GA 30341–3724, Telephone: (770) 488–3056, Fax: (770) 488–4760, E-mail: *CDauer@cdc.gov.*

For financial, grants management, or budget assistance, contact: Angela Webb, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2784, E-mail: *aqw6@cdc.gov.*

VIII. Other Information

Technical Assistance Workshop

Technical assistance will be available for potential applicants during a workshop scheduled for April 26, 2004 in Atlanta, GA at the Atlanta Airport Executive Conference Center. The purpose of the workshop is to help potential applicants understand the scope and intent of the program announcement, Public Health Service funding policies, and application and review procedures. Participation in the workshop is not mandatory. Applicants who wish to attend the workshop will be responsible for their own travel and lodging expenses. Applicants who plan to attend the workshop must RSVP to Christine Dauer at e-mail *CDauer@cdc.gov* by no later than April 18, 2004.

Dated: March 26, 2004.

Edward Schultz,

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

[FR Doc. 04–7306 Filed 3–31–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Evaluation of the Use of Rapid HIV Testing in the United States

Announcement Type: New.
Funding Opportunity Number: 04138.

Catalog of Federal Domestic Assistance Number: 93.941.

Key Dates:
Letter of Intent Deadline: May 3, 2004.
Application Deadline: June 1, 2004.

I. Funding Opportunity Description

Authority: This program is authorized under section 317(k)(2) of the Public Health Service Act, 42 U.S.C. section 247b(k)(2), as amended.

Purpose: The purpose of the program is to evaluate how rapid tests for HIV are being implemented and used in clinical practice and identify potential opportunities to provide guidance to assist sites in making decisions on the appropriate use of these tests. Rapid HIV testing is a new and growing segment of laboratory testing and of HIV diagnosis in this country. These tests can be used in place of the more complex and time-consuming conventional enzyme immunoassay screening tests. Rapid tests can provide test results in a single patient visit, providing earlier opportunities for intervention and decreasing the percentage of HIV-infected people who fail to learn their status using the multi-visit algorithm. Several new rapid HIV tests have been approved by the United States Food and Drug Administration (FDA) during the past year (Reveal ™ Rapid HIV–1 Antibody Test, OraQuick® Rapid HIV–1 Antibody Test, and Uni-gold ™ Recombigen® HIV) and others are in the FDA pipeline. The OraQuick test has been waived from the bulk of the regulatory requirements of the Clinical Laboratory Improvement Amendments (CLIA) and is being implemented in sites that have not typically performed testing before, such as outreach clinics, community-based organizations (CBO), and mobile units. The other two tests are currently categorized as moderate complexity under CLIA, thus requiring users to meet CLIA requirements for non-waived testing, at minimum.

In an effort to assure safe and effective use of these devices, the FDA specified restrictions for their sale and distribution. These restrictions are as follows (from the manufacturer's package insert):

1. ''Sale of the test is restricted to clinical laboratories that have an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met and where there is assurance that operators will receive and use the instructional materials.

2. The test is approved for use only by an agent of a clinical laboratory;

3. Test subjects must receive the ''Subject Information'' leaflet prior to specimen collection, and appropriate information when test results are provided;

4. The test is not approved for use to screen donors of blood, plasma, cells or tissues.''

Since HIV testing is an integral part of HIV diagnosis and surveillance, Centers for Disease Control and Prevention (CDC) also has an interest in ensuring patient safety and the appropriate use of rapid HIV testing. This project will be helpful in determining whether sites using these tests are following the FDA sales restrictions and meeting CLIA requirements, as well as whether there is a need for additional guidance to improve test utilization and testing quality.

This program addresses the ''Healthy People 2010'' focus area(s) of (1) Reducing the burden of HIV infection and the rate of increase of new infections; and (2) Access to Quality Health Services.

