

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* spp., *Burkholderia* spp., *Staphylococcus enterotoxin 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.