DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 800]

Cooperative Agreements To Conduct Research on the Diagnosis and Pathogenesis of Lyme Disease in the United States

Introduction

The Centers for Disease Control and Prevention (CDC) announces the expected availability of Fiscal Year (FY) 1998 funds for a cooperative agreement program to conduct research on Lyme disease and illnesses caused by other related *Borrelia* species. This program's objective is to achieve improved and standardized tools to accurately identify and characterize *B. burgdorferi* infection in humans, including test of cure, and to better understand the natural history of infection and disease caused by *B. burgdorferi* and related *Borrelia* species. These achievements should assist in the development of more effective Lyme disease surveillance, prevention, and control. Topics include: development and evaluation of new and improved diagnostic tests; and studies on the pathogenesis of infection with *Borrelia burgdorferi* and other related *Borrelia* species, including the development of animal models of infection and disease.

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. (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(k)(2) of the Public Health Service Act, as amended (42 U.S.C 241 and 247b(k)(2)).

Smoke-Free Workplace

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

Eligible Applicants

Applications may be submitted by public and private, nonprofit organizations, and governments and their agencies within the United States. Thus, universities, colleges, research institutions, hospitals, other public and private organizations, State and local health departments, or their bona fide agents, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations, and small, minority and/or women-owned, nonprofit businesses are eligible to apply as the principal investigating entities. These United States entities may propose collaborative arrangements with investigators outside the United States, provided the proposal has a direct impact on United States public health.

Participation in proposed activities by scientists and health professionals with expertise and experience in Lyme disease and its associated microbiologic, immunologic and pathologic aspects are desirable. In addition, combined program activities involving State and local health departments, universities, colleges, and private nonprofit organizations are encouraged.

Note: Effective January 1, 1996, Public Law 104–65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 which engages in lobbying activities will not be eligible for the receipt of Federal funds constituting an award, grant (cooperative agreement), contract, loan, or any other form.

Availability of Funds

CDC anticipates that approximately $1 million of the President's budget will be available for FY 1998 cooperative agreements to conduct research on the diagnosis and pathogenesis of Lyme disease in the United States. However, this announcement is made prior to the appropriation of fiscal year 1998 funds to allow new and competing continuation applicants sufficient time to prepare applications, and to enable timely award of the cooperative agreements. On the basis of the President's budget, it is anticipated that approximately $1 million will be available in FY 1998 to fund approximately five new and competing continuation awards. It is expected that the median award will be $200,000, ranging from $50,000 to $300,000. It is expected that the awards will begin on or about February 15, 1998. Awards will be funded 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 the project period are made on the basis of satisfactory progress and the availability of funds. Funds are allocated to develop and standardize more specific and sensitive diagnostic tests and to study the pathogenesis of infection, including aspects related to the natural history of disease and its immunoprotection.

Recipient Financial Participation

There are no matching or cost participation requirements; however, the applicant's anticipated contribution to the overall program costs, if any, should be provided on the application. These funds should not supplant existing expenditures in this disease area.

Background

Lyme disease is one of the most important emerging infectious diseases in the United States, accounting for more than 90% of all reported vector-borne illness. The numbers of reported cases have increased steadily, resulting in a thirty-fold rise between 1982 and 1996. More than 16,000 cases were reported by 44 States to the CDC in 1996.

Lyme borreliosis is a potentially serious and debilitating infection that may lead to subacute and chronic disease of the joints, the peripheral and central nervous system, the heart, and the skin. Questions have been raised about microbial persistence and chronic Lyme disease. Although transplacental transmission has been reported, epidemiologic studies have not shown an association between Lyme disease and adverse outcomes of pregnancy.

Lyme disease cases have been reported nationwide; however, the disease is concentrated in three regions: the northeast and mid-Atlantic, the north central, and the Pacific coastal regions. Distribution of cases is principally related to the density of infected tick vectors. *Ixodes scapularis* is the principal vector throughout the northeastern, mid-Atlantic, and north central States, and is the cause of significant peridomestic transmission. *Ixodes pacificus* transmits the disease in Pacific coastal areas. *Ixodes spinipalpis* maintains an enzootic cycle in Colorado and California. The role of the putative vectors in southern regions of the United States, *Ixodes scapularis* and *Amblyomma americanum*, is not clear.

