DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99118]

Cooperative Agreement for Applied Research on Surveillance of Vaccine Preventable Diseases in Managed Care Settings; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) National Immunization Program (NIP) in cooperation with the Office of Prevention Research, announces the availability of fiscal year (FY) 1999 funds for a cooperative agreement program for Applied Research on Surveillance of Vaccine Preventable Diseases in Managed Care Settings.

The purpose of this program is to fund research designed to enhance the ability of managed care organizations to conduct surveillance for vaccine preventable diseases in the United States. This program addresses the ''Healthy People 2000'' priority area of Immunization and Infectious Diseases.

B. Eligible Applicants

Applications may be submitted by public and private non-profit and for profit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, managed care organizations, small, minority-owned businesses, other public and private nonprofit and profit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

Note: Pub. L. 104–65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

C. Availability of Funds

Approximately $435,000 will be available in FY 1999 to award up to two projects. It is expected that the average award will be $217,500. It is expected that the awards will begin on or about September 1, 1999, and will be made for a 12-month budget period within a project period of 1 year. Funding estimates may change.

D. Program Interests

Applications must address a programmatic interest area as noted below. Applications which propose research studies whose findings have a high probability of being translated into new recommendations for vaccine use by national advisory bodies or whose findings are likely to lead to decreases in vaccine preventable disease morbidity or mortality are encouraged. Examples of possible projects are also given below; these examples are not to be considered as an exhaustive list but include projects NIP views as exemplifying the priority areas.

1. Disease Burden

The use of surveillance information to better define the magnitude of the disease burden posed by vaccine preventable diseases. In particular, there is interest in the disease burden posed by diseases recently made vaccine preventable or about to be made vaccine preventable. Second, there is interest in the disease burden posed by diseases which have been vaccine preventable but where the vaccine is being considered for use in new target groups.

For example, there is interest in improving the detection of pertussis in adolescents and enhancing clinical and laboratory diagnosis to define disease burden in this group.

2. New Approaches to Surveillance

The use of managed care information systems to facilitate ascertainment and reporting of cases of vaccine preventable diseases.

For example, there is interest in the use of electronic medical records to identify potential cases of vaccine preventable diseases for clinical and epidemiological follow-up and for reporting to public health agencies.

Also, there is interest in the evaluation of different approaches for improving the clinical index of suspicion and the application of appropriate diagnostic methods to detect uncommon vaccine preventable diseases.

3. Vaccine Impact

Monitoring the impact of vaccination programs through the use of surveillance data.

For example, there is interest in estimating the impact of rotavirus vaccine in decreasing utilization of health care services.

E. Program Requirements

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

1. Recipient Activities

(a) Design the study: Determine the approaches to take in addressing the questions of interest in the study and develop a study protocol.

(b) Implement the study protocol: Conduct the study according to the protocol and will resolve problems in study implementation as they arise.

(c) Analyze data: Plan the analytic approach to be taken to understand and interpret the principal findings from the study.

(d) Prepare manuscripts and publish results: Prepare a written manuscript describing the main study findings for publication in a peer reviewed journal.

2. CDC Activities

(a) Provide technical and programmatic information: CDC scientists will provide current scientific and programmatic information relevant to the project.

(b) Assist in executing the study: CDC scientists will collaborate as appropriate in each phase of the study including design, implementation, analysis, and publication. Depending on the project funded and on availability, CDC may provide laboratory support.

(c) Assist in the development of a research protocol for Institutional Review Board (IRB) review by all cooperating institutions participating in the research project.

The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan.

F. Submission and Deadline

Letter of Intent (LOI)

Your letter of intent should identify the announcement number, the intended submission deadline, name the principal investigator, and specify the study area addressed by the proposed project. The letter of intent must be submitted on or before June 15, 1999, to: Sharron Orum, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99118, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146.

Application

Submit the original and five copies of PHS–398 (OMB Number 0925–0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398) on or before July 15, 1999, to: Sharron Orum, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99118, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146.

Deadline: Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; or

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

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

G. Evaluation Criteria

Applications that are complete and responsive may be subjected to a preliminary evaluation (triage) by a peer review group to determine if the application is of sufficient technical and scientific merit to warrant further review; the CDC will withdraw from further consideration applications judged to be noncompetitive and promptly notify the principal investigator/program director and the official signing for the applicant organization. Those applications judged to be competitive will be further evaluated by a dual review process. Awards will be made based on priority by Peer Review, programmatic priorities and needs as determined by the secondary review panel, and the availability of funds.

A. The first review will be a peer review of all applications. Evaluation factors will include:

1. The specific aims of the research project, i.e. the objectives and the hypothesis to be tested.

2. The background of the proposal, e.g., the basis for the present proposal, a critical evaluation of existing knowledge, and the knowledge gaps which the proposal is intending to fill.

3. The description of the expected outcome(s), their relevance to program goals, and the extent to which the research findings are likely to improve surveillance of vaccine preventable diseases.

4. The adequacy of the study plan that describes the specific, measurable objectives and the methods by which the objectives will be achieved.

5. The progress of preliminary studies, if any, pertinent to the application.

6. The adequacy of the proposed research design, approaches, and methodology to carry out the research, including quality assurance procedures and plans for data management and statistical analyses.

7. Qualifications, adequacy, and appropriateness of personnel to accomplish the proposed activities.

8. The degree of commitment and cooperation of other interested parties (as evidenced by letters detailing the nature and extent of the involvement).

9. The reasonableness of the proposed budget to the proposed research.

10. Adequacy of existing and proposed facilities and resources.

11. Inclusion of Women and Racial and Ethnic Minorities in Research.

The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes:

a. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

b. The proposed justification when representation is limited or absent.

c. A statement as to whether the design of the study is adequate to measure differences when warranted.

d. 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.

12. Human Subjects

The extent to which the application adequately addresses the requirements of Title 45 CFR Part 46 for the protection of human subjects.

B. The second review will be conducted by a secondary review committee of senior Federal officials. The factors to be considered will include:

1. The results of the peer review.

2. The significance of the proposed activities in relation to the priorities and objectives stated in Healthy People 2000;

3. National needs.

4. Budgetary considerations.

5. Program balance among the major areas of interest:

(a) Disease Burden.

(b) New Approaches to Surveillance.

(c) Vaccine Impact.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Progress reports semiannual;

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

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

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application kit.

AR–1 Human Subjects Requirements
AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2000
AR–12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under Sections 301 and 307 of the Public Health Service Act, 42 U.S.C. section 241 and 242l. The Catalog of Federal Domestic Assistance Number is 93.185.

J. Where To Obtain Additional Information

This and other CDC Announcements may be downloaded from the CDC Internet homepage http://www.cdc.gov. Click on ''funding.''

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

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Sharron Orum, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99118, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone: (770) 488–2716, E-mail: SPO2@cdc.gov.

For program technical assistance, contact: Roger Bernier, PhD, MPH, National Immunization Program, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., MS–E05, Atlanta, Georgia, 30333, Telephone: (404) 639–8204, E-mail: rhb2@cdc.gov.

Dated: May 10, 1999.

John L. Williams,

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

[FR Doc. 99–12205 Filed 5–13–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Government-Owned Inventions; Availability for Licensing

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

ACTION: Notice.

The inventions named in this notice are owned by agencies of the United States Government and are available for licensing in the United States (U.S.) in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for U.S. companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to Thomas E. O'Toole, M.P.H., Deputy Director, Technology Transfer Office, Centers for Disease Control and Prevention (CDC), Mailstop E–67, 1600 Clifton Rd., Atlanta, GA 30333, telephone (404) 639–6270; facsimile (404) 639–6266. Please note that a signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Oligonucleotide Probes for Detecting Enterobacteriaceae and Quinolone-ResistantEnterobacteriaceae

Specific oligonucleotide probes have been developed to be incorporated into methods for the species-specific identification of these *Enterobacteriaceae* in a sample as well as detection and diagnosis of *Enterobacteriaceae* infection in a subject. This invention further provides methods for species-specific identification of these quinolone-resistant *Enterobacteriaceae* as well as the detection and diagnosis thereof.

