

Data Confidentiality Provisions

The data will be collected by an independent consulting firm under terms of its contract. The identifiable information about institutions will be kept confidential in accordance with 42 U.S.C. 299c-3(c). AHRQ and HRSA will relieve only state-level summary data, and not individual hospital responses.

Method of Collection

The 2004 preparedness questionnaire will be administered electronically to each hospital via electronic mail. The estimated annual burden is as follows:

ESTIMATED ANNUAL RESPONDENT BURDEN

Number of questionnaire recipients	Estimated burden/ respondent (minutes)	Total hours of burden
6000	60	6000

The estimate burden is based on the completion of a paper version of the questionnaire by a pilot hospital. The more efficient data collection effort enabled by the electronic format has been taken into account in this estimate. The annualized cost to all potential respondents is estimated at \$209,040 Total (\$34.84/hr [average staff time] × 1 hr. 6000 respondents). Percentage of capital costs, operating costs or maintenance costs are negligible. We propose a census information collection approach as appropriate data on which to develop a stratified, purposive sample is unavailable. Future studies will utilize statistical methods based on our baseline data to develop a sampling scheme.

Request for Comments

In accordance with the above cited Paperwork Reduction Act legislation, comments on the AHRQ's and HRSA's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of functions of AHRQ and HRSA, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and costs) of the proposed collection of information (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: September 17, 2004.

Carolyn M. Clancy,

Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Emerging Infections Programs

Announcement Type: Competing Continuation.

Funding Opportunity Number: CI05-026.

Catalog of Federal Domestic Assistance Number: 93.283.

Key Dates:

Letter of Intent Deadline: October 11, 2004.

Application Deadline: November 1, 2004.

Executive Summary: The purpose of this program announcement is to provide continued support to existing Emerging Infections Programs (EIPs), or to develop new EIPs, as part of the national network. EIPs are population-based centers which assess the public health impact of and respond to emerging infections. Activities of the EIPs fall into these general categories: (1) Active surveillance; (2) applied public health epidemiologic and laboratory activities; and (3) implementation and evaluation of pilot prevention/intervention projects. The EIPs function as a collaborative network of public and private organizations that have an interest in addressing infectious diseases health issues; EIPs maintain sufficient flexibility to address infectious disease health issues as they emerge. EIPs are strategically located to serve a variety of geographical areas and diverse groups of people.

The following guiding principles motivate the work of the EIPs: (1) EIPs aim to be a national resource for surveillance, prevention, and control of emerging infectious diseases—EIP functions go beyond the routine functions of health departments in ways that allow important public health questions to be answered; (2) EIP activities address important issues in infectious diseases, selected with regard to what is appropriate for this population-based infrastructure; (3) EIPs

maintain sufficient flexibility for emergency response and to address new problems as they arise; (4) training is a key function of the EIPs; (5) EIPs develop and evaluate public health practices and transfer what is learned to the public health community; and (6) EIPs give high priority to activities that lead directly to prevention of disease.

I. Funding Opportunity Description

Authority: This program is authorized under the Public Health Service Act Sections 301(a)[42 U.S.C. 241(a)], 317(k)(1)[42 U.S.C. 247b(k)(1)], and 317(k)(2)[42 U.S.C. 247b(k)(2)], as amended.

Purpose: The purpose of the program is to assist in local, state, and national efforts to conduct surveillance and public health epidemiologic and laboratory activities in emerging infectious diseases, and to pilot and evaluate methods for the prevention and control of emerging infectious diseases. 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 Center for Infectious Diseases (NCID): Protect Americans from infectious diseases.

Research Objectives: The overall objective of the EIP cooperative agreement is to assess the public health impact of and respond to emerging infections. Activities of the EIPs fall into these general categories: (1) Active surveillance; (2) applied public health epidemiologic and laboratory activities; and (3) implementation and evaluation of pilot prevention/intervention projects. Specific objectives for research and other activities supported by this cooperative agreement are outlined in the individual Activities, below.

