

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-10 Smoke-Free Workplace Requirements 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/ARs.htm>.

VI.3. Reporting Requirements

You must provide CDC with an original, plus two hard copies, of the following reports:

1. Interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as your non-competing 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. Detailed Line-Item Budget and Justification.
 - e. Additional Requested Information.
 - f. Measures of Effectiveness.
2. Financial status 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.
4. Semi annual progress reports, 30 days after the end of the project period.

These reports must be mailed to the Grants Management or Contract 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 program technical assistance, contact: Jonathan Mermin, MD, MPH, Global Aids Program [GAP], Uganda Country Team, National Center for HIV, STD and TB Prevention, Centers for Disease Control and Prevention [CDC], PO Box 49, Entebbe, Uganda, Telephone: +256-41320776, E-mail: jhm@cdc.gov.

For financial, grants management, or budget assistance, contact: Shirley Wynn, Contract Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone: 770-488-1515, E-mail address: zbx6@cdc.gov.

Dated: June 28, 2004.

Alan Kotch,

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

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BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

HIV/AIDS Surveillance: Development and Evaluation of Education Materials and Tools Used To Ascertain Risk Factor Information for HIV/AIDS Surveillance

Announcement Type: Supplement.
Funding Opportunity Number: 04017 Supplement.

Catalog of Federal Domestic Assistance Number: 93.944.

Application Deadline: August 2, 2004.

I. Funding Opportunity Description

Authority: This program is authorized under the Public Health Service Act Sections 301 (42 U.S.C. 241); and 318B (42 U.S.C. 247c-2), as amended.

Purpose: The purpose of the supplement is to develop and evaluate educational materials and tools to assist in ascertaining risk factor information by HIV/AIDS surveillance programs funded by the HIV Incidence and Case Surveillance Branch in the Division of HIV/AIDS Prevention at the Centers for Disease Control and Prevention. The ultimate goal is for surveillance areas to better ascertain risk factor information in an effort to reduce the proportion of HIV/AIDS cases reported to the national surveillance system without transmission category information.

The decreasing proportion of transmission category information at the national level continues to be a problem. Transmission category information is critical to allocating resources and developing effective prevention activities. Funded areas will develop educational materials and tools to assist surveillance staff, health care partners and providers, and others reporting or abstracting risk factor information for surveillance purposes to obtain more complete ascertainment of risk factor information at the local level. There is also a need to evaluate these materials and tools to determine whether they are useful in improving completeness of ascertainment of risk factor information and if so, what information sources produced the highest yields. This information will

help to inform the HIV/AIDS Surveillance Guidelines revisions. The development and evaluation of materials and tools is intended to take place over a two year period. The evaluation results are intended to immediately inform the HIV/AIDS surveillance program in order to make timely programmatic decisions. Year one funding is intended for formative assessment of barriers to reporting. Year two is intended for materials and tools development and testing of materials and tools. This program addresses the "Healthy People 2010" focus area(s) for HIV.

Status of the ongoing award: PA 04017, HIV/AIDS Surveillance Cooperative Agreement, is in the 1st year of a 3-year project period.

Federal and/or non-Federal investment in that award: In FY 2004, \$45,434,343 was awarded to 65 state, territorial, and local health departments.

The impact on the objectives of the affected program of not making the additional or supplemental award: A principal goal of the HIV/AIDS Cooperative agreement is to better ascertain risk factor information in an effort to reduce the proportion of HIV/AIDS cases reported to the national surveillance system without transmission category information. Without this supplement, we will be unable to develop and evaluate educational materials and tools to assist in ascertaining risk factor information by HIV/AIDS surveillance programs. The development and evaluation of materials and tools is intended to take place over a two year period. The evaluation results are intended to immediately inform the HIV/AIDS surveillance program in order to make timely programmatic decisions. Year one funding is intended for formative assessment of barriers to reporting. During year two, the educational materials and tools will be developed and tested.

Measurable outcomes of the program will be in alignment with one (or more) of the following performance goal(s) for the National Center for HIV STD and TB Prevention (NCHSTP): Strengthen the capacity nationwide to monitor the epidemic, develop and implement effective HIV prevention interventions and evaluate prevention programs.

