Toxicology, Agency for Toxic Substances and Disease Registry, Building 4, Suite 2400, Executive Park Drive, Atlanta, Georgia, (not a mailing address) between 8:00 a.m. and 4:30 p.m., Monday through Friday, except legal holidays.

Availability

This notice announces the availability of the final updated toxicological profile for mercury completing the eleventh set prepared by ATSDR. The following toxicological profile is now available through the U.S. Department of Commerce, National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, Virginia 22161, telephone 1–800–553–6847. There is a charge for these profiles as determined by NTIS.

Toxicological profile	NTIS order No.	CAS No.
MERCURY	PB99–142416	007439–97–6
MERCURIC (II) ACETATE		001600–27–7
MERCURIC (II) SULFIDE		001134–48–5
MERCURIC (I) CHLORIDE		010112–91–1
METHYLMERCURIC CHLORIDE		000115–09–3

Dated: May 20, 1999.

Georgi Jones,

Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.

[FR Doc. 99–13434 Filed 5–26–99; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 99105]

Research Studies to Characterize the Clinical Relevance of HIV Superinfection Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1999 funds for a cooperative agreement program for epidemiologic and laboratory research studies to characterize reinfection with Human Immunodeficiency Virus Type 1 (HIV–1.) This program addresses the ''Healthy People 2000'' priority area of HIV Infection.

The purpose of this program is to characterize the occurrence of reinfection with a second strain of HIV and determine whether reinfection has clinical relevance for the pathogenesis of HIV disease. Specific questions must at least include:

1. Can naturally-occurring reinfection with a second, genotypically distinct strain of HIV–1 be documented after initial infection has been established?

2. (How often?) Does reinfection result in the emergence of a new predominant strain of HIV–1?

3. Is reinfection with a second strain of HIV–1 associated with clinical disease progression, emergence of resistance to antiviral drugs, or other adverse consequences?

B. Eligible Applicants

Applications may be submitted by public and private nonprofit and for-profit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit and for-profit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

Because studies to date suggest that reinfection with a second HIV–1 strain may be rare or difficult to detect, a case-control study design may be most likely to yield expeditious answers to study questions. Funds under this announcement may not be used to establish a prospective cohort. Therefore, successful applicants must demonstrate access to an existing cohort for recruitment of appropriate study subjects for whom stored specimens are available to conduct the necessary retrospective analysis.

C. Availability of Funds

Approximately $500,000 will be available in FY 1999 to fund approximately 2 awards. It is expected that the average new award will be approximately $250,000. It is expected that awards will begin on or about September 30, 1999. Awards will be funded for a 12-month budget period within a project period of up to 3 years. Funding estimates may vary. Continuation awards within the project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

D. Program Requirements

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

1. Recipient Activities

a. Develop Study Protocol: Design an appropriate study to answer the specific research questions related to HIV–1 reinfection.

b. Identify Study Cohort: Identify a cohort of HIV-infected persons from which eligible study subjects can be recruited, for whom (1) sufficient information is available to document a known or likely re-exposure to a second strain of HIV–1; (2) a clinically significant event such as disease progression or emergence of antiviral drug resistance has been recognized; and (3) suitable stored specimens are available for genotypic analysis of viral strains of HIV–1 before and after occurrence of the clinical event.

c. Conduct Productive and Scientifically Sound Studies: Identify, recruit, obtain informed consent, and enroll study participants as determined by the study protocol and the program requirements. Perform the laboratory tests necessary to characterize viral strains as determined by the study protocol. Ideally, recipients would be able to characterize the HIV–1 strain in the source partner epidemiologically associated with reinfection.

d. Publish the Results of the Study: Upon completion, publish the results of the study. At the completion of the funding period, recipients should optimally prepare at least one manuscript based on the funded research for a peer-reviewed journal. All recipients will provide copies of relevant publications and other significant documents to CDC project co-investigators, and any other local agencies or individuals with a special interest in the research project.

e. Share Data and Specimens: Share data and specimens (when appropriate) with other collaborators to answer the project's specific research questions.

2. CDC Activities

a. Assist in Protocol Development: CDC staff will assist in the development

of a research protocol for Institutional Review Board (IRB) review by all cooperating institutions participating in the research project. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

b. Provide Technical Assistance: CDC staff will assist in the design of the research and quality assurance of laboratory methods.

c. Provide Scientific Expertise: CDC staff will provide current scientific and programmatic information relevant to the studies, and will provide technical advice throughout the study, including study design, data analysis and publication.

d. Share Data and Specimens: CDC staff will assist in the dissemination of study results and distribution of specimens.

