DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Cooperative Research and Development Agreement

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

ACTION: Notice.

SUMMARY: The Division of Bacterial and Mycotic Diseases (in the National Center for Infectious Disease, Centers for Disease Control and Prevention) is seeking to explore possible partnerships in applied research to improve public health preparedness and response to bioterrorism associated with use of bacterial and fungal agents. The Division of Bacterial and Mycotic Diseases (DBMD) through its component Branches has lead CDC technical responsibility for a number of Category A, B and C bioterrorism agents and their associated toxins (Bacillus anthracis, Clostridium botulinum, Brucella sps., Burkholderia sps., Staphylococcus entertoxin B, other food- or waterborne bacterial pathogens, and other bacterial agents). DBMD uses epidemiologic, laboratory, clinical, and biostatistical sciences to control and prevent bacterial and mycotic infectious disease. The division conducts applied research in a variety of settings, and translates the findings of this research into public health practice.

The division works in partnership with a variety of public, academic, and for-profit and not-for-profit private sector organizations to achieve public health goals.

Broad categories of bioterrorism-related research of interest to the DBMD include:

1. Rapid evaluation of powder, food, water, and other potential vehicles for presence of bioterrorism agents, and their associated toxins;

2. Epidemiologic investigation of suspected and confirmed bioterrorism events;

3. Pre-, during, and post-bioterrorism event surveillance;

4. Diagnosis of suspect and confirmed bioterrorism-related illness;

5. Treatment of suspect and confirmed bioterrorism-related illness;

6. Post-exposure prophylaxis for prevention of bioterrorism-related illness among exposed persons;

7. Remediation of health risks in environments contaminated or potentially contaminated as a result of BT events.

DBMD is currently involved in a number of bioterrorism-related research activities including, but not limited to:

1. Development and revision of agent-(and toxin-) specific National Bioterrorism Response Plans;

2. Anthrax vaccines;

3. Immunotherapy for anthrax and botulism;

4. Anthrax diagnostics;

5. Antimicrobial susceptibility testing;

6. Epidemiologic and clinical research;

7. Building representative stain collections;

8. Molecular subtyping (and electronic networks for sharing associated data);

9. Identification of virulence factors;

10. Methods for rapid detection of foodborne agents in food and water;

11. Evaluation of unexplained deaths and critical illnesses.

Because CRADA's are designed to facilitate the development of scientific and technological knowledge into useful, marketable products, a great deal of freedom is given to Federal agencies in implementing collaborative research. The CDC may accept staff, facilities, equipment, supplies, and money from the other participants in a CRADA; CDC may provide staff, facilities, equipment, and supplies to the project. CDC MAY NOT PROVIDE FUNDS to the other participants in a CRADA. Responses will be accepted through one year after publication of this notice.

FOR FURTHER INFORMATION CONTACT:

Technical

Bradley Perkins, MD, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Rd. NE., Mail stop C–09, Atlanta, GA 30333. Telephone (404) 639–4721, E-Mail at *BPerkins@CDC.GOV.*

Business

Lisa Blake-DiSpigna, Technology Development Coordinator, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton R. NE., Mail stop E–51, Atlanta, GA 30333. Telephone (404) 498–3262, E-Mail at *LCBS3@CDC.GOV.*

SUPPLEMENTARY INFORMATION:

DBMD is seeking to identify organizations that are interested in a partnership for the common goal of improving the Nation's preparedness and ability to respond to bioterrorism based on mutually agreed rule and principles. Partnerships may be based on existing products—systems or tests, development of new products—systems or tests, evaluation of specific issues, communications strategies, or other exchange of knowledge. Partnerships must be constructed in a way that does not create a real or perceived conflict of interest for CDC, the Department of Health and Human Services, or the Federal Government. DBMD will not engage in partnerships which benefit a partner but provide no clear benefit to the Nation's preparedness and ability to respond to bioterrorism.

Respondents should provide evidence of expertise in the conduct of research that focuses on accomplishments and current capabilities, with supporting documentation (*e.g.*, publications, certifications, resumes, etc.), along with qualifications for the principal investigator who would be involved in the CRADA. A proposed research plan outline should be included with sufficient detail to allow for its merit to be judged on the criteria below. Respondents selected for a CRADA will develop the final research plan in collaboration with CDC.

The key criteria by which CDC will judge a potential partnership are whether:

(1) The partnership leads to significant gains in the Nation's preparedness and ability to respond to bioterrorism.

(2) These gains are worth the effort involved in establishing and maintaining the partnership.

