

and institutions. In particular, the degree to which the applicant demonstrates a healthcare delivery network which includes adequate numbers of facilities in close geographic proximity to one another that share common administration and information systems, and who demonstrate a willingness to fully participate.

3. Operational Plan (40 points)

a. The extent to which the applicant presents clear, time-phased objectives that are consistent with the stated program goal and a detailed operational plan outlining specific activities that are likely to achieve the objective. The extent to which the plan clearly outlines the responsibilities of each of the key personnel. (35 points)

b. The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes: (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. (5 points)

4. Evaluation Plan (15 points)

The extent to which the applicant presents a scientifically valid plan for monitoring the impact of the intervention, including, but not limited to, cost effectiveness.

5. Measures of Effectiveness (5 points)

The extent to which the applicant provides Measures of Effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures must be objective/quantitative and must measure the intended outcome.

6. Budget (Not scored)

The extent to which the applicant presents a reasonable detailed budget with a line-item justification and any other information to demonstrate that the request for assistance is consistent with the purpose and objectives of this cooperative agreement program.

7. Human Subjects (Not scored)

The extent to which the application adequately addresses 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. Semiannual progress reports.
2. Financial status report, no more than 90 days after the end of the budget period.

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

4. Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement.

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

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

- AR-1 Human Subjects Requirements
- AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-7 Executive Order 12372 Review
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-15 Proof of Non-Profit Status
- AR-22 Research Integrity

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301(a) and 317(k)(2) of the Public Health Service Act, [42 U.S.C. sections 241(a) and 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

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."

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Rene' Benyard, Grants Management Specialist, Centers for Disease Control and Prevention, Procurement and Grants Office, Acquisition and Assistance, Branch B, 2920 Brandywine Road, Room 3000, Mailstop K-75, Atlanta, GA 30341-4146, Telephone number: (770)

488-2722, E-mail address:

bnb8@cdc.gov.

For program technical assistance, contact: John Jernigan, M.D., Centers for Disease Control and Prevention, National Center for Infectious Diseases, Division of Healthcare Quality and Promotion, 57 Executive Park South, Room 4109, Mailstop E-68, Telephone number: (404)498-1257, E-mail address: jjernigan@cdc.gov.

Dated: May 4, 2002.

Sandra R. Manning,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02118]

Fellowship Training Programs In Vector-Borne Infectious Diseases; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2002 funds for a cooperative agreement program for a graduate level Fellowship Training Program in Vector-Borne Infectious Diseases, leading to a master's or doctoral degree. This program addresses the "Healthy People 2010" focus area of Immunization and Infectious Diseases.

The purpose of this cooperative agreement is to assist recipients in the development and implementation of a two to three year Fellowship Training Program (FTP) in entomology, arbovirology, and microbiology, which provides a combination of entomologic, virologic, and microbiologic techniques, basic laboratory or epidemiologic training in vector-borne infectious diseases. The goal is to improve the ability of the U.S. public health system to respond to the problem of vector-borne infectious diseases by increasing the number of specialists with demonstrated skills in the public health aspects of vector-borne infectious diseases and to provide them with the essential, pertinent field and research skills.

FTPs should be implemented as new, distinct fellowship positions/tracks in recipient's existing graduate training program. FTPs should be aimed at individuals who wish to pursue an academic career in vector-borne

diseases of public health importance. The objective is to offer a combination of field, laboratory, and research training which will lead to a masters or doctoral degree in entomology, arbovirology, or microbiology. Specific areas of concentration may include mosquito and tick biology, ecology, physiology or behavior, basic arbovirology, serology, laboratory diagnosis, epidemiology, prevention, and control of vector-borne viral and bacterial diseases. Specific areas of research concentration may include entomology, ecology, arbovirology, microbiology, vector-borne bacterial diseases, and vector-borne infectious diseases.

B. Eligible Applicants

Applications may be submitted by public and private non-profit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private non-profit organizations, State and local governments or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau, federally recognized Indian Tribal Governments, Indian Tribes, or Indian Tribal Organizations and Faith-based organizations are eligible to apply.

Assistance will be provided only to organizations with established research and training programs in one or more of the following disciplines: Medical entomology, arbovirology, vector-borne bacterial diseases, and/or vector-borne infectious diseases.

Note: Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant or loan.

C. Availability of Funds

Approximately \$750,000 is available in FY 2002 to fund approximately three awards. It is expected that the average award will be \$250,000, ranging from \$200,000 to \$300,000. It is expected that the awards will begin on or about August 30, 2002, and will be made for a 12-month budget period within a project period of up to three years. 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.

Use of Funds

Recipient cost sharing is required under this program. CDC will provide up to 75 percent of the total cost for items directly related to the support of fellows such as stipends (consistent with Public Health Service policies) and professional travel. CDC funds will not be provided for supplies and equipment or for direct salaries/fringe, travel, space, etc., for recipient's faculty or administrative personnel. In a training grant, recipient's indirect charges are limited to eight percent of direct costs. CDC funds are not intended to supplant recipient's existing infectious disease fellowships, rather they are intended to support new fellowship opportunities that are consistent with the stated purpose of this cooperative agreement program.

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.

1. Recipient Activities

a. Develop and conduct a two to three year FTP that combines entomological, arboviral, microbiological, and bacterial zoonoses field, basic laboratory, and epidemiologic research in prevention and control of vector-borne infectious diseases of public health importance as a distinct and separate track of any existing graduate-level fellowship program.

b. Design and conduct the FTP such that, upon completion of the fellowship, fellows will receive a graduate degree in the field of study.

c. Provide preceptors for training.

d. Develop a fellowship candidate application, review, ranking, and selection process. Based on this process, select applicants to be awarded two-to three-year FTP fellowships.

e. Provide administrative support to fellows during their tenure in the FTP, including the payment of stipends, professional travel, etc. (see Availability of Funds for cost sharing requirements).

f. Assist fellows in publishing and/or otherwise disseminating results of their research.

g. Monitor and evaluate the progress of fellows and progress toward achieving program goals. To measure the overall success of the FTP, establish a mechanism to follow up and report on fellows (e.g., where they work, in what

field, etc.) periodically for up to five years after they complete the FTP.

h. Assure appropriate IRB review by all cooperating institutions participating in the project if the fellows research involves the use of human subjects.

2. CDC Activities

a. Provide preceptors and facilities for research training that occurs at CDC facilities. The entomological, arboviral, microbiological, and laboratory or epidemiologic research training may occur at CDC facilities.

b. 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. Content

Letter of Intent (LOI)

An LOI is optional for this program. The narrative should be no more than 5 double spaced pages, printed on one side, with one-inch margins, and un-reduced font. Your letter of intent will be used to assist CDC in planning the evaluation of applications submitted under Program Announcement 02118 and should include (1) name and address of institution; (2) name, address, and telephone number of contact person; and if proposing that research component be conducted at CDC facilities, (3) name and telephone number of CDC scientist agreeing to participate.

Applications

Use the information in this section and 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 10 single spaced pages, printed on one side, with one-inch margins, and un-reduced fonts.

Specific Instructions

All pages must be clearly numbered, and a complete index to the application and its appendices must be included. All pages of the application and appendices must be easily run through an automatic document feed copier. Thus, do not bind, staple, or paperclip any pages of any copy of the application, and do not include any bound documents (e.g., pamphlets or other publications) in the appendices. Do not include cardboard, plastic, or other page separators between sections.

The application narrative must not exceed 10 pages (excluding abstract, budget, and appendices). Unless indicated otherwise, all information requested below must appear in the narrative. Materials or information that should be part of the narrative will not be accepted if placed in the appendices. The application narrative must contain the following sections in the order presented below:

1. Abstract

Provide a brief (less than two pages) summary of the proposed FTP.

2. Background and Need

Demonstrate an understanding of the background and need for the FTP. Discuss how your proposed FTP track differs from existing tracks/opportunities in your fellowship program and how your proposed FTP track meets the purpose of this cooperative agreement program.

3. Capacity and Personnel

a. Describe applicant's goals, objectives, and efforts to promote the field of entomology and vector-borne infectious diseases. Describe relevant degree programs and sponsored regular national meetings, seminars, and/or workshops devoted to pertinent issues in academic vector-borne infectious diseases with relevance to public health.

b. Demonstrate applicant's experience in academic vector-borne infectious disease education and training in general, including experience in maintaining programs that lead to awarding of graduate degrees in the field. Describe applicant's existing graduate degree fellowship training programs for entomologists, arbovirologists, and/or bacteriologists.

c. Describe applicant's resources, facilities, and professional personnel that will be involved in conducting the project. Include (in an appendix) curriculum vitae for all professional personnel involved with the project. Describe plans for administration of the project and identify administrative resources/personnel that will be assigned to the project. Provide (in an appendix) letters of support from all key participating non-applicant organizations, individuals, etc., which clearly indicate their commitment to participate as described in the operational plan.

d. If proposing that fellows conduct their field, laboratory, or epidemiologic training at CDC facilities, include a letter of support (in an appendix) from the appropriate CDC scientist (cosigned by their Division/Program Principal Management Officer) that clearly

indicates their commitment to participate as described in your application Operational Plan, including agreement to (1) serve as preceptor for the research training and (2) provide space, facilities, supplies, etc., for fellows.

4. Operational Plan

Present a detailed and time phased plan for establishing and conducting the FTP. Describe procedures to accomplish all of the required recipient activities. Describe how the field, laboratory, and research activities will be coordinated within the FTP. Present a plan for monitoring and evaluating the progress of fellows and the progress toward achieving program goals. Describe how the plan will ensure that all fellows become eligible for graduation by the end of fellowship tenure. Describe procedures and plans for assuring any fellow's research that involves the use of human subjects will receive appropriate IRB review by all cooperating institutions participating in the project.

5. Budget

Provide a line item budget and accompanying detailed, line by line justification that demonstrates the request is consistent with the purpose and objectives of this program. Clearly indicate by line item both (a) the full cost and (b) the amount requested from CDC (see Availability of Funds section for further information regarding cost-sharing).

F. Submission and Deadline

Letter of Intent

On or before June 5, 2002, submit the LOI to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Applications

Submit the original and two copies of PHS 5161-1 (OMB Number 0920-0428). Forms are available in the application kit and at www.cdc.gov/od/pgo/forminfo.htm. On or before July 5, 2002, submit the application to the Technical Information Section, 2920 Brandywine Road, Suite 3000 Atlanta, Georgia 30341.

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

1. Received on or before the deadline date or
2. 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 (1) or (2) above are considered late applications, will not be considered, and will be returned to the applicant.

G. Evaluation Criteria

Applicants are required to provide Measures of Effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of Effectiveness must relate to the performance goal (or goals) as stated in section "A. Purpose" of this announcement.

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

1. Background and Need (15 points)

The extent to which the applicant demonstrates an understanding of the background and need for the FTP. Extent to which they clearly demonstrate that their proposed FTP fellowship positions add to and do not supplant existing positions in their fellowship program. The extent to which they demonstrate how the proposed FTP track meets the Purpose of this cooperative agreement program.