Activities: Awardee activities for this program are as follows:

(a) Functions and structure for EIP—Establish and operate an EIP to further local, State, and national efforts to address emerging infectious diseases.

(1) Establish each EIP activity in a defined population, which could include either an entire State or a geographically defined area (or areas) within a State. The population base may vary for various activities. For certain activities, the population base may be defined by a healthcare delivery system such as a health maintenance organization (HMO). To accomplish the objectives of certain EIP activities, a minimum population base of approximately 1,500,000 may be necessary.

(2) Provide effective scientific leadership, coordination, and execution of EIP activities.

(3) Provide effective management to support operation of the EIP.

(4) Organize the EIP so that it maintains the flexibility to respond to new health problems as they emerge.

(5) Operate the EIP so that it can function effectively as part of a national network of EIPs. Collaborate with CDC and other EIPs, through the EIP steering group and other EIP working groups, to establish priorities, to coordinate and monitor projects, and to assure that important emerging infections issues are appropriately addressed.

(6) Ensure that site representatives attend and participate in EIP Steering Group Meetings and other required EIP meetings.

(7) As a part of certain EIP projects, provide specimens such as disease-causing isolates or serum specimens to appropriate organizations (which may include, but is not limited to CDC) for laboratory evaluation (e.g., molecular epidemiologic studies, evaluation of diagnostic tools).

(8) Manage, analyze, and interpret data from EIP projects; publish and disseminate important public health information stemming from EIP projects in collaboration with CDC and other EIP sites.

(9) Monitor and evaluate scientific and operational accomplishments and progress in achieving the purpose of this program.

(10) If a proposed project involves research on human participants, ensure appropriate IRB review.

(11) Information systems used or developed through this cooperative agreement should conform to the Public Health Information Network (PHIN) standards, the goal of which is the creation of standards-based, interoperable public health information systems. For more information on PHIN, the PHIN architecture, PHIN messaging, and PHIN standards, functions, and specifications, see the CDC Web site: <http://www.cdc.gov/phn>. CDC will work with EIP sites to evolve EIP information systems to conform to PHIN standards.

(b) Partnerships—Develop the EIP as a partnership between the health department and other public and private organizations that have an interest in addressing public health issues relating to emerging infectious diseases, e.g., local public health agencies, academic institutions, health care providers, infection control professionals, clinical laboratories, other Federal and state government agencies, and research organizations. Build and draw upon

these relationships for the conduct of specific EIP activities.

(c) Tools and Capacities—Develop and utilize a set of tools or capacities to conduct EIP activities, e.g., active laboratory-based surveillance; medical records review for surveillance or studies; case-control studies; selected laboratory testing of isolates or specimens; surveys (e.g., of laboratories, providers, public); collection of isolates of disease-causing agents in the context of surveillance; network of infection control professionals; and analyses of hospital admission or discharge data.

(d) General EIP Activities—Activities of the EIPs generally fall into three categories:

(1) Active population-based surveillance projects. These may include collection and submission of disease-causing infectious agents to state, CDC, or other laboratories. For example, the surveillance case definition for the condition might involve detection of a positive culture or a drug resistant isolate in a microbiology laboratory, a serologic test result, a histopathologic finding, or a clinical syndrome, depending upon the disease or condition under surveillance. The specific approach to surveillance could also vary depending on the disease or condition under surveillance. Surveillance should be comprehensive (e.g., may include audits to assure complete reporting) with active case-finding.

(2) Applied epidemiologic and applied laboratory projects. Examples of potential projects include: Evaluation of illnesses often not specifically diagnosed for which information about trends and etiology are important (e.g., pneumonia); evaluation of clinical outcomes or risk factors for drug resistant infections; evaluation of the role of human genomics in disease causation and individual susceptibility; and evaluation of the efficacy of pneumococcal and meningococcal conjugate vaccines.

(3) Implementation and evaluation of pilot prevention/intervention projects for emerging infectious diseases. Examples might include, e.g., evaluation of the impact of Group B Streptococcus prevention guidelines, or evaluation of the role of human genomics in public health investigations.