Standardized, more specific and sensitive tests that are rapid and easy to perform are needed for the laboratory diagnosis of Lyme disease. The priority need is for improved test methods to detect antibodies to *B. burgdorferi* antigens in serum and cerebrospinal fluid. There is also a need to develop improved and standardized alternative

test methods, such as antigen capture and polymerase chain reaction.

Purpose

The purposes of these cooperative agreements are to: (1) Develop, validate, and standardize diagnostic tests that are more sensitive and specific than those currently available, and (2) better characterize the etiologic agents, the host-parasite relationships, and the pathogenesis of infection, including the development of immunity to infection.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for conducting selected activities under A., below, and CDC will be responsible for conducting activities under B., below:

A. Recipient Activities

Develop Improved and Standardized Diagnostic Tests, and/or Conduct Studies on the Pathogenesis of Lyme Disease. (Conduct One or More of the Following):

1. Develop more specific and sensitive serologic tests for detection of exposure to *B. burgdorferi* and other closely related *Borrelia* species.

2. Evaluate and standardize the performance of new testing methods, including serologic, polymerase chain reaction or antigen detection methods, which may include field testing.

3. Collect serum and other fluids and tissues to be used in test development from clinically well-characterized patients with objective manifestations of early localized, early disseminated, and late stage Lyme disease (including chronic, refractory disease), and from persons with conditions within the differential diagnosis of Lyme disease. Specimens from patients with bacteriologically confirmed infection are preferred in cases of early Lyme disease.

4. Develop and use animal models of infection and disease to demonstrate the pathogenesis of infection with *B. burgdorferi* and related *Borrelia* species and the natural history of the diseases caused by these agents, and to evaluate approaches to improved diagnosis, immunoprotection and/or treatment of Lyme disease.

B. CDC Activities

1. Provide technical assistance in the design and conduct of research.

2. Assist in performing selected laboratory tests, as appropriate, depending on the needs of the recipient.

3. Assist in the coordination of research activities among different recipient sites.

4. Assist in the analysis of research data.

Technical Reporting Requirements

Semiannual progress reports are required and must be submitted no later than 30 days after each semiannual reporting period. The semiannual progress reports must include the following for each program, function, or activity involved: (1) A comparison of actual accomplishments to the goal established for the period; (2) the reasons for failure, if established goals were not met; and (3) other pertinent information including, when appropriate, analysis and explanation of performance costs significantly higher than expected. The final progress report is required no later than 90 days after the end of the project period. All manuscripts published as a result of the work supported in part or whole by the cooperative agreement will be submitted with the progress reports.

An annual Financial Status Report (FSR) is required no later than 90 days after the end of each budget period. An original and two copies of all reports should be submitted to the Grants Management Branch, CDC.

Application Content

The application should consist of the following:

1. The abstract should summarize the background, needs, goals, objectives and methods of the proposal on one page.

2. The program narrative should include the following sections: background, objectives, methods, plan of operation, and plan of evaluation. List and briefly describe specific, measurable, realistic, and time-phased objectives.

3. A budget justification is required for all budget items and must be submitted with Standard Form 424A, ''Budget Information,'' as part of PHS 5161–1 (Revised 7/92). The budget should include the total funds requested for the project. For applicants requesting funding for subcontracts, include the name of the person or organization to receive the subcontract, the method of selection, the period of performance, and a description of the subcontracted service requested.

4. If the proposed project involves human subjects, whether or not exempt from Department of Health and Human Services (DHHS) regulations, describe in the narrative adequate procedures for the protection of human subjects.

