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).

[FR Doc. 00–20500 Filed 8–11–00; 8:45 am]

BILLING CODE 4163–18–P

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:

1. Recipient Activities

a. Proposals for interventions to reduce the incidence of human Lyme disease and its complications in endemic communities. Note: applicants are expected to carry out all of the following activities over the course of the project period.

(1) In cooperation with community leaders, residents, and local organizations and agencies, implement a population-based intervention strategy to prevent Lyme disease. This could include integrated application of methods to reduce tick abundance, promotion of personal protective practices, education leading to early disease detection and treatment, and the appropriate use of Lyme disease vaccine.

(2) Obtain data on the population's knowledge, attitudes, and practices related to the risk of Lyme disease, as well as factors influencing the adoption of prevention strategies.

(3) Obtain population-based data on current practices to control *I. scapularis* populations, or otherwise prevent Lyme disease, and on the feasibility of implementing specific control strategies.

(4) Establish active surveillance for Lyme disease in the intervention population, and promote active or passive surveillance for Lyme disease throughout the county or state of the applicant's jurisdiction during the project period.

(5) Collect and analyze data on tick abundance and tick infection rates that affect the intervention population. A plan to gather such data on a comparison population as well may enhance the scientific validity of the proposal, but is not a requirement.

(6) Analyze data on human cases of Lyme disease in both the intervention population and other populations within the same state and county during and after the intervention.

(7) Develop a plan to evaluate the intervention strategies' effect on Lyme disease incidence and tick densities in the area.

b. Proposals to develop and evaluate novel approaches to prevent Lyme disease by controlling vector tick populations or otherwise interrupt the transmission cycle of *B. burgdorferi.* Note: applicants are required to complete all components (1–4) for tick control proposals, or only component (5) for anti-tick vaccine proposals, during the project period.

(1) Design innovative methods to reduce tick populations in endemic communities. This may include one or more of the following: improved delivery of existing approved area-wide or host-targeted acaricides, the development of alternative acaricides, habitat modifications, host management, or biological control of ticks.

(2) Implement the tick control strategy in a Lyme disease endemic area.

(3) Evaluate the effect of the intervention on tick densities, infection rates, or human incidence of Lyme disease.

(4) Develop a plan for widespread or commercial dissemination of the tick control strategy.

(5) Develop candidate anti-tick vaccines that have potential to block the transmission of *Borrelia burgdorferi* to people, including any or all of the following:

(a) Utilize molecular biological and/or immunological techniques to identify unique candidate antigens.

(b) Evaluate the immunogenicity of candidate molecules in terms of both the B and T cell responses in a suitable model of tick-transmitted Lyme borreliosis.

(c) Evaluate novel methods of vaccine candidate delivery, *i.e.* plasmid DNA or sustained release vaccine technologies in a suitable model of tick-transmitted Lyme borreliosis.

2. CDC Activities

a. Proposals for interventions to reduce the incidence of human Lyme disease and its complications in endemic communities.

(1) Provide technical assistance, as requested, in the design of the intervention to prevent disease transmitted by *I. scapularis.*

(2) Provide technical assistance, as requested, in the implementation of the population-based intervention.

(3) Assist in the analysis of entomological, microbiological, population-based survey, and case surveillance data.

(4) Assist in the development of recommendations for population-based prevention of diseases transmitted by *I. scapularis* that can be extended to other endemic communities.

(5) Assist in the evaluation of the outcomes of the project and of the applicability to other populations at risk of Lyme disease.

(6) 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.

b. Proposals to develop and evaluate novel approaches to prevent Lyme disease by controlling vector tick populations or otherwise interrupt the transmission cycle of *B. burgdorferi.*

(1) Provide technical assistance in the design, implementation, and evaluation of the intervention strategies, including technical assistance in the evaluation of candidate anti-tick vaccine candidates.

(2) Assist in performing selected laboratory and field procedures, as appropriate depending on the needs of the recipient.

(3) Assist in the coordination of research activities among different recipient sites and between agencies or other groups working on the same project.

(4) Assist in the analysis of research data.

(5) Support efforts to move forward toward registration and dissemination of novel control methodologies.

(6) 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.

If the applicant is not a state or local health department, then the applicant should collaborate with the appropriate state or county health department to assure that Lyme disease surveillance will be carried out during the project period. The community or group of communities in a Lyme disease endemic area (or a population otherwise at high risk of Lyme disease) selected for the population-based intervention project should be identified in the application. Consider identifying non-intervention populations for comparison.

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 10 double-spaced pages, printed on one side, with one-inch margins, and unreduced font.