Activities

Awardee activities for this program are as follows:

- (1) Participate in a conference call (within one month of award) with CDC and other awardees to begin to develop a project plan and 2-year time line;

(2) Collaborate with CDC staff to develop instruments to assess barriers to reporting and collect information on barriers to reporting;

(3) Collaborate with CDC staff to select control and evaluation sites within each area;

(4) From evaluation sites, collect risk factor information using standard public health surveillance methods such as chart reviews, source of information as well as other relevant information utilizing the educational materials and tools in a timeframe determined by the CDC;

(5) Report information collected in item (4) in a format and timeframe determined by the CDC;

(6) Provide qualitative feedback related to the feasibility and acceptability of the educational materials and tools to the CDC in a format and timeframe determined by the CDC; and

(7) Maintain a secure environment to protect the security and confidentiality of data obtained in these evaluation activities.

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

(1) Participate in a conference call (within one month of award) with awardees to begin to develop a project plan and 2-year time line;

(2) Collaborate with awardees to develop instruments to assess barriers to reporting;

(3) Collaborate with awardees to select control and evaluation sites within each area;

(4) Determine timeframe for the collection and reporting of data by the awardees to the CDC;

(5) Maintain a secure environment to protect the security and confidentiality of data obtained in these evaluation activities; and

(6) Analyze data and disseminate project results.

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: \$240,000.

Approximate Number of Awards: 2–3.

Approximate Average Award: \$80,000.

Anticipated Award Date: September 2004.

Budget Period Length: Budget periods will coincide with budget periods for PA04017 funding. The current budget period ends December 31, 2004.

Project Period Length: 2 years 3 months.

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

Surveillance areas should have a large number of cases reported without risk factor information available over a short time period in order to provide sufficient statistical power.

Eligible applicants are state or territorial health departments or directly funded city health departments currently engaged in HIV/AIDS surveillance funded through Program Announcement 04017 with at least 5,000 HIV cases reported to CDC in 2002 as reported in the HIV/AIDS Surveillance Report (2002) and with at least 800 cases initially reported without risk factor information.

Eligible applicants also must have the legal authority to access health care records, consistently and rapidly contact health care providers as part of routine HIV surveillance, and have implemented HIV laboratory- and provider-based reporting since at least January 1, 2001.

III.2. Cost Sharing or Matching

Matching funds are not required for this program.

III.3. Other

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 CDC 1246. Application forms and instructions are available on the CDC web site, at the following Internet address: www.cdc.gov listed under funding. 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 Submission

Application: You must submit a project narrative with your application forms. The narrative must be submitted in the following format:

- Maximum number of pages: 10
- If your narrative exceeds the page limit, only the pages within the page limit will be reviewed.
- Font size: 12 point unreduced.
 - Double spaced.
 - Paper size: 8.5 by 11 inches.
 - Page margin size: One inch.
 - Printed only on one side of page.
 - Held together only by rubber bands or metal clips; not bound in any other way.

Your narrative should address activities to be conducted over the entire project period, and must include the following items in the order listed:

(1) Participate in a conference call (within one month of award) with CDC and other awardees to begin to develop a project plan and 2-year time line;

(2) Collaborate with CDC staff to develop instruments to assess barriers to reporting and collect information on barriers to reporting;

(3) Collaborate with CDC staff to select control and evaluation sites within each area;

(4) From evaluation sites, collect risk factor information using standard public health surveillance methods such as chart reviews, source of information as well as other relevant information utilizing the educational materials and tools in a timeframe determined by the CDC;

(5) Report information collected in item (4) in a format and timeframe determined by the CDC;

(6) Provide qualitative feedback related to the feasibility and acceptability of the educational materials and tools to the CDC in a format and timeframe determined by the CDC; and

(7) Maintain a secure environment to protect the security and confidentiality of data obtained in these evaluation activities.

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. 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 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/pubcomm.htm>. If your

application form does not have a DUNS number field, please write your DUNS number at the top of the first page of your application, and/or include your DUNS number in your application cover letter.

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

Application Deadline Date: August 2, 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/spoc.html>.

IV.5. Funding Restrictions

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

- None

Guidance for completing your budget can be found on the CDC Web site, at the following Internet address: <http://www.cdc.gov/od/pgo/funding/budgetguide.htm>.

IV.6. Other Submission Requirements

Application Submission Address: Submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management—PA #04017 Supplemental, 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.

Your application will be evaluated against the following criteria:

(1) The extent to which the applicant describes its ability to collaborate with CDC and other awardees on projects with a quick turn around time. (20 Points)

(2) The extent to which the applicant demonstrates its ability to develop realistic project plans and time lines and follow through on their completion. (20 Points)

(3) The extent to which the applicant describes its ability to develop instruments to assess barriers to reporting, or other surveillance activities, and to collect information on barriers to these activities. (20 Points)

(4) The extent to which the applicant describes past, current, and proposed collaboration with: the relevant HIV/AIDS organizations and agencies within

the reporting area, CDC, and other states or national organizations involved in coordinating and assuring the quality, completeness, and accuracy of HIV/AIDS surveillance data and can demonstrate the understanding of the importance of following a standard protocol for data collection. (15 Points)

(5) The extent to which the applicant can maintain a secure environment to protect the security and confidentiality of data obtained in these evaluation activities. (15 Points)

(6) The extent to which proposed staffing, organizational structure, staff experience and background, and job descriptions and curricula vitae for both proposed and current staff indicate the ability to carry out the anticipated activities. (10 Points)

(7) The budget is reasonable, clearly justified, consistent with the demonstrated need and proposed activities, and likely to lead to success of the planned activities. (Reviewed, but not scored)

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office staff, 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.

An objective review panel will evaluate complete and responsive applications according to the evaluation criteria listed in the criteria section above.

V.3. Anticipated Announcement and Award Dates

September 1, 2004.

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-4 HIV/AIDS Confidentiality Provisions.
- AR-7 Executive Order 12372.
- AR-8 Public Health System Reporting Requirements.
- AR-9 Paperwork Reduction Act Requirements.
- AR-11 Healthy People 2010.
- AR-14 Accounting System Requirements.
- AR-16 Security Clearance Requirement.

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/ARs.htm>.

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 program technical assistance, contact: Ron Sanders, Program Consultant, National Center for HIV, STD and TB Prevention, Division of HIV AIDS Prevention, 1600 Clifton Road, NE Mail stop E-47, Atlanta, GA 30333, Telephone: 404-639-4678, E-mail: RLS5@cdc.gov.

For financial, grants management, or budget assistance, contact: Kang Lee, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2733, E-mail: kil8@cdc.gov.

Dated: June 28, 2004.

Alan Kotch,

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

[Program Announcement 05003]

Tuberculosis Elimination and Laboratory; Notice of Availability of Funds—Amendment

A notice announcing the availability of fiscal year (FY) 2004 funds for Tuberculosis Elimination and Laboratory was published in the **Federal Register** on May 27, 2004, Volume 69, Number 103, pages 30300-30312. The notice is amended as follows: On page 30300, Column 1, "Application Deadline", change deadline date to July 29, 2004. On page 30308, Column 3, "Application Deadline", change deadline date to July 29, 2004.

Dated: June 28, 2004.

Alan Kotch,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Nonvoting Members Representing Industry Interests on Public Advisory Panels or Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for nonvoting industry representatives to serve on certain device panels of the Medical Devices Advisory Committee in the Center for Devices and Radiological Health.

FDA has a special interest in ensuring that women, minority groups, individuals with physical disabilities, and small businesses are adequately represented on its advisory committees. Therefore, the agency encourages nominations for appropriately qualified candidates from these groups.

DATES: Industry organizations interested in participating in the selection of a nonvoting member to represent industry for vacancies listed in this notice must send a letter to FDA by August 2, 2004, stating their interest in one or more panels. Concurrently, nomination materials for prospective candidates

should be sent to FDA by August 2, 2004. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative.

ADDRESSES: All letters of interest and nominations should be sent to Kathleen L. Walker, Center for Devices and Radiological Health (HFZ-17), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1283, ext. 114, e-mail: KLW@CDRH.FDA.GOV.

FOR FURTHER INFORMATION CONTACT: Kathleen L. Walker, Center for Devices and Radiological Health (HFZ-17), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1283, ext. 114, e-mail: KLW@CDRH.FDA.GOV.

SUPPLEMENTARY INFORMATION: Section 520(f)(3) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360j(f)(3)), as amended by the Medical Device Amendments of 1976, provides that each medical device panel include one nonvoting member to represent the interests of the medical device manufacturing industry.

FDA is requesting nominations for nonvoting members representing industry interests for the vacancies listed below:

Medical Device Panels of the Medical Device Advisory Committee	Approximate Date Representative is Needed
Circulatory System Devices Panel	July 1, 2005
Ear, Nose, and Throat Devices Panel	Nov. 1, 2004
Immunology Devices Panel	Mar. 1, 2005
Medical Devices Dispute Resolution Panel	Oct. 1, 2004
Neurological Devices Panel	Dec. 1, 2004
Obstetrics and Gynecology Devices Panel	Feb 1, 2005
Orthopaedic and Rehabilitation Devices Panel	Sept. 1, 2004

I. Functions

The functions of the medical device panels are listed as follows: (1) Review and evaluate data on the safety and effectiveness of marketed and investigational devices and make recommendations for their regulation; (2) advise the Commissioner of Food