (Includes direct and indirect costs. This amount is an estimate, and is subject to availability of funds.)

*Approximate Number of Awards:* One.

*Approximate Average Award:* $200,000. (Includes direct and indirect costs. This amount is for the first 12-month budget period.)

*Floor of Award Range:* None.

*Ceiling of Award Range:* $200,000. (Includes direct and indirect costs. This ceiling is for the first 12-month budget period.)

*Anticipated Award Date:* August 31, 2005.

*Budget Period Length:* 12 months.

*Project Period Length:* 2 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 are limited to public and private nonprofit organizations and by governments and their agencies, such as: (For profit organizations are not eligible under Section 317(k)(1) [42 U.S.C. 247b(k)(1) of the Public Health Service Act, as amended.)

- Public nonprofit organizations.
- Private nonprofit organizations.
- Small, minority, women-owned businesses.
- 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 Marianna 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*

If you request a funding amount greater than the ceiling of the award range, your application will be considered non-responsive, and will not be entered into the review process. You will be notified that your application did not meet the submission requirements.

*Special Requirements:* If your application fails to meet the following criteria, it will be considered non-responsive and will not be entered into the review process. You will be notified that your application did not meet submission requirements. The applicant must:

- Late applications will be considered non-responsive. See section ''IV.3. Submission Dates and Times'' for more information on deadlines.
- Document in the Appendix that it satisfies the eligibility criteria of Section III.1.
- 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.

*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, provided they document in the Appendix that they represent the provider network for this project. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for CDC programs.

**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. 9/2004). 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: 2.
- Font size: 12-point unreduced.
- Double-spaced.
- Paper size: 8.5 by 11 inches.
- Page margin size: One inch.
- Printed only on one side of page.
- Written in plain language, avoid jargon.

Your LOI must contain the following information:

- Descriptive title of the proposed research.
- Name, address, E-mail address, telephone number, and FAX number of the Principal Investigator.
- Names of other key personnel.
- Participating institutions.
- Number and title of this Announcement.

*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 address activities to be conducted over the entire project period.

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/pubcommt1.htm.*

This announcement uses the non-modular budgeting format.

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:* June 10, 2005.

CDC requests that you send a LOI if you intend to apply for this program. Although the LOI is not required, not binding, and does not enter into the review of your subsequent application, the LOI will be used to gauge the level of interest in this program, and to allow CDC to plan the application review.

*Application Deadline Date:* June 27, 2005.

*Explanation of Deadlines:* LOIs must be received in the CDC Office of Public Health Research (OPHR) and applications must be received in the CDC Procurement and Grants Office by 4:00 p.m. Eastern Time on the deadline date. If you submit your LOI or application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery by the closing date and time. If CDC receives your submission after closing due to: (1) Carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you will be given the opportunity to submit documentation of the carriers guarantee. If the documentation verifies a carrier problem, CDC will consider the submission as having been received by the deadline.

This announcement is the definitive guide on LOI and application content, 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 you did not meet the submission requirements.

CDC will not notify you upon receipt of your submission. If you have a question about the receipt of your LOI or application, first contact your courier. If you still have a question concerning your LOI, contact the OPHR staff at 404–371–5277. If you still have a question concerning your application, contact the PGO–TIM staff at: 770–488–2700. Before calling, please wait two to three days after the submission deadline. This will allow time for submissions to be processed and logged.

*IV.4. Intergovernmental Review of Applications*

Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order (EO) 12372. This order sets up a system for state and local governmental review of proposed federal assistance applications. You should contact your state single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your state's process. Click on the following link to get the current SPOC list: *http://www.whitehouse.gov/omb/grants/spoc.html.*

*IV.5. Funding restrictions*

Restrictions, which must be taken into account while writing your budget, are as follows:

- Funds relating to the conduct of research will not be released until the appropriate assurances and Institutional Review Board approvals are in place.
- Reimbursement of pre-award costs is not allowed.