E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. Applications must not be more than 25 double-spaced pages, printed on one side, with one inch margins and 12 point font (exclusive of official PHS application pages and relevant attachments.) Applications will not be reviewed if the narrative is more than 25 pages, not counting PHS forms and appendices. In the narrative, address the following:

1. Background: Briefly describe your research questions.

2. Study design: Describe: (a) the proposed study design and (b) how this study design will address the specific research questions.

3. Study cohort: Describe: (a) the study cohort from which eligible study subjects will be recruited; (b) how this study cohort was selected; (c) specific clinical and epidemiologic information available for potential study subjects related to the study objectives; and (d) the availability, quality, and condition of stored specimens necessary for the laboratory analysis as determined by the study design. Also provide evidence that the necessary information and specimens from this cohort will be accessible for the purposes of this study.

4. Laboratory methods: Describe the laboratory methods that will be used to characterize the viral strains, and provide evidence that these are adequate to distinguish between different strains of HIV–1 with the same envelope subtype.

5. Organization: Describe: (a) the existing relationship between the proposed study staff, managers of the proposed study cohort, and the laboratory which will perform the study analyses; (b) the proposed organization structure, with lines of authority, for implementing the proposed study; (c) the current working relationship with any research, academic, scientific groups, community-based organizations or other affiliated organizations; and (d) strategy for identification and recruitment of study participants.

6. Capacities: Describe your capacity and experience in: (a) performing previous clinical or laboratory research involving the recruitment of HIV-positive persons and collection of clinical or epidemiologic data; (b) performing genotypic analysis of viral strains of HIV–1; (c) ensuring the hiring of staff for implementing the study in a timely manner; and (d) participating in collaborative research with other research organizations.

7. Personnel: Describe (a) personnel proposed for implementing the research study; (b) roles and responsibilities for each proposed staff; and (c) evidence of qualifications for the responsibilities proposed.

8. Budget and Line-Item Justification: Provide an annualized budget that anticipates the organizational and operational needs to carry out the proposed study.

F. Submission and Deadline

Submit the original and five copies of PHS–398 (OMB Number 0925–0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398). Forms are in the application kit. On or before August 1, 1999 submit the application to: Kevin Moore, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Mail Stop E–15, Atlanta, GA 30341, Email KGM1@cdc.gov.

Deadline: Applications shall be considered as meeting the deadline if they are either received on or before the stated deadline date or sent on or before the deadline date and received in time for submission to the independent review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks are not acceptable proof of timely mailing. Applications that do not meet these criteria are considered late applications, will not be considered, and will be returned to the applicant.

G. Evaluation Criteria

Each application will be evaluated individually based on the evidence submitted against the following criteria by an independent review group appointed by CDC (Note: total possible point value is 110):

1. Demonstration of the applicant's understanding of the research objectives and the ability, willingness, and need to collaborate in the study design and analysis, and (when appropriate) sharing of data and specimens. Evidence should include a brief review of previous studies related to HIV–1 infection, and laboratory methods for characterizing viral strains of HIV–1. (15 points)

2. Quality of an explicit research plan adequate to address the study questions. The research plan should include a specific study design (e.g., case series, case-control analysis) and describe how HIV-infected study subjects will be identified and how their re-exposure to infection with another strain of HIV–1 will be documented. The research plan should specify the anticipated number of subjects, and demonstrate how this study design and subject selection will resolve the study questions. Preference will be given to applicants who propose to evaluate reinfection in persons whose initial infection and possible reinfection are both due to group M, subtype B strains of HIV–1. (25 points)

3.a. Capacity to access a cohort of HIV-infected persons with sufficient epidemiologic information to document re-exposure to HIV–1, adequate descriptive clinical information to identify significant clinical events such as disease progression or emergence of antiviral drug resistance, and the availability of adequate stored specimens to implement the study. (15 points)

b. The degree to which the applicant has met the CDC policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes:

(1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

(2) The proposed justification when representation is limited or absent.

(3) A statement as to whether the design of the study is adequate to measure differences when warranted.