Measurable outcomes of the program will be in alignment with the following performance goal for the Public Health Practice Program Office (PHPPO): Assure the public health infrastructure at the Federal, State and local levels has the capacity to provide essential public health services to the citizens of the nation to respond to bioterrorism, other infectious disease outbreaks, and other public health threats and emergencies and prepare frontline state and local health departments and laboratories to respond to current and emerging public health threats.

Activities:

Awardee activities for this program are as follows:

- Provide leadership in developing a program to determine the scope of rapid HIV test utilization, including the number of sites where rapid HIV tests are offered, the specific tests used, testing volume, purpose for testing, patient populations, and other characteristics related to the sites where rapid HIV testing is being implemented and used.
- Evaluate how these tests are integrated into the health delivery system, for example methods used for specimen collection and handling, results reporting, confirmation of preliminary positive results, and use of results by practitioners.
- Assess the practices used to assure quality (*e.g.*, quality control and quality assurance) and testing personnel training and competency.
- Catalog problem sites that have been identified and reported using these tests, such as follow-up on preliminary positives, false positive or negative results, testing delivery, costs of testing, provision of training to testing personnel.
- Evaluate the financial costs associated with using rapid and conventional (enzyme immunoassay) HIV screening tests in various types of practice settings.
- Recommend specific interventions, such as practice guidelines or training that could improve the utilization and quality of testing using rapid tests.

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:

- Assist the Awardee in identifying sites using rapid HIV tests.
- Provide background information on accepted practices and guidelines for HIV testing.
- Provide technical assistance with the development of data collection instruments.
- Identify subject matter experts on HIV testing and promote collaboration.
- Work with the Awardee to identify potential systematic interventions to promote quality improvement.
- If requested, provide a Health Economist to assist with economic evaluations.
- Collaborate in analyzing the data and information collected and in preparing written summaries.
- Assist in the preparation of manuscripts for peer-reviewed publications.

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: $ 200,000.

Approximate Number of Awards: one.

Approximate Average Award: $ 200,000 (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: Three years.

Throughout the project period, CDC's commitment to the 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 public and private nonprofit organizations and by governments and their agencies, such as:

- Public nonprofit organizations.
- Private nonprofit organizations.
- Universities.
- Colleges.
- Research institutions.
- Community-based organizations.
- Faith-based organizations.
- Federally recognized Indian tribal governments.
- Indian tribes.
- Indian tribal organizations.
- State and local governments or their Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau).
- Political subdivisions of States (in consultation with States).

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.

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. Your application should indicate the extent of your experience in working with clinical laboratories.

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 5161. Application forms and instructions are available on the CDC web site, at the following Internet address: *http://www.cdc.gov/od/pgo/forminfo.htm.*

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

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

- Maximum number of pages: Five.
- 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.
- Written in plain language, avoid jargon.

Your LOI must contain the following information:

- Goals and objectives.
- Methods and Technical Approach.
- Project Management and Staffing.
- Budget—total funds to be requested.

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

- Maximum number of pages: 25. If your narrative exceeds the page limit, only the first pages, which are within the page limit, will be reviewed.
- Font size: 12 point unreduced.
- 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.
- Double spaced.

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

- Purpose and Need.
- Goals and Objectives.
- Methods and Technical Approach.
- Project Management and Staffing.
- Measures of effectiveness to demonstrate accomplishment of program activities.
- Timeline.
- Evaluation Plan.
- Required Resources with budget and justification.
- Performance Measures.

Note: the budget and performance measures sections will not count toward the page limitation.

Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit. This additional information includes:

- Curriculum Vitaes, Resumes, and Organizational Charts.
- Letters of Support.
- References.

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/pubcommt.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

LOI Deadline Date: May 3, 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 1, 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

Executive Order 12372 does apply to this program.

IV.5. Funding Restrictions

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

- None

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.