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:

Mary Lerchen, DrPH, Scientific Review Administrator, CDC/Office of Public Health Research, One West Court Square, Suite 7000, MS D–72.

*Telephone:* 404–371–5277.

*Fax:* 404–371–5215.

*E-mail:* MLerchen@cdc.gov.

*Application Submission Address:* Submit the original and one hard copy of your application by mail or express delivery service to: Technical Information Management ''RFA IP05–096, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

At the time of submission, four additional copies of the application, and all appendices must be sent to: Mary Lerchen, DrPH, Scientific Review Administrator, CDC/Office of Public Health Research, One West Court Square, Suite 7000, MS D–72.

*Telephone:* 404–371–5277.

*Fax:* 404–371–5215.

*E-mail:* MLerchen@cdc.gov.

Applications may not be submitted electronically at this time.

**V. Application Review Information**

*V.1. Criteria*

Applicants 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 equally 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 review criteria are as follows:

*Significance:* Does this study address an important problem in this community? 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, especially, on the use of registries by other private practitioners?

Select two geographically-defined communities composed of 25 or more pediatrics or family practice groups (each of which may have more than one immunization provider) where full active immunization registry participation is rare but exists. One will serve as the intervention community, the other as the control community. The control community, defined as one not subjected to the intervention, should be

approximately the same size and socio-demographic composition as the intervention community. As a guide concerning size, a suitable intervention or control community should have more than five percent but fewer than 30 percent of its practices actively and fully participating prior to the intervention.

Document the number of practices in the intervention and control communities and their degree of registry use, and registry capacity in terms of core standards present (see below).

12 Functional Standards of a Registry:

(1) Electronically store data on all core data elements approved by the National Vaccine Advisory Committee (NVAC);

(2) Establish a registry record within six weeks of birth for each newborn child born in the geographic catchment area;

(3) Enable access to and retrieval of immunization information in the registry at the time of encounter;

(4) Receive & process immunization information within one month of vaccine administration;

(5) Protect the confidentiality of health care information;

(6) Ensure security of health care information;

(7) Exchange immunization records using HL7 standards;

(8) Automatically determine the routine childhood immunization(s) needed, in compliance with current ACIP recommendations, when an individual presents for a scheduled immunization;

(9) Automatically identify individuals due/late for immunization(s) to enable the production of reminder/recall notifications;

(10) Automatically produce immunization coverage reports by providers, age groups, and geographic areas;

(11) Produce official immunization records; and

(12) Promote accuracy and completeness of registry data.

*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?

To what extent has the applicant selected suitable and appropriate intervention and control communities according to the application guidance concerning: (1) The number of practices presently in operation; (2) the number of practices currently using a registry to any extent; (3) the extent to which a single central registry exists for the intervention and control communities; and (4) the extent to which that central registry complies with the functional registry standards described above.

To what extent has the applicant fully engaged the assets of an immunization or child health coalition, as well as university researchers experienced in evaluation science?

Identify the central registry to be used, and include a letter of support from an authorized official of that central registry. Because this application seeks to engage private practice offices in the use of an existing central registry, that registry should be highly functional already. Twelve accepted functional standards of registries listed below are metrics of maturity and performance; the registry to which the provider submits new data must meet Standards 3, 4, 5, and 6, plus any three of the other eight functional standards below. Documentation of the degree to which the applicant's registry meets these standards should be included in the Appendix of the application. Additional information concerning these standards may be found at *http://www.cdc.gov/nip/registry/min-funct-stds2001.htm.*

12 Functional Standards of a Registry:

(1) Electronically store data on all core data elements approved by the National Vaccine Advisory Committee (NVAC);

(2) Establish a registry record within six weeks of birth for each newborn child born in the geographic catchment area;

(3) Enable access to and retrieval of immunization information in the registry at the time of encounter;

(4) Receive & process immunization information within one month of vaccine administration;

(5) Protect the confidentiality of health care information;

(6) Ensure security of health care information;

(7) Exchange immunization records using HL7 standards;

(8) Automatically determine the routine childhood immunization(s) needed, in compliance with current ACIP recommendations, when an individual presents for a scheduled immunization;

(9) Automatically identify individuals due/late for immunization(s) to enable the production of reminder/recall notifications;

(10) Automatically produce immunization coverage reports by providers, age groups, and geographic areas;

(11) Produce official immunization records; and

(12) Promote accuracy and completeness of registry data.

