

leave your name and address and will be instructed to identify the Announcement number of interest, [01003].

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Henry E. Eggink, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone number: 770-488-2740, Email address: hbe7@cdc.gov

For program technical assistance, contact: Joseph Piesman, D.Sc., Division of Vector-Borne Infectious Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Fort Collins, CO 80522, Telephone number: 970-221-6400 Email address: jfp2@cdc.gov.

Dated: August 8, 2000.

John L. Williams,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01005]

Cooperative Agreement for Research on the Laboratory Diagnosis and Pathogenesis of Lyme Disease in the United States; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2001 funds for a cooperative agreement program for Research on the Laboratory Diagnosis and Pathogenesis of Lyme Disease in the United States. CDC is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the focus area of Immunization and Infectious Diseases. For the conference copy of "Healthy People 2010", visit the internet site <http://www.health.gov/healthypeople>.

The purpose of the program is to develop improved and standardized laboratory tests to identify and

characterize infection by *Borrelia burgdorferi* and related *Borrelia* species in humans and to better understand the pathogenic mechanisms of *B. burgdorferi*. Better laboratory methods can facilitate correct diagnosis and appropriate treatment of Lyme disease, thus preventing secondary consequences of infection. Better laboratory methods also can be used for improved surveillance and understanding of the epidemiology of Lyme disease in communities. Pathogenesis studies can enhance understanding of host responses to infection, leading to improved prevention or intervention strategies.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

Note: Public Law 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 \$1,200,000 dollars is available in FY 2001, to fund approximately seven awards. It is expected that the average award will be \$200,000, ranging from \$100,000 to \$300,000. It is expected that the awards will begin on or about February 15, 2001, and will be made for a 12-month budget period within a project period of up to three years. The funding estimate may change.

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.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for one or more of the activities under 1. (Recipient Activities) and CDC will be responsible for the activities listed under 2. (CDC Activities).

1. Recipient Activities

a. Develop laboratory tests that are more sensitive, specific, and reproducible than laboratory methods

currently in use to detect exposure to *B. burgdorferi* and to determine whether a patient is currently infected. Test methods may include, but are not limited to, serology, culture, polymerase chain reaction, or antigen detection.

b. Evaluate and standardize the performance of new testing methods for *B. burgdorferi* infection. These efforts should include both retrospective and prospective evaluations, including testing in clinical practice, and a direct comparison with the performance of two-tiered serologic testing.

c. Investigate aspects of the pathogenesis of infection with *B. burgdorferi* that have a direct link to developing improved methods of diagnosing, treating, or preventing Lyme disease.

d. Use animal models to develop interventions to ameliorate or prevent pathogenic effects of borrelial infection.

e. Determine the role of *Borrelia lonestari* in causing human illness. *B. lonestari* is characterized by PCR as a spirochete infecting *Amblyomma americanum* ticks and is associated with rash related illness, particularly in the southern United States.

2. CDC Activities

a. Provide technical assistance, as requested, in the design or evaluation of laboratory tests for infection with *B. burgdorferi* or *B. lonestari*.

b. Assist in the analysis of laboratory test data, as appropriate, depending on the needs of the recipient.

c. Assist in the acquisition of appropriate samples for study, as requested.

d. Assist in the design and evaluation of experiments using animal models of Lyme disease, as requested.

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

f. 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.

E. 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. The narrative should be no more than 12 double-spaced pages, printed on one side, with one-inch margins, and unrounded font.

Each application should consist of: (1) An abstract; (2) a program narrative; and (3) a detailed budget.

(1) The abstract should summarize the background, needs, goals, objective 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). 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.

Letters of support can be included if applicants anticipate the participation of other organizations or political subdivisions in conducting proposed activities. Specific roles and responsibilities should be delineated.

Required Format

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. Applications should 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 on a new page.

4. All materials must be typewritten, single-spaced, and with a 12 point font on ONLY 8½" by 11" paper.

5. Any reprints, brochures, or other enclosures should be copied (single-sided) on to 8½" by 11" paper by the applicant.

6. All pages should be printed on ONE side only, with at least one-inch margins, headers, and footers.

7. The application narrative for each recipient activity component must be limited to 12 pages, excluding abstract, budget, and appendices.

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

F. Submission and Deadline

Letter of Intent

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. Your letter of intent should include the name and address of institution and name, address and phone number of a contact person. Notification can be provided by facsimile, postal mail, or Email.

On or before September 15, 2000, submit the letter of intent to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Application

Submit the original and two copies of PHS 5161-1 (OMB Number 0937-0189).

On or before October 15, 2000, submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement. 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 independent 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.)

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

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC.