(e) Specific EIP activities—All applicants should propose activities #1–5; additional activities may be proposed (#6–12) at the discretion of the applicant. Each application will be evaluated as a whole (see Criteria for evaluation in Section V.1 below). Therefore, any additional activity proposals should be commensurate with

the applicant's capacity and should be designed to enhance the applications as whole. Applicants are invited to consult with CDC programs in planning their proposed activities. [For details about these activities, see Appendices posted on the CDC Web site: <http://www.cdc.gov/od/pgo/funding/grantmain.htm>.]

(1) Active Bacterial Core surveillance (ABCs) and related activities—ALL applicants should propose this activity. CDC expects to provide support for ABCs activities in all EIPs, although some ABCs activities are expected to be conducted only in certain sites. For more details, see Appendix 1 posted on the CDC Web site: <http://www.cdc.gov/od/pgo/funding/grantmain.htm>.

(2) Active population-based laboratory surveillance for food-borne diseases (FoodNet) and related activities—ALL applicants should propose this activity. CDC expects to provide support for FoodNet activities in all EIPs, although some FoodNet activities are expected to be conducted only in certain sites. For more details, see Appendix 2 posted on the CDC Web site: <http://www.cdc.gov/od/pgo/funding/grantmain.htm>.

(3) Surveillance for respiratory diseases and syndromes—ALL applicants should propose this activity. CDC expects to provide support for five to nine EIPs for one or more aspects of this activity. For more detailed guidance, see Appendix 3 posted on the CDC Web site: <http://www.cdc.gov/od/pgo/funding/grantmain.htm>.

(4) Flexible Response to Emerging Problems—ALL applicants should propose this activity. Each EIP will be expected to participate in a workgroup to review newly emerging infectious disease issues on short notice and contribute to rapid study design, initiation, and completion. For more details, see Appendix 4 posted on the CDC Web site: <http://www.cdc.gov/od/pgo/funding/grantmain.htm>.

(5) EIP rapid population-based survey capacity—ALL applicants should propose this activity. CDC expects to provide support for population-based survey capacity in all EIP sites. For detailed guidance on applying for this activity, see Appendix 5 posted on the CDC Web site: <http://www.cdc.gov/od/pgo/funding/grantmain.htm>.

(6) Integrated hepatitis surveillance—Applicants may choose to propose some or all components of this activity, and CDC may provide some support for each of the components. For detailed guidance and specific eligibility criteria for this activity, see Appendix 6 posted on the CDC Web site: <http://www.cdc.gov/od/pgo/funding/grantmain.htm>.

www.cdc.gov/od/pgo/funding/grantmain.htm.

(7) Surveillance for encephalitis syndrome—Applicants may choose to propose this activity. CDC expects to provide support for up to three EIPs for this activity. For more details, see Appendix 7 posted on the CDC Web site: <http://www.cdc.gov/od/pgo/funding/grantmain.htm>.

(8) Surveillance for Unexplained Deaths (UNEX)—EIPs that are currently conducting UNEX may choose to propose to continue this activity. Any proposal for syndrome surveillance, e.g., respiratory syndromes, should be proposed and managed as part of the corresponding EIP syndrome activity, not separately as part of this activity. For more details, see Appendix 7 posted on the CDC Web site: <http://www.cdc.gov/od/pgo/funding/grantmain.htm>.

(9) Border Infectious Disease Surveillance (BIDS)—Applicants along the U.S./Mexico Border may propose this activity. For more details, see Appendix 7 posted on the CDC Web site: <http://www.cdc.gov/od/pgo/funding/grantmain.htm>.

(10) Incorporate a training activity into the operation of the EIP—Any applicant may propose this activity. See Appendix 7 for details.

(11) Prepare for and engage in activities to assess human genomics risk factors into acute public health investigations—Any applicant may propose this activity. CDC may provide support for one to three sites for this activity. For more details, see Appendix 7 posted on the CDC Web site: <http://www.cdc.gov/od/pgo/funding/grantmain.htm>.

(12) Site-specific EIP activity—Applicants may propose other activities of local interest or concern that are consistent with EIP objectives and guiding principles.

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:

- (a) Provide general coordination for the EIPs as a network.
- (b) Assist in developing collaborative relationships and facilitate multi-site collaboration as needed to support the successful completion of the project.
- (c) Provide consultation, scientific and technical assistance in the operation of the EIP and in designing and conducting individual EIP projects. (Examples include, participating in protocol development, helping with study design, assisting in the development of information systems,

data analysis and dissemination of results, coordinating and facilitating communications among EIPs).

(d) Participate in analysis and interpretation of data from EIP projects. Participate in the dissemination of findings and information stemming from EIP projects.

(e) Assist in monitoring and evaluating scientific and operational accomplishments of the EIP and progress in achieving the purpose and overall goals of this program.

(f) If needed, perform laboratory evaluation of specimens or isolates (e.g., molecular epidemiologic studies, evaluation of diagnostic tools) obtained in EIP projects and integrate results with other data from EIP projects.

(g) If a proposed project involves research with human subjects and CDC scientists will be co-investigators in that research, assist in the development of a research protocol for IRB review by all institutions participating in the research project. The CDC IRB will review and approve the project initially and on, at least, an annual basis until the research project is completed.

(h) Consult with sites to assist evolution of EIP-related information systems to conform to Public Health Information Network (PHIN) standards.

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: \$19,600,000.

Approximate Number of Awards: 9.

Approximate Average Award: \$2,400,000. (This amount is for the first 12-month budget period, and includes both direct and indirect costs.)

Floor of Award Range: \$1,400,000.

Ceiling of Award Range: \$3,500,000.

Anticipated Award Date: December 29, 2004.

Budget Period Length: 12 months.

Project Period Length: 5 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 state 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).

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.

Special Requirements

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.

- Late applications will be considered non-responsive. See "Section IV.3. Submission Dates and Times" for more information on deadlines.

- **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 or Co-Principal Investigators

Any individual with the skills, knowledge, and resources necessary to carry out the proposed EIP activities 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.

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 Submission

Letter of Intent (LOI)

A letter of intent is requested to help plan the application review, but it is not mandatory. Your LOI must be written in the following format:

- Maximum number of pages: 2.
- Font size: 12-point un-reduced.
- 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 include the following information:

- Number and title of this Program Announcement (PA).
- Name of Applicant (*i.e.* State Health Department or *bona fide* agent).

If you are applying as a *bona fide* agent of a state or local government, you must provide a letter from the state as documentation of your status at the time of application.

- Name, address, e-mail address, and telephone number of the Principal Investigator and Co-Investigator.
- Brief description of your eligibility and intent to apply.

Application

Follow the PHS 398 application instructions for content and formatting of your application. If the instructions in this announcement differ in any way from the PHS 398 instructions, follow the instructions in this announcement. 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, focusing in detail on the first year and summarizing plans for subsequent years.

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 announcement uses just-in-time concepts.

This announcement uses the non-modular budgeting format.

In place of the format specified for the Research Plan in PHS Form 398, use the following format:

- Maximum number of pages: 35 single-spaced (excluding budget, budget narrative, appendices, and required forms).

If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed. Materials or information that should be included in the narrative will not be reviewed if placed in the appendices.

- Font size: 12 point un-reduced.
- Paper size: 8.5 by 11 inches.
- Page margin size: One inch.
- Printed only on one side of page.
- Held together only by rubber bands or metal clips; not bound in any other way.

