

Respondents	No. of respondent	No. of responses per respondent	Average burden per responses in hours
All consenting adults with physician-diagnosed chronic liver disease living in catchment areas	500	1	1

Date: August 16, 2001.

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Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02005]

Sexually Transmitted Disease Faculty Expansion Program; 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 cooperative agreements for a Sexually Transmitted Disease (STD) Faculty Expansion Program (FEP). This program will provide resources to medical schools in the United States to support faculty positions specializing in training related to STD prevention and control. This program addresses the "Healthy People 2010" focus area of Sexually Transmitted Diseases.

The purposes of this program are:

1. To enable the awardee institutions to provide STD training and education by developing faculty positions dedicated to the area of STD clinical care, prevention, and control, in medical schools where such clinical and research expertise does not currently exist.

2. To support the development of linkages between health departments and medical schools in the area of STD prevention through jointly appointed staff who strengthen health department STD programmatic activities by undertaking clinical care, research, and teaching responsibilities.

B. Eligible Applicants

Applications may be submitted by public or private medical schools or health science centers in the United States, including the District of Columbia, the Commonwealth of Puerto Rico, any territory or possession of the United States, and all federally recognized Indian tribal governments.

Competition for these funds is limited to those institutions where CDC has not previously funded a Faculty Expansion Program or is not currently funding an STD/HIV Prevention Training Center (PTC). The rationale for this limited competition is that the areas where CDC has previously funded an FEP or is currently funding a PTC already have expertise in STDs and have established training and health department collaborations similar to those described as goals of this announcement.

C. Availability of Funds

Funding for this program is variable throughout the project period. Approximately \$340,000 is expected to be available in FY 2002 to fund approximately four awards. It is expected that the average award for the first year will range between \$65,000 and \$85,000 which is less than the amount expected for year 02. The amount of the award is less in the first year because it is expected that the first 6 months will be devoted to faculty recruitment activities so that the full faculty salary expense will not be incurred until the latter half of year 01.

The initial award is expected to begin on or about February 1, 2002 for a 12-month budget period. Thereafter, four additional noncompetitive continuation awards will be made annually within a program period of up to five years depending upon funding availability. Continuation awards within the program period will depend on satisfactory progress as evidenced by required reports and the availability of funds. It is anticipated that each award for the second year will range from approximately \$130,000 to \$150,000, a commitment level of 100 percent support from CDC. For project years 03 to 05, CDC funding for each award is expected to decrease as the university and/or health department assumes more fiscal responsibility for the faculty member's salary. In year 03, each award is expected to range between \$97,500 and \$112,500, a commitment level of 75 percent support from CDC. In year 04, each award is expected to range between \$65,000 and \$75,000, a commitment level of 50 percent support from CDC. In year 05, each award is expected to range between \$32,500 and \$37,500, representing a CDC level of support of 25 percent. Funding

estimates may change. It is expected that the faculty member's salary in years 03 to 05 will not decrease as CDC funding decreases. The faculty member's annual salary in years 03 to 05 should sum to at least the same level as that established in year 02 when the annual salary is solely funded by CDC. CDC's intent is that the funding of faculty member's salary in years 03 to 05 will be shared by the institution, the collaborating health department, and CDC and provided at a minimum of the year 02 salary level.

Computation of the salary should include cost-of-living and merit increases, if applicable.

In project years 02, 03, or 04, applicants will have the option to apply for supplemental funds (up to \$25,000 per year) for research pilot projects of 1 to 3 years duration.

If the faculty member's career trajectory and academic track includes research as well as teaching, the research experience gained through the pilot projects may increase his/her ability to successfully compete for future research grants. These funds will be awarded on the basis of the merit of the research proposal/protocol submitted and the availability of funds. Criteria for evaluation of proposals will be identified in the guidance for continuation applications for years 02, 03, and 04.

CDC is under no obligation to reimburse such costs if for any reason the application does not receive an award or if the award to the recipient is less than anticipated and inadequate to cover costs. For the purpose of determining contributions, total program costs consist of the items listed under the Use of Funds section.

1. Use of Funds

Funds are awarded for a specifically defined purpose and may not be used for any other purpose or program. It is expected that funds for the 12 month budget period may be used to support:

- a. The salary and benefits of a faculty member,
- b. The salary and benefits of a part-time support person,
- c. Travel to project-related and professional meetings,
- d. Supplies necessary for professional training activities,
- e. Indirect costs, and

f. In years 02, 03, and 04, up to \$25,000/year for CDC-approved research projects (optional).

Funds may not be used to support the following activities:

- a. Leasing space and renovation of facilities,
- b. Providing diagnostic and treatment facilities or services,
- c. Paying other expenses normally supported by the applicant or the collaborating health department,
- d. Replacing training support, and
- e. Supplanting existing sources of funding for a current faculty member since the purpose of this cooperative agreement is to enable the medical school to provide STD training and education by establishing a faculty position in STDs in a clinical department.

2. Recipient Financial Participation

Recipient financial participation is required for this program in accordance with this Program Announcement. As described in Section C. Availability of Funds, institutional support and health department support increases gradually in years 03–05 of the project.

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 as follows:

1. Recipient Activities

- a. Recruit and hire a full-time, qualified faculty person, on a clinical educator track, a tenure track, or their equivalents, with the authority and responsibility to carry out the requirements of this program.
- b. Provide a qualified mentor to guide the new faculty member's academic and research activities.
- c. Provide administrative support to assist the faculty member in carrying out the responsibilities of this program.
- d. Develop and maintain an agreement between a state or local health department and the medical school to carry out the requirements of this program, including the use of the health department's clinical facilities by the faculty member for clinical teaching and research in STDs. It is suggested that the faculty member be either a permanent, part-time employee or a contractor of the health department.
- e. Assess the current STD content in the medical school curriculum and modify it, as appropriate, such that the following occurs:
 - (1) In the preclinical years, didactic STD instruction, sufficient to produce a

sound educational basis for subsequent clinical instruction, is provided.

(2) In the clinical years, additional content on the diagnosis and management of STDs is integrated into existing clinical rotations {e.g., Internal medicine (infectious diseases), primary care, adolescent medicine, obstetrics/gynecology, or other rotations deemed appropriate}, to enhance the information provided in the preclinical years.

f. Provide STD clinical training for third and fourth year medical students sufficient to ensure that they have the skills necessary to prevent, diagnose, and treat STDs.

g. Provide lectures/grand rounds to residents in primary care specialties sufficient to ensure they have adequate knowledge of STD prevention, diagnosis, and treatment.

h. Develop or enhance STD clinical rotations at the collaborating health department for residents in primary care specialties, sufficient to ensure they have adequate skills to diagnose, treat, and prevent STDs.

i. Provide opportunities for STD research for those faculty who seek a career trajectory that includes both teaching and research. Clinical, prevention-oriented or outcome-oriented research in the medical school or health department should be particularly encouraged.

j. Structure the faculty position to maximize the likelihood of long-term financial support after the termination of CDC support.

k. Participate in semi-annual meetings with the CDC project officer and other FEP faculty during the project period to discuss educational strategies, review progress, share resources, and develop and review evaluation and research plans.

l. Develop and carry out an evaluation of STD Faculty Expansion Program effectiveness through analysis and interpretation of data on medical student and resident performance and on the overall impact on state and local STD prevention goals, and report findings in appropriate format to CDC.

m. In years 02–04, those faculty who elect to apply for optional research funds must develop and submit a research application on STD clinical, prevention-oriented, or outcome-oriented research, which will be specified in the years 02–04 continuation applications. These applications will be reviewed for merit by a CDC internal review panel based on the criteria outlined in the years 02–04 continuation applications.

2. CDC Activities

a. Conduct annual site visits as necessary.

b. Provide technical assistance to facilitate: (1) The planning and implementation of curriculum changes, and (2) the planning and implementation of the clinical, outcome, or prevention-oriented research protocols.

c. Provide assistance, as requested and needed, in designing an evaluation of the effectiveness of the FEP through analysis and interpretation of data on medical student and resident performance and the overall impact on state and local STD prevention goals.

d. Arrange semi-annual meetings of CDC-supported FEP members to review accomplishments, discuss educational strategies, share resources and experiences across FEP sites, discuss problems, and review evaluation and research plans.