With respect to Government Intellectual Property (IP) rights to any invention not made solely by a CRADA partner's employees for which a patent or other IP application is filed, CDC has the authority to grant to the CRADA partner an exclusive option to elect an exclusive or nonexclusive commercialization license. This option does not apply to inventions conceived prior to the effective date of a CRADA that are reduced to practice under the CRADA, if prior to that reduction to practice, CDC has filed a patent application on the invention and has licensed it or offered to licensed it to a third party. The terms of the license will fairly reflect the nature of the invention, the relative contributions of the Parties to the invention and the CRADA , the risks incurred by the CRADA partner and the costs of subsequent research and development needed to bring the invention to the marketplace. The field of use of the license will be commensurate with the scope of the research plan.

This CRADA(s) is proposed and implemented under the 1986 Federal Technology Transfer Act: Public Law 99–502, as amended.

Projects that involve the collection of information from 10 or more individuals may be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Responses are preferred in electronic format and can be e-mailed to the attention of Michael J. Detmer at *MDetmer@cdc.gov.* Mailed responses can be sent to the following address: Michael J. Detmer, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Rd. NE., Mail stop C–09, Atlanta, GA 30333.

Dated: June 11, 2003.

Joseph R. Carter,

Associate Director for Management and Operations, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 03094]

Perinatal HIV Prevention in the United States: National Organizations Working Toward Elimination; Notice of Availability of Funds

Application Deadline: August 1, 2003.

A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301(a) and 317K(2) of the Public Health Service Act, (42 U.S.C. 241(a) and 274b (k)(2)), as amended. The Catalog of Federal Domestic Assistance number is 93.943.

B. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2003 funds for a cooperative agreement program for ''Perinatal HIV Prevention in the United States: National Organizations Working Toward Elimination.'' This program addresses the ''Healthy People 2010'' focus area(s) of HIV and Maternal, Infant and Child Health.

The purpose of this program is to: (1) Develop, provide and disseminate technical assistance and other educational and training materials needed to improve perinatal HIV prevention efforts nationally; (2) promote the integration of: universal voluntary HIV testing into prenatal care across the United States, rapid HIV testing for women with unknown HIV status in labor, and offering repeat HIV testing to women at risk for seroconversion during pregnancy; and (3) foster the exchange of information, ideas and experiences of perinatal HIV prevention among maternal and child health providers, HIV care providers and consumers.

Measurable outcomes of the program will be in alignment with one or more of the following performance goals for the National Center for HIV, STD and TB Prevention (NCHSTP): (1) Reduce the number of new HIV infections; (2) increase the proportion of HIV-infected people who know they are infected; (3) increase the proportion of HIV-infected people who are linked to appropriate prevention, care, and treatment services; and (4) strengthen the capacity nationwide to monitor the epidemic, develop and implement effective HIV prevention interventions and evaluate prevention programs.

C. Eligible Applicants

Applications may be submitted by national organizations having demonstrated experience providing needs assessments, capacity building, curricula, and training about prevention of mother to child transmission of HIV (PMTCT) for consumers and health care workers, including: Pediatricians, obstetricians, family practitioners, nurses, nurse-midwives, nurse practitioners, counselors, health educators, PMTCT program managers, and other health care providers. These national organizations may be:

- Public nonprofit organizations
- Private nonprofit organizations
- Faith-based organizations

This program is limited to national organizations that have the capability to serve the broadest U.S. audiences by supporting national efforts to assure consistent messages in training and education.

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.

D. Funding

Availability of Funds

Approximately $700,000 is available in FY 2003, to fund approximately three to four awards. It is expected that the average award will be $175,000, ranging from $50,000 to $225,000. It is expected that the awards will begin on or about September 15, 2003, and will be made for a 12-month budget period within a project period of up to four years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Use of Funds

Funds from this cooperative agreement should not be used for major purchase of equipment or construction. Requests for equipment such as computers and Liquid Crystal Display (LCD) Projectors for training require detailed justification.

Recipient Financial Participation

Matching funds are not required for this program.

Funding Preferences

Funding preference will be given to national organizations with prior experience providing training to health care providers regarding: (1) Incorporation of PMTCT into health care provider education; (2) offering of universal voluntary HIV testing to pregnant women as a routine part of prenatal care; (3) implementation of voluntary rapid HIV testing programs in labor and delivery settings; and (4) to national organizations that have developed and disseminated patient educational materials on HIV, perinatal HIV and its prevention.

E. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities listed in 1. Recipient Activities and CDC will be responsible for the activities listed in 2. CDC Activities.

1. Recipient Activities

a. Provide training and technical assistance to programs and health care providers in sharing and applying knowledge and expertise regarding HIV prevention and perinatal transmission. Specifically, disseminate educational materials, and provide training and technical assistance on approaches to help providers achieve high rates of prenatal HIV testing by using recommended HIV screening practices including opt-out strategies, offering rapid HIV testing for women in labor who present with undocumented HIV status and linking HIV-at risk and HIV-infected women and their infants to comprehensive medical and social services.

b. Sponsor a variety of forums for presentation of information on HIV perinatal reduction (*i.e.*, policies, programs, materials, and other technical