

public health priorities and health-related problems.

Field Assignee: A CDC employee assigned to a grantee, through the cooperative agreement mechanism, for a specified purpose and time period.

Health Promotion: As defined by the Ottawa Charter for Health Promotion (WHO [1987]. Ottawa Charter for Health Promotion. Health Promotion, 1 (4), iii.), refers to the "process of enabling people to increase control over, and to improve, their health." The implementation of this definition requires that health promotion initiatives (i.e., programs, policies, or other organized activities) should be empowering, participatory, holistic, intersectoral, equitable, sustainable, and multistrategy.

Impact Objective: The desired impact of prevention research is change in the behavior or norm of a special group or community that heightens the likelihood of generalizing the research outcomes to reduce disease and death. The measurement of behaviors is the most significant and basic component of an impact evaluation. Knowledge and attitudes are also very important. Within the Prevention Research Centers, impact is measured by attaining outcomes that can be rapidly applied to targeted communities (translation), which includes building the capacity of the community to initiate its own research.

Indicators: A value that exposes the condition of a particular situation or activity without bias or judgment.

Outcome Objective: Outcome objectives focus on the long-term effects (rates of death and illness) of prevention research and translation of outcomes to a specific targeted population. Outcome evaluations are conducted long enough after the translation takes place for behavioral changes to show an affect. For the Prevention Research Centers, outcome is determined by changes in behavior of the targeted population or community.

Participatory Research: Community involvement in all stages of planning, developing, and evaluating the research.

Process Objective: Process objectives indicate the activities that are to be done and how they will be accomplished. Process involves administrative and community activities necessary to efficiently and effectively achieve a positive program impact (behavior change). Process for most prevention research projects include Center Administration; Research and Development; Community Involvement Plans; Professional Education; Applied Community Training; and Monitoring and Evaluation.

Special Interest Project: A research project that supplements the Prevention

Research Center's Cooperative Agreement funded by Centers, Institutes, or Offices (CIO's) within CDC, or other federal agencies.

Special Population: A group of persons with common characteristics or conditions.

Dated: April 3, 1998.

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

[CRADA 98-001]

Cooperative Research and Development Agreement

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

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), National Center for Infectious Diseases, announces the opportunity for potential collaborator(s) to enter into a Cooperative Research and Development Agreement (CRADA) for the development of a worldwide sentinel surveillance system to isolate, characterize, and monitor for the emergence of new retroviruses and divergent HIV variants of public health importance. The reagents generated from this project will be used to validate the sensitivity and specificity of the current HIV screening tests. This research effort is designed to further the development of diagnostics to test for new HIV variants to ensure protection of the blood supply.

Because CRADAs 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. There is a single restriction in this exchange: CDC MAY NOT PROVIDE FUNDS to the other participants in a CRADA. This opportunity is available until May 11, 1998. Respondents may be provided a longer period of time to furnish

additional information if CDC finds this necessary.

FOR FURTHER INFORMATION CONTACT:

Technical: Thomas M. Folks, Ph.D., Chief, HIV/Retrovirus Diseases Branch, Division of AIDS, STD and TB Laboratory Research, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Rd. NE., Mailstop G-19, Atlanta, GA 30333, telephone (404) 639-1010.

Business: Lisa Blake-DiSpigna, Technology Transfer Representative, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Rd. NE., Mailstop C-19, Atlanta, GA 30333, telephone (404) 639-3227, (E-Mail: LCB3@CDC.GOV).

SUPPLEMENTARY INFORMATION: Efforts will be made to sample various regions and risk groups in geographically dispersed countries. Where possible, the optimal sample size will be sufficient to have a high probability of detecting HIV variants present in these populations even if their prevalence is low (<1%). Samples will be tested for antibodies to HIV-1 and HIV-2; sero-reactive specimens will be further processed for sera, plasma, and cells. Attempts will be made to target populations attending STD clinics, counseling and testing centers, antenatal clinics, and TB treatment centers. Asymptomatic individuals reporting high risk behaviors and seronegative persons with elevated reactivity in screening assays will be further investigated. In addition, samples will be obtained whenever possible from sero-discordant couples and symptomatic individuals who have remained seronegative. Such samples will be evaluated using generic retroviral testing to identify new or highly divergent viruses which lack common epitopes with prototypic HIV strains. Specimen collection will be in accordance with CDC Institutional Review Board (IRB) approved protocols. An initial site assessment will be done to determine the prevalence of HIV infection and the feasibility of collecting and processing the requisite number of specimens.

