17163, first column, under ''Purpose'' change to, ''The purpose of the program is to evaluate how to rapid tests for HIV are being implemented and used across the United States in clinical practice, and identify potential opportunities to provide guidance to assist providers in making decisions on the appropriate use of these tests.''

Page 17163, second column under ''Purpose'' last paragraph, add ''Thus, rapid tests for HIV may be used in many different types of venues including physician office laboratories, clinics, hospital emergency rooms other departments, public health departments and non-clinical testing sites.''

Page 17163, third column, under ''Activities'' first bullet, change to, ''Provide leadership in developing a program to determine the national scope of rapid HIV test utilization, with a focus on utilization in the private sector, including the number and type of sites where rapid HIV tests are offered, the specific tests used, testing volume, purpose for testing, characteristics of patient populations tested, and other characteristics related to the sites where rapid HIV testing is being implement and used.''

Page 17163, third column, under ''Activities'' second bullet, change to, ''Evaluate how these tests are integrated into the health care delivery system, for example methods used for specimen collection and handling, results reporting, confirmation of preliminary positive rapid test results, and use of results by practitioners.''

Page 17163, third column, under ''Activities'' third bullet, change to, ''Catalog problems that sites have identified and reported using these tests, such as lack of follow-up on preliminary positives, false positive, or negative results, testing delivery issues, costs of testing, and difficulties with provision of training to testing personnel.''

Page 17164, III.1. Eligible Applicants, delete community-based organizations.

Dated: May 18, 2004.

William P. Nichols,

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

[FR Doc. 04–11633 Filed 5–21–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Testing for Primary HIV Infection in Seronegative Patients

Announcement Type: New.

Funding Opportunity Number: 04119.

Catalog of Federal Domestic Assistance Number: 93.943.

Key Dates:

Letter of Intent Deadline: June 23, 2004.

Application Deadline: July 23, 2004.

Summary: The technology for human immunodeficiency virus (HIV) screening tests has progressively improved over the first generation HIV–1 enzyme-linked immunoassay (EIA) tests licensed in 1985. Newer testing technology can identify infected individuals earlier in the course of their infection. Identifying individuals earlier in the course of infection holds the potential for reducing transmission, increasing diagnosis of infected persons, and improving health outcomes for infected individuals. Because of the high viral load during acute infection, the risk of HIV transmission through sexual and needle contact may be particularly high during this time period.

In both domestic (US) and international settings, methods have been piloted to demonstrate detection of HIV infection early in the course of infection. In these approaches, individuals were tested with standard antibody tests. Individual specimens from patients testing negative on initial screening tests were grouped into pools, which were tested by ribonucleic acid (RNA) amplification. Such pooling strategies have been demonstrated to identify persons with early HIV infection, or primary HIV infection (PHI), before they would have otherwise been identified with early generation, less sensitive EIAs.

Based on experiences reported in the medical literature, RNA screening for PHI appears to be feasible in a setting with moderate HIV prevalence, without anonymous testing, and with sufficient staff to contact those identified with PHI who do not return for their results. However, the utility and costs of screening for acute infection among other populations needs study. Issues include: (1) Whether testing for acute infection can be accomplished in real-time; (2) whether patients return for their test results, particularly those with non-reactive rapid HIV tests; (3) whether patients with PHI who do not return for test results can be contacted for followup; (4) whether identifying PHI increases the yield from partner contact and referral services (PCRS); and (5) whether the utility of the strategy differs in the context of anonymous testing.

Furthermore, pooled RNA testing must be compared not only to insensitive EIAs, but also to other methods that may identify HIV infection earlier than the insensitive EIAs, such as p24 antigen testing (positive approximately 5 days after RNA); third generation EIAs (positive approximately 10 days after RNA); or OraQuick testing (similar to third-generation EIAs). Laboratory results from multiple testing technologies can also be compared to determine potential laboratory criteria for identifying certain specimens which would warrant further testing for PHI (*e.g.*, supplemental testing if a single EIA is positive or if the Western blot is negative or indeterminate, or an EIA is in the ''grey zone'' as defined by signal/cutoff ratios less than 1.0, but greater than a specified threshold). The marginal utility of pooled RNA screening needs to be compared to these other methods of identifying earlier HIV infection.

Identifying persons with acute HIV infection can also serve as the basis for collecting longitudinal follow-up specimens from recently infected individuals, essential for developing, validating, and comparing potential HIV incidence assays.

In this program, specimens from all patients presenting for voluntary HIV testing will be tested with standard antibody tests (EIA or rapid test). Specimens that test antibody-negative on screening tests and those that test antibody-positive on screening tests but negative or indeterminate by confirmatory Western blot or immunofluorescence will be tested with multiple other testing technologies, including pooled nucleic acid testing, p24 antigen testing, a third generation EIA (if not already performed), and (for some specimens) OraQuick and Western blot (if not previously performed). (Please note that patients testing negative with tests performed on finger stick or oral specimens will only be able to participate in this project if venous blood samples are drawn.) Nucleic acid testing and p24 antigen testing must be performed in real-time so that results would be available as soon as usual confirmatory test results (typically two weeks). Demographic data, testing history, and information about self-perceived risk, recent exposures, and PHI symptoms would be collected on all patients who had preliminary evidence

of PHI, but were antibody negative by standard screening. RNA-positive, antibody-negative patients would be followed with antibody tests to confirm seroconversion. All persons with preliminary evidence of PHI would be offered enrollment in a follow-up study to collect additional information by interview and to collect longitudinal (seroconversion and post-seroconversion) specimens in larger quantities.

This activity will be funded in 2 parts. Part 1 applicants will propose collaboration with testing sites to identify and secure appropriate specimens from a variety of setting types with various prevalences within their jurisdiction; they will conduct client follow-up activities and assimilate study data. Part 2 applicants will be laboratories that propose to perform laboratory testing for specimens collected by Part 1 sites and refine pooling strategies for screening antibody negative specimens by nucleic acid testing.

I. Funding Opportunity Description

Authority: This program is authorized under the Public Health Service Act sections 301 and 317 (42 U.S.C. 241 and 247b), as amended.

Purpose: The purpose of the program is to determine the feasibility, effectiveness, and costs of screening for acute infection among seronegative individuals tested for HIV. This program addresses the ''Healthy People 2010'' focus area of HIV.

Measurable outcomes of the program will be in alignment with the following performance goal 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. In addition, this program addresses the Division of HIV/AIDS Prevention priorities: Develop new methods for diagnosing HIV infection, and institute integrated surveillance with emphasis on incidence, behavioral surveillance, and evaluation.

Research Objectives

1. To compare different tests and testing algorithms that could be used to detect acute infection (nucleic acid testing, p24 antigen testing, third-generation EIA, OraQuick, alterations in current diagnostic algorithm) where possible with regard to feasibility, sensitivity, specificity, predictive value, and cost.

2. To determine optimal settings/venues and/or individuals to be screened with a test sensitive for PHI.

3. To collect a panel of longitudinal specimens from a cohort of recently infected individuals.

4. To obtain preliminary information on alternative pooling strategies for nucleic acid testing to optimize cost and predictive value of test results.

Activities

Awardee activities for this program are as follows:

Part 1:

• Develop a protocol in collaboration with other funded sites (including the laboratory funded through part 2 of this announcement) and the CDC. The protocol must be reviewed by the CDC and local IRBs. (Project timeline and budget must allow for sufficient time—approximately 6 months—for the development of the protocol and determination of human subjects status and consent procedures.)

• Identify approximately 50,000 seronegative and indeterminate specimens through customary HIV testing procedures from a variety of setting types with various prevalence within their jurisdiction. Prepare and ship specimens according to applicable regulations within a mutually agreed upon time period to the laboratory funded through Part 2 of this announcement for additional testing. (Please note that patients testing negative with tests performed on finger stick or oral specimens will only be able to participate in this project if venous blood samples are drawn.)

• Collect and maintain database of information linked to initial and follow-up tests, including data routinely collected by the Counseling and Testing System on characteristics of the patient, the testing site, and the HIV test(s) performed. Obtain additional information from the routine HIV diagnostic tests performed, including EIA or rapid test kit manufacturer, EIA signal to cut-off ratio, and, if performed, Western blot manufacturer and banding patterns; maintain this information in an electronic database.

• Work with the CDC to develop and implement post-test counseling messages that incorporate the findings of additional tests performed for identification of PHI as part of this announcement.

• Contact clients who test positive for PHI and who do not return as scheduled 2 weeks following initial testing. Document time and effort required for follow-up activities.

• To patients who test positive for PHI, offer enrollment in a research study to obtain additional data by interview and to collect longitudinal specimens:

◦ Obtain human subjects clearance from CDC and local IRB and consent for participation. (This may require a second protocol.)

◦ Conduct interview to collect demographic data, testing history, and information about self-perceived risk, recent exposures, and PHI symptoms.

◦ Collect follow-up specimens at 2-week intervals until the initial positive test for PHI can be determined to be a true positive or a false positive test result according to the combination of tests performed at the original testing site and at the funded laboratory. These samples should be tested by the laboratory routinely used by the original testing site and according to routine HIV testing protocols. Specimens should also be prepared and sent to the laboratory funded in Part 2 for further testing for PHI.

◦ Obtain a total of 10 longitudinal samples (large volume) on all patients testing positive for PHI at appropriate intervals over a 9–12 month period (as permitted by the project period), with at least 6 of these samples obtained during the first 6 months of follow-up. Utilize DIS services as necessary. Prepare and ship specimens to the funded testing laboratory.

• Participate in periodic conference calls and grantee meetings with other funded sites and the CDC.

• Disseminate findings jointly with CDC and other participating sites.

Part 2:

• Participate with CDC and the health departments funded through Part 1 of this application in the development of testing protocols for the identification of PHI among approximately 100,000 specimens supplied by the Part 1 grantees. Identification of PHI should include pooled, automated HIV nucleic acid, p24 antigen, and 3rd generation EIA testing (if not performed at field site) on all specimens submitted. Other tests, including OraQuick and Western blot testing, should be performed on up to 150 specimens with preliminary evidence of PHI that were not previously tested with these tests in order to evaluate potential laboratory criteria for identification of PHI.

• Secure IRB review and approval by the local IRB. (Project timeline and budget must allow for sufficient time—approximately 6 months—for the development of the protocol and determination of human subjects status.)

• Conduct pooled, automated nucleic acid testing on initial seronegative specimens in real time. All test results must be transmitted to the designated

contact at testing facility within 7 calendar days of receipt of specimens.

• Individually test follow-up specimens of patients who tested positive for PHI at baseline with HIV nucleic acid and p24 antigen tests. Follow-up nucleic acid and p24 antigen testing will be conducted at 2-week intervals until the initial positive test for PHI can be determined to be a true positive or a false positive according to the combination of tests performed at the original testing site and at the funded laboratory.

• Aliquot and store longitudinal specimens from patients who test positive for PHI at baseline (approximately 10 samples per patient collected periodically over a 9–12 month period, see Part I above). Note that no testing will be performed upon longitudinal samples collected after a patient who initially tested positive for PHI has been determined to be infected or not.

• Maintain a database containing all test results and specimen numbers.

• Store frozen samples at −70 °C until the end of the project. Ship all samples to CDC-designated laboratory or permanent storage site.

• In the second year of the project, conduct additional automated, pooled nucleic acid testing (not in real time) to determine alternative pooling strategies to optimize cost and predictive value of pooled, RNA screening.

• Obtain human subjects clearance from local IRB and consent for participation, if required.

• Participate in periodic conference calls and grantee meetings with other funded sites and the CDC.

• Disseminate findings jointly with CDC and other participating sites.

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 in the development and review of the required protocols.

• Provide guidance and assistance in the development of forms and data collection instruments as well as data management systems and procedures.

• Work with Part I grantees to develop post-test counseling messages that incorporate the findings of the additional tests performed as part of this announcement for the identification of PHI.

• Facilitate conference calls, grantee meetings, and site visits.

• Assist in the analysis and dissemination of findings.

II. Award Information

Type of Award: Cooperative Agreement.

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

Fiscal Year Funds: 2004, 2005.

Approximate Total Funding: $2,000,000/2 years.

Approximate Number of Awards: 3 awards: Part 1: 2 awards; Part 2: 1 award.

Approximate Average Award: Part 1: $500,000; Part 2: $1,000,000 (This amount is to be divided over the two-year project period, and includes both direct and indirect costs. Applications should include a budget indicating separately how the funds will be used in Year 1 and Year 2. The award need not be equal for the 2 funding years.)

Floor of Award Range: None.

Ceiling of Award Range: None.

Anticipated Award Date: September 1, 2004.

Budget Period Length: 12 months.

Project Period Length: 2 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 public and private nonprofit organizations and by governments and their agencies, such as:

• Universities.
• Colleges.
• Research institutions.
• Hospitals.
• Community-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

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.

Applicants for Part 1 must demonstrate their ability to provide, in a 12 month period, samples from 50,000 seronegative individuals (the required sample size) tested by serologic methods as part of the CDC-funded Counseling and Testing System in the proposed jurisdiction. In addition, areas must demonstrate that the seropositivity rate of HIV tests in the CDC-funded Counseling and Testing System which will be the source of the specimens is at least 1.5 percent. A sufficiently high level of HIV morbidity is required of the participating sites in order to evaluate the feasibility of this activity at higher morbidity areas and in order to complete this research within the required timeframe.

Applicants for Part 2 must demonstrate experience using automated methods for conducting pooled nucleic acid testing, the ability to return results within 7 calendar days of specimen receipt, and the ability to process 8,000–10,000 specimens per month for the required testing. It is critical that the grantee be able to conduct the pooled nucleic acid testing with automated methods, because nucleic acid testing is vulnerable to contamination and false positive results. Automated methods minimize this problem. Also, because it is expected that results must be available before the client returns to retrieve test results at the testing point, it is required that the grantee be able to accommodate the expected specimen volume and be able to complete test results in a timely manner.

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 racial and ethnic groups underrepresented in the field 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://grants.nih.gov/grants/funding/phs398/phs398.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:

- Maximum number of pages: Three.
- Font size: 12-point unreduced.
- Single 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:

- Descriptive title of the proposed research.
- Evidence, as listed under ''III.3. Eligibility Information—Other,'' that:

○ For Part 1: The applicant can provide the required sample size of 50,000 seronegative individuals with an HIV seropositivity rate of at least 1.5 percent.

○ For Part 2: The applicant has experience using automated methods for conducting pooled nucleic acid testing, the ability to return results within 7 calendar days of specimen receipt, and the ability to process 8,000 to 10,000 specimens per month.

- 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 project period.

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. 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 *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.*

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 23, 2004.

CDC requests that you send an 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: July 23, 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 not 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.

IV.6. Other Submission Requirements

LOI Submission Address: Submit your LOI by express mail, delivery service, fax, or e-mail to: Noreen Qualls, Dr., P.H., Scientific Review Administrator, CDC, National Center for HIV, STD, and TB Prevention, Office of the Associate Director for Science, 1600 Clifton Road, NE., Mailstop E–07, Atlanta, GA 30333, telephone Number: (404) 639–8006, fax: (404) 639–8600, e-mail address: *nqualls@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# 04119, 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 criteria are as follows:

Part 1:

1. *Capacity (40 points):* Does the applicant have the appropriate facilities and staff to conduct this research? Is adequate and objective information provided to demonstrate the availability of sufficient numbers of clients tested and sufficient seropositivity rates? Is the primary investigator well qualified, by education and experience, to lead the project team, hire and train appropriate staff, and provide scientific oversight? Does the applicant currently demonstrate effort, willingness, and success in contacting HIV-infecting clients tested confidentially who do not return for their test results?

2. *Methods (30 points):* Are the proposed methods feasible? Will they accomplish program goals? Does the applicant address required follow-up activities and methods to complete them in a timely manner? Does the applicant address changes to their HIV testing program required to return all results within 2 weeks, to schedule clients to return and to find clients with evidence of PHI who do not return for scheduled post test counseling? Does the applicant provide a reasonable timeline for the completion of the awardee activities?

3. *Objectives (30 points):* Are the objectives reasonable, time-phased and measurable? Does the applicant provide reasonable methods to evaluate their progress toward the timely accomplishment of objectives?

4. Does the application adequately address the requirements of 45 CFR part 46 for the protection of human subjects? (Not 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.)

5. Does the applicant adequately address the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes:

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

b. The proposed justification when representation is limited or absent.

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

d. 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.

6. *Budget (not scored):* Is the budget reasonable for the proposed activities?

Part 2:

1. *Capacity (50 points):* Does the applicant have the appropriate facilities and staff to conduct this research including equipment required to conduct automated sample processing and testing and the ability to hire and train appropriate staff? Does the applicant demonstrate their ability to process the required number of specimens within the required timeframe? Does the applicant have specific experience conducting the tests required for this activity and have the required knowledge to provide scientific oversight for the conduct of the research?

2. *Methods (25 points):* Are the proposed methods feasible? Will they accomplish program goals? Are the proposed methods scientifically sound and do they demonstrate understanding of the problem to be evaluated? Is a specific proposed pooling strategy articulated and justified? Does the applicant provide a reasonable timeline for the completion of awardee activities?

3. *Objectives (25 points):* Are the objectives reasonable, time-phased and measurable? Does the applicant provide reasonable methods to evaluate their progress toward the timely accomplishment of objectives?

4. *Budget (not scored):* Is the budget reasonable for the proposed activities?

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 National Center for HIV/STD/TB Prevention, Division of HIV/AIDS Prevention. 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.

Applicants may apply for Parts 1 or 2 or both. A separate application should be submitted for each Part proposed. Each Part will be evaluated independently by the objective review panel.

In addition, the following factors may affect the funding decision:

Preference will be given to applicants for Part 1 that have larger numbers of clients tested through publicly funded HIV testing programs and higher historical HIV seropositivity rates. For Part 2, laboratories that have demonstrated experience in using automated methods for conducting pooled nucleic acid screening studies will be given preference.

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–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–5—HIV Program Review Panel Requirements
- AR–6—Patient Care
- AR–8—Public Health System Reporting Requirements
- AR–10—Smoke-Free Workplace Requirements
- AR–11—Healthy People 2010
- AR–12—Lobbying Restrictions
- AR–14—Accounting System Requirements
- AR–15—Proof of Non-Profit Status
- AR–21—Small, Minority, and Women-Owned Business
- AR–22—Research Integrity
- AR–23—States and Faith-Based Organizations
- 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/ARs.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 first 12 month 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 Specialist listed in the ''Agency Contacts'' section of this announcement.

VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section—PA #04119, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, telephone: 770–488–2700.

For scientific/research issues, contact: Sheryl Lyss, MD, Extramural Project Officer, CDC, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, MS E–46, Atlanta, Georgia 30333, telephone: 404–639–2093, e-mail: *SLyss@cdc.gov.*

For questions about peer review, contact: Noreen Qualls, Dr.P.H., Scientific Review Administrator, CDC, National Center for HIV, STD, and TB Prevention, Office of the Associate Director for Science, 1600 Clifton Road, NE., Mailstop E–07, Atlanta, GA 30333, telephone number: 404–639–8006, fax: 404–639–8600, e-mail address: *nqualls@cdc.gov.*

For financial, grants management, or budget assistance, contact: Brenda D. 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.*

Dated: May 18, 2004.

William P. Nichols,

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

[FR Doc. 04–11643 Filed 5–21–04; 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 (SEP): Participatory Research on Community Interventions to Increase the Utilization of Effective Cancer Preventive and Treatment Services, Program Announcement Number 04087

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): Participatory Research on Community Interventions to Increase the Utilization of Effective Cancer Preventive and Treatment Services, Program Announcement Number 04087.

Times and Dates: 8:30 a.m.–9 a.m., June 17, 2004 (Open); 9 a.m.–5 p.m., June 17, 2004 (Closed).

Place: Sheraton Midtown Atlanta Hotel at Colony Square, 188 14th Street at Peachtree, Atlanta, GA 30361, Telephone 404.892.6000.

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 Participatory Research on Community Interventions to Increase the Utilization of Effective Cancer Preventive and Treatment Services, Program Announcement Number 04087.

Contact Person for More Information: Elizabeth L. Skillen, PhD, Scientific Review Administrator, Public Health Practice Program Office, Centers for Disease Control, 4770 Buford Highway, NE., MS–K38, Atlanta, GA 30341, Telephone 770.488.2592.

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: May 18, 2004.

Alvin Hall,

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

[FR Doc. 04–11642 Filed 5–21–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Health and Nutrition Examination Survey (NHANES) Stored Biologic Specimens: Guidelines for Proposals To Use Samples and Proposed Cost Schedule

ACTION: Notice and request for comments.

SUMMARY: The National Health and Nutrition Examination Survey (NHANES) is a program of periodic surveys conducted by the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC). Examination surveys, conducted since 1960 by NCHS have provided national estimates of health and nutritional status of the United States civilian non-institutionalized population. To add to the large amount of information collected for the purpose of describing the health of the population in the most recent survey, serum and urine were collected and stored for future research projects.