1. Plan (20 points)

The scientific validity of the proposed research plan and whether the plan addresses a stated purpose of the Cooperative Agreement Announcement.

2. Capacity (40 points)

a. The applicant's expertise in developing laboratory diagnostic tests or investigating pathobiologic events induced by infectious agents.

b. The applicant's experience in research on tick-borne disease and Lyme disease in particular.

c. The extent to which the applicant has the appropriate project personnel, organizational structure, and administrative support to assure meeting proposed objectives.

d. The extent to which the applicant has access to necessary biological materials or study populations.

3. Objectives and prospects for successfully achieving them and the likelihood that the product(s) of the investigation will result in the development of better prevention or intervention measures. (15 points)

4. Evaluation (20 points)

a. The feasibility of completing the proposed studies and meeting measurable objectives within the project period.

b. The extent to which the applicant proposes appropriate methods for evaluating the project and/or designs methods that are adequate to measure differences, when warranted.

5. *Inclusion of Women, Ethnic, and Racial Groups* (5 points). Applicants should meet 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 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. If these provisions are not relevant to the proposed scope of work, state this and 5 points will be credited to the application.

6. Budget (Not scored)

The extent to which the budget is reasonable, clearly justified, and consistent with the intended use of cooperative agreement funds.

7. Human Subjects (Not scored)

Does the application adequately address the requirements of Title 45 CFR part 46 for the protection of human subjects?

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.

For descriptions of the following Other Requirements, 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-3 Animal Subjects Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-15 Proof of Non-Profit Status

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a) and 317(k)(2) of the Public Health Service Act [42 U.S.C. 241(a) and 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.942.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page internet address—<http://www.cdc.gov>. Click on “Funding” then “Grants and Cooperative Agreements.”

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, [01005].

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Henry E. Eggink, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone number: 770-488-2740, Email address: hbe7@cdc.gov.

For program technical assistance, contact: Barbara J. B. Johnson, Ph.D., Division of Vector-Borne Infectious Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Fort Collins, CO 80522, Telephone number 970-221-6400, Email address: bjj1@cdc.gov.

Dated: August 8, 2000.

John L. Williams,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement Number 01004]

Cooperative Agreements To Prevent Lyme Disease in the United States; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of Fiscal Year (FY) 2001 funds for a cooperative agreement program to prevent Lyme disease in human populations exposed to endemic *Borrelia burgdorferi* transmission. CDC is committed to achieving the health promotion and disease prevention objectives of “Healthy People 2010,” a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the focus area of Immunization and Infectious Diseases. For the conference copy of “Healthy People 2010”, visit the internet site <http://www.health.gov/healthypeople>.

The purpose of this cooperative agreement program is to: (1) Promote and support community and other population-based interventions to prevent Lyme disease, and (2) develop novel strategies for Lyme disease prevention that are likely to be successfully implemented in the near future.

This program's overall objective is to lower the incidence of Lyme disease in hyperendemic states to 9.6 per 100,000 population or less by the year 2010. Eligible applicants may request support for the following two areas: interventions to reduce the incidence of human Lyme disease and its complications in endemic communities or high risk populations, and to develop and evaluate novel strategies to prevent Lyme disease by controlling vector tick populations or otherwise interrupt the transmission cycle of *B. burgdorferi*.

The incidence of Lyme disease in the United States has been increasing and is likely to continue to increase unless affected communities and populations at risk develop and implement integrated control and prevention strategies. Principal Lyme disease interventions include the use of area-wide and host-targeted acaricides; habitat modification; avoidance of tick-infested habitat; personal protective measures, including tick checks and early tick removal; early disease detection and treatment; and vaccination. In addition, there is a need

to explore new methods of Lyme disease prevention that may yield higher levels of community and individual participation than existing strategies.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations, and by governments and their agencies, that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, state and local governments, or their bona fide agents, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations.

Note: Public Law 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

Funds will be awarded in two separate categories of prevention projects.

Approximately \$2,000,000 is available in FY 2001 to fund approximately five awards for community-based or other population-based interventions to prevent Lyme disease. It is expected that the awards will be \$400,000, ranging from \$200,000 to \$600,000.

Approximately \$600,000 is available in FY 2001 to fund approximately four awards for developing and evaluating novel strategies to prevent Lyme disease. It is expected that the awards will be \$150,000 ranging from \$100,000 to \$200,000.

It is expected that the awards will begin on or about February 15, 2001, and will be made for a 12-month budget period within a project period of up to three years. The Funding estimates may change.

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.

Funding Preference

Funding preference will be given to proposals that incorporate integrated strategies for population-based control of tick-borne diseases.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. (Recipient Activities), and CDC will be responsible for the activities listed under 2. (CDC Activities) below: