the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Application Submission and Deadline

The original and two copies of the application PHS Form 5161–1 (Revised 7–92, OMB Number 0937–0189) must be submitted to Sharron P. Orum, Grants Management Officer, Procurement and Grants Office, Centers for Disease Control and Prevention, 255 East Paces Ferry Road, NE., Room 300, Mail Stop E–15, Atlanta, GA 30305, on or before August 8, 1997.

1. *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 objective 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 will not be accepted as proof of timely mailing.)

2. *Late Applications:* Applications that do not meet the criteria in 1.(a) or 1.(b) above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where to Obtain Additional Information

A complete program description and information on application procedures may be obtained in an application package. Business management technical assistance may be obtained from Nealean K. Austin, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mail Stop E–18, Atlanta, GA 30305; telephone (404) 842–6508 or the Internet at, nea1@cdc.gov. Programmatic technical assistance may be obtained from Heidi Holt, Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway NE., Mail Stop K–64, Atlanta, GA 30341–3724; (770) 488–3085, or the Internet at: hym3@cdc.gov.

You may also obtain this announcement, and other CDC announcements, from one of two Internet sites on the actual publication date: CDC's homepage at http://www.cdc.gov or the Government Printing Office homepage (including free on-line access to the **Federal Register** at http://www.access.gpo.gov).

Please refer to Announcement number 773 when requesting information and submitting an application.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report; stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report; stock No. 017–001–00473–1) referenced in the Introduction through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325; telephone (202) 512–1800.

Dated: July 1, 1997.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–17699 Filed 7–7–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 778]

Extraumural Applied Research Program in Emerging Infections; Novel Methods for Identification of Emerging Infections

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1997 funds for competitive cooperative agreements and/or grants to support applied research on emerging infections.

The CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Immunization and Infectious Diseases. (For ordering a copy of Healthy People 2000, see the section WHERE TO OBTAIN ADDITIONAL INFORMATION.)

Authority

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

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products, and Public Law 103–227, the Pro-Children's Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care and early childhood development services are provided to children.

Eligible Applicants

Applications may be submitted by public and private non-profit organizations and governments and their agencies. Thus, universities, colleges, research institutions, hospitals, other public and private organizations, including State and local governments or their bona fide agents, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations, and small, minority- and/or women-owned businesses are eligible to apply.

Note: An organization described in section 501(c)(4) of the Internal Revenue Code of 1986 which engages in lobbying activities shall not be eligible to receive Federal funds constituting an award, grant, contract, loan, or any other form.

Availability of Funds

Approximately $1,205,000 is available in FY 1997 to fund 7 to 11 awards in six specific focus areas as follows:

Focus Area #1

Evaluating Algorithms to Diagnose Emerging Causes of Infectious Diarrhea: Approximately $480,000 is available to make 2–3 awards with a maximum project period of 3 years.

Focus Area #2

Rapid Identification of Emerging and Unusual Pathogenic Bacteria by Partial 16S rRNA Sequencing: Approximately $60,000 is available to make one award with a maximum project period of 3 years.

Focus Area #3

Development and Evaluation of Improved Tests for Malaria Diagnosis in the United States: Approximately $100,000 is available to make 1–2 awards with a maximum project period of 2 years.

Focus Area #4

Development of Improved Diagnostic Tests for Leishmaniasis: Approximately $150,000 is available to make 1–2 awards with a maximum project period of 2 years.

Focus Area #5

Identification of Unrecognized Etiologic Agents in Idiopathic Sexually Transmitted Disease Syndromes: Approximately $300,000 is available to make one to two awards with a maximum project period of 2 years.

Focus Area #6

Development of Non-culture Molecular Epidemiologic Detection/Typing Methods for *Treponema pallidum* or *Haemophilus ducreyi*: Approximately $115,000 is available to make one award for a maximum project period of 2 years.

For Focus Areas 2 and 3, only cooperative agreement applications will be accepted. For Focus Areas 1, 4, 5, and 6, either grant or cooperative agreement applications will be accepted.

Applicants must specify the type of award for which they are applying, either grant or cooperative agreement. CDC will review all applications in accordance with the Evaluation Criteria section of this announcement. Before issuing awards, CDC will determine whether a grant or cooperative agreement is the appropriate instrument based upon the need for substantial CDC involvement in the project.

It is expected that awards will begin on or about August 30, 1997, and will be made for a 12-month budget period within a project period of up to three years (maximum project period varies by Focus Area—see above). Funding estimates may vary and are subject to change.

Continuation awards within the project period will be made on the basis of satisfactory progress and availability of funds.

Use of Funds

Restrictions on Lobbying

Applicants should be aware of restrictions on the use of Department of Health and Human Services (HHS) funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352 (which has been in effect since December 23, 1989), recipients (and their subtier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying Congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition, the FY 1997 Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act, which became effective October 1, 1996, expressly prohibits the use of 1997 appropriated funds for indirect or ''grass roots'' lobbying efforts that are designed to support or defeat legislation pending before State legislatures. Section 503 of this new law, as enacted by the Omnibus Consolidated Appropriations Act, 1997, Division A, Title I, Section 101(e), Pub. L. No. 104–208, (September 30, 1996), provides as follows:

Sec. 503(a) No part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress, * * * except in presentation to the Congress or any State legislative body itself.

(b) No part of any appropriation contained in this Act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

Background

Once expected to be eliminated as a public health problem, infectious diseases remain the leading cause of death worldwide. In the United States and elsewhere, infectious diseases increasingly threaten public health and contribute significantly to the escalating costs of health care.

In 1992, the Institute of Medicine of the National Academy of Sciences published a report entitled *Emerging Infections, Microbial Threats to Health in the United States* highlighting the threat of emerging infections and making specific recommendations to address the threat. This report emphasized a critical leadership role for CDC in a national effort to detect and control infectious disease threats.

In partnership with other Federal agencies, State and local health departments, academic institutions, and others, CDC has developed a plan for revitalizing the nation's ability to identify, contain, and prevent illness from emerging infectious diseases. The plan, *Addressing Emerging Infectious Disease Threats; A Prevention Strategy for the United States*, identifies objectives in four major areas: surveillance, applied research, prevention and control, and infrastructure.

Under the objective for applied research, the plan proposes to integrate laboratory science and epidemiology to optimize public health practice in the United States. One component of these efforts is to implement an extramural program for research in emerging infectious disease surveillance, epidemiology, and prevention, which will fill the gaps in existing support for such research. In FY 1996, CDC initiated the Extramural Applied Research Program in Emerging Infections (EARP) and made competitive grant and cooperative agreement awards to seven institutions for projects in the areas of antimicrobial resistance and tickborne diseases. In FY 1997, CDC will make additional competitive grant and/or cooperative agreement awards in two areas: hepatitis C virus infection and novel methods for identification of emerging infections. This announcement specifically addresses novel methods for identification of emerging infections and solicits applications in the following six specific focus areas:

Focus Area #1: Evaluating Algorithms To Diagnose Emerging Causes of Infectious Diarrhea

Without specific diagnostic algorithms, health professionals and laboratories do not know when to test for many emerging diarrheal disease pathogens. CDC will assist in the development of guidelines for health professionals that recommend when to order specific diagnostic tests for patients with diarrheal diseases, and for diagnostic laboratories that recommend what diangostic tests to perform. Lack of guidelines such as these severely limits the ability of laboratories to adequately detect and report cases of infectious diarrhea caused by emerging pathogens such as *Cyclospora cayetanensis*, *Cryptosporidium parvum*, *Escherichia coli* 0157:H7, and common viral agents. Health professionals may consider tests to identify diarrheal pathogens to be too expensive and of low yield. Laboratories are reluctant to conduct routine surveillance for many emerging pathogens, since to do so would require expensive additional testing procedures. It might be cost-effective, however, for health professionals and laboratories to test for these and other pathogens under specific circumstances once guidelines are available.

For example, during the waterborne outbreak of cryptosporidiosis in Milwaukee in 1993, CDC scientists discovered that a simple 3-component screening algorithm would increase the positive predictive value that a stool specimen contained detectable *C. parvum* oocysts from 27 percent to 63 percent. Another recent CDC study of the diagnosis of *C. parvum* reported that laboratories in Connecticut that tested for *C. parvum* only upon physician request reported a positivity rate of 2.8

percent compared with a rate of 5.2 percent for laboratories that used multiple critiera. In a large multi-center study the rate of isolation of *E. coli* 0157:H7 from patients with diarrhea increases from 0.4 percent among all patients to 7.8 percent among patients with visibly bloody stools.

In addition to factors that are present for all health care providers under capitated managed care where health care providers receive a flat fee per patient seen, there are additional incentives to reduce the number of disgnostic tests performed unless they can be shown clearly as cost-beneficial. Current data are inadequate, however, to calculate the cost or the benefit of performing specific diagnostic tests or starting empiric treatment for specific clinical presentations. As increasing proportions of the population receive their health care under systems of capitated managed care, we are likely to see more empiric treatment of diarrhea with no confirmatory tests for the etiology of the illness.

Focus Area #2—Rapid Identification of Emerging and Unusual Pathogenic Bacteria by Partial 16S rRNA Sequencing

Standard batteries of biochemical tests are no longer adequate to identify a growing number of emerging and unusual bacterial pathogens. Specialized procedures are necessary for identification of emerging and unusual pathogenic strains that are difficult or impossible to identify in the average clinical laboratory. 16S rRNA sequencing is one specialized procedure that has the potential to allow for rapid molecular identification of pathogens. Many species of bacteria could be identified on the basis of their full 16S rRNA sequence. Sequences of many unusual and emerging bacterial pathogens, as well as their presumed non-pathogenic relatives, need to be determined and entered into sequence databases. It should then be possible to rapidly identify most pathogenic species on the basis of a unique partial sequence, and to use this methodology to largely replace routine identification methods.

Focus Area #3—Development and Evaluation of Improved Tests for Malaria Diagnosis in the United States

Every year, approximately 1,000 cases of malaria are reported in the United States (U.S.). Nineteen deaths due to malaria were recorded in the U.S. during the period 1992–1994. Of particular concern, cases of locally transmitted malaria have been reported practically on an annual basis in densely populated areas (New York City, Houston, and Palm Beach County, Florida). The substantial U.S. public health impact of malaria is very likely to increase in the future due to increased international travel combined with a worldwide resurgence of malaria. This resurgence is attributable to factors such as inadequate control programs, increasing drug and insecticide resistance, and global warming.