(4) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with communities and recognition of mutual benefits. (5 points)

4. Capability to employ laboratory methods sufficient to differentiate

among viral strains of HIV–1 with the same envelope subtype. Evidence should include a justification for the laboratory techniques selected, documentation of either proficiency with these methods or specific plans and commitments to access services from a laboratory which has demonstrated this proficiency, and assurance that capacity is adequate to accomplish the analyses necessary for the proposed research. Letters of support from collaborating institutions or organizations should be included. (15 points)

5. Demonstration of a history of conducting comparable research studies. Research studies related to the molecular biology, genetic diversity, or genetic evolution of HIV–1 are of greatest interest. (10 points)

6. The capacity to effectively manage the study as evidenced by the proposed organizational structure, the quality and experience of proposed personnel with realistic and sufficient percentage-time commitments; clarity of the described duties and responsibilities of project personnel; adequacy of the facilities; and plans for administration of the project including project oversight and data management. Evidence should document qualifications of a prospective PI and other key personnel, and, if indicated, support arrangements with a university, community-based or other affiliated organization, etc. (15 points)

7. A comprehensive schedule, including a time line, for accomplishing the activities of the research and an evaluation plan that identifies methods and instruments for evaluating progress in designing and implementing the research objectives. (10 points)

8. Other (Not Scored).

a. Budget: The budget will be reviewed to determine the extent to which it is reasonable, clearly justified, consistent with the intended use of funds, and allowable. All budget categories should be itemized.

b. Human Subjects: Whether or not exempt from the Department of Health and Human Services (DHHS) regulations, are procedures adequate for the protection of human subjects?

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of

1. Annual progress reports;

2. Financial status report, no more than 90 days after the end of the budget period; and

3. Final financial status and performance reports, no more than 90 days after the end of the project period. Send all reports to the Grants Management Specialist identified in the paragraph Where to Obtain Additional Information.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application kit.

AR–1 Human Subjects Requirements
AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–4 HIV/AIDS Confidentiality Provisions
AR–6 Patient Care
AR–7 Executive Order 12372 Review
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2000

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under Sections 301 and 311 of the Public Health Service Act, [42 U.S.C. 241 and 243], as amended. The Catalog of Federal Domestic Assistance number is 93.943.

J. Where To Obtain Additional Information

To receive additional written information and to request an application kit, call 1–888–GRANTS4 (1–888–472–6874). You will be asked to leave your name and address and to identify the Announcement number, 99105. If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Kevin Moore, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Mail Stop E–15, Atlanta, GA 30341, Telephone (770) 488–2737, E-mail address KGM1@cdc.gov.

For a detailed description of the additional requirements in Attachment 1, to download forms required by this announcement, and to review other CDC program announcements, see the CDC home page on the Internet: www.cdc.gov.

For program technical assistance, contact Kay Lawton, Division of HIV/AIDS Prevention, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mail Stop E–46, Atlanta, Georgia 30333, telephone (404) 639–6131, E-mail address KEL1@cdc.gov.

Dated: May 21, 1999.

John L. Williams,

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

[FR Doc. 99–13493 Filed 5–26–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

CDC Advisory Committee on HIV and STD Prevention: Meeting

In accordance with section l0(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: CDC Advisory Committee on HIV and STD Prevention.

Times and Dates: 8:30 a.m.–5 p.m., June 24, 1999; 8:30 a.m.–3 p.m., June 25, 1999.

Place: Corporate Square Office Park, Corporate Square Boulevard, Building 11, Room 1413, Atlanta, Georgia 30329.

Status: Open to the public, limited only by the space available. The meeting room will accommodate approximately 100 people.

Purpose: This Committee is charged with advising the Director, CDC, regarding objectives, strategies, and priorities for HIV and STD prevention efforts including maintaining surveillance of HIV infection, AIDS, and STDs, the epidemiologic and laboratory study of HIV/AIDS and STDs, information/education and risk reduction activities designed to prevent the spread of HIV and STDs, and other preventive measures that become available.

Matters to be Discussed: Agenda items include issues pertaining to (1) syphilis elimination (2) HIV Prevention Community Planning and (3) encouraging early diagnosis of HIV infection. Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Paulette Ford, Committee Management Analyst, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, NE, M/S E–07, Atlanta, Georgia 30333, telephone 404/639–8008, fax 404/639–8600, e-mail pbf7@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 21, 1999.

Carolyn J. Russell,

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

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