The nature of the intended intervention and its evaluation must be specified. If the proposed intervention involves direct communication with office practice staff, the applicant must include in the Appendix letters of support indicating agreement concerning their access to a variety of types of provider offices, or alternatively, note their experience in conducting on-site interventions in practitioners' offices and discuss ways they intend to overcome such barriers.

Show evidence via letter(s) of support that they plan to work in partnership with the state and/or local immunization registry manager.

*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)?

The applicant must have active and substantial participation from each of three groups: (1) University faculty; (2) state and/or local health department personnel; and (3) an immunization coalition. If such a coalition does not presently exist, the applicant must describe how either a broad-based coalition or advisory board will be developed during the first six months. This group should consist of physicians and nurses who treat children, health educators, and pharmacists; officials from government health department and other key health and social services; administrative representatives from health care organizations, licensed child care centers, health maintenance organizations, insurers, and hospitals; and interested parents, business, and community leaders. University faculty should be qualified and interested in conducting program evaluation research. Explicit, detailed, written commitments should be provided as letters of support in the Appendix of the application, and will strengthen the application.

*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? Are letters of support included, if appropriate?

Has the supplied evidence indicated project support and full engagement by immunization coalitions, university, and public health?

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

1. To what extent has the applicant provided detail indicating the functioning level of the central registry that indicates its full functional capacity according to the guidelines provided above?

2. As an indication of its degree of functionality, the central registry to which the providers submit new data must meet Standards 3, 4, 5, and 6 described above plus any three of the eight other functional standards outlined there.

3. Has the applicant addressed each of the special requirements under Section III.3?

*Protection of Human Subjects from Research Risks:* Does the application adequately address the requirements of Title 45 Part 46 for the protection of human subjects? The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed.

*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. The priority score should not be affected by the evaluation of the budget.

*V.2. Review and Selection Process*

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) and for responsiveness by the OPHR. 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 announcement will be evaluated for scientific and technical merit by an appropriate peer review group or charter study section, a Special Emphasis Panel (SEP), convened by the OPHR in accordance with the review criteria listed above. As part of the initial merit review, all applications will:

- Undergo a process in which only those applications deemed to have the highest scientific merit by the review group, generally the top half of the applications under review, will be discussed and assigned a priority score.
- Receive a written critique.
- Receive a second programmatic level review by the Office of Science, National Immunization Program.
- Undergo a peer review by a SEP. The SEP will be selected from the NIH pool of scientists or recommendations from the National Immunization Program to serve as reviewers on SEPs. Applications will be ranked for the secondary review according to scores submitted by the SEP. Only those applications deemed to have the highest scientific merit by the review group, generally the top half of the applications under review, will be discussed and assigned a priority score.

*Award Criteria:* Criteria that will be used to make award decisions during the programmatic review include:

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

Preference will be given to applicants with experience working collaboratively with CDC or other granting agency, particularly on immunization research projects.

*V.3. Anticipated Announcement and Award Dates*

Award Date: August 31, 2005.

**VI. Award Administration Information**

*VI.1. Award Notices*

Successful applicants will receive a Notice of Award (NoA) from the CDC Procurement and Grants Office. The NoA shall be the only binding, authorizing document between the recipient and CDC. The NoA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

*VI.2. Administrative and National Policy Requirements*

45 CFR Part 74 and Part 92

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: *http://www.access.gpo.gov/nara/cfr/cfr-table-search.html.*

The following additional requirements apply to this project:

- AR–1 Human Subjects Requirements.
- AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research.
- AR–7 Executive Order 12372.
- AR–10 Smoke-Free Workplace Requirements.
- AR–11 Healthy People 2010.
- AR–12 Lobbying Restrictions.
- AR–15 Proof of Non-Profit Status.
- AR–22 Research Integrity.
- AR–24 Health Insurance Portability and Accountability Act Requirements.
- AR–25 Release and Sharing of Data.