This situation must be addressed by vigilant surveillance and prompt clinical management of all cases of malaria occurring in the U.S. Both strategies require a timely and correct diagnosis of the disease. However, available information indicates that malaria diagnosis is not optimally performed in the U.S. In a recent survey of samples sent to CDC's National Malaria Reference Laboratory (NMRL) by various health institutions (including State health departments, hospitals, and commercial laboratories), the diagnosis made by the NMRL differed from that made at the health institution in 21 percent of the samples. This is due mainly to the fact that the international accepted method for diagnosing malaria (the microscopic examination of a Giemsa-stained blood smear) requires a degree of microscopy experience that most clinical laboratorians in the U.S. lack due to their infrequent contact with malaria samples.

One solution to this problem would be a diagnostic test that depends, not on the experience and skills of a microscopist, but on more objective, quantifiable criteria. Several malaria diagnostic tests that follow this approach are currently on the market or in various development phases. Such tests identify malaria parasites by nucleic acid fluorescence or by detecting parasite-specific antigens or enzymes. However, none of these tests satisfy all desirable criteria for a malaria diagnostic tool applicable to clinical laboratory practice in the U.S. Such criteria include: (a) sensitivity at least equal to that of microscopy (4) parasites per ul. of blood), (b) detection of all 4 known species of human malaria parasites, (c) specificity above 95 percent, (d) simplicity of performance, and (e) rapidity of execution (results available in less than 1 hour). In addition, none of these tests have been adequately evaluated under strictly controlled conditions in U.S. health facilities.

Focus Area #4—Development of Improved Diagnostic Tests for Leishmaniasis

Leishmaniasis, a parasitic infection caused by several species of protozoa in the genus Leishmania, can cause serious, sometimes fatal, disease in humans. Leishmaniasis is considered by the World Health Organization to be one of the top five parasitic infections afflicting mankind today. The infection is transmitted through the bite of infected sandflies and occurs in several forms: cutaneous, mucosal, and visceral leishmaniasis. The mucosal form can result in disfiguring destruction of the nose and mouth, while the visceral form, as indicated by the name, localizes in the viscera and bone marrow and results in severe and life-threatening infection. Leishmaniasis in its various forms occurs throughout the tropical areas of Central and South America, in countries around the Mediterranean Sea, and in the Middle East, Africa, and portions of South East Asia. The disease is currently viewed as being epidemic in India and Sudan. U.S. citizens traveling to endemic areas, especially Central and South America, are exposed and frequently acquire infection.

Currently available serologic assays for viscerotrophic leishmaniasis have unacceptable sensitivity and specificity levels, both for the species of Leishmania causing the infection as well as for determining whether the person has an active infection or past exposure. Diagnostic laboratories have not been able to adequately resolve this issue because of poor assay performance. The U.S. Congress and the Department of Defense have been concerned about the possibility that leishmaniasis accounts for symptoms in some individuals with Gulf War Syndrome, and the need for better diagnostic tests is repeatedly raised in Congressional hearings. Since currently available tests have unacceptable sensitivity and/or specificity levels or are highly invasive with a significant false negative rate, there is a clear need for improved diagnostic capabilities related to leishmaniasis, especially the viscerotrophic form thought to occur in the Gulf War Syndrome. The development of a suitably formatted assay to detect Leishmania infections would allow diagnostic laboratories to be able to distinguish current infections from past exposure and to begin to differentiate the causative agents.

Suspected cases of cutaneous leishmaniasis are routinely diagnosed through microscopic examination of stained histologic sections taken from the lesion site. In some instances, the number of organisms is high and the infection can be diagnosed microscopically with little difficulty. However, in many instances there are few organisms and microscopic

examination does not permit confirmation of infection. Immunohistologic staining with appropriate monoclonal/polyclonal antibodies or molecular based probes might provide much more sensitive approaches.

Focus Area #5—Identification of Unrecognized Etiologic Agents in Idiopathic Sexually Transmitted Disease Syndromes

For a significant proportion of clinical cases of male unrethritis and pelvic inflammatory disease (PID) in women, no demonstrated etiology can be found. It is likely that other unidentified sexually transmitted organisms have yet to be identified in these syndromes. In the U.S., urethritis in men is a common sexually transmitted infection; over 200,000 cases of gonorrhea were reported to CDC and over 250,000 cases of non-specific urethritis were seen by private physicians in 1995. Besides *Neisseria gonorrhoeae*, urethritis in men can be caused by *Chlamydia trachomatis, Trichomonas vaginalis,* Herpes Simplex Virus (HSV), Mycoplasma genitalium, and Ureaplasma species; however, no etiologic agent can be identified in nearly 25 percent of cases. Among women with PID, C. trachomatis, N. gonorrhoeae, and vaginal anaerobes are recognized etiologic agents, yet in 25–50 percent of cases, no causal organisms can be identified.

Potentially unidentified agents could emerge and become significant public health problems as gonorrhea and chlamydial infections are successfully controlled. There is suggestive evidence that this is occurring. For example, in Seattle where gonorrhea and chlamydial infections have been controlled, approximately 70 percent of the urethritis in local men has no known etiology. It is likely that similar agents are involved in PID. The identification of additional agents for urethritis in men, which may also be associated with PID in women, will help develop better prevention strategies for this costly and serious complication. Available data strongly suggest that there are unidentified sexually transmitted organisms associated with idiopathic syndromes such as urethrities in men and PID.

Focus Area #6—Development of Nonculture Molecular Epidemiologic Detection/Typing Methods for Treponema pallidum or Haemophilus ducreyi

Most genital ulcer disease (GUD) is caused by one or more of three sexually transmitted agents; Haemophilus ducreyi, Treponema pallidum, and HSV. GUD caused by the bacterial agents H. ducreyi and T. pallidum accounts for approximately 17,000 cases each year in the U.S. Bacterial GUD infections also occur frequently in developing countries and several out-breaks of chancroid (H. ducreyi) in the U.S. have been directly traced to importation of strains from overseas. Along with the morbidity associated with primary infections with these organisms, a serious potential sequelae is the development of syphilis, including neuro- and congential syphilis.

Bacterial GUDs may be easily cured with antimicrobial agents if the etiologic agents are accurately diagnosed (although antimicrobial resistance is emerging in H. ducreyi). Examination of ulcers with microbiologic and research polymerase chain reaction (PCR) detection methods indicate that it is not possible to accurately determine the etiology of infections by the physical appearance of the ulcers. The diagnosis of these agents is further complicated by the fact that T. pallidum cannot be cultured in vitro and H. ducreyi may be recovered from fewer than 50 percent of specimens from infected patients. Development of non-culture methods for detecting and typing strains of T. pallidum and H. ducreyi in ulcer specimens would allow medical practitioners to more quickly determine the etiology of and effectively treat GUDs. It would also allow researchers to determine the molecular epidemiology of these infections, identify strain type associated with antimicrobial resistance, and devise and monitor targeted control methods to eliminate GUD.

Purpose

The purpose of the Extramural Applied Research Program in Emerging Infections (EARP) is to provide financial and technical assistance for applied research projects on emerging infections in the U.S. As a component of EARP, the purpose of this grant/cooperative agreement announcement is to provide assistance for projects addressing novel methods for identification of emerging infections. Specifically, applications are solicited for projects addressing any of the following six focus areas:

Focus Area #1

Evaluating Algorithms to Diagnose Emerging Causes of Infectious Diarrhea. The objective is to determine the costs and effectiveness of different diagnostic algorithms for emerging agents of infectious diarrhea.

Focus Area #2

Rapid Identification of Emerging and Unusual Pathogenic Bacteria by Partial 16S rRNA Sequencing. The objective is to develop a rapid identification system using 16S rRNA sequencing for emerging, atypical, and unclassified pathogenic bacteria.

Focus Area #3

Development and Evaluation of Improved Tests for Malaria Diagnosis in the U.S. The objective is to develop and evaluate a malaria diagnostic test that does not require microscopic examination of blood smears and: (a) is at least as sensitive as microscopy (4 parasites per ul. of blood), (b) can detect all 4 known species of human malaria parasites, (c) has a specificity of at least 95 percent, (d) is simple to perform, and (e) can provide results in less than 1 hour.

Focus Area #4

Development of Improved Diagnostic Tests for Leishmaniasis. The objective is to develop improved diagnostic assays for viscerotrophic and cutaneous forms of leishmaniasis that are formatted using modern immunologic and molecular tools. The assays would be formatted in such a way that they would be readily transferable to laboratories, provide acceptable sensitivity and specificity for the detection and diagnosis of Leishmania infections in humans, and when performed under appropriate conditions, provide the degree of accuracy necessary so that specific medical treatments can be safely initiated.

Focus Area #5

Identification of Unrecognized Etiologic Agents in Idiopathic Sexually Transmitted Disease Syndromes.

Focus Area #6

Development of Non-culture Molecular Epidemiologic Detection/Typing Methods for Treponema pallidum or Haemophilus ducreyi.

Applicants may submit separate applications for projects in one or more focus areas. (See section on APPLICATION for detailed instructions.)

Program Requirements

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

A. Recipient Activities

Focus Area #1

1. Evaluate Algorithms to Diagnose Emerging Causes of Infectious Diarrhea:

a. Identify a patient population where health professionals will be encouraged to collect stool specimens on all patients presenting with diarrhea.

b. Determine the etiology of infectious diarrhea in patients who seek medical care for diarrhea by collecting and testing clinical specimens for bacterial enteric pathogens such as Salmonella, Shigella, Campylobacter, Escherichia coli 0157, Listeria monocytogenes, and Yersinia, viral pathogens such as rotovirus, enteric adenovirus and astrovirus, and parasitic pathogens such as Cyclospora cayetanesis and Cryptosporidium parvum.

c. Collect information on patients for whom stool specimens are ordered such as specific signs and symptoms reported by patients at their first medical encounter, prior treatment, and epidemiologic exposures such as a history of foreign travel.

d. Develop diagnostic algorithms using clinical characteristics associated with identification of pathogens in stool specimens to increase the positive predictive value of diagnostic tests.

e. Determine the cost-effectiveness of the diagnostic algorithms.

f. Publish and/or otherwise disseminate the study findings.

Focus Area #2

1. Perform Rapid Identification of Emerging and Unusual Pathogenic Bacteria by Partial 16S rRNA Sequencing:

a. Identify appropriate known pathogenic and control bacterial strains and design and conduct a blinded comparison study to determine the utility of 16S rRNA sequencing for the rapid identification of pathogenic bacterial strains.

(1) Fully sequence 16S rRNA of selected strains to update the database of sequences.

(2) Retrospectively identify by partial 16S sequencing, strains that have been previously biochemically identified.

(3) Prospectively identify by partial 16S rRNA sequencing all strains received as unknowns in the CDC Special Bacteriology Reference Laboratory (CDC will perform standard biochemical identification tests and cell wall fatty acid analyses on the same strains.). Compare accuracy, time, and cost of each method. Where there are disagreements, identify strains by the gold standard of DNA relatedness.

(4) Conduct comparative sequencing studies on selected strains to determine reproducibility, accuracy, and variability of sequencing and of identification.

b. Publish and/or otherwise disseminate the study findings.

Focus Area #3

1. Develop and Evaluate Improved Tests for Malaria Diagnosis in the United States:

a. Develop a new diagnostic test or improve currently available test(s) that: (a) are at least as sensitive as microscopy (4 parasites per ul. of blood), (b) able to detect all 4 known species of human malaria parasites, (c) have a specificity of at least 95 percent, (d) are simple to perform, and (e) can provide results in less than 1 hour. Field-robustness and distinctive diagnostic reaction (e.g., color change) are desirable characteristics.

b. Conduct a first phase of evaluation of the new or improved test(s). This should involve testing clinical samples for malaria under blinded conditions and using mainly samples collected from non-human primates experimentally infected with human malaria parasites and malaria-infected human blood samples, both of which can be made available by CDC.

c. Conduct field evaluations of the test(s) in endemic countries (e.g., a large-scale assessment in a short time period where n>=500) and in U.S. facilities. The actual U.S. field testing will likely require a longer time period due to low frequency of malaria, and should involve collaboration with State health departments, hospitals, and commercial laboratories.

d. Publish and/or otherwise disseminate results.

Focus Area # 4

1. Develop an Improved Diagnostic Test for Leishmaniasis:

a. Develop new or improved assay(s) for viscerotrophic or cutaneous leishmaniasis that provide significantly better sensitivity and specificity than currently available assays.

b. Evaluate the assay(s) (e.g., through blinded evaluation of selected panels of sera). CDC can provide limited assistance in preparing serum panels, parasite isolates, animal model support, and outlets to the field.

c. Publish and/or otherwise disseminate results.

Focus Area # 5

1. Identify Unrecognized Etiologic Agents in Idiopathic Sexually-Transmitted Disease Syndromes:

a. Obtain swab specimens from 18 to 39 year old sexually active men with urethritis attending sexually transmitted disease clinics. In those samples for which no etiology can be identified either by traditional laboratory methods (e.g., culture) or specific DNA amplification methods (polymerase chain reaction or ligase chain reaction for N. gonorrhoeae, C. trachomatis and M. genitalium), use molecular biological tools to identify causative infectious agents. One example of an appropriate approach would be: Extract DNA, amplify 16S rRNA-specific DNA by polymerase chain reaction (PCR) using several sets of universal bacterial primers, and sequence the amplified DNA directly with an automated sequencer. Clone the amplified material into Escherichia coli, and sequence the inserts using automated sequencing. Use the sequences to search existing Genbank files for relatedness with known organisms. This approach has been used successfully to identify the agents of cat scratch fever, bacillary angiomatosis, Whipple's disease, and the putative agent of Kaposi's sarcoma. Although this approach will identify only new bacterial etiologies, the favorable response of idiopathic urethritis and PID to antibiotic therapy suggests bacterial causation.

b. Publish and/or otherwise disseminate results.

Focus Area #6

1. Develop Non-culture Molecular Epidemiologic Detection/Typing Methods for Treponema pallidum or Haemophilus ducreyi:

a. Develop comprehensive methods for detecting and typing strains of T. pallidum and/or H. ducreyi in ulcer specimens with the vitro materials. In the case of T. pallidum, the method(s) developed should be able to differentiate between the T. pallidum subspecies pallidum, pertenue, and endemicum.

b. Determine if the methods developed can be used to detect/type strains in ulcer specimens.

c. In the event that previously untyped strains are identified in the evaluation phase, expand the typing system to include new types.

d. Publish and/or otherwise disseminate results.

B. CDC Activities

1. Research Project Grants (Focus areas 1, 4, 5, and 6 only)

A research project grant is one in which substantial programmatic involvement by CDC is not anticipated by the recipient during the project period. Applicants for grants must demonstrate the ability to conduct the proposed research with minimal

assistance, other than financial support, from CDC. This includes possessing sufficient resources for clinical, laboratory, and data management services and level of scientific expertise to achieve the objectives described in their research proposal without substantial technical assistance from CDC.

2. Cooperative Agreements

In a cooperative agreement, CDC is available to assist recipients in conducting the proposed research. The application should be presented in a manner that demonstrates the applicant's ability to address the research problem in a collaborative manner with CDC. In addition to the financial support provided, CDC may collaborate by: (a) providing technical assistance in the design and conduct of the research, (b) performing selected laboratory tests as appropriate and necessary, (c) participating in data management, the analysis of research data, and the interpretation and presentation of research findings, and (d) providing biological materials (e.g., strains, reagents, etc.) as necessary for studies.

Technical Reporting Requirements

An original and two copies of a narrative progress reports are required semiannually. The first semiannual report is required with each year's non-competing continuation application and should cover program activities from date of the previous report (or date of award for reporting in the first year of the project).

An original and two copies of the second semiannual progress and Financial Status Report (FSR) are due 90 days after the end of each budget period and should cover activities from the date of previous report. Progress reports should address the status of specific project objectives and should include copies of any publications resulting from the project.

The final performance report and FSR are required no later than 90 days after the end of the project period. All reports should be directed to the CDC Grants Management Officer at the address referenced in the following section.

Application Process

Notification of Intent To Apply

In order to assist CDC in planning and executing the evaluation of applications submitted under this Program Announcement, all parties intending to submit application(s) are requested to inform CDC of their intention to do so as soon as possible but not later than 10 business days prior to the application due date. Notification should include: (1) name and address of institution; (2) name, address, and phone number of contact person, and (3) which focus area(s) application(s) will be submitted for.

Notification can be provided by facsimile, postal mail, or electronic mail (E-mail) to Sharron Orum, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–18, Atlanta, Georgia 30305, facsimile: (404) 842–6513, Internet: SP02@cdc.gov.

Application

Applicants may apply for assistance for projects in one or more of the six separate focus areas identified under PURPOSE and PROGRAM REQUIREMENTS section above. IF APPLICANT IS APPLYING FOR ASSISTANCE FOR MORE THAN ONE FOCUS AREA, A SEPARATE AND COMPLETE APPLICATION MUST BE SUBMITTED FOR EACH FOCUS AREA.

All applicants must develop their application(s) in accordance with PHS Form 398, information contained in this grant/cooperative agreement announcement, and the instructions outlined below. In order to ensure an objective, impartial, and prompt review, applications must conform to the following instructions:

General Instructions

Due to the need to reproduce copies of the applications for the reviewers, ALL pages of each application MUST be in the following format:

1. The original and two (2) copies of the application must 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. All materials must be typewritten, single-spaced, using a font no smaller than size 12, and on 8½″ by 11″ white paper.

4. Any reprints, brochures, or other enclosures must be copied onto 8½″ by 11″ white paper by the applicant. NO BOUND MATERIALS WILL BE ACCEPTED in the narrative or appendices.

5. All pages must be printed on ONE side only, with at least 1″ margins, headers, and footers.

Special Instructions

The application narrative for each application/focus area must not exceed 10 pages (excluding 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. (REMINDER: If proposing projects under multiple focus areas, submit a separate and complete application for each project):

1. Abstract:

Provide a brief (two pages maximum) abstract of the project. Clearly identify the specific focus area being addressed and the project period proposed (not to exceed maximum as indicated in AVAILABILITY OF FUNDS section). Clearly identify the types of award that is being applied for—grant or cooperative agreement.

2. Background and Need:

Discuss the background and need for the proposed project. Demonstrate a clear understanding of the purpose and objectives of the focus area.

3. Capacity and Personnel:

Describe applicant's past experience in conducting activities similar to that being proposed. 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. (if any), which clearly indicate their commitment to participate as described in the operational plan. Do not include letters of support from CDC personnel. Letters of support from CDC will not be accepted. Award of a grant or cooperative agreement implies CDC participation as outlined in the PROGRAM REQUIREMENTS section of this announcement.

4. Objectives and Technical Approach:

Present specific objectives for the proposed project which are measurable and time-phased and are consistent with the PURPOSE and RECIPIENT ACTIVITIES sections for the specific focus area. Present a detailed operational plan for initiating and conducting the project which clearly and appropriately addresses these objectives (if proposing a multi-year project, provide a detailed description of first-year activities and a brief overview of subsequent-year activities).

Clearly identify specific assigned responsibilities for all key professional personnel. Include a clear description of applicant's technical approach/methods which are directly relevant to the above objectives. Describe specific study protocols or plans for the development of study protocols. Describe the nature and extent of collaboration with CDC (if proposing a cooperative agreement) and/or others during various phases of the project. Describe in detail a plan for evaluating progress toward achieving process and outcome project objectives.

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. If requesting funds for any contracts, provide the following information for each proposed contract: (1) Name of proposed contractor, (2) breakdown and justification for estimated costs, (3) description and scope of activities to be performed by contractor, (4) period of performance, and (5) method of contractor selection (e.g., sole-source or competitive solicitation). (See sample budget included in application package.)

Note: If indirect costs are requested from CDC on a new or continuation application, a copy of the organization's current negotiated Federal indirect cost rate agreement or cost allocation plan must be provided.

6. Human Subjects:

Whether or not exempt from DHHS regulations, if the proposed project involves human subjects, describe adequate procedures for the protection of human subjects. Also, ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects.

Evaluation Criteria

The applications will be reviewed and evaluated according to the following criteria:

1. Background and Need (10 points)

Extent to which applicant demonstrates a clear understanding of the background, purpose, and objectives of the focus area being addressed.

2. Capacity (45 points)

Extent to which applicant describes adequate resources and facilities (both technical and administrative) for conducting the project. Extent to which applicant documents that professional personnel involved in the project are qualified and have past experience and achievements in research related to that proposed as evidenced by curriculum vitae, publications, etc. If applicable, extent to which applicant includes letters of support from non-applicant organizations, individuals, etc., and the extent to which such letters clearly indicate the author's commitment to participate as described in the operational plan.

3. Objectives and Technical Approach (45 points total)

a. Extent to which applicant describes objectives of the proposed project which are consistent with the purpose of the focus area being addressed and which are measurable and time-phased. (10 points)

b. Extent to which applicant presents a detailed operational plan for initiating and conducting the project which clearly and appropriately addresses all Recipient Activities for the specific programmatic focus area being addressed. Extent to which applicant clearly identifies specific assigned responsibilities of all key professional personnel. Extent to which the plan clearly describes applicant's technical approach/methods for conducting the proposed studies and extent to which the approach/methods are appropriate and adequate to accomplish the objectives. Extent to which applicant describes specific study protocols or plans for the development of study protocols that are appropriate for achieving project objectives. Extent to which applicant meets CDC requirements regarding the inclusion of women, racial and ethnic minority populations are appropriately represented in applications involving human research. Extent to which applicant describes adequate and appropriate collaboration with CDC (if proposing a cooperative agreement) and/or others during various phases of the project. (30 points)

c. Extent to which applicant provides a detailed and adequate plan for evaluating progress toward achieving project process and outcome objectives. If the proposed project involves notifiable conditions, the degree to which applicant describes an adequate process for providing necessary information to appropriate State and/or local health departments. (5 points)

4. Budget (not scored)

Extent to which the proposed budget is reasonable, clearly justifiable, and consistent with the intended use of grant/cooperative agreement funds.

5. Human Subjects (not scored)

If the proposed project involves human subjects, whether or not exempt from the Department of Health and Human Services (DHHS) regulations, the extent to which adequate procedures are described for the protection of human subjects. Note: Objective Review Group (ORG) recommendations on the adequacy of protections include: (1) protections appear adequate and there are no comments to make or concerns to raise, (2) protections appear adequate, but there are comments regarding the protocol, (3) protections appear inadequate and the ORG has concerns related to human subjects, or (4) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are inadequate as to make the entire application unacceptable.

Executive Order 12372 Review

This program is not subject to Executive Order 12372 Review.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.283.

Other Requirements

Paperwork Reduction Act

Projects that involve the collection of information from ten or more individuals and funded by the grant/cooperative agreement will be subject to review and by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations (45 CFR Part 46) regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing evidence of this assurance in accordance with the appropriate guidelines and form provided in the application kit.

In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved or will support the research. If American Indian community is involved, its tribal

government must also approve that portion of the project applicable to it.

Women, Racial and Ethnic Minorities

It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian, Alaskan Native, Asian, Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the **Federal Register**, Vol. 60, No. 179, pages 47947–47951, dated Friday, September 15, 1995.

Animal Subjects

If the proposed project involves research on animal subjects, the applicant must comply with the ''PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions.'' An applicant organization proposing to use vertebrate animals in supported activities must file an Animal Welfare Assurance with the Office for Protection from Research Risks at the National Institutes of Health.

Application Submission and Deadline

The original and five copies of each application PHS Form 398 must be submitted to Sharron Orum, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–18, Atlanta, Georgia 30305, on or before August 8, 1997.

1. *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 objective 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.)

2. *Late Applications:* Applications which do not meet the criteria in 1(a) or 1(b) above are considered late applications. Late applications will not be considered and will be returned to the applicant.

Where To Obtain Additional Information

To receive additional written information call (404) 332–4561. You will be asked to leave your name, address, and telephone number and will need to refer to Announcement 778. You will receive a complete program description, information on application procedures, and application forms.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Oppie M. Byrd, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mailstop E–18, Atlanta, Georgia 30305, telephone (404) 842–6546, facsimile (404) 842–6513, E-mail oxb3@cdc.gov.

Programmatic technical assistance may be obtained from the following individuals:

Focus Area #1

Evaluating Algorithms to Diagnose Emerging Causes of Infectious Diarrhea: Robert V. Tauxe, M.D., M.P.H., or David L. Swerdlow, M.D., National Center for Infectious Diseases, Division of Bacterial and Mycotic Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop A–38, Atlanta, Georgia 30333, (for Dr. Tauxe) telephone (404) 639–2206, E-mail address rvt1@cdc.gov, (for Dr. Swerdlow) telephone (404) 639–3234, E-mail address dls3@cdc.gov.

Focus Area #2

Rapid Identification of Emerging and Unusual Pathogenic Bacteria by Partial 16S rRNA Sequencing: Don J. Brenner, Ph.D, National Center for Infectious Diseases, Division of Bacterial and Mycotic Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop D–11, Atlanta, Georgia 30333, telephone (404) 639–2841, E-mail address djb3@cdc.gov.

Focus Area #3

Development and Evaluation of Improved Tests for Malaria Diagnosis in the United States: Phuc P. Nguyen-Dinh, M.D., National Center for Infectious Diseases, Division of Parasitic Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop F–13, Atlanta, Georgia 30333, telephone (770) 488–4435, E-mail address ppn1@cdc.gov.