Inventor: Linda M Weigel, et al.
U.S. Patent Application SN: 60/080,375 (CDC Ref. #: I–003–98/0)

Compositions and Methods for Detecting Adult *Taenia Solium*

Compositions and methods for the detection of adult *Taenia solium* and the diagnosis and treatment of *T. solium* infection are described. The compositions contain one or more adult *T. solium* polypeptides which can be useful as diagnostic agents for the detection of adult tapeworm infection.

Inventor: Victor Tsang, et al.
U.S. Patent Application SN: 60/111,334 (CDC Ref. #: I–028–97/0)

Recombinant Multi-Valent Malarial Vaccine

This invention relates generally to the development and use of a recombinant, multi-valent and multi-stage malaria vaccine and more specifically relates to an antigenic protein useful for preventing or treating *P. falciparum* malarial infections. The invention further provides a vaccine against malaria that is effective in inhibiting reproductive growth of the parasite within a human or animal after initial infection. Also, this invention provides a method for conferring immunity against different stages in the life cycle of the malarial parasite, *P. falciparum*. Furthermore, the invention includes antibodies against a recombinant protein containing antigenic epitopes to various stages of a malarial Plasmodium species that may be useful as research or diagnostic reagents for the detection and measurement of *P. falciparum* in a biological sample.

Inventor: Altaf A. Lal, et al.
U.S. Patent Application SN: 60/097,703 (CDC Ref. #: I–004–98/0)

Reagent and Method for Detecting *Cryptosporidium Parvum* Oocysts

A reagent and method for the specific and highly sensitive detection of *C. parvum* in which the reagent is an antibody for a soluble *C. parvum* sporozoite antigen. The method comprises of an immunoassay in which the antibody is used to detect or quantify *C. parvum* sporozoite in a sample. The assay allows recognition and detection of *C. parvum* in turbid samples. And since there exists a lack of crossreactivity with other *Cryptosporidium* species, the assay is also highly specific for *C. parvum* contamination or infection.

Inventor: Victor Tsang, et al.
U.S. Patent Application SN: 60/111,225 (CDC Ref. #: I–039–98/0)

Isolation of a New Human Retrovirus

A new isolate of a human retrovirus has been identified in several cases of foamy virus infection in persons at risk for this occupational exposure to simian retroviruses. This new isolate demonstrates a number of phenotypic differences from previously isolated foamy viruses by its immune reactivity, cell tropism, cytopathcity and growth kinetics. Due to its human-derived/adapted nonpathogenic nature, this new isolate may be suitable as a potential gene therapy vector.

Inventor: Paul A. Sandstrom
U.S. Patent Application SN: 60/105,811 (CDC Ref. #: I–034–97/0)

Methods and Compositions for the Detection of Human Herpesvirus

Methods and compositions for the detection and diagnosis of infectious diseases are provided. In particular, efficient and sensitive compositions and methods for the detection of human herpesvirus 8 are provided. The diagnostic compositions and methods of the invention involve the use of peptides representative of dominant antigenic regions of human herpesvirus in detection assays. Such assays are highly specific, sensitive and accurate.

Inventor: Chou-Pong Pau
U.S. Patent Application SN 60/086,695 (CDC Ref. #: I–018–98/0)

Methods and Reagents for Molecular Detection of HIV–1 Groups M, N, and O

This invention provides reagents and assays for detecting HIV–1 groups M and O and optionally HIV–1 group N and SIVcpz. Nucleic acid primers for the hybridization to, amplification and subsequent detection are also provided for. The nucleic acid amplification assays can detect small concentrations of HIV and are also useful for qualitative and quantitative examinations.

Inventor: Renu B. Lal, et al.
U.S. Patent Application SN: 60/118,357 (CDC Ref. #: I–020–98/0)

Nucleic Acid Vaccines for the Prevention of Flavivirus Infection

This novel vaccine for flaviviruses comprises of recombinant nucleic acids that contain genes for structural proteins of flaviviruses, such as Japanese encephalitis virus (JEV). These vaccines serve as a transcriptional unit for the biosynthesis of the virus protein antigens when administered in vivo. Furthermore, the invention provides for a method of immunizing a subject against infection by a flavivirus.