DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Monitoring Atypical HIV Strains Among Persons Newly Diagnosed With HIV Using Dried Blood Spots vs. Diagnostic Sera


Key Dates:

I. Funding Opportunity Description

Authority: This program is authorized under the Public Health Service Act Sections 301 and 318(b) (42 U.S.C. 241 and 247c), as amended.

Purpose: The purpose of the program is to expand the ability of health departments to perform surveillance of the prevalence of atypical strains of HIV, including drug resistant strains and non-B subtypes, by piloting the use of dried blood spots as an additional specimen type for this purpose. The use of serum from an HIV diagnostic blood draw for surveillance of atypical strains is the methodology used in several HIV resistance surveillance projects in various stages of implementation with different health departments. Some diagnostic sites and clinical centers cannot currently be included in these projects, due to logistical problems with specimen availability, processing or volume. The purpose of CDC funding for this activity is to allow state and local health departments, including those that are participating in atypical HIV strain surveillance and those that are not participating, to:

1. Identify HIV diagnostic sites, counseling, testing and referral centers, and/or clinical sites where HIV drug resistance surveillance in newly diagnosed persons cannot take place using the serum/plasma based methodology funded under PA 01194, PA 04017, and PA 00005 because of one or more of the following conditions:
   a. Blood draws are not used for HIV diagnosis.
   b. Blood draw volumes are consistently too low for 1 ml of serum to be set aside for HIV genotyping.
   c. The use of sera from the diagnostic blood draw for HIV genotyping is not practical because the time between blood draw and processing is consistently greater than 96 hours, rendering the amplification of virus for HIV drug resistance genotyping problematic.
   d. Sites where the use of DBS for atypical HIV strain surveillance is more acceptable than the use of sera to staff or participants, or where fewer resources may be required to collect DBS than sera.

2. Identify the subset of those sites that:
   a. Sites where blood draws are not used for HIV diagnosis.
   b. Sites where blood draw volumes are consistently too low for 1 ml of serum to be set aside for HIV genotyping for the purpose of atypical strain surveillance.
   c. Sites where the use of sera from the diagnostic blood draw for HIV genotyping is not practical because the time between blood draw and processing is consistently greater than 96 hours, rendering the amplification of virus for HIV drug resistance genotyping problematic.
   d. Sites where the use of DBS for atypical HIV strain surveillance is more acceptable than the use of sera to staff or participants, or where fewer resources may be required to collect DBS than sera.

(4) To evaluate the resources needed and the logistics involved in collecting and transporting specimens and amplifying HIV for genotyping from DBS, compared with using HIV diagnostic sera, for routine atypical HIV strain surveillance.

Activities

Awardee activities for this program are as follows:
1. Identify HIV diagnostic sites, counseling, testing and referral centers, and/or clinical sites where HIV drug resistance surveillance in newly diagnosed persons cannot take place using the serum/plasma based methodology funded under PA 01194, PA 04017, and PA 00005 because of one or more of the following conditions:
   a. Blood draws are not used for HIV diagnosis.
   b. Blood draw volumes are consistently too low for 1 ml of serum to be set aside for HIV drug resistance genotyping.
   c. The use of sera from the diagnostic blood draw for HIV genotyping is not practical because the time between blood draw and processing is consistently greater than 96 hours, rendering the amplification of virus for HIV drug resistance genotyping problematic.
   d. DBS are more acceptable to staff or participants, or their collection, processing, and transport may require fewer resources than sera.

2. Identify the subset of those sites from which DBS could be obtained for equal to or greater than 90 percent of persons newly diagnosed with HIV in each site, either at the time of HIV diagnosis or no more than three months after diagnosis.
3. Identify comparison sites from which HIV diagnostic sera are being used, or can be used, for routine surveillance of atypical strains of HIV, in which logistics, resources, and staff time needed to collect and process specimens can be compared to those in sites where DBS will be collected. These sites may include, but are not limited to, sites already participating in atypical HIV strain surveillance under PA 00005, PA 01194, or PA 04017.

4. Identify one or more sites in which paired specimens (sera or plasma + DBS) can be collected no more than three months after diagnosis from at least 20 persons newly diagnosed with HIV annually. (Note that the paired specimens may be collected from a blood draw required for routine surveillance or clinical purposes no more than three months following diagnosis, but need not necessarily be collected as part of a diagnostic blood draw.)

5. Develop and implement (after appropriate ethics review) a protocol to obtain and transfer DBS from selected sites identified in (2), sera from sites identified in (3), and at least 20 paired specimens consisting of sera or plasma + DBS from any atypical strain surveillance site, to a laboratory collaborating with CDC and local health department staff on surveillance of HIV drug resistance in newly diagnosed persons through HIV drug resistance genotyping under PA 00005, PA 01194, or PA 04017.

6. Record or download minimum specimen tracking and non-identifying demographic and clinical information, in formats currently used in HIV drug resistance surveillance funded under 00005, 01194, and 04017, to be transferred to CDC.

7. Make available the option for each participant to designate a provider to receive a clinician-friendly hard copy report of HIV drug resistance and subtype results from the genotyping laboratory, similar to that currently produced in current HIV drug resistance surveillance protocols.

8. Store HIV drug resistance genotyping data electronically and analyze them along with risk factor information for use in HIV prevention and public health programs.

9. Record minimum data to evaluate labor and resources used to collect and process DBS, and to collect and process diagnostic sera, for surveillance of atypical strains of HIV.

10. Collaborate with CDC in analyzing the data. Provide results and share data with network participants, other collaborators in the field, and with CDC.

11. Attend an annual meeting to discuss project activities and methods for data and specimen collection to facilitate representative surveillance.

12. Collaborate with CDC in evaluating the feasibility and efficiency of using DBS to supplement or replace serum-based surveillance to monitor prevalence of HIV drug resistance and non-B HIV subtypes in persons newly infected or newly diagnosed with HIV. Further collaborate with CDC in planning the extension of the method as part of routine surveillance of atypical HIV strains, if the method proves successful and if funds are available.

13. In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC Activities for this program are as follows:

1. Assist in the development of a protocol or project description for Institutional Review Board (IRB) review at all cooperating institutions participating in the project to request a non-research determination. The IRB review at each cooperating institution will be done by an Office of Human Research Protection (OHRP)-approved IRB with either a single, multiple, or federal-wide project assurance. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the project is completed, or until a non-research determination is received.

2. Provide assistance in the design and conduct of the project and statistical analysis.

3. Provide assistance in training, if requested.

4. Provide assistance in locating or contracting with a laboratory participating in CDC-funded HIV drug resistance surveillance genotyping to provide HIV genotypic testing of the DBS and sera (or plasma). Work with participating laboratories to develop laboratory procedures to extend and validate current HIV genotyping methods for use with DBS.

5. Assist in the analysis of the data and the presentation and publication of results.

6. Collaborate with participants in evaluating the feasibility and cost effectiveness of using DBS to supplement or replace collection of diagnostic sera to monitor prevalence of atypical strains in persons newly infected or newly diagnosed with HIV. Further collaborate in planning the extension of the project as a long-term network, if the pilot is successful and if funds are available.

II. Award Information

Type of Award: Cooperative Agreement.

CDC involvement in this program is listed in the Activities Section above.

Fiscal Year Funds: 2004.

Approximate Total Funding: $500,000.

Approximate Number of Awards: Six.

Approximate Average Award: $83,000

(This amount is for the first 12-month budget period, and includes both direct and indirect costs.)

Floor of Award Range: None.

Ceiling of Award Range: $200,000

(This ceiling is for the first 12-month budget period.)

Anticipated Award Date: September 1, 2004.

Budget Period Length: 12 months.

Project Period Length: Five years.

Throughout the project period, CDC’s commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government.

III. Eligibility Information

III.1. Eligible Applicants

Applications may be submitted by health departments of States, U.S. territories or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, and the six independently-funded city health departments of Chicago, Houston, Los Angeles, New York City, Philadelphia, and San Francisco.

A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If you are applying as a bona fide agent of a state or local government, you must provide a letter from the state or local government as documentation of your status. Place this documentation behind the first page of your application form.

Areas conducting these activities must have a sufficient volume of newly diagnosed HIV cases in order to assess the correlation in results between DBS and sera or plasma with adequate statistical precision.

Eligible applicants are limited to areas that have an HIV case reporting system in place as of April 1, 2004.

III.2. Cost Sharing or Matching

Matching funds are not required for this program.
III.3. Other

CDC will accept and review applications with budgets greater than the ceiling of the award range.

If your application is incomplete or non-responsive to the requirements listed in this section, it will not be entered into the review process. You will be notified that your application did not meet submission requirements.

Individuals Eligible To Become Principal Investigators: Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for CDC programs.

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.

IV. Application and Submission Information

IV.1. Address To Request Application Package

To apply for this funding opportunity, use application form PHS 398 (OMB number 0925–0001 rev. 5/2001). Forms and instructions are available in an interactive format on the CDC Web site, at the following Internet address: http://www.cdc.gov/od/pgo/forminfo.htm.

Forms and instructions are also available in an interactive format on the National Institutes of Health (NIH) Web site at the following Internet address: http://www.grants.nih.gov/grants/funding/phps398/phps398.html.

If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO–TIM) staff at: 770–488–2700. Application forms can be mailed to you.

IV.2. Content and Form of Application Submission

Letter of Intent (LOI): Your LOI must be written in the following format:

• Descriptive title of the proposed research.
• Evidence that at least 40 cases of HIV were diagnosed in the area in the latest 12 months for which data are available, accompanied by a brief description of the method by which the figures were obtained (including the elimination of duplicates).
• Name, address, E-mail address, and telephone number of the Principal Investigator.
• Names of other key personnel.
• Participating institutions.
• Number and title of this Program Announcement (PA).

Application: Follow the PHS 398 application instructions for content and formatting of your application. For further assistance with the PHS 398 application form, contact PGO–TIM staff at 770–488–2700, or contact GrantsInfo, telephone (301) 435–0714, e-mail: GrantsInfo@nih.gov.

Your research plan should address activities to be conducted over the entire five-year project period. Your detailed line-item budget narrative should cover the costs of activities for first one-year budget period.

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a Federal grant or cooperative agreement from the Federal government. Your DUNS number must be entered on line 11 of the face page of the PHS 398 application form. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access http://www.dunandbradstreet.com or call 1–866–705–5711.

For more information, see the CDC Web site at: http://www.cdc.gov/od/pgo/funding/pubaccount.htm. This PA uses just-in-time concepts. Additional requirements that may require you to submit additional documentation with your application are listed in section “VI.2. Administrative and National Policy Requirements.”

IV.3. Submission Dates and Times

LOI Deadline Date: June 1, 2004.

CDC requests that you send a LOI if you intend to apply for this program. Although the LOI is not required, not binding, and does not enter into the review of your subsequent application, the LOI will be used to gauge the level of interest in this program, and to allow CDC to plan the application review.

Application Deadline Date: June 21, 2004.

Explanation of Deadlines: Applications must be received in the

CDC Procurement and Grants Office by 4 p.m. eastern time on the deadline date. If you send your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If CDC receives your application after closing due to: (1) carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you will be given the opportunity to submit documentation of the carriers guarantee. If the documentation verifies a carrier problem, CDC will consider the application as having been received by the deadline.

This announcement is the definitive guide on application submission address and deadline. It supersedes information provided in the application instructions. If your application does not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that your application did not meet the submission requirements.

CDC will not notify you upon receipt of your application. If you have a question about the receipt of your application, first contact your courier. If you still have a question, contact the PGO–TIM staff at: 770–488–2700. Before calling, please wait two to three days after the application deadline. This will allow time for applications to be processed and logged.

IV.4. Intergovernmental Review of Applications

Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order (EO) 12372. This order sets up a system for state and local governmental review of proposed federal assistance applications. You should contact your state single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your state’s process.

Click on the following link to get the current SPOC list: http://www.whitehouse.gov/omb/grants/sproc.html.

IV.5. Funding Restrictions

Restrictions, which must be taken into account while writing your budget, are as follows:

Funding cannot be used for purchase of major laboratory equipment for the performance of HIV genotyping. (Laboratory supplies and labor for specimen processing may be included.)
If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement should be less than 12 months of age.

Awards will not allow reimbursement of pre-award costs.

IV.6. Other Submission Requirements

LOI Submission Address: Submit your LOI by express mail, delivery service, fax, or e-mail to: Andrew Vernon, Scientific Review Administrator, CDC, National Center for HIV, STD and TB Prevention, Office of the Director, Associate Director for Science, 1600 Clifton Road, Mail-Stop E-07, Atlanta, Georgia, 30333. telephone number: 404-639-8000, fax: 404-639-8600, e-mail address: avernon@cdc.gov.

Application Submission Address: Submit the original and five hard copies of your application by mail or express delivery service to: Technical Information Management-PA# 04118, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

Applications may not be submitted electronically at this time.

V. Application Review Information

V.1. Criteria

You are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the “Purpose” section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

The goals of CDC-supported research are to advance the understanding of biological systems, improve the control and prevention of disease and injury, and enhance health. In the written comments, reviewers will be asked to evaluate the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals.

The scientific review group will address and consider each of the following criteria in assigning the application’s overall score, weighting them as appropriate for each application. The application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative, but is essential to move a field forward.

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) and for responsiveness by NCHSTP. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

Applications that are complete and responsive to the PA will be evaluated for scientific and technical merit by an appropriate peer review group or charter study section convened by NCHSTP in accordance with the review criteria listed above. As part of the initial merit review, all applications may:

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support? Has the applicant demonstrated collaborative planning by the state and local health department, the state or local HIV diagnostic laboratory, and one or more HIV diagnostic or clinical sites from which DBS can be obtained?

