

Specialist listed in the "Agency Contacts" section of this announcement.

VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2700.

For program technical assistance, contact: Neil Rainford, Project Officer, 4770 Buford Hwy., NE., MS-K60, Atlanta, GA 30341-3724, Telephone: 770-488-1122, E-mail: NRainford@cdc.gov.

For financial, grants management, or budget assistance, contact: Nancy Pillar, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Suite 3000, Atlanta, GA 30341, Telephone: 770-488-2721, E-mail: NPillar@cdc.gov.

Dated: May 10, 2004.

William P. Nichols,

Acting 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

Postdoctoral Fellowship Training Program (PFTP) in Infectious Diseases

Announcement Type: Competing Continuation.

Funding Opportunity Number: 04108.

Catalog of Federal Domestic

Assistance Number: 93.283.

Key Dates: Letter of Intent Deadline: June 1, 2004.

Application Deadline: June 14, 2004.

I. Funding Opportunity Description

Authority: This program is authorized under Sections 301 and 317(k)(2) of the Public Health Service Act, [42 U.S.C. 241 and 247b(k)(2)], as amended.

Purpose: The purpose of this cooperative agreement is to support recipients in conducting a two- to three-year Postdoctoral Fellowship Training Program in Infectious Diseases (PFTP) which provides a combination of clinical training and basic laboratory or epidemiology training in infectious diseases. The goal is to improve the ability of the U.S. public health system to respond to the problem of infectious diseases by increasing the number of academic infectious disease physicians with demonstrated skills in the public

health aspects of infectious diseases and to provide them with the essential, pertinent clinical and research skills.

PFTPs should be implemented as new distinct fellowship positions/tracks in grantee's existing infectious disease postdoctoral training program for physicians. PFTPs should be aimed at physicians with training in infectious diseases who wish to pursue a career in academic infectious diseases of public health importance. The objective is to offer a combination of clinical and research training which will lead to eligibility for certification in infectious diseases by the American Board of Internal Medicine or the American Board of Pediatrics.

Specific areas of clinical concentration may include: Clinical rotations in infectious diseases, infectious diseases in transplant recipients, clinical microbiology, outpatient infectious diseases, pediatric infectious diseases, or infectious disease pharmacology. The recipient must be able to provide support for physicians of unusual ability and promise or proven achievement by giving them an opportunity to conduct clinical, laboratory, and epidemiologic research on significant public health problems caused by infectious diseases. Specific areas for research training may include: Viral and rickettsial infections, nosocomial infections, antimicrobial resistance, vector-borne infectious diseases, respiratory and food-borne bacterial diseases, parasitic diseases, sexually transmitted diseases, and acquired immunodeficiency syndrome. This program addresses the "Healthy People 2010" focus area(s) of Immunization and Infectious Disease.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Center for Infectious Diseases (NCID): Protect Americans from infectious disease.

Activities: Awardee activities for this program are as follows:

- As a distinct and separate track of recipient's existing infectious disease postdoctoral fellowship program, conduct a two-to three-year PFTP that combines clinical and basic laboratory or epidemiologic research training in prevention and control of infectious diseases of public health importance.
 - Design and conduct the PFTP such that upon completion of the fellowship, fellows will become eligible for certification in infectious diseases by the American Board of Internal Medicine or the American Board of Pediatrics.
 - Provide preceptors for training.

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

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

- Monitor and evaluate the progress of fellows and progress toward achieving program goals. To measure the overall success of the PFTP, 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 PFTP.

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC Activities for this program are as follows:

- Some of the laboratory and epidemiologic training component of the PFTP may occur at CDC facilities under CDC staff preceptors. CDC may provide preceptors and/or facilities for training that occurs at CDC facilities. It is not a requirement that any of the training occur at CDC facilities or under the guidance of CDC staff.

II. Award Information

Type of Award: Cooperative Agreement.

Fiscal Year Funds: 2004.

Approximate Total Funding: \$150,000.

Approximate Number of Awards: 2.

Approximate Average Award: \$75,000 (This amount is for the first 12-month budget period, and includes both direct and indirect costs).

Floor of Award Range: None.

Ceiling of Award Range: \$115,000.

Anticipated Award Date: July 1, 2004.

Budget Period Length: 12 months.

Project Period Length: Up to 5 years.

Throughout the project period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government.

III. Eligibility Information

III.1. Eligible Applicants

Applications may only be submitted by university-affiliated schools of medicine in the United States with infectious disease programs accredited by the Accreditation Council for Graduate Medical Education (ACGME).

Only one application per eligible school of medicine will be accepted.

III.2. Cost Sharing or Matching

Grantee cost-sharing is required under this program. CDC will provide up to 50 percent of the total cost for items directly related to the support of fellows such as stipends and professional travel. CDC funds will not be provided for supplies and equipment, any costs of research conducted by fellows as part of their training (except for stipends), or for direct salaries/fringe, travel, space, etc., for recipient's faculty or administrative personnel. CDC funds are not intended to supplant recipient's existing infectious disease fellowships, rather they are intended to support new/additional fellowship opportunities that are consistent with the stated Purpose of this grant program.

III.3. Other

If you request a funding amount greater than the ceiling of the award range, your application will be considered non-responsive, and will not be entered into the review process. You will be notified that your application did not meet the submission requirements.

If your application is incomplete or non-responsive to the requirements listed in this section, it will not be entered into the review process. You will be notified that your application did not meet submission requirements.

Eligibility is limited to university-affiliated U.S. schools of medicine with infectious disease programs accredited by the Accreditation Council for Graduate Medical Education (ACGME) as these are the only institutions that will have existing infectious disease fellowships for physicians that this grant program seeks to enhance. ACGME-accredited medical schools are the only institutions that can prepare fellows for eligibility for certification in infectious diseases by the American Board of Internal Medicine or American Board of Pediatrics as required by this program.

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.

IV. Application and Submission Information

IV.1. Address To Request Application Package

To apply for this funding opportunity use application form PHS 5161. For hard-copy submission of application,

application forms and instructions are available on the CDC web site, at the following Internet address: www.cdc.gov/od/pgo/forminfo.htm. To submit your application electronically, please utilize the forms and instructions posted for this announcement at www.grants.gov. If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO-TIM) staff at: 770-488-2700. Application forms can be mailed to you.

IV.2. Content and Form of Submission

Letter of Intent (LOI): Your LOI must be written in the following format:

- Maximum number of pages: 1
- Font size: 12-point un-reduced
- Single spaced
- Paper size: 8.5 by 11 inches
- Page margin size: One inch
- Printed only on one side of page
- Written in plain language, avoid jargon

Your LOI must contain the following information:

- Name of applicant institution
- Point of contact name address, phone number, and E-mail address

Application: You must submit a project narrative with your application forms. The narrative must be submitted in the following format:

- Maximum number of pages: 10 If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.
- Font size: 12 point un-reduced
- Single spaced
- Paper size: 8.5 by 11 inches
- Page margin size: One inch
- Printed only on one side of page
- Held together only by rubber bands or metal clips; not bound in any other way.

Your narrative should address activities to be conducted over the entire project period, and must include the following items in the order listed:

- Abstract
- Provide a brief (less than two pages) summary of the proposed PFTP.

Abstract does NOT count toward the narrative page limitation.

- Background and Need

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

- Capacity and Personnel
 - Describe applicant's goals, objectives, and efforts to promote the field of academic infectious diseases.

- Demonstrate applicant's experience in academic infectious diseases education and training in general, including experience in maintaining programs that lead to eligibility for certification in infectious diseases by the American Board of Internal Medicine or the American Board of Pediatrics.

- Describe applicant's existing postdoctoral fellowship training programs for physicians in infectious diseases. Describe applicant's resources, facilities, and professional personnel that will be involved in conducting the project.

- Operational Plan
 - Present a detailed and time-phased plan for establishing and conducting the PFTP.

- Describe the proposed structure, timeline, and procedures for the PFTP. Clearly address all Activities listed in Section I, above.

- Identify key staff and their assigned responsibilities for operating the PFTP.
- Present a plan for monitoring and evaluating the progress of fellows during and after PFTP.

- Describe how you will ensure that all fellows become eligible for certification in infectious diseases by the American Board of Internal Medicine by the end of fellowship tenure.

