

by Internet or CDC WONDER electronic mail at <ldc2@ccddn1.em.cdc.gov.

Please refer to Announcement 652 when requesting information and submitting an application.

Potential applicants may obtain a copy of "Healthy People 2000" (Full Report; Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report; Stock No. 017-001-00473-1) referenced in the "Introduction" through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325; telephone (202) 512-1800.

There may be delays in mail delivery and difficulty in reaching the CDC Atlanta offices during the 1996 summer Olympics. Therefore, CDC suggests using Internet, following all instructions in this announcement and leaving messages on the contact person's voice mail for more timely responses to any questions.

Dated: June 24, 1996.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

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[Announcement Number 645]

Applied Research in Emerging Infections—Tickborne Diseases

Introduction

The Centers for Disease Control and Prevention (CDC) is implementing a program for competitive cooperative agreements and/or research project grants to support applied research on emerging infections. CDC announces the availability of fiscal year (FY) 1996 funds for cooperative agreements and/or research project grants to conduct applied research on domestic tickborne diseases (e.g., ehrlichiosis, babesiosis, Rocky Mountain spotted fever, tularemia, Colorado tick fever, etc.). 1. CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Immunization and Infectious Diseases.

1. Note: An existing CDC cooperative agreement program supports research focusing on Lyme disease caused by *Borrelia burgdorferi*, specifically. Therefore, this new program will not support research projects which focus substantially on classical Lyme disease caused by *B. burgdorferi*.

(For ordering a copy of Healthy People 2000, see the section Where To Obtain Additional Information.)

Authority

This program is authorized under Sections 301 and 317 of the Public Health Service Act, as amended (42 U.S.C. 241 and 247b).

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products, and Public Law 103-227, the Pro-Children's Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day-care, health care and early childhood development services are provided to children.

Eligible Applicants

Applications may be submitted by public and private, nonprofit and for-profit organizations and governments and their agencies. Thus, universities, colleges, research institutions, hospitals, other public and private organizations, including State and local governments or their bona fide agents, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations, and small, minority- and/or women-owned businesses are eligible to apply.

Availability of Funds

Approximately \$300,000 is available in FY 1996 to fund approximately two to four awards. It is expected that approximately two-thirds of the funds will be made available for the first programmatic focus (epidemiologic studies focusing on ehrlichiosis) and one-third for the second (development of improved diagnostic tests for babesiosis). Awards will begin on or about September 30, 1996, and will be made for a 12-month budget period within a project period of up to three years. Funding estimates may vary and are subject to change. Continuation awards within an approved project period will be made on the basis of satisfactory progress and availability of funds.

Purpose

The purpose of the emerging infections extramural research program is to provide financial and technical assistance for applied research projects on emerging infections in the United States. As a component of the emerging infections extramural research program, the purpose of this grant/cooperative announcement is to provide assistance for tickborne disease projects addressing

the following two programmatic focus areas:

1. Epidemiologic studies focusing on ehrlichiosis
2. Development and evaluation of improved diagnostic tests for babesiosis.

Applicants may submit separate applications for projects in one or both programmatic areas. See Application Content of the program announcement included in the application kit for detailed application instructions.

Program Requirements

Applicants may apply and receive support for projects under one or both of the two programmatic focus areas. In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under either A.1. or A.2., or both, below; and CDC will be responsible for conducting activities under B., below:

A. Recipient Activities

1. Epidemiologic Studies

Implement an active prospective ehrlichiosis surveillance system in a geographic area where the disease(s) (monocytic or granulocytic) is/are believed to be present, utilizing case finding based on a standardized clinical case definition. Cases should be laboratory confirmed, using standardized methods such as isolation or direct detection of the etiologic agent from clinical specimens by antigen detection or PCR; and/or serology. Laboratory diagnosis should be validated by retesting clinical specimens in a reference laboratory. A population based study in which incidence can be calculated and that simultaneously captures incident cases of babesiosis in the same location is most desirable.