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

LOI Submission Address: Submit your LOI by express mail, delivery service, fax, or e-mail to: Tracy L. Carter, M.P.H., Laboratory Program Specialist, Centers for Disease Control and Prevention, PHPPO/DLS Mailstop G–25, 4770 Buford Highway, Atlanta, GA 30341, Telephone: 770–488–2523, Fax: 770–488–8282, E-mail: *tsc1@cdc.gov.*

Application Submission Address: Submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management—PA# 04138, 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. Methods and Technical Approach (30 points).

a. Does the applicant clearly and succinctly describe the steps to be taken in the planning and implementation of the proposed cooperative agreement?

b. Are the methods to be used to carry out the responsibilities of the proposed cooperative agreement feasible and explained in sufficient detail?

2. Project Management and Staffing (30 points).

a. Does the applicant describe a project management and staffing plan, and demonstrate sufficient knowledge, expertise, and other resources required to perform the responsibilities in this project?

b. Does the applicant describe the staff qualifications and time allocations of key personnel to be assigned to this project, facilities and equipment, and other resources available for performance of this project?

3. Goals and Objectives (20 points).

a. Does the applicant clearly describe an understanding of the objectives of this project, the relevance of the proposal to the stated objectives, and any unique characteristics of populations to be studied?

b. Are the goals and objectives measurable, specific, and achievable?

4. Evaluation Plan and Timeline (20 points).

Does the applicant describe the schedule for accomplishing the activities to be carried out in this project and methods for evaluating the accomplishments?

5. Proposed Budget (reviewed but not scored).

Is the proposed budget reasonable, clearly justified, and consistent with the intended use of funds?

6. Performance Goals (reviewed but not scored).

Is the application consistent with the Government Performance and Results Act of 1993?

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by the PHPPO. 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 criteria

listed in the ''V.1. Criteria'' section above.

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–10 Smoke-Free Workplace Requirements.
- AR–11 Healthy People 2010.
- AR–12 Lobbying Restrictions.
- AR–15 Proof of Non-Profit Status.
- Executive Order 12372 does apply to this announcement.

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. Budget.

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.

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: James V. Lange, Ph.D., Project Officer, Centers for Disease Control and Prevention, PHPPO/DLS MS G–23, 4770 Buford Hwy, Atlanta, GA 30341–3717, Telephone: 770–488–8096, E-mail: *JLange@cdc.gov.*

For financial, grants management, or budget assistance, contact: Sharon Robertson, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2748, E-mail: *sqr2@cdc.gov.*

Dated: March 26, 2004.

Edward Schultz,

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

[FR Doc. 04–7325 Filed 3–31–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Incidence of Needlestick and Sharps Injuries and Medical Safety Device Availability/Use Among Non-Hospital Health Care Workers, Request for Applications OH–04–003

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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Incidence of Needlestick and Sharps Injuries and Medical Safety Device Availability/Use Among Non-Hospital Health Care Workers, Request for Applications OH–04–003.

Times and Dates: 8 a.m.–8:30 a.m., May 4, 2004 (Open). 8:30 a.m.–5 p.m., May 4, 2003 (Closed).

Place: Embassy Suites Hotels, 1900 Diagonal Road, Alexandria, VA 22314, Telephone (703) 684–5900.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Request for Applications OH–04–003.

For Further Information Contact: Price Connor, Ph.D., Scientific Review Administrator, Office of Extramural Programs, National Institute for Occupational Safety and Health, CDC, 1600 Clifton Road NE., Atlanta, GA 30329, MS–E74, Telephone (404) 498–2511.

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 CDC and the Agency for Toxic Substances and Disease Registry.

Dated: February 27, 2004.

Alvin Hall,

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

[FR Doc. 04–7310 Filed 3–31–04; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 69296, October 20, 1980, as amended most recently at 69 FR 15344–15345, dated March 25, 2004) is amended to revise the mission statement of the Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion.

Section C–B, Organization and Functions, is hereby amended as follows: Add the following items to the mission statement for the *Office of the Director (CL81):*

(8) Develops health communication campaigns at the national and State levels; (9) guides the production and distribution of print, broadcast, and electronic materials, for use in programs at the national and State