Your narrative should address activities to be conducted over the entire project period, and must include the following items in the order listed:

- (1) Capacity to carry out the functions and responsibilities of an EIP.
- (2) Operational plan for the EIP in general and for specific EIP activities. (Include descriptions of populations for each proposed activity.)
- (3) Measures of Effectiveness (Include Measures for each of the specific EIP activities proposed.)
- (4) Human 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:

- Documentation of *bona fide* agent status.
- Letters of support (Do not solicit or include letters of support from CDC personnel.)
- *Curricula vitas*.
- Detailed budget justification (*i.e.*, supporting budget information outlined in "Budget and Budget Narrative" below.)

- Documentation of relevant accomplishments, such as abstracts, manuscripts, or bibliographies, may be included in appendices.

Budget and Budget Narrative

This part of the application does not count toward the narrative page limit. For each line-item (as identified on the PHS Form 398, Page 4), show both Federal and non-Federal (*e.g.*, State funding) shares of total cost for the EIP. For each staff member listed under the Personnel line item, indicate their specific responsibilities relative to each of the proposed projects. All other line-items should also be clearly justified. In addition to the budget justification, provide an estimate of the budget for each separate activity or project (*e.g.*, FoodNet, ABCs, etc. as outlined above in Section I, Activities, section (e)). If requesting funds for any contracts, provide the following information for each proposed contract: (1) Name of proposed contractor; (2) breakdown and justification for estimated costs; (3) description and scope of activities to be performed by contractor; (4) period of performance; and (5) method of contractor selection (*e.g.* sole-source or competitive solicitation).

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

October 11, 2004.

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

November 1, 2004.

Explanation of Deadlines

Applications must be received in the CDC Procurement and Grants Office by 4 p.m. eastern standard 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. If CDC receives your application 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 carrier's guarantee. If the documentation verifies a carrier problem, CDC will consider the application as having been received by the deadline.

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. If you still have a question, contact the PGO-TIM staff at: (770) 488-2700. Before calling, please wait two to three days after the application deadline. This will allow time for applications 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.
- Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

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: Angela Slaughter, National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC), 1600 Clifton Rd, NE., Mailstop D-59, Atlanta, GA 30333, Telephone: (404) 371-5357, e-mail address: aslaughter@cdc.gov.

Application Submission Address

Submit the original and four hard copies of your application by mail or express delivery service to: Technical Information Management—CI05-026, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

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.

Your application will be evaluated against the following criteria:

- (1) Capacity to carry out the functions and responsibilities of an EIP. (50 points)
 - (a) Does the applicant demonstrate a clear understanding of the objectives of the EIP in the following aspects?
 - (i) Background and objectives of this cooperative agreement program.
 - (ii) The roles and responsibilities of participation in the EIP network.
 - (iii) The requirements, responsibilities, problems, constraints, and complexities that may be encountered in establishing and operating the EIP.
 - (b) EIP functions and structure.

(i) To what extent does the applicant's plan for establishing and operating the EIP clearly describe the proposed organizational and operating structure/procedures; and clearly identify the roles and responsibilities of all participating agencies, organizations, institutions, and individuals?

(ii) To what extent does the applicant describe how the EIP as a whole will be established in a defined population with a minimum population base of approximately 1,500,000 persons?

(iii) To what extent does the applicant clearly describe how the EIP, or its design for the EIP, is flexible and able to swiftly address new public health challenges in infectious diseases?

(iv) Does the applicant plan to provide effective scientific leadership and coordination, and adequate administrative infrastructure, to manage an EIP?

(v) Does the applicant demonstrate ability to operate the EIP so it can function effectively as part of a national network of EIPs?

(vi) To what extent does the applicant describe plans for collaboration with CDC and other EIP sites in the establishment and operation of the EIP and individual EIP projects, including project design/development (e.g., protocols), management and analysis of data, and synthesis and dissemination of findings?

(c) Partnerships.

(i) To what extent does the applicant demonstrate ability to develop and maintain strong cooperative relationships with public and private, local and regional, medical, public health, laboratory, academic, and community organizations? Does the applicant provide sufficient evidence of its ability to solicit and secure programmatic collaboration and support from such organizations?

(ii) Are the applicant's partnerships with necessary and appropriate organizations adequate for establishing and operating the proposed EIP and for conducting individual EIP projects?