Protection of Human Subjects from Research Risks: Does the application adequately address the requirements of 45 CFR part 46 for the protection of human subjects? This will not be scored; however, an application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.

Inclusion of Women and Minorities in Research: Does the application adequately address the requirements of the CDC Policy 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; and (4) a statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.
• Undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority score.
• Receive a written critique.
• Receive a second level review by the CDC, NCHSTP, Division of HIV/AIDS Prevention (DHAP) Senior Staff.

Award Criteria: Criteria that will be used to make award decisions include:
• Scientific merit (as determined by peer review).
• Availability of funds.
• Programmatic priorities.

V.3. Anticipated Announcement and Award Dates

VI. Award Administration Information

VI.1. Award Notices
Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

VI.2. Administrative and National Policy Requirements

45 CFR Part 74 and Part 92

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: http://www.access.gpo.gov/nara/cfr/cfr-table-search.html.

The following additional requirements apply to this project:
• AR–1 Human Subjects Requirements
• AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
• AR–5 HIV Program Review Panel Requirements
• AR–7 Executive Order 12372
• AR–9 Paperwork Reduction Act Requirements
• AR–10 Smoke-Free Workplace Requirements
• AR–11 Healthy People 2010
• AR–12 Lobbying Restrictions
• AR–14 Accounting System Requirements
• AR–22 Research Integrity
• AR–24 Health Insurance Portability and Accountability Act Requirements
• AR–25 Release and Sharing of Data

Additional information on these requirements can be found on the CDC Web site at the following Internet address: http://www.cdc.gov/od/pgo/funding/AHs.htm.

VI.3. Reporting
You must provide CDC with an original, plus two hard copies of the following reports:
1. Interim progress report, (use form PHS 2590, OMB Number 0925–0001, rev. 5/2001 as posted on the CDC website) no less than 90 days before the end of the budget period. The progress report will serve as your non-competitive continuation application, and must contain the following elements:
   a. Current Budget Period Activities Objectives.
   b. Current Budget Period Financial Progress.
   c. New Budget Period Program Proposed Activity Objectives.
   d. Budget.
   e. Additional Requested Information.
   f. Measures of Effectiveness.
2. Financial status report and annual progress report, no more than 90 days after the end of the budget period.
3. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management Specialist listed in the “Agency Contacts” section of this announcement.

VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, telephone: 770–488–2700.

For scientific/research issues, contact: Diane Bennett, M.D., Extramural Project Officer, CDC, National Center for HIV, STD and TB Prevention, Division of HIV/AIDS Prevention, 1600 Clifton Road, Mail-Stop E–47, telephone: 404–639–5349, e-mail: dbennett@cdc.gov.

For questions about peer review, contact: Andrew Vernon, Scientific Review Administrator, CDC, National Center for HIV, STD and TB Prevention, Office of the Director, Associate Director for Science, 1600 Clifton Road, Mail-Stop E–07, Atlanta, Georgia 30333, telephone: 404–639–8000, e-mail: avernor@cdc.gov.

For financial, grants management, or budget assistance, contact: Brenda Hayes, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, telephone: 770–488–2741, e-mail: bkh4@cdc.gov.

For financial, grants management, or budget assistance in the territories, contact: Vincent Falzone, Contract Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, telephone: 770–488–2763, e-mail: vcf6@cdc.gov.


William P. Nichols,
Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Healthcare Infection Control Practices Advisory Committee

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 meeting.

Name: Healthcare Infection Control Practices Advisory Committee (HICPAC).

Times and Dates: 8:30 a.m.–5 p.m., June 21, 2004; 8:30 a.m.–4 p.m., June 22, 2004.

Place: Swissotel, 3391 Peachtree Road, NE., Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available.

Purpose: The committee is charged with providing advice and guidance to the Secretary, the Assistant Secretary for Health, the Director, CDC, and the Director, National Center for Infectious Diseases (NCID), regarding (1) the practice of hospital infection control; (2) strategies for surveillance, prevention, and control of infections (e.g., nosocomial infections), antimicrobial resistance, and related events in settings where healthcare is provided; and (3) periodic updating of guidelines and other policy statements regarding prevention of healthcare-associated infections and healthcare-related conditions.

Matters to be Discussed: The agenda items will include issues related to public reporting of healthcare-associated infection rates; influenza vaccination of healthcare personnel; infection control issues in ambulatory care settings; strategies for surveillance of healthcare-associated infections; and