E. Application Content

Letter of Intent (LOI)

CDC requests (but does not require) that potential applicants submit a letter of intent to apply for these funds on or before September 17, 2001 to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement. The narrative should be no more than two pages, double-spaced, printed on one side, with one-inch margins, and 12-point font. Your letter will be used for planning purposes related to convening an independent review group. Your letter of intent should include the following information: Program Announcement Number; name and address of academic institution; name, address and telephone number of contact person; and the specific objectives to be addressed by the proposed project. 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 40 double-spaced pages, printed on one side, with one-inch margins and 12-point font. All pages, including appendices, should be numbered sequentially. Letters of support, organizational charts, biosketches, and position descriptions should be included in an appendix. The narrative must contain the following sections in the order presented below:

1. *Abstract:* Provide no more than a two-page summary of your application including a brief statement of need (include data on STD incidence or prevalence in your state and local geographic area), the name of the institution and clinical department where the STD faculty member will be housed, the anticipated track for the proposed faculty member, the name of the mentor, the name of the collaborating health department, the number of hours of STD didactic and clinical offerings currently in place, the number of hours and content of STD didactic and clinical offerings proposed for both medical students and residents, and the plan for continued funding for the STD faculty member.

2. *Background and Need for Support:* Describe your understanding of the purpose of the cooperative agreement, including the need in your state and local geographic area and your institution for a dedicated STD faculty position. Describe your commitment to the development of a faculty position, to changes in the medical school curriculum and resident training, and to a collaborative arrangement with the health department.

This must be documented by:

a. A written commitment for partial funding of the faculty position for years 03–05 (co-signed by the department chairperson and dean of the medical school).

b. A written commitment supporting the proposed changes to the medical school curriculum to fulfill the Program Requirements (co-signed by the chair of the curriculum committee or dean for academic affairs).

c. A written agreement or contract with the local or state health department acknowledging and agreeing to a collaborative relationship, partial financial support for the faculty member, and the use of STD clinic facilities for training and research.

d. A written commitment from the proposed mentor to assume responsibility for facilitating academic and research development of the faculty member (include the mentor's curriculum vitae).

e. A written commitment from the directors of primary care residency programs agreeing to the STD training as described in Program Requirements.

Provide a demographic description of your medical students. Include number of students per class, gender, and ethnic/racial characteristics (may be in table format). In addition, provide current status of STD training for medical students in your institution. Specifically identify the amount of time allotted for, and placement of, content

as identified in part c. and d. of Recipient Activities.

3. *Objectives:* Identify process and impact objectives related to program requirements.

4. *Program Plan:*

a. Provide a description of proposed changes in the medical school curriculum to include additional STD training. Indicate the number and placement of additional hours of didactic and clinical training. Describe any innovative/integrated content offerings or courses related to the intent of the cooperative agreement.

b. Provide a description of proposed resident training.

c. Provide a description of the health department STD clinic facilities, including physical layout and number of STD patients seen in the most recent 12-month period, categorized by sex, age, race/ethnicity, and diagnosis. Identify other personnel in the health department who might serve as resource personnel or preceptors.

d. Provide a description of ongoing research and/or opportunities for the faculty member to do STD research within the medical school and/or through the health department.

e. Provide a plan for continued support of the faculty member after the termination of CDC support.

f. Provide a written agreement from the medical school administration to provide office space and to provide administrative support for the faculty member, including a description of the space and personnel.

5. *Program Implementation Methods:*

a. Provide a list of qualifications for the proposed STD faculty member (may include a sample advertisement).

b. Provide a description of the proposed faculty search plan with time line.

c. Describe the appointment process for the new faculty.

d. Provide a timetable for the implementation of the program plan.

6. *Evaluation Plan:*

a. Provide an outline of a plan for evaluating the effect of improved STD training on medical student and house staff knowledge/behavior.

b. Provide an outline of a plan for evaluating the effect of medical school/health department collaboration on state and local STD prevention goals.

7. *Budget.* Provide a budget using PHS 398 (Rev 05/01) forms 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 program. The budget should include travel to one project-related meeting during year 01 and two project-related trips per year

thereafter. At least one meeting each year will be held at CDC in Atlanta.

F. Submission and Deadline

Application

On or before October 23, 2001, submit the original and two copies of the application on Form PHS 398 (adhere to the instructions on the Errata Instruction sheet for PHS 398). Forms are available in the application kit and at the following Internet address: <http://www.cdc.gov/od/pgo/forminfo.htm>.

Submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

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

1. Received on or before October 23, 2001; 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 which do not meet the criteria in 1. or 2. above will be returned to the applicant.

G. Evaluation Criteria

Each application will be evaluated individually against the following criteria by a Special Emphasis Panel appointed by CDC:

1. The need for faculty expertise in STDs in the school and geographic area. The strength of the program plan in addressing the need for a faculty member with clinical and research expertise in STDs in the school and geographic area. (15 points)

2. The strength of the agreement with the health department. The quality of the documentation of a commitment from the state or local health department to provide financial support for the faculty member and to provide clinic facilities that routinely examine and treat a sufficient number of STD clients for training medical students and house staff. The degree to which the applicant demonstrates innovative approaches to the medical school/health department collaboration that will contribute to locally relevant STD prevention research, training, and programmatic activities. (20 points)

3. The extent to which the proposed program plan addresses the program requirements. The extent to which the

applicant documents commitments from the medical school to implement the curriculum changes described under program requirements. The extent to which the applicant documents commitment from residency program directors to implement the training described under program requirements. Consideration will be given to those schools that demonstrate the greatest commitment of additional hours for high quality instruction to students and residents over the life of the project. (20 points)

4. The quality of the assurance to support the faculty member during tenure of the project. The extent to which the department submitting the application demonstrates a commitment to assuring research opportunities and financial support for the faculty member during the grant period. The qualifications and involvement of the designated mentor to assure the success of this endeavor. The quality of the plan to provide administrative support to help the faculty member meet the program requirements. (10 points)

5. The quality of the documentation of proposed qualifications for the STD faculty member. The quality of the description of the selection or search process, including a proposed time frame. (10 points)

6. The quality of the plan for evaluating the training's effectiveness, in terms of improved STD knowledge/ behaviors of medical students and residents and the achievement of prevention goals. (15 points)

7. The quality of the documentation indicating a strong commitment to structure the faculty position and integrate the proposed curriculum and training so that these will be continued as CDC support decreases and eventually terminates. (10 points)

8. The budget will be evaluated for the extent to which it is reasonable, clearly justified, and consistent with the intended use of the funds. The level of support will depend on the availability of funds. (not scored)

H. Other Requirements:

Technical Reporting Requirements: Provide CDC with the original plus two copies of:

1. Progress reports are due on July 31 and January 31 in years 01 and 02 and on January 31 in years 03–05 in a format determined by CDC.

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.

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

Any materials developed in whole or in part with CDC funds will be subject to a nonexclusive, irrevocable, royalty-free license to the government to reproduce, translate, publish, or otherwise use and authorize others to use for government purposes.

The following additional requirements are applicable to this program. For a complete description of each, 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-4 HIV/AIDS Confidentiality Provisions
- AR-5 HIV program
- AR-6 Patient Care
- AR-7 Executive Order 12372 Review
- AR-8 Public Health System Reporting Requirements
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-21 Small, Minority, and Women-owned Business
- AR-22 Research Integrity

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under Section 318 of the Public Health Service Act, [42 United States code 247c-1], as amended. The Catalog of Federal Domestic Assistance number is 93.978.

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. If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Mr. Kang Lee, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000 MS-E15, Atlanta, GA 30341-4146,

Telephone: (770) 488-2733, E-mail address: kil8@cdc.gov.

For programmatic technical assistance, contact: Dr. Marianne Scharbo-DeHaan, Chief, Medical Education and Evaluation Section, Training and Health Communications Branch, Division of STD Prevention, National Center for HIV, STD, and TB Prevention (NCHSTP), Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop E-02, Atlanta, GA 30333, Telephone: (404) 639-8360, E-mail address: zpp2@cdc.gov.

Dated: August 17, 2001.

John L. Williams,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Opportunity To Collaborate in the Evaluation of Rapid Diagnostic Tests for Syphilis

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

ACTION: Opportunities for collaboration for evaluation of rapid diagnostic tests for syphilis. The Centers for Disease Control and Prevention (CDC), National Center for HIV, STD, and TB Prevention (NCHSTP), Division of STD Prevention, has an opportunity for collaboration to evaluate rapid diagnostic tests for syphilis. These evaluations will include evaluation of the sensitivity in primary, secondary and latent syphilis, and of the specificity of the test.

SUMMARY: The Division of STD Prevention of the National Center for HIV, STD, and TB Prevention (NCHSTP) at the Centers for Disease Control and Prevention (CDC) of the Department of Health and Human Services (DHHS) seeks one or more companies who have developed or are distributing a rapid diagnostic test for syphilis and are interested in marketing the test for use in the United States. The Division of STD Prevention is interested in evaluating such tests. The evaluation will include determination of the sensitivity in primary, secondary and latent syphilis and of the specificity of the test. This collaboration will have an expected duration of two (2) to three (3) years. The goals of the collaboration include the timely development of data