A table of contents should precede the narrative, and appropriate content headings should be clearly identified within the narrative. Applications which do not conform to the length requirements will be penalized points on review (see evaluation criteria).

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 1″ 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 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 10, 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). Forms are in the application kit.

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 by an independent review group appointed by CDC.

1. Proposals for interventions to reduce the incidence of human Lyme disease and its complications in endemic communities.

a. Demonstrated high endemicity of Lyme disease in both target and comparison communities. (10 points)

b. Demonstrated support for the intervention from community residents and organizations. (10 points)

c. Documented expertise of the applicant in strategies to control populations of *I. scapularis* or in other methods to prevent Lyme disease. (10 points)

d. Demonstrated epidemiologic expertise in measuring population-based occurrence of disease and health outcomes. (10 points)

e. Likelihood that any proposed tick control strategies will result in substantial reductions of tick abundance in the target community. (13 points)

f. Likelihood that community education efforts will promote Lyme disease prevention within the target community. (12 points)

g. Quality of the plan to use Lyme disease vaccine (according to published CDC Advisory Committee on Immunization Practices guidelines), and for monitoring vaccine use in the intervention community. (5 points)

h. Likelihood that the proposed intervention will be practical and sustainable in the target community and can be implemented in other endemic communities. (10 points)

i. Demonstrated capacity and intent to conduct and maintain effective Lyme Disease surveillance throughout the country or state of the applicant's jurisdiction during the project period. (10 points) (Note: If the applicant is not a state or local health department, then the applicant should indicate collaboration with the appropriate state or county health department to assure that Lyme disease surveillance will be carried out during the project period.)

j. Conformity of application narrative to stated requirements (no more that 10 single-spaced pages, no less than 12 point type. (5 points)

Note: Applications which are either more than 10 single spaced pages, or use less than 12 point type, or both, will receive 0 points for this criterion.

k. Inclusion of Women, Ethnic, and Racial Groups 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, and (3) 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 (5 points). If these provisions are not relevant to the proposed scope of work, state this, and 5 points will be credited to the application.

l. Budget (Not scored) The extent to which the budget is reasonable, clearly justified, and consistent with the intended use of cooperative agreement fund.

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

n. Animal Research (Not scored) If applicable, does the application adequately address the requirements for ethical research using animals?

2. Proposals to develop and evaluate novel approaches to prevent Lyme disease by controlling vector tick populations or otherwise interrupt the transmission cycle of *B. burgdorferi.*

a. Extent to which the proposed method of tick control or anti-tick vaccines is scientifically valid and feasible. (20 points)

b. Scientific quality of the plan to evaluate the proposed prevention method (20 points)

c. Documented expertise of the applicant in tick control research or tick immunology, including publication of results in peer-reviewed scientific journals. (30 points)

d. Likelihood that the proposal will lead to a useful and practical prevention strategy that can be widely disseminated in community-based or other campaigns to prevent and control Lyme disease. (20 points)

e. Conformity of application narrative to stated requirements (no more that 10 single-spaced pages, no less than 12 point type. (5 points) Note: applications which are either more than 10 single-spaced pages, or use less than 12 point type, or both, will receive 0 points for this criterion).

f. Inclusion of Women, Ethnic, and Racial Groups 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, and (3) 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 (5 points). If these provisions are not relevant to the proposed scope of work, state this and 5 points will be credited to the application.

g. Budget (Not scored)

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

h. Human Subjects (Not scored)

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

i. Animal Research (Not scored)

If applicable, does the application adequately address the requirements for ethical research using animals?

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Semiannual progress reports;

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

3. Final financial report 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–9 Paperwork Reduction Act 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 [42 U.S.C. 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, [01004].

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:

Edward B. Hayes, M.D., Joseph Piesman, D.Sc, Kathleen Orloski, D.V.M., M.S. or David Dennis, M.D., MPH, 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 or ebh2@cdc.gov.

Dated: August 8, 2000.

John L. Williams,

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

[FR Doc. 00–20499 Filed 8–11–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1401]

Draft Guidance for Industry on Administrative Procedures for CLIA Categorization; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry entitled ''Guidance for Administrative Procedures for CLIA Categorization.'' The Center for Devices and Radiological Health is issuing this draft guidance document to provide information to manufacturers on how to submit requests for complexity categorization under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and how FDA will notify the manufacturer of the complexity categorization.

DATES: Submit written comments on the draft guidance document by November 13, 2000.

ADDRESSES: Submit written requests for single copies on a 3.5diskette of the draft guidance document entitled ''Guidance for Administrative Procedures for CLIA Categorization'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance document.