Goals: The primary goal of this project is to collect isolates of representative emerging retroviruses and divergent HIV strains from persons with various transmission risk factors, representing different regions worldwide to help in understanding the degree of genetic diversity among emerging variants and what HIV strains predominate in these populations. Special emphasis will be given to monitoring for the presence of divergent HIV variants that are distinct from already characterized HIV-1/2

subtypes and to define the extent of variability within recognized subtypes. The secondary goal is to collect specimens representing these variants and recognized subtypes (A-I) to prepare a panel of sera collected from people whose infecting virus has been sequenced. The panel will be used to evaluate the sensitivity and specificity of existing and newly developed HIV antibody tests with regard to these strains and to assist, if necessary, in modifying these tests to broaden their sensitivity. Specimens will primarily be blood, but may include urine or oral fluids to evaluate diagnostic tests using these specimens. The research efforts in support of this CRADA are focused on the combined use of molecular and epidemiologic data to examine the question of whether certain HIV strains have distinctive patterns of transmission and disease progression in infected individuals.

The CRADA partner will be expected to provide both financial as well as scientific resources. Substantial involvement in specimen testing including molecular and biochemical analysis of viruses and viral components would be anticipated from the CRADA partner.

Respondents should provide evidence of expertise in the development and marketing of clinical diagnostics (prior experience with HIV preferred) and supporting data (e.g., publications, proficiency testing, certifications, resumes, etc.) of qualifications for the laboratory director and laboratory personnel who would be involved in the CRADA. The respondent will develop the final research plan in collaboration with CDC but should provide an outline of a research plan for review by CDC in judging applications.

Applicant submissions will be judged according to the following criteria:

1. Knowledge of molecular diagnostics including: epitope specific and recombinant based immunoassays, rapid tests, and nucleic acid based detection assays.
2. Working knowledge of nucleic acid sequencing, PCR, eukaryotic expression of recombinant antigens, and the large scale production of said products.
3. Operational experience in an international setting.
4. Procedural understanding of and experience in the development and marketing of HIV diagnostics in the United States.

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

The responses must be made to: Lisa Blake-DiSpigna, Program Analyst,

National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop C-19, Atlanta, GA 30333.

Dated: April 3, 1998.

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

Ethics Subcommittee of the Advisory Committee to the Director, Centers for Disease Control and Prevention: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following subcommittee meeting.

Name: Ethics Subcommittee of the Advisory Committee to the Director, CDC.

Time and Date: 9 a.m.-3 p.m., April 27, 1998.

Place: CDC, Building 16, Room 5126, 1600 Clifton Road, NE, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 25 people.

Purpose: This subcommittee will anticipate, identify, and propose solutions to strategic and broad ethical issues facing CDC.

Matters To Be Discussed: Agenda items will include updates from the Associate Director for Science, Dixie E. Snider, M.D., followed by a discussion on issues surrounding the potential destruction of the smallpox virus, privacy and confidentiality of data collection, and scientific misconduct other than falsification, fabrication, and plagiarism.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Linda Kay McGowan, Acting Executive Secretary, Advisory Committee to the Director, CDC, 1600 Clifton Road, NE, M/S D-24, Atlanta, Georgia 30333, telephone 404/639-7080.

Dated: April 2, 1998.

Nancy C. Hirsch,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Consolidation of United States Ports Designated To Conduct Rodent Infestation Inspections and Issue Deratting and Deratting Exemption Certificates

AGENCY: Centers for Disease Control and Prevention, Department of Health and Human Services, HHS.

ACTION: Notice.

SUMMARY: In accordance with International and U.S. Federal regulations, the Centers for Disease Control and Prevention (CDC) has, for many years, inspected ships for rodent infestation and issued Deratting and Deratting Exemption Certificates at 18 major U.S. ports, as well as, by special arrangement, more than 100 smaller ports. To streamline these operations and increase cost effectiveness, CDC has consolidated the ports where it conducts these activities. As of October 1, 1997, CDC began conducting these inspections only at the ports of Baltimore, MD; Honolulu, HI; Houston, TX; Jacksonville, FL; Los Angeles, CA; Miami, FL; New Orleans, LA; New York, NY; San Francisco, CA; Savannah, GA; and Seattle, WA.

EFFECTIVE DATE: October 1, 1997.

FOR FURTHER INFORMATION CONTACT: David F. Rogers, Acting Chief, Program Operations Branch, Division of Quarantine, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), Mailstop E-03, Atlanta, Georgia 30333, (404) 639-8107, FAX (404) 639-2599, E-mail dfr1@cdc.gov.

SUPPLEMENTARY INFORMATION:

Purpose and Background

This announcement provides notification of CDC's consolidation of the ports in the U.S. where rodent infestation inspections of ships are conducted and Deratting and Deratting Exemption Certificates are issued.

In accordance with Article 17 of the International Health Regulations, published by the World Health Organization (WHO), Geneva, the United States is required to (1) ensure that a sufficient number of U.S. ports have the capacity to inspect ships for the issue of Deratting Exemption Certificates and (2) depending upon the volume and incidence of international traffic, approve a number of these ports and maintain the capacity to perform rodent infestation inspections and issue