

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

HIV/AIDS Surveillance

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I. Funding Opportunity Description

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

Purpose: The purpose of the program is to monitor the HIV epidemic through core surveillance of HIV/AIDS cases; HIV incidence; HIV behavioral surveillance; capacity building for epidemiologic and program evaluation activities; enhanced surveillance for perinatal prevention; for special evaluations of these HIV Surveillance programs; and supplemental projects to assess surveillance of transmission of atypical strains of HIV, including antiretroviral drug resistant virus; unusual modes of transmission of HIV; and assessments of HIV prevalence. FY 2004 is the first year of a three-year project period. Recipients may implement certain required or supplemental activities in years one, two or three, depending on eligibility criteria and when HIV case surveillance activities have been, or will be implemented. Recipients will need to submit a competitive application for each supplemental project described in Parts IV and V of this announcement in the year in which funds are requested. See further discussion on this subject in Parts IV and V. This program addresses the "Healthy People 2010" focus area for HIV.

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

Part I. Core Surveillance

AIDS case surveillance is conducted in all States and U.S. Territories, and the cities of Chicago, Houston, Los Angeles, New York, Philadelphia, and San Francisco. HIV infection case

surveillance is not yet conducted in all States or territories, but CDC recommends that all areas should conduct HIV infection case surveillance as an integrated component of their HIV/AIDS surveillance activities. The National HIV/AIDS Surveillance System is the primary source of population-based information on persons with HIV/AIDS in the United States.

The primary purpose of providing cooperative agreement funds for the core HIV/AIDS Surveillance program is to assist all State and territorial health departments to conduct the following activities:

1. Monitor the number of annual cases of HIV diagnosed, the prevalence of persons living with HIV infection, and HIV-related morbidity (including AIDS) and mortality in adults, adolescents and children.
2. Monitor perinatal exposure to HIV and HIV infection in infants.
3. Monitor behaviors related to HIV testing, risks/exposure to HIV infection, and access to care in HIV-infected populations.
4. Identify changes in trends of HIV transmission.
5. Assist State and local health departments to use these data as a guide for allocation of many federal resources for HIV treatment, care, and other services provided to HIV-infected persons and affected communities, and for prevention and treatment services planning and evaluation.
6. Evaluate the performance of HIV/AIDS surveillance systems.
7. Implement projects to supplement the information available through HIV and AIDS case reporting to enhance and extend the ability of States and local areas to plan for public health programs.

Part II. HIV Incidence Surveillance

The purpose of HIV Incidence Surveillance is to provide reliable and scientifically valid estimates of the number of newly acquired infections at the local, State, territorial, and national level. The purpose of CDC funding for this activity is to provide support to State, territorial and local health departments for development of the infrastructure in newly funded areas, and expansion of activities in areas previously funded for this activity, to incorporate HIV incidence estimation into HIV Surveillance. The ultimate goal is for States, territories, and the separately funded cities to be able to:

1. Collect and test the diagnostic blood specimens from all newly diagnosed HIV infections reported from public and private laboratories and providers to HIV Surveillance.

2. Collect the HIV testing information needed for the statistical estimates of incidence.

3. Calculate population-based estimates of HIV incidence.

4. Use these to identify emerging epidemics, monitor trends in transmission, target prevention resources and interventions to areas and populations most heavily affected, and evaluate programs designed to prevent the transmission of HIV.

Part III. Capacity Building for Epidemiologic and Program Evaluation Activities

There are multiple sources of data available to health departments that can be analyzed to guide program planning and assess the impact of HIV prevention programs in a health department's jurisdiction. These include surveillance, program evaluation and data from special projects. There are systems and guidances in place for various data sets. Opportunities to use these data are often not exploited to better assess HIV status and prevention efforts in a jurisdiction because of the limited availability of trained and dedicated personnel with the capacity to collectively or comprehensively analyze and synthesize these types of information.

The purpose of providing funds for this activity is to improve the epidemiologic, evaluative, analytic, and dissemination capabilities of health departments that currently have limited resources. The specific purpose of this support is to allow health departments to hire dedicated, professional staff. Staff employed through this funding will assist health departments to develop and implement a more integrated use of these independent, but related data sets by:

1. Analyzing and interpreting HIV/AIDS surveillance and other health-related data to describe the HIV/AIDS epidemic within their jurisdiction in terms of person, place and time for various populations.

2. Producing consolidated epidemiologic profiles that meet the needs of both CDC-supported HIV prevention planning programs and HRSA-supported HIV care planning programs.

3. Collecting, analyzing, interpreting, and disseminating surveillance, program, and other health-related data to assess the effectiveness of HIV prevention efforts.

4. Providing technical assistance to community planning groups on the use of HIV and other public health data for program planning and evaluation.

5. Collaborating with CDC to develop the systematic collection and analysis of

community-related and program data which can be used with HIV/AIDS surveillance data to track progress towards goals identified in CDC's HIV Prevention Strategic Plan (http://www.cdc.gov/nchstp/od/hiv_plan/default.htm).

Part IV. Enhanced Surveillance for Perinatal Prevention

The purpose of providing funds for this activity is to target and follow the progress toward maximal reduction of perinatal HIV transmission. Specifically, this support is to allow State and local health departments to evaluate (1) the impact of implementation of efforts to maximally reduce perinatal HIV transmission; (2) prevention failures for perinatal HIV transmission; (3) the efficacy of zidovudine (ZDV) and other antiretroviral medications in preventing perinatal HIV transmission; (4) potential adverse outcomes of perinatal and postnatal antiretroviral therapy; and (5) the Public Health Service recommendations for opportunistic infection prophylaxis by:

1. Conducting medical record reviews of mother/infant pairs and longitudinal follow-up of all HIV exposed children to ascertain knowledge of maternal HIV infection status before birth, HIV incidence, AIDS incidence, and death, the use of maternal and neonatal ZDV and its efficacy in preventing HIV transmission, and the use of other antiretroviral medications.
2. Conducting medical record reviews to evaluate recommendations for opportunistic infection prophylaxis and initiation of HIV evaluation and treatment in children.
3. Assessing potential adverse outcomes of exposure to antiretroviral medications among infected and uninfected children in the short term (e.g., birth defects, ascertained through record reviews and registry matches) and in the long term (e.g., by matching to tumor registries).
4. Matching HIV/AIDS registries to birth registries to ensure complete ascertainment of mother/infant pairs.
5. Collaborating with CDC to track progress towards the maximal reduction of perinatal HIV transmission.

Part V. Laboratory Testing for Recent HIV Infection

The Serologic Testing Algorithm for Recent HIV Seroconversion (STARHS) is the currently accepted method used for estimation of HIV incidence. With STARHS, confirmed HIV-positive samples are analyzed with a Less Sensitive HIV Enzyme-Linked Immunosorbent Assay (LS-EIA) which identifies antibodies at a point later in

the course of infection than the routine test. In performance of STARHS, the standard testing methodology for a commercially available HIV Enzyme-Linked Immunosorbent Assay (EIA) is altered by reducing the incubation time and increasing the dilution of the sample according to extremely precise criteria. Quantitative values from these tests are evaluated against control values and cut-off points to estimate the likelihood that that sample was collected from an individual who was infected with HIV within a finite period of time before the sample was collected. Because the testing procedures must be conducted with extreme precision, multiple control samples are run in tandem with each sample run. Other tests to identify recent HIV infection are currently being developed. In order to adopt those for more widespread use, new tests will need to be run on samples tested with the existing method to validate the new methodology.

STARHS has not been approved by the Food and Drug Administration (FDA) for routine use. STARHS is conducted under an Investigational New Drug/Device (IND) authorization from the FDA which allows for testing in controlled settings in which performance is closely monitored and data with regard to unforeseen adverse events and aggregate results are reported through CDC. All IND laboratories are required to participate in a quarterly proficiency testing program administered by CDC. A limited number of laboratories participate in the CDC-sponsored IND.

Since 1999, CDC has supported six health department laboratories to conduct the STARHS on stored, unlinked HIV-positive samples from HIV testing programs and research projects. This testing was for research purposes, therefore, it was not necessary to complete testing and return test results quickly. Laboratories were allowed to hold specimens, run them in batches, and schedule testing to accommodate the time requirements for their other work. For HIV Incidence Surveillance, laboratories will be required to return results to submitting health departments quickly. The current laboratory protocol allows for either manual or automated dilution and processing. For this activity, only laboratories that agree to use automated methods will be supported in order to maximize the number of tests they will be able to process and to optimize the accuracy and consistency of STARHS results. Laboratories will be selected to maximize efficiency, ensure timely availability of test results for all

geographic areas and to standardize methodology.

Part VI. Behavioral Surveillance

CDC's HIV/AIDS Strategic Plan has identified that monitoring behaviors that place people at risk for HIV infection is a key element of an integrated surveillance system. Measures of behavior are necessary to quantify progress in the plan's objectives. In addition, the plan identifies that studies of HIV incidence in special populations, including populations at high risk for infection, are an important strategy to provide locally relevant data for prevention resource allocation. The objectives of this program are to develop an ongoing surveillance system to ascertain the prevalence of HIV risk behaviors among groups at high risk for HIV infection for use in developing and directing national prevention services and programs; and to evaluate the impact of a variety of prevention efforts.

This announcement provides an opportunity to capitalize on experience recruiting at-risk individuals from non-healthcare community settings using a scientifically sound methodology to develop an ongoing system for surveillance of behaviors related to HIV acquisition. This system will assess risk behaviors and trends in behaviors over time among adults 18 years old and older at high risk for HIV infection through sexual behavior between men and injection drug use. These studies may be expanded to include high risk heterosexuals. In addition, access to and utilization of HIV prevention programs, including HIV testing, will be assessed. Each funded site will be expected to enroll at least 500 Men Who Have Sex with Men (MSM) and 500 Injection Drug Users (IDUs). Funded sites will also be expected to collaborate with CDC directly funded community-based organizations (CBOs) and CBOs funded by States/cities through the community planning process for allocating Federal HIV prevention funds, schools of public health, universities, ethnographers and behavioral scientists.

Part VII. Core Surveillance in the Pacific Island Jurisdictions

AIDS case surveillance is conducted in all U.S. dependencies, possessions, and independent nations that make up the six Pacific Island jurisdictions referred to as the Pacific Island Jurisdiction AIDS Advisory Group (PIJAAG). These islands and island groups are American Samoa, Guam, Marshall Islands, Palau, the Commonwealth of the Northern Mariana Islands and the Federated States of

Micronesia. HIV infection case surveillance is not yet conducted in all these areas, but CDC recommends that all areas should conduct HIV case surveillance as an integrated component of their HIV/AIDS surveillance activities. However, there are substantial public health, logistical and medical infrastructure challenges to conducting core surveillance in these island jurisdictions.

The objective of this proposal is to support the infrastructure and activities necessary to enable newly identified HIV/AIDS cases to be reported to the Centers for Disease Control and Prevention's Statistics and Data Management Branch. Preparatory to this end, each island jurisdiction must be authorized by local public health law, rule or regulation to collect and report the necessary medical and socio-demographic information to the CDC. A letter, signed by the jurisdiction's senior public health official, must be sent to Dr. Matthew McKenna, Chief for Informatics, HIV Incidence and Case Surveillance Branch (HICSB) declaring the jurisdiction's intent to report previously unidentified HIV/AIDS cases to the CDC. Also a copy of the jurisdiction's legal authority to report HIV/AIDS cases to the CDC will be needed.

The primary purpose of providing cooperative agreement funds for the core HIV/AIDS Surveillance program is to assist all State and territorial health departments to conduct the following activities:

1. Monitor the number of annual cases of HIV diagnosed, the prevalence of persons living with HIV infection, and HIV-related morbidity (including AIDS) and mortality in adults, adolescents and children.
2. Monitor perinatal exposure to HIV and HIV infection in infants.
3. Monitor behaviors related to HIV testing, risks/exposure to HIV infection, and access to care in HIV-infected populations.
4. Identify changes in trends of HIV transmission.
5. Assist territorial and local health departments to use these data as a guide for allocation of many federal resources for HIV treatment, care, and other services provided to HIV-infected persons and affected communities, and for prevention and treatment services planning and evaluation.
6. Conduct basic evaluation and quality control assessment of the surveillance data collected.

Activities

Awardee activities for this program are as follows:

Part I. Core Surveillance

Recipient Activities

1. Plan and conduct HIV/AIDS surveillance activities in collaboration and coordination with CDC, and, where appropriate, with State and local professional associations; health care providers and institutions serving, diagnosing, or providing treatment and care for persons with HIV/AIDS, including laboratories providing HIV, CD4+ lymphocyte and HIV-1 Ribonucleic Acid Determination (*i.e.* viral load) testing; organizations that serve persons at increased risk of HIV/AIDS (*e.g.*, drug treatment facilities, STD clinics, family planning agencies, maternal and infant care programs, comprehensive hemophilia treatment centers, correctional facilities); community groups and organizations, especially those with a racial and ethnic minority membership and focus; and HIV/AIDS service organizations.

a. Active case finding.

At a minimum, all recipients shall conduct active case finding (*i.e.* soliciting case reports in a timely manner directly from potential reporting sources) in large in- and out-patient facilities serving HIV-infected persons and in laboratories, where feasible and permitted by law, and shall conduct a systematic review of death certificates. Other required components of active surveillance programs include educating providers on their reporting responsibilities, establishing on-going communication with all reporting sites and providing them feedback, conducting routine visits to reporting sources, and establishing awareness of and support for surveillance activities. In particular, in areas where a large volume of reports or limited resources preclude timely investigation of new case reports, special efforts shall be made to inform providers of their importance in promptly notifying the health department of any cases with unusual transmission, laboratory or clinical circumstances/characteristics. The minimum information required to report a case of HIV infection or AIDS to CDC's HIV/AIDS Reporting System (HARS) is the alpha-numeric (soundex) code of the patient's name (patient and physician names should not be submitted to CDC); state-assigned patient identifier number; HIV/AIDS diagnosis information, including date(s) of diagnosis; and the patient's date of birth, race/ethnicity, and sex.

Two additional variables that are critical to ascertain are initial CD4 count and mode of HIV exposure. In an effort to better characterize the extent of disease at diagnosis, and the impact of

targeted testing efforts on identifying persons early in the course of their infections, information on CD4 count at initial diagnosis shall be collected. This information should be submitted to CDC as part of the case record. Information on the mode of HIV exposure is also essential in order to monitor epidemic trends and target prevention interventions. Therefore, timely follow-up to complete risk history shall be conducted. Funding limitations may preclude complete investigations of all cases, but at a minimum, States are expected to follow-up a representative sample of reported cases to ascertain risk according to a protocol developed by CDC and the recipient.

Where pediatric HIV exposure and infection surveillance is conducted, recipients shall also collect data on maternal HIV test history, prenatal and neonatal antiretroviral therapy, and other variables relevant to the evaluation of recommended actions to prevent perinatal HIV transmission. For areas with the highest burden of perinatal HIV transmission, additional funds are available to conduct enhanced surveillance activities for HIV-infected mothers and their children (See section D, Funding, above; and Part IV, Enhanced Surveillance for Perinatal Prevention, below in this section)

b. Follow-up investigations of cases/populations of special epidemiologic significance.

Recipients shall develop procedures for promptly notifying CDC of unusual occurrences of HIV transmission and for using CDC-developed protocols and criteria to conduct epidemiologic and laboratory investigations of cases that may have rare or previously unidentified modes of HIV transmission, unusual clinical manifestations, or unusual laboratory test results. These include transfusion and transplant-related cases, cases of HIV transmitted in health care or other occupational settings, cases of HIV-2 infection, cases transmitted through female-to-female sexual contact, cases with potentially unusual HIV strain variants, and cases with clinical evidence of HIV infection but negative HIV test results.

Recipients may also propose activities to better describe the epidemic in specific populations of epidemiologic significance or interest (*e.g.* for example, persons diagnosed concurrently with HIV and TB or HIV and STDs), or in collaboration with prevention and care partners to augment the collection of risk behaviors in cases reported initially with no reported risk (NRR) or projects to collect risk behaviors of cases using

novel methods of risk assessment such as computer-assisted interviews.

c. Evaluation of the performance of the surveillance system.

Recipients shall continue to evaluate the attributes of their HIV/AIDS surveillance system according to protocols provided by CDC that have been developed as part of focused pilot projects. Ongoing evaluation will continue regardless of the status of, or procedures used, to conduct HIV/AIDS surveillance (e.g. AIDS or HIV reporting, or name or code-based reporting).

All evaluation projects should include critical reviews of surveillance methods and redirection of resources to those case-finding methods that are the most accurate and productive. Using the recommendations published in "CDC Guidelines for National Human Immunodeficiency Virus Case Surveillance, Including Monitoring for Human Immunodeficiency Virus Infection and Acquired Immunodeficiency Syndrome" (see Attachment A for summary) these evaluations should include routine analysis of surveillance data to discover possible sources of under reporting and delays in reporting, monitoring data quality, and assessing completeness of reporting by statistical methods developed by CDC (e.g. multiple source capture-recapture) or comparing surveillance registries with alternate databases that are not routinely used for case finding (e.g., Medicaid databases).

At least once a year, all recipients shall routinely re-abstract demographic, risk, laboratory, and clinical data from a representative sample of records to assess the quality and validity of information collected.

d. Interstate reciprocal notification of newly identified HIV/AIDS cases.

Recipients should routinely interact with other reporting areas using a list of potential inter-State duplicates supplied by CDC to ensure that reciprocal notification of newly identified HIV/AIDS cases, perinatal exposure cases, and deaths from HIV infection is executed. Routine engagement in this activity will minimize the number of duplicate case reports in the national data system. This communication is supported by the Council of State and Territorial Epidemiologists (Position statement 01-ID-04). It should be carried out by appropriately trained and authorized surveillance staff, in a confidential manner consistent with local security, confidentiality and reporting policies and procedures. Recipients will use the same system for reciprocal notification of HIV, AIDS, perinatal HIV exposure and deaths among persons with HIV infection,

including provision of appropriate identifying information (e.g., name or other identifier). Currently, because of the diversity and limitations of the coded identifiers used by reporting areas in States engaged in alternatives to confidential, name-based reporting for HIV cases, there is no scientifically validated, systematic way for CDC to identify potential duplicates for HIV cases in those areas. These areas are encouraged to communicate with nearby reporting areas to identify the most accurate and efficient methods for minimizing duplication across State reporting jurisdictions.

e. Analysis and dissemination of HIV/AIDS surveillance data and promoting their uses of prevention and health services planning and evaluation.

All recipients should routinely disseminate reports of aggregate surveillance data for epidemic monitoring and education of the public and reporting sources and should promote uses of HIV/AIDS surveillance data for prevention and health services planning and evaluation. These activities should include: Providing HIV/AIDS surveillance data and ongoing epidemiologic assistance to community planning groups; disseminating surveillance data through publications and presentations; participating in planning and implementation meetings; conducting analyses to monitor trends, assess need for health-care resources, and project the future impact of the disease; and providing feedback to reporting sources on ways in which the surveillance data have been used to promote public health.

f. Conduct activities to improve the quality, efficiency, and productivity of the core surveillance program.

As part of core surveillance (given availability of either increased core funding or a redirection of existing core surveillance funding) all recipients shall also conduct one or more surveillance activities to develop and test new approaches to conducting surveillance whose aim is to improve the quality of the data, develop more efficient methods of case ascertainment, ensure accurate and valid case report information, and maximize the performance of the system. In particular, areas should develop technical information systems that facilitate electronic reporting of HIV and AIDS surveillance data from health care providers and public and private laboratories to health departments. Examples of focused analyses and evaluations of surveillance data that applicants may conduct include:

(1) Assessing how priority populations access or receive referrals to prevention and treatment services in public and private settings (e.g., treatment for HIV infection and prevention of opportunistic infections).

(2) Assessing the association of stage of disease (i.e., HIV or AIDS) with interstate migration.

(3) Better defining trends (through analysis of HARS reports or chart reviews or interviews):

(a) In various populations (e.g., Native Americans, health-care workers, substance-abusing pregnant women).

(b) For various AIDS-defining conditions or opportunistic infections (e.g., Tuberculosis, Mycobacterium Avium Complex (MAC)).

(c) In conjunction with other Federal, State, local prevention and care programs (e.g., HRSA Ryan White CARE locations).

g. Reporting of data using CDC standards and software.

Recipients should ensure that data collection forms and electronic data formats used to submit case reports from laboratories, clinical records, and patient interviews contain CDC's recommended standard data elements/questions on HIV testing behaviors, risk/exposure behaviors, and treatment access/adherence behaviors. In addition, during this project period, recipients should report HIV/AIDS case surveillance data to CDC on at least a monthly basis using either standardized software or according to data submission standards established by CDC.

Data from reporting areas using coded identifiers for HIV surveillance will be eligible for inclusion in national surveillance reports after these systems are evaluated using published performance standards (see Attachment A) through the implementation of protocols established by CDC. Areas using coded identifier systems will need to use customized data transfer and storage systems (either electronic or hardcopy) in order to accommodate the diversity of codes, inconsistencies in codes between areas (e.g. inability to generate soundex in some areas), and inability of areas using coded reporting to reciprocally notify and de-duplicate cases with other areas using standardized lists generated by CDC. Specific data management systems will be developed by CDC in consultation with the local areas. These areas should continue to report AIDS cases and deaths to CDC using HARS or its identified equivalent, as is current practice.

h. Security.

Consistent with "Appendix C" of CDC's "Guidelines for HIV/AIDS Surveillance," applicants must ensure that the program requirements detailed in the Security Standards are attained as indicated by the signature of the Overall Responsible Party (ORP) on the attached form (Attachment B). HIV/AIDS surveillance funds will be restricted unless the signed ORP form has been submitted to CDC.

i. All applicants are required to attend CDC-sponsored conferences and workshops consistent with recipient activities in accordance with the budget allocated.

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:

a. Provide training in surveillance methods, study methods, and surveillance program planning and management.

b. Provide laboratory training that includes current scientific and technical information about the practical and the theoretical sensitivity and specificity of the different serological tests.

c. Coordinate and convene conferences, develop routine communications, provide guidelines and standards for the conduct of surveillance program activities, and communicate with recipients to develop, refine, and disseminate HIV/AIDS surveillance program information that describes effective methods to carry out program activities and monitor progress.

d. Provide: (1) Criteria for the surveillance definition of nationally reported HIV infection/disease (including AIDS); (2) prototype (model) case report forms; and (3) assistance in establishing and maintaining software for collecting, transferring and evaluating HIV/AIDS surveillance data.

e. Participate in the analysis and dissemination of information and data gathered from program activities and facilitate the transfer and utilization of information and technology among all States and communities.

f. Provide standardized protocols, data collection forms, data entry capability for core surveillance and time-limited studies, and on a routine basis generate lists of records of potential inter-State duplicate cases to facilitate reciprocal notification and de-duplication of HIV, AIDS, perinatal exposure cases as well as deaths from HIV infection.

g. Assist in the evaluation of the overall effectiveness of program operations, including the impact of

surveillance data on the development of public policy and on targeting and evaluating HIV Prevention Community Planning activities.

h. Assist States to better use the national HIV/AIDS surveillance data provided to CDC by States for public health policy formulation; to obtain and allocate federal resources for HIV/AIDS surveillance, prevention, and care; and to evaluate national public health recommendations. Promote and facilitate coordination of CDC surveillance data and activities with other CDC programs and other agencies of the federal government.

i. Provide technical assistance in the area of information technology to assure that reporting areas using electronic transfer of HIV/AIDS surveillance data:

(1) Adhere to appropriate confidentiality and security procedures; (2) execute the necessary data management and analytic procedures to assure data integrity and accuracy; and (3) provide guidance to grantees in obtaining equipment that possesses the necessary technologic capabilities to process and transfer data using either CDC provided software or according to standards developed by CDC for reporting to the national system. Supplemental funds may be provided by CDC contingent on the availability of funds and the magnitude of the identified requirements for information technology improvements in areas that do not currently have adequate infrastructure to manage data according to current or emerging CDC specifications.

j. Disseminate national surveillance data for public health research purposes through routine reports, articles in books and peer-reviewed journals, and presentations.

k. Maintain a secure and confidential national HIV/AIDS surveillance database.

Part II. HIV Incidence Surveillance

Recipient Activities

a. Collaborate with CDC, laboratories, providers and affected communities to develop the capacity to conduct population-based HIV incidence surveillance.

b. Collaborate with CDC (and other funded project sites) in project design, implementation, and evaluation.

c. Collaborate with CDC in the development of area specific protocols that demonstrate the ability to link HIV case data to laboratory specimens, and to HIV testing history information to meet the statistical data requirements for HIV incidence estimates.

d. Collaborate with public and commercial HIV testing laboratories

(within and outside the state) to secure an aliquot of serum from original diagnostic HIV tests and have it shipped to the state public health laboratory or an appropriately designated lab that is authorized to store specimens for the area health department.

e. Identify, in a timely fashion, which diagnostic specimens represent HIV infection cases new to the State HIV Surveillance system.

f. Prepare and transport aliquots of serum from the original diagnostic HIV test of new HIV infection cases from the state public health laboratory to a CDC designated STARHS testing laboratory.

g. Obtain adequate information on HIV testing history from a sufficient number of persons with newly identified, recent HIV infections, reported from private and public providers to allow for HIV incidence estimation. The sources and methods for acquiring this testing history information, and the procedures for linking, or unlinking, these data from surveillance records with personal identifiers when computing incidence estimates will be developed collaboratively with CDC.

h. In some areas results from investigational tests such as STARHS may be linked to identifying information on individual patients. These protocols must be approved by a local IRB, and undergo review by CDC and the Food and Drug Administration (FDA) before they can be implemented.

i. On at least a monthly basis, report to CDC the data necessary to conduct incidence surveillance using either standardized software or according to data submission standards provided by CDC.

j. Areas conducting HIV incidence surveillance have the unique capacity to identify active transmission of atypical strains of HIV, including antiretroviral drug resistant virus. As part of incidence surveillance, areas may collaborate with CDC to develop procedures for obtaining the appropriate specimens to monitor transmission of such atypical strains.

k. Maintain a secure environment to protect the security and confidentiality of data obtained during this surveillance activity.

l. All applicants are required to attend CDC-sponsored conferences and workshops consistent with recipient activities in accordance with the budget allocated.

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:

a. Provide training in HIV incidence surveillance and estimation methodology.

b. Provide laboratory training that includes current scientific and technical information required to obtain, ship, and process specimens according to existing standards of safety in order to obtain reliable results for incidence estimation.

c. Coordinate and convene conferences, provide guidelines, provide technical assistance for development as well as review and approval of protocols, develop materials such as model consent forms and procedural standards for the conduct of incidence surveillance program activities. CDC will communicate regularly with recipients to develop, refine, and disseminate HIV information that describes effective methods to carry out program activities and monitor progress.

d. Provide support in the form of technical assistance, and where necessary and available, supplemental funding to establish and maintain information systems adequate for collecting, transferring and evaluating HIV incidence surveillance data.

e. Provide technical assistance for activities designed to assess and monitor the active transmission of atypical strains of HIV, including antiretroviral resistant virus.

f. Participate in the analysis and dissemination of information and data from these program activities.

g. Assist in the evaluation of the overall effectiveness of program operations, including the impact of incidence data on the development of public policy and on targeting and evaluating HIV Prevention Community Planning activities.

h. Maintain a secure and confidential national data system for HIV Incidence Surveillance and estimation.

i. Coordinate the identification and interaction between areas supported to conduct HIV incidence surveillance and designated CDC STARHS laboratories.

j. Conduct at least one site visit during a program announcement funding period to each grantee to assess progress toward meeting program objectives and provide such technical assistance as is necessary as determined by the grantee and CDC.

k. Provide technical assistance in the area of information technology to assure that reporting areas using electronic transfer of HIV/AIDS surveillance data: (1) Adhere to appropriate confidentiality and security procedures; (2) execute the necessary data management and analytic procedures to assure data integrity and accuracy; and

(3) provide guidance to grantees in obtaining equipment that has the necessary technologic capabilities to process and transfer data using either CDC provided software or according to standards developed by CDC for reporting to the national system. Supplemental funds may be provided by CDC contingent on the availability of funds and the magnitude of the identified requirements for information technology improvements in areas that do not currently have adequate infrastructure to manage data according to current or emerging CDC specifications.

1. Coordinate with recipients and private and public health laboratories to promote the efficient transport and processing of diagnostic specimens for identification of newly diagnosed persons and execution of STARHS, or other CDC approved testing for recent HIV infections.

Part III. Capacity Building for Epidemiologic and Program Evaluation Activities

Recipient Activities

a. Employ and sufficiently support trained staff who will develop or enhance the recipient's capacity to plan and conduct epidemiologic and program evaluation activities in collaboration and coordination with CDC, and state and local HIV prevention and care community planning groups; and

b. Promote uses of the HIV/AIDS surveillance, program, and other health-related data for the planning and evaluation of HIV prevention and care services. These uses should address two components:

(1) Epidemiologic activities. These activities should include providing or recommending the use of HIV/AIDS and other public health surveillance data. Activities should also include the analysis, interpretation, and presentation of these data in describing the HIV/AIDS epidemic in the recipient's jurisdiction in terms of socio-demographic, geographic, behavioral, and clinical characteristics for use in the epidemiologic profile for HIV prevention and care community planning.

(2) Program evaluation activities. These activities should include collecting, analyzing, and reporting process and outcome data that can be used:

(a) To assess the effectiveness of various types of interventions.

(b) To monitor achievement of the health department's goals and objectives.

(c) To provide program data to CDC in appropriate and useful formats so that

data may be aggregated by CDC to monitor progress in achieving the goals and objectives of its strategic plan.

(d) To assess the impact of HIV prevention efforts in health department jurisdictions.

c. All applicants are required to attend CDC-sponsored conferences and workshops consistent with recipient activities in accordance with the budget allocated.

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:

a. Develop and promote the use of standard guidelines for development of epidemiologic profiles and program evaluation for HIV prevention and care community planning.

b. Assist recipients to better use HIV/AIDS surveillance, program, and other health-related data for HIV prevention and care community planning and to evaluate HIV prevention program effectiveness.

c. Collaborate with recipients to facilitate the use of surveillance, program, and other health-related data to monitor achievement of CDC and HRSA prevention and care planning goals and objectives.

d. Assist recipients to use surveillance, evaluation, and other health-related data to assess the impacts of HIV prevention efforts (e.g., to inform policy and service delivery issues).

e. Collaborate with grantees to ensure appropriate transfer of data.

Part IV. Enhanced Surveillance for Perinatal Prevention

Recipient Activities

Implement and continue surveillance for perinatal HIV exposure and pediatric HIV infection by performing the following activities:

a. Conduct medical record review of mother/infant pairs and longitudinal follow-up of all HIV exposed children to ascertain knowledge of maternal HIV infection status before birth, HIV incidence, AIDS incidence, and death, the use of maternal and neonatal ZDV and its efficacy in preventing HIV transmission, and the use of other antiretroviral medications.

b. Conduct medical record review to evaluate recommendations for opportunistic infection prophylaxis and initiation of HIV evaluation and treatment in children.

c. Assess potential adverse outcomes of antiretroviral exposure among infected and uninfected children in the short term (e.g., birth defects,

ascertained through record reviews and registry matches) and in the long term (e.g., by matching to tumor registries).

d. Match HIV/AIDS registries to birth registries to ensure complete ascertainment of mother/infant pairs.

e. Regularly report data to CDC in a secure manner using CDC-provided forms and software.

f. All applicants are required to attend CDC-sponsored conferences and workshops consistent with recipient activities in accordance with the budget allocated.

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:

a. Provide training in surveillance methodology, study methodology, and in program planning and management.

b. Provide laboratory training that includes current scientific and technical information about the practical and the theoretical sensitivity and specificity of the different serological tests.

c. Develop, refine, and disseminate HIV/AIDS surveillance program information that describes effective methods to carry out program activities and monitor progress.

d. Provide: (1) Criteria for the surveillance definition of nationally reported HIV infection/ disease; (2) case report forms; and (3) assistance in establishing and maintaining the computerized HARS.

e. Participate in the analysis and dissemination of information and data gathered from program activities and facilitate the transfer and utilization of information and technology among all States and communities.

f. Provide standardized protocols, data collection forms, and computer software.

g. Assist in the evaluation of the overall effectiveness of program operations, including the impact of enhanced perinatal surveillance data on the development of public policy and on targeting and evaluating HIV Prevention Community Planning activities.

h. Provide standard data collection forms, questionnaires, and computer software for the supplemental surveillance projects.

i. Disseminate national perinatal surveillance data for public health research purposes through routine reports, articles, and presentations.

j. Maintain a secure and confidential national HIV/AIDS surveillance database.

Part V. Laboratory Testing for Recent HIV Infection

Recipient Activities

a. Conduct testing according to the protocols and requirements stipulated in the existing CDC IND agreement.

b. Establish local procedures for specimen testing and processing.

c. Conduct quality control for each run, and on an ongoing basis, participate in CDC's quality assurance program. Establish quality criteria for inclusion or exclusion of testing runs.

d. Establish protocols for collaborating health departments for the preparation and shipping of specimens. Laboratories may specify the type of vial and conditions for acceptable specimens, designate the days of the week that specimens will be received, specify how specimens will be labeled (label type, numbering system, barcoding), shipped, and the format for packing lists.

e. Return test results to submitting health department within seven days of receipt of specimen.

f. Develop data management systems for tracking specimens, raw data including control values and specimen results consistent with the IND protocol.

g. Ensure the confidentiality of data and specimens.

h. Obtain, from collaborating health departments, protocols and documentation of institutional review board approval (or non-research determination) that allowed for the initial specimen collection and for incidence testing. Track testing results by protocol for required reports.

i. Conduct testing for other CDC supported research projects.

j. Establish mechanism for tracking all costs (staff time, project resources and reagents) associated with testing for specimens not associated with national HIV incidence.

k. All applicants are required to attend CDC-sponsored conferences and workshops consistent with recipient activities in accordance with the budget allocated.

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:

a. Provide protocols for conducting tests for recent HIV infection.

b. Facilitate the distribution or designation of assigned collaborating health departments to ensure optimal work loads for funded laboratories and optimal ability to return results in a timely manner.

c. Provide proficiency testing program.

d. Provide resources to collaborating health departments for the collection, processing and shipping of specimens to funded laboratories.

e. Provide technical assistance to laboratories on testing methods.

f. Provide computer software for interpretation of testing results, quality control and for tracking results for required reports.

VI. Behavioral Surveillance

Recipient Activities

a. Collaborate with CDC and other funded project sites in the design, implementation and evaluation of proposed activities. Participate in required planning meetings with other funded sites and CDC at an out of state location to be determined by CDC and grantees.

b. Collaborate with CDC and other funded sites to develop a multi-site protocol and questionnaire.

c. Collaborate with CDC in the development of site specific operational plans.

d. Engage Community Based Organizations (CBOs) funded directly by CDC or by States/cities through the Community Planning process, behavioral scientists, ethnographers, schools of public health, or universities in the formative research and questionnaire development.

e. Collaborate with local HIV/AIDS prevention program to assess exposure to and use of HIV prevention programs.

f. Maintain a secure environment to protect the security and confidentiality of data obtained in this activity.

g. Report project data to CDC in a timely manner according to established protocols for data collection, storage and transfer.

h. Disseminate study data for use in state/local prevention, and in treatment services planning and evaluation.

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:

a. Lead the development of a standardized multi-site protocol and questionnaire.

b. Facilitate the development of site-specific operational plans.

c. Provide training in the methodology (including formative research), program planning and management.

d. Provide technical assistance to support implementation of agreed upon methods to accomplish project objectives.

e. Provide assistance in establishing and maintaining the computerized

database to record information collected in this activity.

f. Participate in the analysis and dissemination of data. Conduct and/or coordinate analyses of the multi-site data and distribute information to support national HIV prevention efforts.

g. Lead the development of computer programs to evaluate performance indicators and data quality.

h. Assist in the evaluation of the overall effectiveness of program operations. Provide timely feedback on reported data for quality assurance purposes.

i. Maintain a secure and confidential national database.

Part VII. Core Surveillance in the Pacific Island Jurisdictions

Recipient Activities

Plan and conduct HIV/AIDS surveillance activities in collaboration and coordination with CDC, and, where appropriate, with professional associations; health care providers and institutions serving, diagnosing, or providing treatment and care for persons with HIV/AIDS, including facilities or organizations providing HIV, CD4+ lymphocyte and HIV-1 Ribonucleic Acid Determination (*i.e.* viral load) testing; organizations that serve persons at increased risk of HIV/AIDS (*e.g.*, drug treatment facilities, STD clinics, family planning agencies, maternal and infant care programs, correctional facilities); community groups and organizations. Specific areas with laboratories capable of providing confirmatory testing services (*i.e.* Western Blot or IFA) should indicate a willingness and describe their capacity to serve as central data coordination areas by working with other island jurisdictions that submit specimens for such confirmatory testing. These descriptions should include a process for assuring compliance with security and confidentiality requirements.

Collaboration with CDC includes attendance at meetings and workshops that address recipient HIV/AIDS surveillance activities described in this announcement. In accordance with available funds, all applicants should plan to attend CDC-sponsored conferences and workshops consistent with recipient activities.

a. Active case finding

At a minimum, all recipients shall conduct active case finding (*i.e.* soliciting case reports in a timely manner directly from potential reporting sources) in appropriate in-patient and out-patient facilities serving HIV-infected persons and in laboratories, where feasible and permitted by law,

and shall conduct a systematic review of death certificates. Other required components of active surveillance programs include educating providers on their reporting responsibilities, establishing on-going communication with all reporting sites and providing them feedback, conducting routine visits to reporting sources, and establishing awareness of and support for surveillance activities. The minimum information required to report a case of HIV infection or AIDS to CDC's HARS is the alpha-numeric (soundex) code of the patient's name (patient and physician names should not be submitted to CDC); state-assigned patient identifier number; HIV/AIDS diagnosis information, including date(s) of diagnosis; and the patient's date of birth, race/ethnicity, and sex.

An additional variable that is critical to ascertain is the initial CD4 count. In an effort to better characterize the extent of disease at diagnosis, and the impact of targeted testing efforts on identifying persons early in the course of their infections, information on CD4 count at initial diagnosis shall be collected. This information should be submitted to CDC as part of the case record. Information on the mode of HIV exposure is also essential in order to monitor epidemic trends and target prevention interventions. Therefore, timely follow-up to complete risk history shall be conducted.

b. Follow-up investigations of cases/populations of special epidemiologic significance. Recipients shall develop procedures for promptly notifying CDC of unusual occurrences of HIV transmission and for using CDC-developed protocols and criteria to conduct epidemiologic and laboratory investigations of cases that may have rare or previously unidentified modes of HIV transmission, unusual clinical manifestations, or unusual laboratory test results. These include transfusion and transplant-related cases, cases of HIV transmitted in health care or other occupational settings, cases of HIV-2 infection, cases transmitted through female-to-female sexual contact, cases with potentially unusual HIV strain variants, and cases with clinical evidence of HIV infection but negative HIV test results.

c. Evaluation of the performance of the surveillance system.

Recipients shall continue to assess the quality of their HIV/AIDS surveillance system and the data generated from this set of activities. Assessment will continue regardless of the status of, or procedures used, to conduct HIV/AIDS surveillance (*e.g.* AIDS or HIV reporting, or name or code-based reporting).

Evaluation activities should include critical reviews of surveillance methods and redirection of resources to those case-finding methods that are the most accurate and productive. Using the recommendations published in "CDC Guidelines for National Human Immunodeficiency Virus Case Surveillance, Including Monitoring for Human Immunodeficiency Virus Infection and Acquired Immunodeficiency Syndrome", assessments should include routine analysis of surveillance data to discover possible sources of under reporting and delays in reporting, monitoring data quality. At least once a year, recipients shall routinely re-abstract demographic, risk, laboratory, and clinical data from a sample of records to assess the quality and validity of information collected.

d. Inter-island and inter-state reciprocal notification of newly identified HIV/AIDS cases.

Recipients should routinely interact with other reporting areas to assure coordinate reporting between the island jurisdictions and ensure that reciprocal notification of newly identified HIV/AIDS cases, perinatal exposure cases, and deaths from HIV infection is executed. Routine engagement in this activity will improve the efficiency in reporting to CDC and minimize the number of duplicate case reports in the national data system. This communication is supported by the Council of State and Territorial Epidemiologists (Position Statement 01-ID-04). It should be carried out by appropriately trained and authorized surveillance staff, in a confidential manner consistent with local security, confidentiality and reporting policies and procedures. Recipients will use the same system for reciprocal notification of HIV, AIDS, perinatal HIV exposure and deaths among persons with HIV infection, including provision of appropriate identifying information (*e.g.*, name or other identifier).

e. Analysis and dissemination of HIV/AIDS surveillance data and promoting their uses of prevention and health services planning and evaluation.

All recipients should routinely disseminate reports of aggregate surveillance data for epidemic monitoring and education of the public and reporting sources and should promote uses of HIV/AIDS surveillance data for prevention and health services planning and evaluation. These activities should include: providing HIV/AIDS surveillance data and ongoing epidemiologic assistance to community planning groups; disseminating surveillance data through publications and presentations;

participating in planning and implementation meetings; conducting analyses to monitor trends, assess need for health-care resources, and project the future impact of the disease; and providing feedback to reporting sources on ways in which the surveillance data have been used to promote public health.

f. Reporting of data using CDC standards and software.

Recipients should ensure that data collection forms used to submit case reports from laboratories, clinical records, and patient interviews contain CDC's recommended standard data elements/questions on HIV testing behaviors, risk/exposure behaviors, and treatment access/adherence behaviors.

g. Security

Consistent with "Appendix C" of CDC's "Guidelines for HIV/AIDS Surveillance," recipients must ensure that the program requirements detailed in the Security Standards are attained as indicated by the signature of the Overall Responsible Party (ORP) on the attached form. HIV/AIDS surveillance funds will be restricted unless the signed ORP form has been submitted to CDC.

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:

a. Provide training in surveillance methods, study methods, and surveillance program planning and management.

b. Provide laboratory training that includes current scientific and technical information about the practical and the theoretical sensitivity and specificity of the different serological tests.

c. Coordinate and convene conferences, develop routine communications, provide guidelines and standards for the conduct of surveillance program activities, and communicate with recipients to develop, refine, and disseminate HIV/AIDS surveillance program information that describes effective methods to carry out program activities and monitor progress.

d. Provide: (1) Criteria for the surveillance definition of nationally reported HIV infection/disease (including AIDS), (2) prototype (model) case report forms, and (3) assistance in establishing and maintaining software for collecting, transferring and evaluating HIV/AIDS surveillance data.

e. Participate in the analysis and dissemination of information and data gathered from program activities and facilitate the transfer and utilization of

information and technology among all States and communities.

f. Assist in the evaluation of the overall effectiveness of program operations, including the impact of surveillance data on the development of public policy and on targeting and evaluating HIV Prevention Community Planning activities.

g. Assist areas to better use the national HIV/AIDS surveillance data provided to CDC by areas for public health policy formulation; obtaining and allocating federal resources for HIV/AIDS surveillance, prevention, and care; and evaluation of national public health recommendations. Promote and facilitate coordination of CDC surveillance data and activities with other CDC programs and other agencies of the federal government.

h. Provide technical assistance in the area of data storage and management to assure that reporting areas: (1) Adhere to appropriate confidentiality and security procedures; and (2) execute the necessary data management and analytic procedures to assure data integrity and accuracy.

i. Disseminate national surveillance data for public health research purposes through routine reports, articles in books and peer-reviewed journals, and presentations.

j. Maintain a secure and confidential national HIV/AIDS surveillance database.

II. Award Information

Type of Award: Cooperative Agreement.

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

Part I. Core Surveillance

Fiscal Year Funds: 2004.

Approximate Total Funding: \$34,000,000.

Approximate Number of Awards: 65.

Approximate Average Award: \$500,000.

Floor of Award Range: \$9,000 to \$4,000,000.

Ceiling of Award Range: \$4,000,000.
Anticipated Award Date: April 1, 2004.

Budget Period Length: 9 months.

Project Period Length: 2 years and 9 months.

Considerations for Funding Levels: All technically acceptable applications will be funded. The following items are general considerations that will affect decisions on funding levels.

1. Greatest consideration will be given to areas with an HIV case reporting system as of the due date of this application.

2. Areas that do not meet criterion one, but have a written plan with

established regulations or laws that will enable HIV case reporting to be in place as of April 1, 2004 will receive greater consideration than areas with no immediate plans for implementation of such a reporting system.

3. The presence of at least one Ryan White Title I Eligible Metropolitan Area (EMA) within the jurisdiction of the applicant.

4. The applicant's description of:

(a) Surveillance evaluation activities that are in place.

(b) Information from surveillance evaluation activities demonstrating that the HIV case reporting system meets the minimum performance standards for HIV case reporting published in "CDC Guidelines for National Human Immunodeficiency Virus Case Surveillance, Including Monitoring for Human Immunodeficiency Virus Infection and Acquired Immunodeficiency Syndrome". These standards are summarized in Attachment A (as posted with this announcement on the CDC Web site.)

5. Additional programmatic consideration will be based on increases or decreases in the volume of reported cases of HIV or AIDS and their implications for HIV/AIDS surveillance program activities.

Part II. HIV Incidence Surveillance

Fiscal Year Funds: 2004.

Approximate Total Funding: \$15,000,000.

Approximate Number of Awards: 35.

Approximate Average Award: \$250,000.

Floor of Award Range: \$130,000 to \$790,000.

Ceiling of Award Range: \$790,000.
Anticipated Award Date: April 1, 2004.

Budget Period Length: 9 months.

Project Period Length: 2 years and 9 months.

Consideration for Funding Levels: All technically acceptable applications will be funded. Funding levels will be determined by a formula using the highest new annual AIDS case count estimated for either of the two most recent calendar years available. Additional programmatic consideration will be based on trends in reported cases of HIV and the implications for HIV Incidence surveillance program activities.

Part III. Capacity Building for Epidemiologic and Program Evaluation Activities

Fiscal Year Funds: 2004.

Approximate Total Funding: \$2,100,000.

Approximate Number of Awards: 21.

Approximate Average Award:
\$100,000.
Floor of Award Range: None.
Ceiling of Award Range: \$100,000.
Anticipated Award Date: April 1, 2004.

Budget Period Length: 9 months.
Project Period Length: 2 years and 9 months.

Consideration for Funding Levels: All technically acceptable applications will be funded.

Part IV. Enhanced Surveillance for Perinatal Prevention

Fiscal Year Funds: 2004.
Approximate Total Funding:
\$1,800,000.
Approximate Number of Awards: 20.
Approximate Average Award:
\$82,000.
Floor of Award Range: \$30,000 to \$200,000.
Ceiling of Award Range: \$200,000.
Anticipated Award Date: April 1, 2004.

Budget Period Length: 9 months.
Project Period Length: 2 years and 9 months.

Funding Preferences

Because Part IV is competitive, applications for activity under this Part will be evaluated by an Objective Review Panel. Some applicants may not be funded.

The following items are general considerations that will affect decisions on funding levels:

1. Greatest preference will be given to areas that receive categorical funding from CDC for perinatal prevention program activities.

2. Secondary preference will be given to areas that possess an authorized reporting system for pediatric HIV exposure as well as adult, adolescent, and pediatric HIV infection.

3. Additional programmatic funding considerations will be based on the estimated number of HIV infected women giving birth (Source: 1994 Survey of Childbearing Women) and its implications for HIV/AIDS surveillance program activities.

Part V. Laboratory Testing for Recent HIV Infection

Fiscal Year Funds: 2004.
Approximate Total Funding:
\$800,000.
Approximate Number of Awards: 2 to 3.
Approximate Average Award:
\$320,000.

Floor of Award Range: \$270,000 to \$400,000.
Ceiling of Award Range: \$400,000.
Anticipated Award Date: April 1, 2004.

Budget Period Length: 9 months.
Project Period Length: 2 years and 9 months.

Funding Preferences

Because Part V is competitive, applications for activity under this Part will be evaluated by an independent review panel (formerly Objective Review Panel). Some applicants may not be funded.

Preference will be given to sites that achieve the best distribution and representation of geographic regions (e.g., Northeast, South, and West).

Preference will be given to areas that demonstrate the greatest degree of automation in sample processing and testing.

Part VI. Behavioral Surveillance

Fiscal Year Funds: 2004.
Approximate Total Funding:
\$10,000,000.
Approximate Number of Awards: 25.
Approximate Average Award:
\$400,000.
Floor of Award Range: \$350,000 to \$450,000.
Ceiling of Award Range: \$450,000.
Anticipated Award Date: April 1, 2004.

Budget Period Length: 9 months.
Project Period Length: 2 years and 9 months.

Consideration for Funding

All technically acceptable applications will be funded.

Part VII. Core Surveillance in the Pacific Island Jurisdictions

Fiscal Year Funds: 2004.
Approximate Total Funding:
\$100,000.
Approximate Number of Awards: 6.
Approximate Average Award:
\$17,500.
Floor of Award Range: \$10,000 to \$25,000.
Ceiling of Award Range: \$25,000.
Anticipated Award Date: April 1, 2004.

Budget Period Length: 9 months.
Project Period Length: 2 years and 9 months.

Considerations for Funding Levels

All technically acceptable applications will be funded. The following items are general considerations that will affect decisions on funding levels.

1. Greatest consideration will be given to areas that have a functional laboratory physically located on an island within the funded island jurisdiction that is either currently able, or could, with a reasonable investment

in the appropriate equipment, accept, process, and distribute results for confirmatory HIV diagnostic tests. This laboratory should be able to execute Western Blot or immunofluorescence assay (IFA) tests. The health department on an island jurisdiction with such a facility should be able to serve as a central data collection center that coordinates available clinical information on cases confirmed through processing of specimens from other island jurisdictions.

2. The next greatest consideration will be given to areas with an HIV case reporting system as of the due date of this application.

3. Areas that do not meet criterion one, but have a written plan with established regulations or laws that will enable HIV case reporting to be in place as of April 1, 2004 will receive greater consideration than areas with no immediate plans for implementation of such a reporting system.

4. Additional programmatic consideration will be based on increases or decreases in the volume of reported cases of HIV or AIDS and their implications for HIV/AIDS surveillance program activities.

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

Eligible Applicants

Part I. Core Surveillance

Applications may be submitted by health departments of States, U.S. territories or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, and the six independently-funded city health departments of Chicago, Houston, Los Angeles, New York City, Philadelphia, and San Francisco. All eligible applicants for core HIV/AIDS surveillance activities will be funded. Funding will include activities that expand the uses and improve the quality of HIV/AIDS surveillance data to more effectively guide public health policy and provide relevant information necessary to direct and evaluate prevention and care activities.

Part II. HIV Incidence Surveillance

In order to ensure execution of this complex project, and provide estimates for incidence that possess adequate

statistical precision, eligible sites must possess HIV reporting systems, and they must have a sufficient number of reports on new, annual HIV diagnoses.

Therefore, eligibility is limited to applicants previously funded for this activity as part of the supplemental awards provided through Program Announcement 00005. States will be eligible regardless of the AIDS case count if there is an independently funded city health department within the State that has either been previously funded, or will be funded under the criteria described below.

New applicants eligible for these funds will include those areas which will have HIV case reporting as of April 1, 2004, and have, according to the National AIDS Reporting System maintained by CDC, at least 300 new AIDS cases in either of the calendar years during the budget period.

The known eligible sites are: Alabama, Arizona, California, Chicago, Colorado, Connecticut, District of Columbia, Florida, Georgia, Houston, Illinois, Indiana, Kentucky, Los Angeles, Louisiana, Maryland, Massachusetts, Michigan, Mississippi, Missouri, New Jersey, New York State, New York City, North Carolina, Ohio, Oklahoma, Pennsylvania, Philadelphia, Puerto Rico, San Francisco, South Carolina, Tennessee, Texas, Virginia, and Washington.

Part III. Capacity Building for Epidemiologic and Program Evaluation Activities

Recipient health departments must have sufficient disease burden for analytic activities to provide information with sufficient statistical and epidemiologic precision.

Therefore, assistance will be provided to moderate morbidity States reporting from 240 to 1500 AIDS cases from July 2000 through June 2001, (Centers for Disease Control, HIV/AIDS Surveillance Report, 2000;13(no.1):6) and States or territories previously funded for fewer than five of the following supplemental surveillance projects.

Projects include the following and correspond to the appropriate sections of Part II of FY2000's Program Announcement 00005 and Activities One through Four of FY2001's Program Announcement 00005B: (1) Adult/Adolescent Spectrum of Disease (ASD); (2) Survey of HIV Disease and Care (SHDC); (3) Survey of HIV Disease and Care plus Interview Supplement (SHDC+); (4) Supplement to HIV/AIDS Surveillance (SHAS); (5) New Supplemental Interview Projects; (6) Enhanced Surveillance for Perinatal Prevention; (7) Alternate Approaches;

(8) Regional Technical Assistance Centers; (9) HIV Testing Survey; and (10) Estimation of HIV incidence.

Known eligible applicants are: Alabama, Arizona, Connecticut, Delaware, District of Columbia, Georgia, Illinois, Indiana, Kentucky, Louisiana, Massachusetts, Mississippi, Missouri, Nevada, North Carolina, Ohio, Oklahoma, Puerto Rico, South Carolina, Tennessee, and Virginia.

Part IV. Enhanced Surveillance for Perinatal Prevention

This is a complex activity that requires substantial resources, commitment on the part of the affected surveillance program, and a sufficient number of events to provide reasonably precise assessments of the effectiveness of perinatal prevention efforts.

Therefore, eligible applicants are limited to the high-morbidity areas (estimated 60 or more HIV-positive women giving birth—Source: 1994 Survey of Childbearing Women) previously funded by CDC for Enhanced Perinatal Surveillance, or to areas that have received categorical funding from CDC for perinatal HIV prevention program activities.

Eligible applicants should have implemented, or plan to implement, HIV surveillance for adults and children (including reporting HIV-exposed infants) as an extension of their AIDS surveillance activities, by April 1, 2004. If this has not occurred, the applicant may propose to continue to conduct these activities in selected facilities serving large numbers of HIV-infected women and their infants using established research (*i.e.*, IRB) procedures for case ascertainment.

Known eligible applicants are: Alabama, California, Chicago, Connecticut, Delaware, District of Columbia, Florida, Georgia, Houston, Illinois, Los Angeles, Louisiana, Maryland, Massachusetts, Michigan, Mississippi, New Jersey, New York, New York City, North Carolina, Pennsylvania, Philadelphia, Puerto Rico, Ohio, Tennessee, Texas, Virginia, and South Carolina.

Part V. Laboratory Testing for Recent HIV Infection

Because this is a technically sophisticated technique, only laboratories that are already participating in the IND with prior experience conducting large numbers of STARHS tests and documented proficiency will be considered.

Part VI. Behavioral Surveillance

Eligibility will be limited to the State or local health departments which

include the top 26 Metropolitan Statistical Areas (MSA's) by number of people living with AIDS at the end of 2000 as reported in "HIV/AIDS Surveillance Supplemental Report," (2002;8(No.2:18-19)).

These are the directly funded city health departments of Los Angeles, CA; San Francisco, CA; Chicago, IL; New York City, NY; Philadelphia, PA; Houston, TX; and, the State health departments containing the following MSAs: Phoenix, AZ; San Diego, CA; Denver, CO; New Haven, CT; Washington, DC; Miami, and Ft. Lauderdale, FL; Atlanta, GA; New Orleans, LA; Boston, MA; Baltimore, MD; Detroit, MI; St. Louis, MO; Las Vegas, NV; Newark, NJ; Nassau-Suffolk, NY; San Juan, PR; Dallas, TX; Norfolk, VA; and, Seattle, WA.

Projects will be supported only within the MSA listed and only within the geographic bounds of the funded entity (where MSAs extend beyond the jurisdiction of the eligible state or city health department). Recruitment venues may be limited to the geographic subdivision (*e.g.*, city, county, health district) within the MSA with the highest AIDS morbidity where it would be impractical to conduct surveillance in the entire area.

Part VII. Core Surveillance in the Pacific Island Jurisdictions

Applications may be submitted by health departments of American Samoa, Guam, Marshall Islands, Palau, the Commonwealth of the Northern Mariana Islands and the Federated States of Micronesia.

All technically acceptable applicants for core HIV/AIDS surveillance activities will be funded. Funding will include activities that facilitate the development and improvement in the quality of HIV/AIDS surveillance data to more effectively guide public health policy and provide relevant information necessary to direct and evaluate prevention and care activities.

Other Eligibility Requirements: None.

Cost Sharing or Matching: Matching funds are not required for this program.

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

How to Obtain Application Forms: To apply for this funding opportunity use application form PHS 5161-1. Forms 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.

This program announcement is the definitive guide on application format, content, and deadlines. It supersedes information provided in the application instructions. If there are discrepancies between the application form instructions and the program announcement, adhere to the guidance in the program announcement.

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 <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 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.

Content and Form of Submission

Application: Applications for activities under Section I, II, III, VI, and VII will receive a Technical Acceptability Review. Part IV and Part V will be evaluated separately by an independent and separate objective review panel. To facilitate this review, submit separate and complete applications for each activity under Parts I, II, III, IV, V, VI, and VII for which you are applying, including separate budgets and narrative justifications, that can stand alone as an application for review purposes.

You must submit a signed original and two copies of your application forms. You must include a project narrative with your application forms. Your narrative must be submitted in the following format:

Part I. Core Surveillance

- Maximum number of pages: 30 pages double spaced, including up to five pages of program plans and budgets for years 2005 and 2006, excluding reports and appendices. Applications

with narratives in excess of 30 pages will be returned to the applicant and not considered for funding.

- Font size: 12 point un-reduced.
- Paper size: 8.5 by 11 inches.
- Page margin size: 1 inch.
- Printed only on one side of page.
- Held together only by rubber bands or metal clips; not bound in any other way.

Format:

In developing this Part of the application, your narrative must follow the format below:

1. Program Need and Resources.
2. Collaboration and Use of Data.
3. Objectives.
4. Program Plan and Methods for Implementation.
5. Program Evaluation Plan.
6. Project Management and Staffing Plan.
7. Budget.
8. Attachments.

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

1. Describe proposed active case-finding efforts, follow-up of priority cases, and activities that promote uses of HIV and AIDS surveillance data for prevention planning.
2. Describe procedures for critically reviewing surveillance methodologies to promote efficient and effective use of resources, disseminating data for public health purposes, ensuring that the surveillance program contributes to the goals and public health mission of the health department, using surveillance data to evaluate the effectiveness of State/local prevention efforts, policies, and programs, and using surveillance data to target and evaluate proposed community-based interventions.

Also, describe proposed activities that will facilitate the efficiency, reliability, completeness of variables and accuracy of HIV/AIDS surveillance data. Examples of such activities include procedures that facilitate the identification and investigations of cases of public health importance (e.g. atypical or variant HIV sub-types or strains), with specific outcomes and co-morbidities (e.g., persons diagnosed concurrently with HIV and TB or HIV and STDs), or collaborations with prevention and care partners (e.g., projects to assess the availability of data on risk behaviors in Prevention Counseling and Referral Systems [PCRS], or assessment of the validity of CD4 or viral load reporting as a marker of receiving regular care and treatment of HIV).

3. If HIV case surveillance is, or will soon be implemented, and case reports

are used to facilitate voluntary prevention referral services [e.g. PCRS], or conduct registry matching with other public health programs in the health department (e.g., tuberculosis, STD), document steps to ensure that such practices are consistent with the Security and Confidentiality Standards (as published in "Appendix C" of the Guidelines for HIV/AIDS Surveillance) and consistent with CDC and State or local IRB requirements for secondary uses of surveillance data.

4. PCRS can be conducted without linkage to surveillance information. Some areas may elect to link surveillance information to PCRS. In areas that link surveillance reporting and PCRS activities, CDC recommends that these activities should be evaluated to assure that the programmatic objectives of PCRS are attained without unnecessarily compromising community and provider support for surveillance program activities. These evaluations should be executed in partnership with HIV prevention programs. Applicants should document that such evaluations are jointly funded and conducted by the surveillance and HIV/AIDS prevention program staff.

5. Describe existing evaluation activities to assess the performance attributes of the HIV/AIDS surveillance system according to published CDC recommendations (Attachment A). This description should include the methods and results associated with efforts to limit the number of inter-state duplication of HIV, AIDS, perinatal exposure and HIV infection deaths across States, and intra-state reporting areas through reciprocal notification of cases. Provide documentation that the applicant will collaborate with CDC to conduct evaluations during the period of this cooperative agreement according to established and validated protocols developed by CDC.

6. Describe State laws, rules, or regulations pertaining to the protection or release of surveillance information; and physical security of hard copies and electronic files containing confidential surveillance information; any laws, rules, regulations, or health department policies that require or permit the release of patient identifying information collected under the HIV/AIDS surveillance system to entities outside of the public health department and measures the health department has taken to ensure that the confidentiality of individuals reported to the surveillance system is protected from further or unlawful disclosure. As part of the application, you must submit a signed copy of the form (Attachment B) designating the ORP and attesting that

all Program Requirements as stipulated in the Security Standards in Appendix C of the "Guidelines for HIV/AIDS Surveillance" have been attained.

7. Provide a description of the personnel, and the level of support provided through CDC funding for each staff person involved with HIV/AIDS core surveillance activities. A description of the experience, training, credentials and activities of these staff members should be included. Curriculum vitae should be included as attachments to the application for those staff members occupying supervisory, leadership, and advanced technical or scientific positions.

8. Budget

a. In the travel category, include a total for local travel and a total for out-of-state travel.

b. The following information is required for all proposed contracts: name of contractor, period of performance, method of selection (e.g., competitive or sole source), description of activities, justification for subcontracting, and itemized budget.

c. Submit a single budget and justification for core surveillance Recipient Activities.

Following receipt of your FY 2004 award, CDC may request additional activity- or project-specific budgetary information.

Part II. HIV Incidence Surveillance

- Maximum number of pages: 20 double spaced, including up to five pages of program plans and budgets for years 2005 and 2006 excluding reports and appendices. Applications with narratives in excess of 20 pages will be returned to the applicant and not considered for funding.

- Font size: 12 point un-reduced.
- Paper size: 8.5 by 11 inches.
- Page margin size: 1 inch.
- Printed only on one side of page.
- Held together only by rubber bands or metal clips; not bound in any other way.

Format:

In developing this Part of the application, your narrative must follow the format below:

1. Program Plan.
2. Objectives.
3. Methods for Implementation.
4. Program Evaluation Plan.
5. Budget.
6. Attachments.

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

1. Describe the characteristics of the HIV reporting system including regulations or statutes that authorize the

collection of HIV data, length of time it has been in place, major sources of reports, whether laboratory reporting exists, and if so, if electronic laboratory reporting is used. This description must also verify that diagnosed HIV infections are reported in a timely manner.

2. Describe the potential ability of the surveillance system to coordinate with laboratory partners, including public health laboratories and commercial laboratories responsible for HIV testing in the state, to obtain aliquots of blood for STARHS testing.

3. How the recipient will collaborate with CDC to assure appropriate and efficient preparation and transport from the lab of diagnosis to the public health lab, and then from the public health lab to reference laboratories for STARHS testing.

4. Describe how HIV testing histories will be obtained (either before or after STARHS testing) from persons identified as recently infected by the STARHS assay, or its equivalent. The strategies for acquiring these data should include a diverse sample of persons from public and private facilities to assure representative and adequately precise population-based estimates for incidence.

5. Describe how HIV case data will be linked to results from laboratory specimens, and to HIV testing history information.

6. In addition to linking STARHS results to information in the HIV reporting system, in some settings a set of specimens will be tested in an unlinked fashion. Describe how specimens from such individuals will be anonymized, and data for this component of the surveillance system will be managed.

7. Describe the number, activities, level of support and qualifications of the personnel who will be involved in the HIV Incidence Surveillance program.

8. Budget

a. In the travel category, include a total for local travel and a total for out-of-state travel.

b. The following information is required for all proposed contracts: name of contractor, period of performance, method of selection (e.g., competitive or sole source), description of activities, justification for subcontracting, and itemized budget.

c. Submit a single budget and justification for HIV Incidence Surveillance Recipient Activities.

Following receipt of your FY 2004 award, CDC may request additional activity- or project-specific budgetary information.

Part III. Capacity Building for Epidemiologic and Program Evaluation Activities

- Maximum number of pages: 15 double-spaced pages including up to five pages of program plans for years 2005 and 2006, excluding reports and appendices. Applications with narratives in excess of 15 pages will be returned to the applicant and not considered for funding.

- Font size: 12 point un-reduced.
- Paper size: 8.5 by 11 inches.
- Page margin size: 1 inch.
- Printed only on one side of page.
- Held together only by rubber bands or metal clips; not bound in any other way.

Format:

In developing this Part of the application, your narrative must follow the format below:

1. Program Need and Resources.
2. Plan and Objectives.
3. Methods.
4. Staffing.
5. Budget.
6. Attachments.

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

Describe how staff hired for this project will:

1. Provide on-going assistance in the development and use of the epidemiologic profile, program, and other health-related data for HIV prevention and care community planning.

2. Assist HIV prevention and care community planning groups with evaluation activities.

3. Describe the number, and type of activities, the level of support and qualifications of the personnel who will be involved in the HIV Incidence Surveillance program.

4. Budget

a. In the travel category, include a total for local travel and a total for out-of-state travel.

b. The following information is required for all proposed contracts: name of contractor, period of performance, method of selection (e.g., competitive or sole source), description of activities, justification for subcontracting, and itemized budget.

c. Submit a single budget and justification for Capacity Building for Epidemiologic and Program Evaluation Activities Recipient Activities.

Following receipt of your FY 2004 award, CDC may request additional activity- or project-specific budgetary information.

Part IV. Enhanced Surveillance for Perinatal Prevention

• Maximum number of pages: The narrative should be no more than 15 double-spaced pages, including up to five pages of program plans and budgets for years 2005 and 2006, excluding reports and appendices. Applications with narratives in excess of 15 pages will be returned to the applicant and not considered for funding.

- Font size: 12 point unrounded.
- Paper size: 8.5 by 11 inches.
- Page margin size: 1 inch.
- Printed only on one side of page.
- Held together only by rubber bands or metal clips; not bound in any other way.

Format:

In developing this Part of the application, your narrative must follow the format below:

1. Program Plan.
2. Objectives.
3. Methods.
4. Evaluation.
5. Proposed Data Uses.
6. Staffing.
7. Budget.
8. Attachments.

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

1. Describe the current ability of surveillance activities to collect information on all HIV exposed infants and HIV infected mothers. Applicants that will not implement HIV reporting to include HIV exposure reporting by April 1, 2004 and apply for a time-limited research project must submit evidence that the proposed activity will be approved by an IRB as required by CDC.

2. Describe the methods that will be used in identifying and linking data on HIV exposed infants and HIV infected mothers; conducting systematic chart reviews to complete abstraction forms and HIV/AIDS case report forms; conducting longitudinal follow-up of HIV exposed infants to ascertain infection status and initiation of HIV related treatment and care; and assessing short-and/or long-term outcomes in HIV exposed infants.

3. Describe the methods that will be used in evaluating the Enhanced Surveillance of Perinatal Prevention activities, to include a description of the timeliness and completeness of data collection and submission of data to CDC.

4. Describe how the data from Enhanced Surveillance of Perinatal Prevention will be coordinated with and used to improve perinatal prevention activities.

5. Describe the number, activities, level of support and qualifications of the personnel who will be involved in the Enhanced Surveillance of Perinatal Prevention.

6. Budget

a. In the travel category, include a total for local travel and a total for out-of-state travel.

b. The following information is required for all proposed contracts: name of contractor, period of performance, method of selection (*e.g.*, competitive or sole source), description of activities, justification for subcontracting, and itemized budget.

c. Submit a single budget and justification for Enhanced Surveillance of Perinatal Prevention Activities.

Following receipt of your FY 2004 award, CDC may request additional activity-or project-specific budgetary information.

Part V. Laboratory Testing for Recent HIV Infection

• Maximum number of pages: The narrative should be no more than 15 double-spaced pages printed on one side, including up to five pages of program plans and budgets for years 2005 and 2006 excluding reports and appendices. Attachments should not exceed an additional 25 pages, including budget and budget narrative. Required forms do not count toward page limits. Applications with narratives in excess of 15 pages will be returned to the applicant and not considered for funding.

- Font size: 12 point unrounded.
- Paper size: 8.5 by 11 inches.
- Page margin size: 1 inch.
- Printed only on one side of page.
- Held together only by rubber bands or metal clips; not bound in any other way.

Format:

In developing this Part of the application, your narrative must follow the format below:

1. Technical Competence.
2. Capacity.
3. Evaluation.
4. Staffing.
5. Budget.
6. Attachments.

VI. Behavioral Surveillance

• Maximum number of pages: The program narrative should be no more than 15 double-spaced pages. Attachments should not exceed an additional 25 pages, including budget and budget narrative. Required forms do not count toward page limits. Applications with narratives in excess of 15 pages will be returned to the applicant and not considered for funding.

- Font size: 12 point unrounded.
- Paper size: 8.5 by 11 inches.
- Page margin size: 1 inch.
- Printed only on one side of page.
- Held together only by rubber bands or metal clips; not bound in any other way.

Format:

In developing this Part of the application, your narrative must follow the format below:

1. Program Plan.
2. Objectives.
3. Methods.
4. Evaluation.
5. Proposed Data Uses.
6. Staffing.
7. Budget.
8. Attachments.

Part VII. Core Surveillance in the Pacific Island Jurisdictions

• Maximum number of pages: The narrative should be no more than 15 double-spaced pages, including up to five pages of program plans and budgets for years 2005 and 2006, excluding reports and appendices. Applications with narratives in excess of 30 pages will be returned to the applicant and not considered for funding.

- Font size: 12 point unrounded.
- Paper size: 8.5 by 11 inches.
- Page margin size: 1 inch.
- Printed only on one side of page.
- Held together only by rubber bands or metal clips; not bound in any other way.

Format:

In developing this Part of the application, your narrative must follow the format below:

1. Program Need and Resources.
2. Collaboration and Use of Data.
3. Objectives.
4. Program Plan and Methods for Implementation.
5. Program Evaluation Plan.
6. Project Management and Staffing Plan.
7. Budget.
8. Attachments.

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

1. Describe proposed plans for developing active case-finding efforts, follow-up of priority cases, and activities that promote uses of HIV and AIDS surveillance data for prevention planning.

2. Describe procedures for critically reviewing surveillance methodologies to promote efficient and effective use of resources; disseminating data for public health purposes; ensuring that the surveillance program contributes to the goals and public health mission of the

health department; using surveillance data to evaluate the effectiveness of prevention efforts, policies, and programs; and using surveillance data to target and evaluate proposed community-based interventions.

3. Describe existing or proposed assessment activities to improve the performance attributes of the HIV/AIDS surveillance system. This description should include the methods to improve the completeness of reporting, limit the number of inter-island duplicates of HIV, AIDS, and promote the accuracy of the data.

4. In specific areas where there is laboratory capacity to perform confirmatory testing (*i.e.* Western Blot or IFA) describe the capacity to serve as central data coordination area through collaboration with other island jurisdictions that submit specimens for such confirmatory testing. These descriptions should include a process for assuring compliance with security and confidentiality requirements.

5. Describe State laws, rules, or regulations pertaining to the protection or release of surveillance information; physical security of hard copies and electronic files containing confidential surveillance information; any laws, rules, regulations, or health department policies that require or permit the release of patient identifying information collected under the HIV/AIDS surveillance system to entities outside of the public health department and measures the health department has taken to ensure that the confidentiality of individuals reported to the surveillance system is protected from further or unlawful disclosure. As part of the application, you must submit a signed copy of the form (Attachment B) designating the ORP and attesting that all Program Requirements as stipulated in the Security Standards in Appendix C of the "Guidelines for HIV/AIDS Surveillance" have been attained.

6. Provide a description of the personnel, and the level of support provided through CDC funding for each staff person involved with HIV/AIDS core surveillance activities. A description of the experience, training, credentials and activities of these staff members should be included. Curriculum vitae should be included as attachments to the application for those staff members occupying supervisory, leadership, and advanced technical or scientific positions.

7. Budget

a. In the travel category, include a total for local travel and a total for out-of-state travel.

b. The following information is required for all proposed contracts:

name of contractor, period of performance, method of selection (*e.g.*, competitive or sole source), description of activities, justification for subcontracting, and itemized budget.

c. Submit a single budget and justification for core surveillance Recipient Activities. Following receipt of your CY 2004 award, CDC may request additional activity-or project-specific budgetary information.

Funding Restrictions:

Funding restrictions, which must be taken into account while writing your budget for parts I–VII are as follows:

- Funds are awarded for a specifically defined purpose described in this announcement and may not be used for any other purpose or program.
- Funds may be used to support personnel and to purchase equipment, supplies, and services directly related to project activities.
- Funds may not be used to supplant State or local health department funds available for HIV Prevention and Surveillance.
- Funds may not be used to provide direct medical care or prevention case management.

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 must be less than 12 months of age.

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>.

Submission Date, Time, and Address:
Application Deadline Date: January 16, 2004.

Application Submission Address:
Submit your application by mail or express delivery service to:

Technical Information Management–PA# 04017, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

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 program announcement is the definitive guide on application format, content, and deadlines. 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 you did not meet the submission requirements.

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. CDC will not be sending post cards acknowledging receipt of applications.

Intergovernmental Review of Applications

Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order (EO) 12372. This order sets up a system for state and local governmental review of proposed federal assistance applications. You should contact your state single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your state's process. Click on the following link to get the current SPOC list: <http://www.whitehouse.gov/omb/grants/spoc.html>.

V. Application Review Information

Review 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:

A Technical Acceptability Review will be conducted by CDC for Parts I, II, III, VI, and VII. Parts IV and V will involve Objective Review Panels. The individual "Parts" are further discussed below.

Part I. Core Surveillance

The following criteria will be used to evaluate applications for their technical acceptability:

1. Program Need and Resources: The extent to which the applicant describes the requirements for, and activities of, the HIV/AIDS surveillance system that includes a presentation of existing strengths and limitations. The extent to which this overview includes: the program need in terms of HIV/AIDS morbidity (*i.e.*, delineation of the annual number of HIV/AIDS cases and case rates); extent and level of funding devoted to prevention, treatment, and care programs in the area that require HIV/AIDS surveillance data for resource allocation and program planning; uses of surveillance data, including linkages to public health program activities such as PCRS; ability to analyze data that allows for the identification of trends in emerging modes of HIV transmission (by various demographic indicators and behaviors); all existing and potential sources of HIV/AIDS cases; a description of HIV/AIDS reporting procedures and resources in the area including a presentation of data items currently collected; ongoing quality assurance procedures to promote data quality; sources of funding beyond federal monies provided by CDC; the flow of data through the reporting system; existing policies and procedures that are written and implemented for security, confidentiality, data dissemination and surveillance procedural activities; educational and training activities undertaken to develop and enhance the skills of surveillance staff and staff in reporting facilities; a copy of the most recent annual surveillance report; State legislation and/or regulations pertaining to the reporting, collection, uses and dissemination of HIV/AIDS surveillance data.

2. Collaboration and Use of Data: The extent to which the applicant describes past, current, and proposed collaboration with: the relevant HIV/AIDS organizations and agencies within the reporting area; CDC, and other States or national organizations involved in coordinating and assuring the quality, completeness, and accuracy of HIV/AIDS surveillance data; locally and Federally-funded prevention, treatment and care programs such as the CDC prevention programs or the Ryan White Care Act; and the extent HIV/AIDS surveillance data are used to assist public and private partners (*e.g.*, community planning groups, AIDS Service Organizations) as a guide for allocating HIV prevention and care

resources, and as a means to evaluate the success of their intervention programs.

3. Proposed Objectives: The extent to which program objectives are: specific, measurable, time-phased, and realistic; related to recipient activities, program purpose and program activities; derived from needs identified in the resources and needs assessment; and consistent with national HIV/AIDS surveillance program objectives.

4. Program Plan and Methods for Implementation: The extent to which the applicant adequately describes the procedures and methods to be used to accomplish the program objectives for their surveillance program; and describes how program plans and procedures will facilitate achievement of national objectives for HIV/AIDS surveillance.

5. Program Evaluation Plan: The applicant provides an evaluation plan that is appropriate for measuring progress toward program area and national HIV/AIDS surveillance objectives; the plan should include a specified time-line and methods for identifying promoters and barriers to program success.

6. Project Management and Staffing Plan: The extent to which proposed staffing, organizational structure, staff experience and background, identified training needs or plan, and job descriptions and curricula vitae for both proposed and current staff indicate ability to carry out the purposes of the program.

7. Budget: The budget is reasonable, clearly justified, consistent with the demonstrated need and proposed activities, and likely to lead to program success.

Part II. HIV Incidence Surveillance

1. Program Plan: The degree to which the applicant provides evidence of their understanding of the project goals and conceptual background through the presentation of a coherent plan that describes all the necessary activities and personnel needed to conduct HIV Incidence surveillance. Quality of plans for conducting data analysis and presentation showing how data have been and will be used to improve state and local HIV prevention programs and HIV services and care.

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

3. Methods for Implementation: The extent to which the applicant demonstrates the technical capability to conduct the project using the appropriate data collection and analytic

methods. Specific technical capabilities to be reviewed for each project include: The ability to identify new HIV infections reported to the surveillance system in a timely manner; collaboration with laboratory partners, including public health laboratories and commercial laboratories responsible for HIV testing in the state, to obtain aliquots of blood for STARHS testing; preparation and transport of specimens to reference laboratories for STARHS testing; obtainment of sufficient HIV testing history information; linkage of HIV case data to laboratory specimens, and to HIV testing history information; and in areas that execute unlinked STARHS, the extent to which the methods are feasible and appropriate.

4. Program Evaluation Plan: The applicant provides an evaluation plan that is appropriate for measuring progress toward program area and national HIV Incidence surveillance objectives; the plan should include a specified time-line and methods for identifying promoters and barriers to program success.

5. Budget: The budget is reasonable, clearly justified, consistent with the demonstrated need and proposed activities, and likely to lead to program success.

Part III. Capacity Building for Epidemiologic and Program Evaluation Activities

1. Program Need and Resources: The extent to which the applicant describes the need for resources to achieve the purpose. The detail should include how awardees will collaborate with public and private partners (such as, HIV prevention and care community planning groups and AIDS service organizations) to use surveillance, program, and other health-related data to enhance community planning, evaluation, and monitoring achievement of goals and objectives.

2. Plan and Objectives: The extent to which the applicant describes its plan for achieving the purpose, including presentation of goals, objectives, activities, and time frames along with narrative discussion. The narrative discussion should include:

- a. Objectives for the collection, use, analysis, interpretation of surveillance, program, and other health-related data to enhance epidemiologic and program evaluation activities.

- b. Discussion of the "Recipient Activities" outlined above.

3. Methods: The extent to which the applicant describes how surveillance and other health-related data will be used to improve epidemiologic and program evaluation activities, including,

but not limited to, prevention and care community planning, assessment of prevention program effectiveness, and the monitoring of goals and objectives. Requests should include discussion of various data sets and specific studies that may be available to assist with assessment of the impact of HIV prevention activities in the jurisdiction.

4. Staffing: The extent to which the qualifications, duties, responsibilities, and time allocation of proposed staff (including potential contractors) are discussed, and how these attributes are justified and appropriate to accomplish the purpose and implement the recipient activities. Discussion should include the degree to which proposed staff will be able to provide appropriate scientific oversight as well as programmatic and administrative support for the proposed activities.

5. Budget: Budgets will be assessed to ensure they are reasonable, clearly justified, consistent with the demonstrated need and proposed activities, and likely to lead to program success.

Part IV. Enhanced Surveillance for Perinatal Prevention

Note: Applications submitted for this Part will be reviewed by an independent objective review panel appointed by CDC that will evaluate each application against the following criteria:

1. Methods (25 points): The extent to which the applicant demonstrates technical capability to conduct the project using the appropriate data collection and analytic methods. Specific methods for accomplishing the following technical activities should be described:

a. Identifying and linking data on related infected mothers and HIV exposed children.

b. Conducting systematic chart reviews, abstraction forms and HIV/AIDS case report forms.

c. Conducting longitudinal follow-up of HIV-exposed infants to ascertain infection status and initiation of HIV related treatment and care.

d. Past ability to conduct the project including a description of the timeliness and completeness of data collection and submission on mother-infant pairs.

2. Program Plan (20 points): The extent to which the applicant provides a clear and feasible plan for enhancing surveillance activities for children and women by expanding core perinatal surveillance by collecting data:

a. On all children born to HIV-infected women (including zidovudine (ZDV) and other antiretroviral therapy used during pregnancy, at labor or delivery, and to the neonate; opportunistic infection prophylaxis; initiation of HIV evaluation and care; HIV infection status; and short as well as long-term outcomes in antiretroviral exposed and unexposed children).

b. On HIV-infected women who deliver a live infant, to assess the counseling and therapy they received during pregnancy, the date of their HIV diagnosis, dates of initiation of prenatal care, dates of initiation of ZDV and other antiretroviral therapy, pregnancy outcomes, stage of HIV disease, and HIV risk behaviors.

c. Applicants that will not implement HIV reporting by April 1, 2004 and apply for a time-limited research project must submit evidence that the proposed activity will be approved by an IRB as required by CDC.

3. Objectives (15 points): The extent to which the objectives are specific (with time frames), realistic, and address the required recipient activities.

4. Evaluation (15 points): The extent to which realistic plans for evaluation of project activities have been developed, and the quality of such plans. Includes a description of the timeliness of the system and the completeness of ascertainment of mother-infant pairs.

5. Proposed Data Uses (15 points): The extent to which data have, or will, assist in HIV prevention and care activities, so that these data are used for formulating public health strategies and targeting resources. In areas that received categorical CDC funding for perinatal prevention activities, the extent to which the applicant describes how the data from this system will be coordinated with and be used to improve these activities.

6. Staffing (10 points): The extent to which proposed staffing, organizational structure, staff experience and background, identified training needs or plan, and job descriptions and curricula vitae for both proposed and current staff indicate ability to carry out the purposes of the program.

7. Budget (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.

Part V. Laboratory Testing for Recent HIV Infection

Note: Applications submitted for this Part will be reviewed by an independent objective review panel appointed by CDC that will evaluate each application against the following criteria:

1. Technical Competence (40 points): Ability to perform the assay for incident HIV infection with an extremely high degree of reliability, as evidenced by previous successful proficiency conducting this test and demonstrated satisfactory participation in the CDC quality assurance program for this test. Applicants should include quality control charts from actual testing conducted over the most recent three months.

2. Capacity (40 points): Ability to process and test at least 6,000 specimens per month, using acceptable automated testing equipment and protocols. Ability to track receipt of specimens and report results within seven days of receipt of specimen using appropriate data and specimen management systems. Availability of adequate, dedicated laboratory space and equipment for receipt, testing and short-term storage of a large volume of specimens.

3. Staff capabilities and Project Oversight (20 points): Demonstrates inclusion of scientific oversight as appropriate for the complexity of the proposed activities, as evidenced by: (a) Project administration plans; (b) ability to recruit, hire, and train appropriate number and type of personnel to conduct a large number of highly complex tests; and (c) qualifications, research and laboratory experience of the staff who will participate in this project documented in attached CVs of key staff. This includes evidence of ability to collaborate and conduct testing for external, collaborating organization (e.g., documentation from state health departments for which they have conducted testing in the past) including attached letters of support from current collaborators and a letter from the State or City health department human resources office director confirming their ability to recruit and hire appropriate staff within three months of the start of the funding.

4. Budget (Not scored): The extent to which the budget is reasonable, clearly justified, and consistent with the intended use of funds.

Part VI. Behavioral Surveillance

The technical acceptability of the application will be evaluated based on the following criteria:

1. The degree to which the applicant provides evidence of their understanding of the project protocol and objectives. The extent to which plans for evaluation of project activities have been developed and are realistic. Quality of plans for data analysis and presentation showing how data have been and will be used to improve state and local HIV prevention programs and HIV services and care.

2. The extent to which the applicant provides evidence of their ability to implement study methodology. The extent to which the applicant provides evidence of their ability to recruit/sample 500 MSM and 500 IDUs within the budget period.

3. The quality of the applicant's plan to develop, implement and administer the project operations and the degree to which the objectives and time schedules are reasonable, time-phased and appropriate for accomplishing project activities. The quality of the applicants plan to address Recipient Activities outlined in Section E (1). The degree to which the applicant has met the CDC policy requirements regarding the inclusion of ethnic, racial groups in the proposed research. This includes:

a. The proposed plan for the inclusion of both sexes' 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.

4. A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

5. The degree to which the qualifications, duties, responsibilities, and time allocation of proposed staff (including potential contractors), are justified and appropriate to accomplish study objectives. The degree to which the proposed staff will be able to provide appropriate scientific oversight, as well as programmatic and administrative support for the proposed activities. The extent to which collaborating entities (e.g., HIV prevention programs, community groups, community gatekeepers, CBOs, behavioral scientists) are appropriate (i.e., meet specific needs), sufficient, promote project objectives, and document their ability in letters of support.

6. The extent to which the budget is reasonable, clearly justified, and consistent with the intended use of funds.

Part VII. Core Surveillance in the Pacific Island Jurisdictions

The following criteria will be used to evaluate applications for their technical acceptability:

1. Program Need and Resources: The extent to which the applicant describes the requirements for, and activities of, the HIV/AIDS surveillance system that includes a presentation of existing strengths and limitations. The extent to which this overview includes: The program need in terms of HIV/AIDS morbidity; extent and level of funding devoted to prevention, treatment, and care programs in the area that require HIV/AIDS surveillance data for resource allocation and program planning; uses of surveillance data; ability to analyze data that allows for the identification of trends in emerging modes of HIV transmission (by various demographic indicators and behaviors); existing and potential sources of HIV/AIDS cases; a description of HIV/AIDS reporting procedures if they are in place; ongoing quality assurance procedures to promote data quality; sources of funding beyond federal monies provided by CDC; existing policies and procedures that are written and implemented for security, confidentiality, data dissemination and surveillance procedural activities; educational and training activities undertaken to develop and enhance the skills of surveillance staff and staff in reporting facilities; a copy of the most recent annual surveillance report; area legislation and/or regulations pertaining

to the reporting, collection, uses and dissemination of HIV/AIDS surveillance data.

2. Collaboration and Use of Data: The extent to which the applicant describes past, current, and proposed collaboration with: The relevant HIV/AIDS organizations and agencies within the reporting area; locally and Federally-funded prevention, treatment and care programs such as the CDC prevention programs or the Ryan White Care Act; and the extent HIV/AIDS surveillance data are used to assist public and private partners (e.g., community planning groups, AIDS Service Organizations) as a guide for allocating HIV prevention and care resources.

3. Proposed Objectives: The extent to which program objectives are: specific, measurable, time-phased, and realistic; related to recipient activities, program purpose and program activities; derived from needs identified in the resources and needs assessment; consistent with local and national HIV/AIDS surveillance program objectives.

4. Program Plan and Methods for Implementation: The extent to which the applicant: Adequately describes the procedures and methods to be used to accomplish the program objectives for their surveillance program; describes how program plans and procedures will facilitate achievement of national objectives for HIV/AIDS surveillance.

5. Program Evaluation Plan: The applicant provides an evaluation plan that is appropriate for measuring progress toward program area and national HIV/AIDS surveillance objectives; the plan should include a specified time-line and methods for identifying promoters and barriers to program success.

6. Project Management and Staffing Plan: The extent to which proposed staffing, organizational structure, staff experience and background, identified training needs or plan, and job descriptions and curricula vitae for both proposed and current staff indicate ability to carry out the purposes of the program.

7. Budget: The budget is reasonable, clearly justified, consistent with the demonstrated need and proposed activities, and likely to lead to program success.

Review and Selection Process: A Technical Acceptability Review will be conducted by CDC for Parts I, II, III, VI, and VII. Parts IV and V will involve Objective Review Panels.

VI. Award Administration Information

Award Notices: If your application is to be funded, you 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.

Administrative and National Policy Requirements: 45 CFR Part 74 and 92.

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-7 Executive Order 12372
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions

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>.

Additionally, CDC recognizes that HIV/AIDS surveillance data are critical to the development and implementation of HIV/AIDS prevention programs and that responsiveness to the needs of prevention program managers and Community Planning Groups (CPGs) requires the commitment of resources and personnel that are funded under the surveillance cooperative agreement. These activities include analyzing and interpreting surveillance data, preparing reports for use by the CPGs, and conducting other related activities that directly improve and support HIV prevention activities. HIV Prevention Cooperative Agreement funds may be used to support unmet HIV/AIDS surveillance activities described above or projects to address data gaps or unmet State or local needs for supplemental surveillance or serosurveillance data, provided there is concurrence of CPGs and approval by the CDC Grants Management Official.

Reporting Requirements

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

1. Interim Progress Report will be submitted annually and will be due on the date (usually in the late summer of the year preceding the budget period)

indicated in your Notice of Grant Award from CDC. The Interim 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. Requested amount for the continuation award, to be submitted in accordance with your projected level of funding for the 2005 and 2006 budget periods.
- e. Detailed line item budget and justification for the amount requested.
- f. Modifications/adjustments concerning changes to support proposed subcontracts, if any.
- g. A description of any programmatic and staffing changes. Please submit a listing of your current staff and an organizational chart in support of your CDC program.

2. Annual Progress Report is due 90 days after the end of each budget period. The Annual Progress Report for years 2004, 2005 and 2006 should cover the entire budget period.

Annual progress reports will include a data requirement that demonstrates measures of effectiveness. (See the beginning of section "H. Evaluation Criteria" for the definition of measures of effectiveness.)

The progress report must include the following for each program, function, or activity involved:

- a. A description of the program accomplishments and a comparison of actual accomplishments with the objectives established in the work plan for the funding period.
 - b. Other pertinent information that includes, but is not limited to analysis and explanation of unexpected delays or high costs of performance.
 - c. A listing of presentations and publications produced by, supported by, or related to program activities.
3. Annual Financial Status Report, no more than 90 days after the end of the budget period.
 4. Final financial and performance report for the entire project period (2004–2006), no more than 90 days after the end of the project period.
- Send all reports to the Grants Management and Contracting Officer identified 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 business management and budget assistance in the states, contact: Carlos Smiley, Grants Management and Contracting Officer, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2722, E-mail address: anx3@cdc.gov.

For business management and budget assistance in the territories, contact: Vincent Falzone, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2763, E-mail: vcf6@cdc.gov.

For program technical assistance with Parts I–IV and VII of this announcement, contact: Debra Hayes-Hughes, Deputy Chief, Surveillance Branch, Division of HIV/AIDS Prevention-Surveillance and Epidemiology, National Center for HIV, STD and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road, Mailstop E–47, Atlanta, GA 30333, Telephone Number (404) 639–2050, E-mail address: dsh1@cdc.gov.

For program technical assistance with Parts V and VI of this announcement, contact: Ken A. Bell, Deputy Chief, Behavioral and Clinical Surveillance Branch, Division of HIV/AIDS Prevention-Surveillance and Epidemiology, National Center for HIV, STD and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road, Mailstop E–46, Atlanta, GA 30333, Telephone Number (404) 639–2970, E-mail address: kbell@cdc.gov.

Edward Schultz,

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

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