5. Also, ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects by including a description of the composition of the proposed study population (for example, addressing the inclusion of women and members of minority groups and their sub-populations in the section that will describe the research design). The applicant will provide an explanation when the investigator cannot control the race, ethnicity and/or sex of the subjects. See Other Requirements for additional information.

When applicable, letters of support must be included in an appendix if applicants anticipate the participation of other organizations or political subdivisions in conducting proposed activities. Specific roles and responsibilities must be delineated.

Notice of Intent To Apply

In order to assist CDC in planning for and executing the evaluation of applications submitted under this Program Announcement, all parties intending to submit an application are requested to inform CDC of their intention to do so no later than June 13, 1997. Notification should include: (1) Name and address of institution; (2) name, address and telephone number of contact person; and (3) which programmatic focus area application will be submitted under. Notification may be provided by facsimile or postal mail to Sharron P. Orum, Grants Management Officer, Grants Management Branch, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 305, Mailstop E–18, Atlanta, GA 30305, facsimile (404) 842–6513.

Required Format for Applications

Due to the need to reproduce copies of the applications for the reviewers, ALL pages of the application MUST be in the following format.

1. The original and two copies must be UNSTAPLED and UNBOUND.

2. ALL pages must be clearly numbered, and a complete index to the application and its appendices must be included.

3. Begin each separate section (background, objectives, methods, plan of operation, and plan of evaluation) on a new page.

4. All materials must be typewritten, single-spaced, using a font no smaller than a size 10, and typed ONLY on 8½'' by 11'' paper.

5. Any reprints, brochures, or other enclosures must be copied onto 8½'' by 11'' paper by the applicant.

6. All pages must be printed on ONE side only, with at least 1'' margins, headers, and footers.

7. The application narrative must be *limited to 10 pages*, excluding abstract, budget, and appendices.

8. Materials that are part of the basic plan must not be placed in the appendices.

Applications which do not conform to these instructions will not be accepted.

Evaluation Criteria

Applications will be reviewed and evaluated according to the following criteria (Total 100 points):

1. The extent to which background information and other data demonstrate that the applicant has the appropriate organizational structure, administrative support, and technical expertise to conduct the work proposed and has access to stated target populations or other study objects. (10 points)

2. The degree to which the proposed objectives are consistent with the purpose as defined in the ''Purpose'' section of this application and are specific, measurable, and time-phased. (20 points)

3. The degree to which the research plans will enable the applicant to achieve the stated objectives. The plans should specify the who, what, where, how, and timing for the start and completion of each activity. (30 points)

4. The quality of the research methods and instruments to be used. (If the proposal involves human subjects, the degree to which the applicant has met CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research will be evaluated. 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.) (20 points)

5. The quality of the proposed methods for evaluating the project.(10 points)

6. The extent to which qualifications (including expertise and experience in relevant work) of project personnel, and the projected level of effort by each toward accomplishment of the proposed activities demonstrate the ability to successfully conduct the proposed work. (10 points)

7. The extent to which the budget is reasonable, clearly justified, and consistent with the intended use of cooperative agreement funds. (not scored)

Funding Priorities

Priority will be given to applications which focus on the development, validation, and standardization of new and improved diagnostic tests; and to conduct research on the pathogenesis of disease, especially as related to the use of animal models to better understand the natural history of infection and disease in humans.

Interested persons are invited to comment on the proposed funding priorities. All comments received on or before June 12, 1997, will be considered before the final funding priorities are established. If any funding priority should change as a result of any comments received, a revised Announcement will be published in the **Federal Register** and revised applications will be accepted prior to the final receipt of applications.

Written comments should be addressed 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 305, Mailstop E–18, Atlanta, GA 30305.

All comments should reference the Program Announcement Number 800.

Executive Order 12372 Review

This program is not subject to the Executive Order 12372 review.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.942.

Other Requirements

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 which demonstrates that the project will be subject to initial and continuing review by an appropriate institutional review committee. 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 any American Indian community is involved, its Tribal government must also approve that portion of the project applicable to it. The applicant will be responsible for providing evidence of this assurance in accordance with the appropriate guidelines and forms provided in the application kit.