(d) EIP tools and capacities.

To what extent does the applicant demonstrate past experience and documentation of accomplishments in conducting active surveillance, applied epidemiologic research, applied laboratory research, and prevention research, in general, and on emerging infectious diseases, including antimicrobial resistant, food-borne and waterborne, and currently or potentially vaccine preventable diseases? Is a list of relevant papers and abstracts included in an appendix?

(2) Operational Plan for the EIP in general and for specific EIP activities. (40 points)

(a) General EIP Activities:

(i) To what extent is the quality of the proposed projects (as requested in the Application Content section above), taken as a whole, consistent with EIP guiding principles, public health needs, intent of this program, feasibility, methodology/approach, and collaboration/participation of partner organizations? Does the proposal include clear descriptions of the population bases for each project, and include descriptions of race and ethnic distributions and descriptions of various special populations as they relate to the proposed activities, such as the rural or inner-city poor, under-served women and children, the homeless, immigrants and refugees, and persons infected with HIV?

(ii) Does the applicant demonstrate support from non-applicant participating agencies, institutions, organizations, laboratories, individuals, and consultants included in the operational plan? Does the applicant provide (in an appendix) letters of support which clearly indicate collaborators' commitment to participate in the EIP and define their roles?

(iii) Does the applicant clearly identify key professional personnel to be assigned to the EIP and EIP projects as well as key professional personnel from other participating or collaborating institutions, agencies, and organizations outside of the applicant's agency that will be assigned to EIP activities? (Is curriculum vitae for each person included in an appendix?) Is there a clear identification of participants' respective roles in the management and operation of the EIP? Do participants have adequate experience in conducting work comparable to that described in this announcement?

(iv) For projects involving human subjects 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.

(b) Specific EIP Activities:

(i) What is the quality of each proposed project with respect to planned approach and methodology, as well as consistency with EIP guiding principles, public health needs, intent of this program, and collaborations?

(ii) For each proposed activity, is there a clear definition of the geographic area and population base in which the activity will operate (different activities may use different populations)?

(iii) For each proposed activity, is there evidence of support from non-applicant participating agencies, institutions, organizations, laboratories, individuals, consultants, etc., included in the operational plan? Does the applicant provide (in an appendix) letters of support which clearly indicate collaborators' commitment to participate in the EIP and define their roles?

(iv) For each proposed activity, does the applicant clearly identify key professional personnel to be assigned to the EIP and EIP projects as well as key professional personnel from other participating or collaborating institutions, agencies, and organizations outside of the applicant's agency that will be assigned to EIP activities (provide a curriculum vitae for each in an appendix). Clear identification of participants' respective roles in the management and operation of the EIP? Do participants have adequate experience in conducting work comparable to that proposed in this announcement?

(3) Measures of Effectiveness (10 points)

(a) Does the applicant provide measures of effectiveness for each proposed activity that will demonstrate the accomplishment of the cooperative agreement objectives identified in Section B "Purpose" of this program announcement?

(b) Are the measures objective and quantitative, and do they adequately measure the intended outcome of each activity?

(4) Budget (not scored)

Is the line-item budget detail broken out for each activity (or project) and contract, clearly justified, and consistent with the purpose and objectives of this program? Does the applicant show both Federal and non-Federal (e.g., State funding) shares of total cost for the EIP?

(5) Human Subjects (not scored)

Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects? (Not 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.)

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by National Centers for Infectious Diseases (NCID) Office of Surveillance. 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.

An objective review panel will evaluate complete and responsive applications against the evaluation criteria. In addition, the following factors may affect the funding decision:

- Funding preference may be given to approved applications that would enhance the geographic diversity of the network to achieve appropriate geographic representation in the EIPs.
- Funding preference may also be given to competing continuation applications over applications for programs not already receiving support under this cooperative agreement.