2. Development and Evaluation of Improved Diagnostic Tests for Babesiosis:

a. Develop and evaluate improved laboratory methods for the diagnosis of babesiosis, which may include methods for antibody or antigen detection, molecular techniques, and isolation of the parasite from clinical specimens. Consider such characteristics of the test as sensitivity (e.g., ability to detect subpotent infection), specificity (e.g., ability to distinguish *Babesia* infection from other infections and conditions, ability to distinguish persistent from remote *Babesia* infection, genus- vs. species-level specificity), and ease of automation.

b. As part of certain projects and as appropriate, obtain and provide such

materials as isolates; human serum, whole blood, and other fluids and tissues; and diagnostic test reagents to a national reference laboratory (e.g., for development of a reference collection of specimens).

B. CDC Activities

1. Research Project Grants

A research project grant is one in which substantial programmatic involvement by CDC is not anticipated by the recipient during the project period. Applicants for grants must demonstrate an ability to conduct the proposed research with minimal assistance, other than financial support, from CDC. This would include possessing sufficient resources for clinical, laboratory, and data management services and a level of scientific expertise to achieve the objectives described in their research proposal without substantial technical assistance from CDC.

2. Cooperative Agreements

A cooperative agreement implies that CDC will assist recipients in conducting the proposed research. The application should be presented in a manner that demonstrates the applicant's ability to address the research problem in a collaborative manner with CDC. In addition to the financial support provided, CDC will collaborate by: (a) Providing technical assistance in the design and conduct of the research; (b) performing selected laboratory tests as appropriate; (c) participate in data management, the analysis of research data, and the interpretation and presentation of research findings; and (d) provide biological materials (e.g., strains) as necessary for studies, etc.

3. Determination of Which Instrument to Use

Applicants must specify the type of award for which they are applying, either grant or cooperative agreement. The funding agency will review the applications in accordance with the evaluation criteria. Before issuing awards, CDC will determine whether a grant or cooperative agreement is the appropriate instrument based upon the need for substantial CDC involvement in the project.

Evaluation Criteria

The applications will be reviewed and evaluated according to the following criteria:

1. Background and Need (20 Points)

Extent to which applicant's discussion of the background for the proposed project demonstrates a clear

understanding of the purpose and objectives of this grant/cooperative agreement program. Extent to which applicant illustrates and justifies the need for the proposed project that is consistent with the purpose and objectives of this grant/cooperative agreement program.

2. Capacity (40 Points Total)

a. Extent to which applicant describes adequate resources and facilities (both technical and administrative) for conducting the project. (10 points)

b. Extent to which applicant documents that professional personnel involved in the project are qualified and have past experience and achievements in research related to that proposed as evidenced by curriculum vitae, publications, etc. (20 points)

c. Extent to which applicant includes letters of support from non-applicant organizations, individuals, etc. Extent to which the letters clearly indicate the author's commitment to participate as described in the operational plan. (10 points)

3. Objectives and Technical Approach (40 Points Total)

a. Extent to which applicant describes objectives of the proposed project which are consistent with the purpose and goals of this grant/cooperative agreement program and which are measurable and time-phased. (10 points)

b. Extent to which applicant presents a detailed operational plan for initiating and conducting the project, which clearly and appropriately addresses all Recipient Activities for the specific programmatic focus area being addressed in the application. Extent to which applicant clearly identifies specific assigned responsibilities of all key professional personnel. Extent to which the plan clearly describes applicant's technical approach/methods for conducting the proposed studies and extent to which the plan is adequate to accomplish the objectives. Extent to which applicant describes specific study protocols or plans for the development of study protocols that are appropriate for achieving project objectives. (15 points)

c. Extent to which applicant describes adequate and appropriate collaboration with CDC and/or others during various phases of the project. (10 points)

d. Extent to which applicant provides a detailed and adequate plan for evaluating study results and for evaluating progress toward achieving project objectives. If the proposed project involves notifiable conditions, the degree to which applicant describes an adequate process for providing

necessary information to appropriate State and/or local health departments. (5 points)

4. Budget (Not Scored)

Extent to which the proposed budget is reasonable, clearly justifiable, and consistent with the intended use of grant/cooperative agreement funds.

5. Human Subjects (Not Scored)

If the proposed project involves human subjects, whether or not exempt from the Department of Health and Human Services (DHHS) regulations, the extent to which adequate procedures are described for the protection of human subjects. Note: Objective Review Group (ORG) recommendations on the adequacy of protections include: (1) protections appear adequate and there are no comments to make or concerns to raise, or (2) protections appear adequate, but there are comments regarding the protocol, or (3) protections appear inadequate and the ORG has concerns related to human subjects, or (4) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are inadequate as to make the entire application unacceptable, and (5) protections appear adequate that women, racial and ethnic minority populations are appropriately represented in applications involving human research.

Executive Order 12372 Review

This program is not subject to Executive Order 12372 Review.

Public Health System Reporting Requirements

This program is subject to the Public Health System Reporting Requirements. Under these requirements, all community-based nongovernmental applicants must prepare and submit the items identified below to the head of the appropriate State and/or local health agency(s) in the program area(s) that may be impacted by the proposed project no later than the receipt date of the Federal application. The appropriate State and/or local health agency is determined by the applicant. The following information must be provided:

a. A copy of the face page of the application (SF 424).

b. A summary of the project that should be titled "Public Health System Impact Statement" (PHSIS), not exceed one page, and include the following:

(1) A description of the population to be served;

(2) A summary of the services to be provided;

(3) A description of the coordination plans with the appropriate State and/or local health agencies.

If the State and/or local health official should desire a copy of the entire application, it may be obtained from the State Single Point of Contact (SPOC) or directly from the applicant.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.283.

Other Requirements

Paperwork Reduction Act

Projects that involve the collection of information from ten or more individuals and funded by the grant/cooperative agreement will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations (45 CFR Part 46) regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing evidence of this assurance in accordance with the appropriate guidelines and form provided in the application kit.

In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved or will support the research. If the American Indian community is involved, its tribal government must also approve that portion of the project applicable to it.

Women, Racial and Ethnic Minorities

It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian, Alaskan Native, Asian, Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic

minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the Federal Register, Vol. 60, No. 179, pages 47947-47951, dated Friday, September 15, 1995.

Animal Subjects

If the proposed project involves research on animal subjects, the applicant must comply with the "PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions." An applicant organization proposing to use vertebrate animals in PHS-supported activities must file an Animal Welfare Assurance with the Office for Protection from Research Risks at the National Institutes of Health.

Application Submission and Deadline

The original and two copies of each application PHS Form 5161-1 (revised 7/92, OMB Number 0937-0189) must be submitted to Sharron Orum, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E-18, Atlanta, Georgia 30305, on or before August 12, 1996.

1. *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 submission to the objective review group. (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.)

2. *Late Applications:* Applications which do not meet the criteria in 1. a. or 1. b. above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where to Obtain Additional Information

A complete program description and information on application procedures are contained in the application package. An application package and business management and technical

assistance may be obtained from Locke Thompson, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E-18, Room 300, Atlanta, Georgia 30305, telephone (404) 842-6595, or through the Internet or CDC Wonder electronic mail at: lxt1@opspgo1.em.cdc.gov.

Programmatic technical assistance may be obtained from the following persons: For epidemiologic studies, James G. Olson, Ph.D., National Center for Infectious Diseases, Division of Viral and Rickettsial Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop G-13, Atlanta, Georgia 30333, telephone (404) 639-1075. For babesia diagnostics: Barbara Herwaldt, M.D., Division of Parasitic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop F-22, Atlanta, Georgia 30333, telephone (770) 488-7772.

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Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: State JOBS plan (ACF-106).
OMB No.: 0970-0108.