- Measures of Effectiveness (see Section V.1.—Evaluation Criteria, below, for more information regarding measures of effectiveness).

- Budget (does NOT count towards page limitation)

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 cost-sharing requirement in Section III.2., above.).

- Appendices: The following additional required information should be included in the application appendices. The appendices will not be counted toward the narrative page limit. This additional information includes:

- Curriculum vitae for key professional personnel involved with the project.

- Documentation of ACGME accreditation.

- If proposing that fellows conduct any of their laboratory or epidemiologic training at CDC facilities and/or under the preceptorship of CDC staff, include in the appendix letters of support from the appropriate CDC scientist(s) that clearly indicates their commitment to participate as described in your

application. If any training is to occur at CDC facilities, letters of support also need to be co-signed by the CDC scientist's Division Principal Management Officer and the letter must clearly indicate the Division's willingness to provide space, supplies, use of equipment/facilities, etc., for fellows during their training at CDC.

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access www.dunandbradstreet.com or call 1-866-705-5711. For more information, see the CDC web site at: <http://www.cdc.gov/od/pgo/funding/pubcommt.htm>. If your application form does not have a DUNS number field, please write your DUNS number at the top of the first page of your application, and/or include your DUNS number in your application cover letter.

Additional requirements that may require you to submit additional documentation with your application are listed in section "VI.2. Administrative and National Policy Requirements."

IV.3. Submission Dates and Times

LOI Deadline Date: June 1, 2004.

CDC requests that you send a LOI if you intend to apply for this program. Although the LOI is not required, not binding, and does not enter into the review of your subsequent application, the LOI will be used to gauge the level of interest in this program, and to allow CDC to plan the application review.

Application Deadline Date: June 14, 2004.

Explanation of Deadlines:

Applications must be received in the CDC Procurement and Grants Office by 4 p.m. Eastern Time on the deadline date. If you send your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If CDC receives your application after closing due to: (1) Carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you will be given the opportunity to submit documentation of the carriers guarantee. If the documentation verifies a carrier problem, CDC will consider the

application as having been received by the deadline.

This announcement is the definitive guide on application submission address and deadline. It supersedes information provided in the application instructions. If your application does not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that your application did not meet the submission requirements.

CDC will not notify you upon receipt of your application. If you have a question about the receipt of your application, first contact your courier. If you still have a question, contact the PGO-TIM staff at: 770-488-2700. Before calling, please wait two to three days after the application deadline. This will allow time for applications to be processed and logged.

IV.4. Intergovernmental Review of Applications

Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order (EO) 12372. This order sets up a system for state and local governmental review of proposed federal assistance applications. You should contact your state single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your state's process. Click on the following link to get the current SPOC list: <http://www.whitehouse.gov/omb/grants/spoc.html>.

IV.5. Funding Restrictions

Restrictions, which must be taken into account while writing your budget, are as follows:

- These awards will be training grants. For training grants, recipient's indirect charges are limited to 8 percent of direct costs.
- Also, see Section III.2., Cost Sharing for additional funding restrictions.

Guidance for completing your budget can be found on the CDC Web site, at the following Internet address: <http://www.cdc.gov/od/pgo/funding/budgetguide.htm>.

IV.6. Other Submission Requirements

LOI Submission Address: Submit your LOI by express mail, delivery service, fax, or E-mail to: Greg Jones, M.P.A., Public Health Analyst, Office of the Director, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop C12, Atlanta, GA 30333, Fax: (404) 639-3106, E-mail: GJJones@cdc.gov.

Application Submission Address: Submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management—PA# 04108, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341 or You may submit your application electronically at: www.grants.gov.

V. Application Review Information

V.1. Criteria

You are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the grant or cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the "Purpose" section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation. Your application will be evaluated against the following criteria:

1. Background and Need (15 points): Does the applicant demonstrate an understanding of the background and need for the PFTP? Do they clearly demonstrate that their proposed PFTP adds positions to and does not supplant existing positions in their fellowship program? Do they demonstrate how the proposed PFTP meets the Purpose of this program announcement?

2. Capacity:

a. Institutional (25 points): Does the applicant demonstrate that they have been and are devoted to promoting the field of academic infectious diseases, e.g., by conducting regular national meetings and workshops devoted to current topics? Does the applicant document experience in education and training in academic infectious diseases, including documentation of relevant degree programs offered and evidence of experience in successfully preparing students for certification in infectious diseases by the American Board of Internal Medicine or the American Board of Pediatrics? Does the applicant demonstrate significant institutional experience in managing postdoctoral fellowship training programs for physicians in the area of infectious diseases? Do they document that they have a successful existing postdoctoral fellowship program in infectious diseases that will serve as the platform for the proposed PFTP fellowships?

b. Staff and administrative (25 points): Does the applicant describe adequate resources and facilities (clinical,

academic, and administrative) for conducting the PFTP? Do they document that their professional personnel involved in the PFTP are qualified and have past experience and achievements related to that proposed? If proposing that fellow's research be conducted at CDC facilities, does the applicant include Letters of Support as described in Application Content section IV.2., above (*i.e.*, that are signed by the appropriate CDC officials and that clearly indicate their commitment to participate as proposed in the application).

3. Operational Plan (30 points): Is the applicant's proposed operational plan clear and detailed and address all Activities listed in Section I? Do they include a detailed time schedule or Gant chart for the first year of the program? Does the applicant clearly indicate specific staff that will be responsible for implementation and operation of the PFTP? Does the applicant's plan meet the purpose and goals of this cooperative agreement program?

4. Measures of Effectiveness (5 points): Does the applicant provide measures of effectiveness as described in the paragraph above such that effective "outcome" evaluation can be accomplished?

5. Budget (Not scored): Is the proposed budget reasonable, clearly justified, and consistent with the intended use of grant funds?

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by the National Center for Infectious Diseases. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

An objective review panel will evaluate complete and responsive applications according to the criteria listed in the "V.1. Criteria" section above.

In addition, the following factors may affect the funding decision:

Preference will be given to competing continuation applications over applications for programs not already receiving support under the PFTP program.

V.3. Anticipated Announcement and Award Dates

Anticipated Award Date: July 1, 2004.

VI. Award Administration Information

VI.1. Award Notices

Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

VI.2. Administrative and National Policy Requirements

45 CFR Part 74 and Part 92

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.

The following additional requirements apply to this project:

- AR-7 Executive Order 12372
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-16 Security Clearance Requirement

Additional information on these requirements can be found on the CDC web site at the following Internet address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

VI.3. Reporting Requirements

You must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:
 - a. Current Budget Period Activities Objectives.
 - b. Current Budget Period Financial Progress.
 - c. New Budget Period Program Proposed Activity Objectives.
 - d. Budget.
 - e. Additional Requested Information.
 - f. Measures of Effectiveness.
 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.
- These reports must be mailed to the Grants Management or Contract

Specialist listed in the "Agency Contacts" section of this announcement.

VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2700.

For program technical assistance, contact: Greg Jones, M.P.A., Public Health Analyst, Office of the Director, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop C12, Atlanta, GA 30333, Telephone: (404) 639-4180, Fax: (404) 639-3106, E-mail: GJJones@cdc.gov.

For financial, grants management, or budget assistance, contact: Jeff Napier, Contract Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2628, E-mail: jxn1@cdc.gov.

Dated: May 10, 2004.

William P. Nichols,

Acting 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

Request for Applications to Determine the Pharmacokinetics of Clostridium Botulinum Neurotoxins A, B, C, E, and F

Announcement Type: New.
Funding Opportunity Number: 04099.
Catalog of Federal Domestic Assistance Number: 93.283.

Key Dates:

Letter of Intent Deadline: June 1, 2004.

Application Deadline: June 28, 2004.

Executive Summary: The Centers for

Disease Control and Prevention (CDC) invites investigator-directed research grant applications that will lead to an understanding of the relationship between oral exposure to Clostridium botulinum neurotoxin, morbidity, and lethality. Research should include, but is not limited to, the establishment and implementation of methods and procedures in non-human primates for determination of the pharmacokinetics of both the di-chain and progenitor forms of C. botulinum neurotoxins A, B, C, E, and F. The information gathered by this study will help guide policy development and most importantly