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-7 Executive Order 12372

- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements

- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-22 Research Integrity

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 Requirements

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. 5/2001 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 elements:

(a) Current Budget Period Activities Objectives including report specifically on progress towards stated Measures of Effectiveness from the current budget period (*i.e.*, previous application).

(b) Current Budget Period Financial Progress.

(c) New Budget Period Program Proposed Activity and Objectives.

(d) Budget.

(e) Measures of Effectiveness.

(f) Additional Requested Information

(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 or Contract 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 program technical assistance, contact: Catherine Rebmann, National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC), 1600 Clifton Rd, NE., Mailstop D-59, Atlanta, GA 30333, Telephone (404) 371-5363, e-mail address: csr9@cdc.gov.

For financial, grants management, or budget assistance, contact: Lynn Walling, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: (770) 488-2612, e-mail: lqw5@cdc.gov.

VIII. Other Information

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

Visit these websites for additional information about the EIPs:

<http://www.cdc.gov/ncidod/EID/vol9no7/03-0083.htm>,

<http://www.cdc.gov/ncidod/osr/site/eip/index.htm>,

<http://www.cdc.gov/ncidod/osr/site/eip/publications.htm>.

Dated: September 20, 2004.

William P. Nichols,

Acting 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

[CMS-3154-N]

Medicare Program; Request for Nominations for Members for the Medicare Coverage Advisory Committee

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice requests nominations for consideration for membership on the Medicare Coverage Advisory Committee (MCAC).

DATES: Nominations will be considered if received at the designated address, as provided below, no later than 5 p.m. on September 30, 2004.

ADDRESSES: You may mail nominations for membership to the following address: Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Attention: Michelle Atkinson, 7500 Security Blvd., Mail Stop: Central Building 1-09-06, Baltimore, MD 21244.

A copy of the Secretary's Charter for the Medicare Coverage Advisory Committee can be obtained from Maria Ellis, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, 7500 Security Blvd., Mail Stop: Central Building 1-09-06, Baltimore, MD 21244, or by e-mail to mellis@cms.hhs.gov. The charter is also posted on the web at <http://www.cms.hhs.gov/mcac/8b1-1.asp>.

FOR FURTHER INFORMATION CONTACT: Michelle Atkinson, 410-786-2881.

SUPPLEMENTARY INFORMATION:

Background

On December 14, 1998, we published a notice in the **Federal Register** (63 FR 68780) announcing establishment of the Medicare Coverage Advisory Committee (MCAC). The Secretary signed the initial charter for the Medicare Coverage Advisory Committee on November 24, 1998. The charter was renewed by the Secretary and will terminate on November 24, 2004, unless renewed again by the Secretary.

The Medicare Coverage Advisory Committee is governed by provisions of the Federal Advisory Committee Act, Pub. L. 92-463, as amended (5 U.S.C. App. 2), which sets forth standards for the formulation and use of advisory committees, and is authorized by section 222 of the Public Health Service Act as amended (42 U.S.C. 217A).

The MCAC consists of a pool of 100 appointed members. Members are selected from among authorities in clinical medicine of all specialties, administrative medicine, public health, epidemiology and biostatistics, methodology of trial design, biologic and physical sciences, health care data and information management and analysis, the economics of health care, medical ethics, and other related professions. A maximum of 88 members are standard voting members, 12 are nonvoting members, 6 of whom are representatives of consumer interests, and 6 of whom are representatives of industry interests.

The MCAC functions on a committee basis. The committee reviews and evaluates medical literature, reviews technology assessments, and examines data and information on the effectiveness and appropriateness of medical items and services that are covered or eligible for coverage under Medicare. The Committee works from an agenda provided by the Designated Federal Official that lists specific issues, and develops technical advice to assist us in determining reasonable and necessary applications of medical services and technology when we make national coverage decisions for Medicare.

A few vacancies exist on the current MCAC roster, and terms for some members currently serving will expire in 2004. Accordingly, we are requesting nominations for both voting and nonvoting members to serve on the MCAC. Nominees are selected based upon their individual qualifications and not as representatives of professional associations or societies. We have a