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 to Awardee Institutions.'' An applicant organization proposing to use vertebrate animals in CDC-supported activities must file an Animal Welfare Assurance with the Office for the Protection from Research Risks at the National Institutes of Health.

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 will 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.

Application Submission and Deadline

The original and two copies of the application form PHS 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 305, Mailstop E–18, Atlanta, GA 30305, on or before July 28, 1997.

1. *Deadline:* Applications will 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 the U.S. Postal Service. Private metered postmarks will 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 and will be returned to the applicant.

Where To Obtain Additional Information

To receive additional written information, call (404) 332–4561. You will be asked to leave your name, address, and telephone number. Please refer to Announcement #800. You will receive a complete program description, information on application procedures and application forms. If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Gladys T. Gissentanna, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mailstop E–18, Atlanta, GA 30305, telephone (404) 842–6801. Programmatic technical assistance may be obtained from David Dennis, M.D. or Duane Gubler, Sc.D., Division of Vector-Borne Infectious Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), Fort Collins, CO 80522, telephone (970) 221–6400. You may also obtain this announcement from one of two Internet sites on the actual publication date: CDC's homepage at http://www.cdc.gov or the Government Printing Office homepage (including free on-line access to the Federal Register at http://www.access.gpo.gov). Other CDC Announcements are also listed on the Internet on the CDC homepage.

Please refer to Announcement Number 800 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.

Dated: May 8, 1997.

Joseph R. Carter,

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

[FR Doc. 97–12606 Filed 5–13–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Safety and Occupational Health Study Section; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

Name: Safety and Occupational Health Study Section (SOHSS), National Institute for Occupational Safety and Health (NIOSH).

Times and Dates: 8 a.m.–5 p.m., June 10, 1997; 8 a.m.–5 p.m., June 11, 1997.

Place: Embassy Suites Hotel, Meeting Room, 1900 Diagonal Road, Alexandria, Virginia, 22314.

Status: The meeting will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Public Law 92–463. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Purpose: The Safety and Occupational Health Study Section will review, discuss and evaluate grant applications in response to NIOSH's standard grants review and funding cycles pertaining to research issues in occupational safety and health and allied areas.

It is the intent of NIOSH to support broad based research endeavors in keeping with the Institute's program goals which will lead to improved understanding and appreciation of the magnitude of the aggregate health burden associated with occupational injuries and illnesses, as well as to support more focused research projects which will lead to improvements in the delivery of occupational safety and health services and the prevention of work-related injury and illness. It is anticipated that research funded will enable the philosophy of NIOSH as articulated in the Institute's vision statement: Delivering on the Nation's Promise: Safety and Health at Work for All People . . . Through Research and Prevention. Research funded will examine and evaluate current and emerging problems in occupational safety and health in a variety of settings for health and injured workers.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Pervis C. Major, Ph.D., Scientific Review Administrator, Office of Extramural Coordination and Special Projects, Office of the Director, NIOSH, 1095 Willowdale Road, Morgantown, West Virginia 26505. Telephone 304/285–5979.

Dated: May 7, 1997.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–12610 Filed 5–13–97; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Collection; Common Request

Proposed Project(s):

Title: ACF Uniform Discretionary Grant Application Form.

OMB No.: 0970–0139.

Description: ACF has more than forty discretionary grant programs. The proposed information collection form would be a uniform discretionary application form usable for all of these grant programs to collect the information from grant applicants needed to evaluate and rank applicants and protect the integrity of the grantee selection process. All ACF discretionary grant programs would be eligible but not required to use this application form. The application consists of general information and instructions; the Standard Form 424 series that requests basic information, budget information and assurances; the Program Narrative requesting the applicant to describe how these objectives will be reached; and certifications. Guidance for the content of information requested in the Program Narrative is found in OMB Circulars A–102 and A–110.

Respondents: Applicants for ACF Discretionary Grant Programs.

Annual Burden Estimates: