

surveillance registries in ten states (including metropolitan Atlanta). Control infants are randomly selected from birth certificates or birth hospital records. Mothers of case and control infants are interviewed using a computer-assisted telephone interview.

Parents are asked to collect cheek cells from themselves and their infants for DNA testing. Information gathered from both the interviews and the DNA specimens will be used to study independent genetic and environmental factors as well as gene-environment

interactions for a broad range of carefully classified birth defects.

This request is submitted to obtain OMB clearance for three additional years. There is no cost to respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Type of burden	Number of respondents	Frequency of response	Average burden/response (in hours)	Annual burden (in hours)
NBDPS case/control interview	400	1	1	400
Biologic specimen collection	1,200	1	10/60	200
Total				600

Dated: June 21, 2005.

Joan F. Karr,

Acting Reports Clearance Officer, 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

Augmenting Laboratory Outcomes in HIV Assessment (ALOHA)

Announcement Type: Supplemental (04017).

Funding Opportunity Number: AA120.

Catalog of Federal Domestic Assistance Number: 93.944.

Key Dates:

Application Deadline: August 5, 2005.

I. Funding Opportunity Description

Authority: This program is authorized under sections 317(k)(2) and 318b of the Public Health Service Act (42 U.S.C. Sections 247b(k)(2) and 247c), as amended.

Purpose: CD4+ T-lymphocyte (CD4) and viral load (VL) tests are used to stage disease and, when opportunistic infections (OI) are present, to guide therapeutic decisions. Because CD4 and VL testing should be performed throughout the course of HIV disease, reporting of these lab tests has been used as a marker for whether HIV-infected persons are receiving healthcare. Augmenting Laboratory Outcomes in HIV Assessment (ALOHA) will augment routine HIV/AIDS surveillance data collection for the purpose of assessing the completeness and validity of laboratory (i.e., CD4 count and VL) and OI information. This will be accomplished by the following:

1. Assessing the stage of HIV disease at initial diagnosis among a cohort of newly diagnosed HIV-infected persons, over the age of 13, using routine and augmented laboratory and clinical information.

2. Better characterizing CD4 count and VL, and correlating this laboratory information with available data on OIs. If, after complete enumeration of lab and OI information, OIs add little to nothing to help stage HIV disease, then future surveillance practices may be streamlined.

3. Identifying surveillance practices (e.g., laboratory reporting requirements, electronic lab reporting, and program policies or organization) that affect the completeness and accuracy of surveillance laboratory data.

4. Assessing lab reporting as a marker for access and adherence to care following HIV diagnosis.

5. Identifying correlates for not being in care, as indicated by the presence or absence of laboratory reports.

6. Systematically evaluating the availability of clinical and laboratory data on the prevalence of common comorbid conditions (e.g., hepatitis B, hepatitis C, tuberculosis, and cancer) that are associated with risk factors for HIV infection and influence the clinical course of HIV disease. Data on these conditions will be compared to levels of CD4 and VL to assess the effects of comorbid conditions on levels of immunosuppression at the time of HIV diagnosis.

A variety of HIV/AIDS reporting areas with different surveillance practices and procedures will be sought for ALOHA. This project will attempt to include an area that currently warehouses lab results, specifically CD4, in a separate lab results database, and does not report this information to the national HIV/AIDS surveillance system. The completeness of reporting for CD4 results will be assessed to determine if

these reports truly indicate access to care. This proportion has not been reliably estimated by national surveillance data. Some reporting areas report a high proportion (greater than 75 percent) of newly diagnosed cases with CD4 and/or VL results within 12 months of diagnosis.

The factors that contribute to the ability of lower morbidity areas to report completely has not been fully examined, but may be due to their ability to conduct active case finding and medical record abstraction. These practices may have national surveillance policy implications. Since lab reporting data is critical to the expectations of the Morbidity Monitoring Project (MMP), an area will be sought to provide validation of lab reporting as a marker for receiving health care, and to collect information about reasons for no lab testing and the inability to link a person to care.

Lastly, ALOHA will include at least one area that will match its HIV/AIDS case registry to infectious disease databases to identify, apart from medical record review, OIs that occurred six months before and after HIV diagnosis. Examples of these databases include the National Electronic Disease Surveillance System (NEDSS); cancer, hepatitis or tuberculosis registries; or prescription medication databases (e.g., Medicaid or AIDS Drug Assistance Program).

As part of this project, participating areas will conduct their usual surveillance activities for information on CD4 and VL lab results and OIs. These activities include active case surveillance, medical record review and data extraction for newly diagnosed cases (over the age of 13). When no lab result is received by the HIV/AIDS surveillance program, ongoing active case follow-up will be needed to determine case disposition and record specific categorical information, such as

the source of CD4 and OI results and, alternatively, reasons for no CD4 testing (e.g., lost to follow-up, did not return for HIV test results, etc). Surveillance information will be entered into the national HIV/AIDS surveillance system and uploaded monthly to CDC; ancillary data will be sent to CDC without personal identifiers.

Annual reported cases to CDC will be used as an eligibility criterion. Eligible areas are restricted to those submitting HIV data to CDC because this project is an evaluation of data included in the national HIV/AIDS reporting system, which includes only those surveillance data collected in confidential name-based systems, and because HIV (not AIDS) cases are currently more likely to be missing CD4 information. Because a limited number of sites (approximately five to seven sites) will be funded, racial and ethnic diversity of cases among each of the participating sites will be required to ensure a measure of representation of national data.

This program addresses the "Health People 2010" focus area of HIV. 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. Accurately linking incoming lab results to all HIV and AIDS cases or an agreed upon sample, over the age of 13, in the local HIV/AIDS registry, and transmitting that information to the national HIV/AIDS surveillance system for the duration of ALOHA.

2. Conducting active surveillance and medical record abstraction, following a protocol developed in collaboration with CDC, of all cases or the agreed upon sampled cases. A minimum of 500 diagnosed HIV/AIDS cases annually, of which 300 cases were initially diagnosed with HIV (not AIDS), will be prospectively followed for a period of time (to be determined through collaborative development of a protocol). This protocol will include the collection of CD4 and VL results, OIs, and ancillary information on data collection forms.

3. Conducting active, ongoing follow-up of cases without any CD4 or VL results following diagnosis. Identifiable reasons for lack of linkage or failure to access health care will be sought from medical records and recorded on project data collection forms. No interview of

cases will occur as part of this follow-up.

4. Documenting methods of linking lab results to registry cases, including methods of reconciling possible matches.

5. Participating in a conference call (within one month of the award) with CDC and other awardees to begin to develop a project plan and 16-month timeline.

6. Collaborating with CDC staff members to develop data collection forms for ancillary information about co-morbidities and barriers to reporting lab results, as well as whether samples for CD4/VL testing are drawn at post test counseling, possible reasons for no CD4/VL testing, and the inability to link newly diagnosed persons to care.

7. Meeting with CDC. The area project collaborator will travel to Atlanta for one meeting and participate in monthly conference calls related to planning, coordinating, and conducting this project.

8. Transferring collected data to CDC monthly.

CDC Activities for this program are as follows:

1. Conduct a conference call, within one month of award, to develop a project plan and time line for the collection and reporting of data to CDC.

2. Support and assist training needed to conduct project including monthly conference calls with awardees.

3. Collaborate with awardees to develop strategies for enhancing surveillance activities that address barriers to reporting of opportunistic infections, CD4, and viral load test results.

4. Receive data monthly, assess data quality, and store data in secure environment.

5. Provide quarterly analytic progress reports to participating areas.

6. Analyze data and write reports in collaboration with awardees.

II. Award Information

Type of Award: Cooperative agreement.

Fiscal Year Funds: 2005.

Approximate Total Funding: \$500,000 (This amount is an estimate, and is subject to availability of funds.)

Approximate Number of Awards: Five to Seven.

Approximate Average Award: \$100,000 (This amount is for the first 12-month budget period, and includes both direct and indirect costs.)

Floor of Award Range: \$75,000.

Ceiling of Award Range: \$125,000.

Anticipated Award Date: August 31, 2005.

Budget Period Length: Four months.

Project Period Length: 16 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

1. 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. Eligible applicants must have reported a minimum of 500 HIV and AIDS cases in 2003, of which at least 300 are HIV cases, as reflected in Volume 15 (Tables 14 and 16) of the CDC HIV/AIDS Surveillance Report. Single reporting areas that do not have sufficient cases may form a consortium with an adjoining area or areas so that the combined total number of HIV and AIDS cases is at least 500, of which at least 300 are HIV cases reported in 2003. Areas wishing to collaborate must designate a lead grantee for protocol implementation, data collection, communication, and coordination of financial remuneration.

2. Eligible applicants must be located in areas where persons of color (Asian, Pacific Islanders, Black, American Indian/Alaskan Native, Hispanic and Multiracial) comprise more than 30 percent of new HIV/AIDS cases with known race/ethnicity.

Known eligible areas include: Alabama, Arizona, Colorado, Florida, Houston, Indiana, Louisiana, Michigan, Mississippi, Missouri, New Jersey, New York, New York City, North Carolina, Ohio, Pennsylvania, Puerto Rico, South Carolina, Tennessee, Texas, and Virginia.

Eligible areas are restricted to those with confidential, name-based HIV (with or without AIDS at the time of diagnosis) reporting (those submitting HIV data to CDC) because this project will augment surveillance data with complete laboratory data and other sources of surveillance data where the use of name is the most accurate method to link HIV surveillance data to supplemental data. Furthermore, to most efficiently use available resources, the standard surveillance software will be used and only those areas with confidential, name-based reporting currently submit both HIV and AIDS data to CDC.

In each area, HIV morbidity must be sufficient to allow for adequate sample sizes therefore, annual reported cases to CDC will be used as a criterion for eligibility. The sizes of the samples must be large enough to be able to detect HIV opportunistic infections which are uncommon.

Eligible applicants must have reported to the CDC HIV/AIDS reporting system a minimum of 500 HIV and AIDS cases in 2003, of which at least 300 are HIV cases, as reflected in Volume 15 (Tables 14 and 16) of the CDC HIV/AIDS Surveillance Report. Single reporting areas that do not have sufficient cases may form a consortium with an adjoining area or areas so that the combined total number of HIV and AIDS cases is at least 500, of which at least 300 are HIV cases reported in 2003.

Eligible applicants are areas where persons of color (Asian, Pacific Islanders, Black, American Indian/Alaskan Native, Hispanic and Multiracial) comprise $\geq 30\%$ of new HIV/AIDS cases with known race/ethnicity. Because a limited number of sites will be funded, racial and ethnic diversity of cases among each of the participating sites will be required to ensure a measure of representation of national data.

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.

Special Requirements: If the application is incomplete or non-responsive to the special requirements listed in this section, it will not be entered into the review process. The applicant will be notified the application did not meet submission requirements.

- Late applications will be considered non-responsive. See section "IV.3. Submission Dates and Times" for more information on deadlines.

- **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.

The following are general considerations that will affect decisions on funding levels. At least one unique reporting area for each of the following categories should be funded:

- *Separate laboratory results database that complements the national HIV/AIDS surveillance system data.*

Areas have received, entered, and maintained CD4 counts, with or without VL values, for HIV/AIDS registry cases, in a separate laboratory database for a period of not less than one year from application date. This activity should be ongoing, with plans to further expand capacity, including VL reporting if this is not already being conducted. Areas that have not routinely uploaded CD4 counts to the national HIV/AIDS surveillance system will be required to do so. Source of lab results (e.g., electronic lab reporting, results received on paper, medical record extraction, etc.) will be recorded.

- *More than 55 percent of the area's combined HIV and AIDS cases have at least one CD4 count within 12 months of initial HIV diagnosis.* At least one CD4 count, obtained within 12 months following the initial diagnosis, was reported for most (greater than 55 percent) of the combined HIV and AIDS cases diagnosed in 2002 and 2003. This information should have been transmitted to CDC as part of the national HIV/AIDS surveillance system. Areas may average two years of diagnostic data to reach the 55 percent prevalence estimate, if each year's cases do not exceed 55 percent.

- *Current participant in the Morbidity Monitoring Project.* Not all cases enrolled in the Morbidity Monitoring Project (MMP), formerly announced as the Morbidity and Risk Behavior Surveillance Project, will be eligible for this project. Systematic sampling of newly diagnosed cases will be used to identify the population for ALOHA. At a minimum, include 500 HIV/AIDS cases annually, of which no less than 300 cases were initially diagnosed with HIV only. All cases included in ALOHA will require medical record abstraction and possible case follow-up. Cases enrolled in both the MMP and ALOHA will be identified as such.

- *Experience conducting large electronic database matching to HIV/AIDS case registry.* Areas will be required to match to another database to add comprehensive OI and co-morbidity information to their HIV/AIDS case registry. OIs will be limited to those diagnosed six months before and after initial HIV diagnosis. Database areas may match to include infectious disease (e.g., NEDSS; hepatitis, cancer or tuberculosis registries), prescription medication databases (e.g., Medicaid; AIDS Drug Assistance Program; etc.), or other databases with similar information. It may be necessary to match to multiple databases to provide a comprehensive review of OIs for a newly diagnosed case. The participating HIV/AIDS surveillance program will

need a memorandum of understanding or similar written agreement with the program that manages the matched-to database. Case follow-up that examines periods of antibiotic/antiviral use should provide information about opportunistic infections being treated, if this is not obvious from the class of medication.

IV. Application and Submission Information

IV.1. Address to Request Application Package

To apply for this funding opportunity, use application form CDC 5161-1.

Electronic Submission: CDC strongly encourages the applicant to submit the application electronically by utilizing the forms and instructions posted for this announcement on <http://www.Grants.gov>, the official Federal agency wide E-grant Web site. Only applicants who apply on-line are permitted to forego paper copy submission of all application forms.

Paper Submission: 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 access to the Internet is not available, or if there is difficulty accessing the forms on-line, contact the CDC Procurement and Grants Office Technical Information Management Section (PGO-TIM) staff at 770-488-2700 and the application forms can be mailed.

IV.2. Content and Form of Submission

Application: A project narrative must be submitted with the application forms. The narrative must be submitted in the following format:

- Maximum number of pages: 15 pages. If the narrative exceeds the page limit, only the first pages that are within the page limit will be reviewed.
- Font size: 12 point unreduced
- Line spacing: Double-spaced
- Paper size: 8.5 by 11 inches
- Page margin: One inch
- Printing: Only on one side of page
- Binding: Hold document together only by rubber bands or metal clips; do not bind document in any other way.

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

- Program Plan
- Objectives
- Understanding
- Methods
- Performance Measures
- Budget Justification (not included in the narrative page limitation)

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

- State laboratory reporting laws
- Evidence of legal authority to follow-up, and abstract medical records
- State specific statistics to support application

- Curriculum Vitas or Resumes

The agency or organization is 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, go to <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/pubcomm.htm>.

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

Additional requirements that may require submittal of additional documentation with the application are listed in section "VI.2. Administrative and National Policy Requirements."

IV.3. Submission Dates and Times

Application Deadline Date: August 5, 2005.

Explanation of Deadlines:

Applications must be received in the CDC Procurement and Grants Office by 4 p.m. Eastern Time on the deadline date.

Applications may be submitted electronically at <http://www.grants.gov>. Applications completed on-line through Grants.gov are considered formally submitted when the applicant organization's Authorizing Official electronically submits the application to <http://www.grants.gov>.

Electronic applications will be considered as having met the deadline if the application has been submitted electronically by the applicant organization's Authorizing Official to Grants.gov on or before the deadline date and time.

If submittal of the application is done electronically through Grants.gov (<http://www.grants.gov>), the application will be electronically time/date stamped, which will serve as receipt of submission. Applicants will receive an

e-mail notice of receipt when CDC receives the application.

If submittal of the application is by the United States Postal Service or commercial delivery service, the applicant must ensure that the carrier will be able to guarantee delivery by the closing date and time. If CDC receives the submission after the closing date 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, the applicant will be given the opportunity to submit documentation of the carrier's guarantee. If the documentation verifies a carrier problem, CDC will consider the submission as having been received by the deadline.

If a hard copy application is submitted, CDC will not notify the applicant upon receipt of the submission. If questions arise on the receipt of the application, the applicant should first contact the carrier. If the applicant still has questions, contact the PGO-TIM staff at (770) 488-2700. The applicant should wait two to three days after the submission deadline before calling. This will allow time for submissions to be processed and logged.

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

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. To get the current SPOC list, go to <http://www.whitehouse.gov/omb/grants/spoc.html>.

IV.5. Funding Restrictions

The following restrictions must be taken into account while writing your budget:

- Funds may not be used for research.
- Reimbursement of pre-award costs is not allowed.

If requesting indirect costs in the budget, a copy of the indirect cost rate

agreement is required. If the indirect cost rate is a provisional rate, the agreement should be less than 12 months of age.

Guidance for completing the 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:
Electronic Submission: CDC strongly encourages applicants to submit applications electronically at <http://www.Grants.gov>. The application package can be downloaded from <http://www.Grants.gov>. Applicants are able to complete it off-line, and then upload and submit the application via the Grants.gov Web site. E-mail submissions will not be accepted. If the applicant has technical difficulties in Grants.gov, customer service can be reached by e-mail at <http://www.grants.gov/CustomersSupport> or by phone at 1-800-518-4726 (1-800-518-GRANTS). The Customer Support Center is open from 7 a.m. to 9 p.m. Eastern Time, Monday through Friday.

CDC recommends that submittal of the application to Grants.gov should be early to resolve any unanticipated difficulties prior to the deadline. Applicants may also submit a back-up paper submission of the application. Any such paper submission must be received in accordance with the requirements for timely submission detailed in Section IV.3. of the grant announcement. The paper submission must be clearly marked: "BACK-UP FOR ELECTRONIC SUBMISSION." The paper submission must conform to all requirements for non-electronic submissions. If both electronic and back-up paper submissions are received by the deadline, the electronic version will be considered the official submission.

It is strongly recommended that the applicant submit the grant application using Microsoft Office products (e.g., Microsoft Word, Microsoft Excel, etc.). If the applicant does not have access to Microsoft Office products, a PDF file may be submitted. Directions for creating PDF files can be found on the Grants.gov Web site. Use of file formats other than Microsoft Office or PDF may result in the file being unreadable by staff.

or

Paper Submission: Applicants should submit the original and two hard copies of the application by mail or express delivery service to: Technical Information Management—RFA# AA120, CDC Procurement and Grants

Office, 2920 Brandywine Road, Atlanta, GA 30341.

V. Application Review Information

V.1. Criteria

Applicants 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 application will be evaluated against the following criteria:

1. Methods (30 points)

The extent to which the applicant demonstrates the technical capability to conduct the project using appropriate data collection and analytic methods for the following:

a. Accurately linking incoming lab results to all HIV and AIDS cases.

b. Transmitting that information to the national HIV/AIDS surveillance system for the duration of ALOHA.

c. Conducting active surveillance and medical record abstraction, including CD4 and VL results, OIs, and ancillary information, following a protocol developed in collaboration with CDC.

d. Conducting active, ongoing follow-up of cases.

e. Documenting methods for linking lab results to registry cases, including methods of reconciling possible matches.

f. Describing specific activities in support of the general funding considerations (Section III.3., bullets 1–4).

2. Understanding of Project Objectives (25 points)

The applicant's understanding of ALOHA objectives and the applicant's specific role in achieving those objectives.

3. Performance Measures (20 points)

The applicant's ability to evaluate progress, including:

a. Measures of success in improving CD4, VL, and OI ascertainment and their impact on overall reporting, compared with cases diagnosed in calendar year 2004.

b. Documenting collaboration with CDC staff to develop data collection forms for ancillary information about co-morbidities, barriers to reporting lab results, whether samples for CD4/VL testing are drawn at post test counseling, possible reasons for no CD4/

VL testing, and the inability to link newly diagnosed persons to care.

c. Transfer data collected to CDC on a monthly basis.

4. Program Plan (15 points)

Applicants must demonstrate that they meet the eligibility criteria. Applicants must indicate the general consideration (Section III.3., bullets 1–4) under which they want to be evaluated (choose only one) and provide supporting documentation, as needed. Is the plan adequate to carry out the proposed objectives? How complete and comprehensive is the plan for the entire project period? Does the plan include quantitative process and outcome measures?

5. Objectives (10 points)

The extent to which the objectives are specific (with time frames), realistic, and address the required recipient activities.

6. Budget Justification (Reviewed, but not scored).

The extent to which the budget is reasonable, clearly justified, and consistent with the intended use of funds. All budget categories should be itemized.

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) 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 criteria listed in the "V.1. Criteria" section above. The objective review process will follow the policy requirements as stated in the GPD 2.04 [<http://198.102.218.46/doc/gpd204.doc>].

Applications will be funded according to their score and rank, which will be determined by the review panel. All persons serving on the panel will be external to the funding division of NCHSTP. In addition, the following factor may affect the funding decision: At least one applicant should be funded in each of the four general consideration areas (See Section III.3., bullets 1–4).

CDC will provide justification for any decision to fund out of rank order.

V.3. Anticipated Award Date

August 31, 2005.

VI. Award Administration Information

VI.1. Award Notices

Successful applicants will receive a Notice of Award (NoA) from the CDC Procurement and Grants Office. The NoA shall be the only binding, authorizing document between the recipient and CDC. The NoA 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

Successful applicants must comply with the administrative requirements outlined in 45 CFR Part 74 and Part 92 as Appropriate. The following additional requirements apply to this project:

- AR-4 HIV/AIDS Confidentiality Provisions
- AR-5 HIV Program Review Panel Requirements
- AR-7 Executive Order 12372
- AR-8 Public Health System Reporting Requirements
- 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-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>.

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>.

An additional Certifications form from the PHS5161-1 application needs to be included in the Grants.gov electronic submission only. Applicants should refer to <http://www.cdc.gov/od/pgo/funding/PHS5161-1-Certificates.pdf>. Once the applicant has filled out the form, it should be attached to the Grants.gov submission as Other Attachments Form.

VI.3. Reporting Requirements

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

1. Interim progress report, due 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. Measures of Effectiveness.
 - f. Additional Requested Information.
2. Annual progress report, due 90 days after the end of the budget period.
 3. Financial status report, no more than 90 days after the end of the budget period.
 4. Final financial and performance reports, no more than 90 days after the end of the project period.

VII. Agency Contacts

We encourage inquiries concerning this announcement. For general questions, 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: Debra Hayes-Hughes, Project Officer, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., MS E-47, Atlanta, GA 30333, Telephone: 404-639-4493, E-mail: DHayes-Hughes@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: 404-498-1917, E-mail: kil8@cdc.gov.

VIII. Other Information

This and other CDC funding opportunity announcements can be found at <http://www.cdc.gov>. Click on "Funding," then "Grants and Cooperative Agreements."

Dated: June 28, 2005.

Alan A. Kotch,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Report of a New System of Records

AGENCY: Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS).

ACTION: Notice of a new System of Records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new system of records titled, "Health Insurance Portability and Accountability Act (HIPAA) Information Tracking System (HITS), System No. 09-70-0544." The Office of E-Health Standards and Services (OESS) has been delegated the responsibility to regulate and enforce compliance for violations of Transactions and Code Sets, Security, and Unique Identifier provisions of HIPAA. Enforcement of these provisions is a complaint driven process; seeking voluntary compliance from all HIPAA covered entities. OESS has procured the services of a contractor to provide a database for complaint intake and management, to manage and maintain the overall electronic complaint process. Due to investigatory activities, CMS is exempting this system from the notification, access, correction and amendment provisions of the Privacy Act of 1974.

The purpose of this system is to store the results of all OESS regional investigations, to determine if there were violations as charged in the original complaint, to investigate complaints that appear to be in violation of the Transactions and Code Sets, Security, and Unique Identifier provisions of HIPAA, to refer violations to law enforcement activities as necessary, and to maintain and retrieve records of the results of the complaint investigations. Information retrieved from this SOR will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency, HIPAA entities, or by a contractor or consultant; (2) assist another Federal or state agency in the enforcement of HIPAA regulations where sharing the information is necessary to complete the processing of a complaint, contribute to the accuracy of CMS's proper payment of Medicare benefits, and/or enable such agency to administer a Federal health benefits program; (3) support constituent requests made to a congressional

representative; (4) support litigation involving the agency; and (5) combat fraud and abuse in certain health benefits programs. We have provided background information about the modified system in the "Supplementary Information" section below. Although the Privacy Act requires only that CMS provide an opportunity for interested persons to comment on the proposed routine uses, CMS invites comments on all portions of this notice. See "Effective Dates" section for comment period.

DATES: *Effective Date:* CMS filed a new SOR report with the Chair of the house Committee on Government Reform and Oversight, the Chair of the Senate Committee on Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on June 28, 2005. We will not disclose any information under a routine use until 30 days after publication. We may defer implementation of this SOR or one or more of the routine use statements listed below if we receive comments that persuade us to defer implementation.

ADDRESSES: The public should address comment to the CMS Privacy Officer, Mail-stop N2-04-27, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.-3 p.m., eastern daylight time.

FOR FURTHER INFORMATION CONTACT: Michael Phillips, Health Insurance Specialist, OESS, CMS, 7500 Security Boulevard, Mail Stop S2-24-15, Baltimore, Maryland 21244-1849, Telephone Number (410) 786-6713, mphillips@cms.hhs.gov.

SUPPLEMENTARY INFORMATION: HITS is used by OESS staff and consists of an electronic repository of information and documents and supplementary paper document files. The HITS system allows OESS to integrate all of OESS' various business process including all of its investigation activities to allow real time access and results reporting and other varied information management needs. HITS provides (1) a single, central, electronic repository of all OHS complaint documents and information including investigative files, correspondence, and administrative records; (2) easy, robust capability to search all of the information in OESS' repository; (3) better quality control at the front end with simplified data entry and stronger data validation; (4) tools to help staff work on and manage their casework; and (5) includes supplementary paper files. The system