2. Capacity (Total 50 points)

a. Institutional

The extent to which the applicant demonstrates that they have been and are devoted to promoting the field of vector-borne infectious diseases. Extent to which the applicant has promoted the field of vector-borne infectious diseases by conducting regular national meetings and workshops devoted to current topics. The extent to which the applicant documents experience in education and training in entomology, arbovirology, and vector-borne infectious diseases, including documentation of relevant degree programs offered and evidence of experience in successfully preparing students to work in the field. The extent to which the applicant demonstrates significant institutional experience in managing graduate-level fellowship training programs in the area of vector-borne infectious diseases. The extent to which the applicant documents they have a successful existing program(s) in vector-borne infectious diseases. (25 points)

b. Staff and Administrative

The extent to which the applicant describes adequate resources and facilities (clinical, academic, and administrative) for conducting the FTP. The extent to which the applicant documents the past experience and qualifications of their professional personnel who will be involved in the FTP by *curriculum vitae*, publications, etc. If proposing that fellow's research be conducted at CDC facilities, the extent to which applicant includes a letter of support as described in Application Content section 3.b., above (i.e., that is signed by the appropriate CDC officials and that clearly indicates their commitment to participate as proposed in the application). (25 points)

3. Operational Plan (25 points)

The extent to which the proposed operational plan is clear, detailed, time-phased, and meets the purpose and goals of this cooperative agreement program. The extent to which the proposed operational plan addresses all required Recipient Activities. If specific fellow(s) research projects are proposed that involve the use of human subjects, the degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes:

- a. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.
- b. The proposed justification when representation is limited or absent.
- c. A statement as to whether the design of the study is adequate to measure differences when warranted.
- d. A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

4. Evaluation Plan (5 points)

The extent to which the applicant demonstrates the quality of the proposed plan to monitor, evaluate, and track individual fellows and overall plan to evaluate activities and objectives.

5. Measures of Effectiveness (5 points)

The extent to which the applicant provides Measures of Effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures must be objective/quantitative and must measure the intended outcome.

6. Budget (Not scored)

The extent to which the proposed 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. Semiannual progress reports.
2. Financial status report no more than 90 days after the end of the budget period.
3. Final financial and performance reports no more than 90 days after the end of the project period.
4. Applicants are required to provide Measures of Effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement.

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

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

- 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-7 Executive Order 12372 Review
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under Sections 301 [42 U.S.C. 241] and 317(k)(2) [42 U.S.C. 247b(k)(2)] of the Public Health Service Act, as amended. The Catalog of Federal Domestic Assistance Number is 93.283.

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."

If you have questions after reviewing the contents of all the documents,

business management technical assistance may be obtained from: René Benyard, Grants Management Specialist, Centers for Disease Control and Prevention, Procurement and Grants Office, Acquisition and Assistance, Branch B, 2920 Brandywine Road, Room 3000 Atlanta, GA 30341-4146, Telephone number: (770) 488-2722, E-mail: bnb8@cdc.gov.

For program technical assistance, contact: Mel Fernandez, Program Management Official, Centers for Disease Control and Prevention (CDC), National Center for Infectious Diseases, Division of Vector-Borne Infectious Diseases, P. O. Box 2087, Rampart Road, Foothills Campus, Fort Collins, CO 80521 Telephone: (970) 221-6426, E-mail: jjernigan@cdc.gov.

Dated: May 4, 2002.

Sandra R. Manning,

Director, Procurement and Grants Office,
Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

The Fifth Annual FDA/OCRA Educational Conference in Irvine, CA on Emerging Regulatory Issues and How to Handle Them; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), in cosponsorship with the Orange County Regulatory Affairs Discussion Group (OCRA) is announcing its fifth annual educational conference entitled "Emerging Regulatory Issues and How to Handle Them." The public workshop is intended to give the drugs, devices, and biologics industries an opportunity to interact with FDA reviewers and compliance officers from FDA's centers and district offices, as well as other industry experts. The main focus of this interactive workshop is to provide information regarding regulatory changes such as the antibioteerrorism initiatives that are taking place within the Federal, State, and local agencies; how these activities are affecting the approval process of product submissions to FDA and Foreign governments; and how companies could prepare for an onslaught of new requirements as a result of the sweeping regulatory changes.