Additional information on these requirements can be found on the CDC Web site at the following Internet address: *http://www.cdc.gov/od/pgo/funding/ARs.htm.*

*VI.3. Reporting*

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

1. Interim progress report, (use form PHS 2590, OMB Number 0925–0001, rev. 9/2004 as posted on the CDC Web site) no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following additional elements:

a. Progress Toward Measures of Effectiveness.

b. Additional Information Requested by Program.

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

3. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management Specialist listed in the ''Agency Contacts'' section of this announcement.

**VII. Agency Contacts**

We encourage inquiries concerning this announcement.

For general questions, 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: Susan Chu, PhD, MSPH, Extramural Program Official, National Immunization Program, Centers for Disease Control and Prevention, National Immunization Program, MS E–05, 1600 Clifton Road NE, Atlanta, GA 30333. Telephone: 404–639–8727. E-mail: *SChu@cdc.gov.*

For questions about peer review, contact: Mary Lerchen, DrPH, Scientific Review Administrator, CDC/Office of Public Health Research, One West Court Square, Suite 7000, MS D–72. Telephone: 404–371–5277. Fax: 404–371–5215. E-mail: *MLerchen@cdc.gov.*

For financial, grants management, or budget assistance, contact: Yolanda Ingram-Sledge, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341. Telephone: 770–488–2787. E-mail: *Ysledge@cdc.gov.*

### VIII. Other Information

This and other CDC funding opportunity announcements can be found on the CDC Web site, Internet address: *www.cdc.gov.* Click on ''Funding'' then ''Grants and Cooperative Agreements.''

Dated: May 5, 2005.

**William P. Nichols,**

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

[FR Doc. 05–9371 Filed 5–10–05; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2005N–0045]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Records; Electronic Signatures

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by June 10, 2005.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

**FOR FURTHER INFORMATION CONTACT:** Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### Electronic Records; Electronic Signatures—(21 CFR Part 11) (OMB Control Number 0910–0303)—Extension

FDA regulations in part 11 (21 CFR part 11) provide criteria for acceptance of electronic records; electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records. Under these regulations, records and reports may be submitted to FDA electronically provided the agency has stated our ability to accept the records electronically in an agency-established public docket and that the other requirements of part 11 are met.

The recordkeeping provisions in part 11 (§§ 11.10, 11.30, 11.50, and 11.300) require standard operating procedures (SOPs) to assure appropriate use of, and precautions for, systems using electronic records and signatures: (1) Section 11.10 specifies procedures and controls for persons who use closed systems to create, modify, maintain, or transmit electronic records; (2) section 11.30 specifies procedures and controls for persons who use open systems to create, modify, maintain, or transmit electronic records; (3) section 11.50 specifies procedures and controls for persons who use electronic signatures; and (4) section 11.300 specifies controls to ensure the security and integrity of electronic signatures based upon use of identification codes in combination with passwords. The reporting provisions (§ 11.100) require persons to certify in writing to FDA that they will regard electronic signatures used in their systems as the legally binding equivalent of traditional handwritten signatures.

The burden created by the information collection provision of this regulation is a one-time burden associated with the creation of SOPs, validation, and certification. The agency anticipates the use of electronic media will substantially reduce the paperwork burden associated with maintaining FDA required records.

The respondents are businesses and other for-profit organizations, State or local governments, Federal agencies, and nonprofit institutions.

In the **Federal Register** of February 7, 2005 (70 FR 6447), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 11.100 | 4,500 | 1 | 4,500 | 1 | 4,500 |

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.