Focus Area #4

Development of Diagnostic Tests for Leishmaniasis: Mark L. Eberhard, Ph.D., or Marianna Wilson, M.S., National Center for Infectious Diseases, Division of Parasitic Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop F–13, Atlanta, Georgia 30333, (for Dr. Eberhard) telephone (770) 488–4419, E-mail address mle1@cdc.gov, (for Ms. Wilson) telephone (770) 488–4431, E-mail address myw1@cdc.gov.

Focus Area #5

Identification of Unrecognized Etiologic Agents in Idiopathic Sexually Transmitted Disease Syndromes: Consuelo Beck-Sagué, M.D., or Cheng-Yen Chen, Ph.D., National Center for Infectious Diseases, Division of AIDS/HIV, STD, and TB Laboratory Research, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop C–12 (Dr. Beck-Sagué) or G–39 (Dr. Chen), Atlanta, Georgia 30333, (for Dr. Beck-Sagué) telephone (404) 639–3467, E-mail cmb1@cdc.gov, (for Dr. Chen) telephone (404) 639–1535, E-mail address cyc1@cdc.gov.

Focus Area #6

Development of Non-culture Molecular Epidemiologic Detection/Typing Methods for *Treponema pallidum* or *Haemophilus ducreyi*: Victoria Pope, Ph.D., or David L. Trees, Ph.D., National Center for Infectious Diseases, Division of AIDS/HIV, STD, and TB Laboratory Research, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop D–13, Atlanta, Georgia 30333, (for Dr. Pope) telephone (404) 639–3224, E-mail address vxp1@cdc.gov, (for Dr. Trees) telephone (404) 639–2134, E-mail address dlt1@cdc.gov.

Please refer to Announcement Number 778 when requesting information regarding this program.

You may also obtain this announcement from one of two Internet sites on the actual publication date: CDC's homepage at http://www.cdc.gov or at the Government Printing Office homepage (including free on-line access to the **Federal Register** at http://www.access.gpo.gov).

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report,

Stock No. 017–001–00473–1) referenced in the INTRODUCTION through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402–9325, telephone (202) 512–1800.

Dated: July 1, 1997.

Joseph R. Carter,

Acting Associate Director for Management and Operations Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 789]

Research and Demonstration Programs in Surveillance, Prevention, and Control of Healthcare-Associated Infections and Antimicrobial Resistant Infections

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1997 funds to provide assistance for cooperative agreements to develop research and demonstration programs in the surveillance, prevention, and control of healthcare-associated infections and antimicrobial resistant infection.

CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Immunization and Infectious Diseases. (For ordering a copy of Healthy People 2000, see the section Where to Obtain Additional Information.)

Authority

This program is authorized under Section(s) 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.

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and to promote the nonuse of all tobacco products, and Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Applications may be submitted by public and private nonprofit health care delivery systems and organizations. Thus, universities, colleges, research institutions, hospitals, other public and private non-profit organizations are eligible to apply.

Note: Effective January 1, 1996, Public law 104–65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 which engages in lobbying activities shall not be eligible for the receipt of Federal funds constituting an award, grant (cooperative agreement), contract, loan, or any other form.

Availability of Funds

Approximately $700,000 will be available in Fiscal Year 1997 to fund 2 to 3 cooperative agreements. The award is expected to begin on or about September 29, 1997, for a 12-month budget period within a project period of up to 3 years. The funding estimate is subject to change. Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds. There are no matching or cost participation requirements; however, the applicant's anticipated contribution to the overall program costs, if any, should be provided in the application.

Restrictions on Lobbying

Applicants should be aware of restrictions on the use of Department of Health and Human Services (HHS) funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352 (which has been in effect since December 23, 1989), recipients (and their subtier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying Congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition, the FY 1997 Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act, which became effective October 1, 1996, expressly prohibits the use of 1997 appropriated funds for indirect or ''grass roots'' lobbying efforts that are designed to support or defeat legislation pending before State legislatures. Section 503 of this new law, as enacted by the Omnibus Consolidated Appropriations Act, 1997, Division A, Title I, Section 101(e), Pub. L. No. 104–208 (September 30, 1996), provides as follows:

Sec. 503: (a) No part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress, . . . except in presentation to the Congress or any State legislative body itself.

(b) No part of any appropriation contained in this Act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

Background

Nosocomial, or hospital-acquired, infections occur at a rate of 5 to 10 per hundred admissions in U.S. hospitals. An estimated 30,000 patients die each year as a direct result of nosocomial bloodstream infection. Furthermore, many nosocomial infections are associated with an extended length of stay, substantial morbidity, and prolonged therapy. It has been estimated that nosocomial infections have a direct cost of $5 billion to $10 billion annually in this country.

Purpose

The purpose of these cooperative agreements is to provide assistance in establishing centers of excellence for research and demonstration to improve the surveillance, prevention, and control of healthcare-associated infections and antimicrobial resistant infections. For purposes of this program announcement, centers of excellence in the surveillance, prevention, and control of healthcare-associated infections and antimicrobial resistant infections are defined as those recipients who are successfully conducting the activities delineated below. Thus, recipients will establish centers by developing programs with three components: (1) program to conduct research and demonstrate academic leadership in healthcare epidemiology and infection control; (2) program to adapt and implement infection control and healthcare epidemiology practice across the full range of settings in an integrated health care delivery model; (3) program to conduct training of healthcare epidemiologists and infection control practitioners that utilizes quality