Request for OMB Review and Approval

Adult and Pediatric HIV/AIDS Confidential Case Reports

for National HIV/AIDS Surveillance

OMB # 0920-0573

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Adult and Pediatric HIV/AIDS Confidential Case Reports for National HIV/AIDS Surveillance

(OMB No. 0920-0573)

A. Justification

1. Circumstances Making the Collection of Information Necessary

Since the beginning of the AIDS epidemic in the United States in 1981, the Center for Disease Control and Prevention (CDC) has collected national surveillance data on this important infectious disease. Over the years, as the science and epidemiology of HIV disease has evolved, the surveillance system has been updated to meet the nation's needs for information (refer to regular renewals under OMB #0920-0573). Today, national Adult and Pediatric HIV/AIDS Confidential Case Reports are collected as part of the HIV/AIDS Reporting System (HARS). The National Center for HIV, STD, and TB Prevention (NCHSTP), Division of HIV/AIDS Prevention (DHAP), CDC in collaboration with health departments in the states, territories, and the District of Columbia, conducts national surveillance for cases of human immunodeficiency virus (HIV) infection and the acquired immunodeficiency syndrome (AIDS), the end-stage disease caused by infection with HIV. This data collection system is currently being collected under OMB approval No. 0920-0573**.** HIV/AIDS surveillance data collection by CDC is authorized under Sections 304 and 306 of the Public Health Service Act (42 USC 242b and 242k) **(Attachment A).** Notification of the request for OMB clearance was published in the Federal Register on August 18, 2005, Volume 70, Number 159, Page 48551-48553 **(Attachment B).**

Currently, 59 areas (states/territories/possessions) mandate and collect AIDS surveillance data. In addition, as of September 2006, 50 areas mandate and collect confidential name-based surveillance data on HIV cases which have not progressed to AIDS in adults/adolescents and children using the HIV/AIDS case report forms. In response to CDC recommendations that all states and territories adopt the same confidential name-based surveillance methods used to report AIDS nationally to report HIV infections, we anticipate that over the next three years, all areas will mandate collection of name-based HIV surveillance data. Therefore, the estimated burden for the next three years is based on HIV case reporting in 59 areas.

The purpose of HIV/AIDS surveillance data is to monitor trends in HIV/AIDS and describe the characteristics of infected persons (e.g., demographics, risk behaviors, clinical and laboratory markers of HIV disease, manifestations of severe HIV disease, and deaths due to AIDS). Since AIDS was first recognized in 1981, a total of 916,997 AIDS cases have been reported through December 31, 2004 in the United States. In addition, 229,411 cases of HIV (not AIDS) cases have been reported to CDC through 2004. Because HIV infection results in untimely death and most often infects younger adults in the prime years of life, large amounts of federal, state, and local government funding have been allocated to address all aspects of HIV infection, including prevention and treatment. HIV/AIDS surveillance data are widely used at all government levels to assess the impact of HIV infection on morbidity and mortality, to allocate medical care resources and services, and to guide prevention and disease control activities. Data collected as part of the national HIV/AIDS surveillance

system are an integral part of CDC's disease surveillance efforts contributing invaluable data toward CDC's overarching goals of health promotion and disease prevention.

The data CDC collects through the national HIV/AIDS surveillance system provide the sole source of comprehensive, complete national HIV/AIDS statistics collected in a timely and standardized manner. If HIV/AIDS data are not collected, reliable and consistent information will not be available on the extent and distribution of the HIV/AIDS epidemic in the United States. Federal health officials will not be able to efficiently detect and respond to cases of public health importance or changes in morbidity patterns. CDC's primary mechanism for supporting communities in the identification of local HIV prevention priorities is called HIV prevention community planning. Community planning provides local communities across the United States with surveillance data, behavioral data, and other scientific information to make informed decisions about where and how to target resources locally. Effective assessment of federal, state, and local HIV/AIDS prevention and control efforts, based on timely and standardized data, would not be possible without the collection of these data. Ultimately, the goal of preventing HIV/AIDS in the United States cannot be achieved without a national HIV/AIDS surveillance system.

Currently, AIDS case counts are used to guide the distribution of funds for many federal programs as well as programs at the State and local level that assist persons living with HIV. The largest of these is the Ryan White Comprehensive AIDS Resources Emergency Act (RWCA) which funds treatment and care for persons who could not otherwise afford expensive, life-saving therapies. Concerns have been raised that such allocations are not

equitable because the epidemic is not adequately reflected by AIDS cases alone, and that areas with emerging HIV epidemics are under-funded because all cases of HIV disease are not included. A related concern with basing allocations on AIDS cases is that jurisdictions are not compensated for providing early access to care and treatment. Therefore, interest has grown in using HIV as well as AIDS data to guide these funding decisions. The current RWCA states that cases of HIV disease rather than cases of AIDS will be used in FY 2007. A compilation of the 2000 RWCA re-authorization is provided by Health Resources and Services Administration (HRSA) at http://hab.hrsa.gov/law/compile.htm. It is anticipated that the RWCA, when reauthorized, will also incorporate the use of HIV disease data to guide funding of these important care programs making the continued collection of high quality data on both HIV and AIDS through the national HIV/AIDS surveillance system critical.

CDC provides funding through cooperative agreements to all U.S. States, Territories, and possessions to conduct surveillance for HIV/AIDS. Cases are reported to state/local health departments by laboratories, physicians, hospitals, clinics, and other health care providers using standard adult and pediatric case report forms. Case report forms are usually completed using information obtained from medical records or from health care providers.

CDC is seeking a 3-year OMB approval to continue data collection of the HIV/AIDS case reports (**Attachments C, D, and E**) with additional data elements on supplemental surveillance activities including: 1) testing and treatment history for improved monitoring of HIV incidence (**Attachment F**), 2) specimen quality and sequence information for improved monitoring of drug resistance and HIV-1 subtypes (**Attachment G**), and 3) enhanced

information on HIV infected mothers and their infants to maximally reduce perinatal transmission (**Attachment H**). We are also proposing a modification to both the Adult/Adolescent and Pediatric HIV/AIDS confidential case report forms which includes the addition of a blank space in the top portion and bottom portion of the forms. Participating State and local health department will then have the option of using this space to assign a local identifier number. This number would be for local use only and not be reported to CDC.

2. Purpose and Use of Information Collection

CDC maintains the national HIV/AIDS surveillance system to monitor the scope of the HIV/AIDS epidemic in the United States. These data are the primary data source used to evaluate prevention and care programs and to focus prevention efforts at the national, State and local levels. Furthermore these data are critical to accomplishing the CDC goal of reducing the HIV/AIDS morbidity and mortality in the United States, increasing HIV testing, and eliminating racial and ethnic disparities in new HIV infections and AIDS diagnoses. The system, initiated in 1981, has been modified several times to better monitor and respond to changes in HIV/AIDS morbidity. These modifications address changes in the surveillance case definition as well as changes in the data collection system. The most recent modifications were in 1993 (http://www.cdc.gov/mmwr/preview/mmwrhtml/00032890.htm) and 1999 (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4813a1.htm). In 1993, the AIDS surveillance definition was expanded to include all HIV infected adults who have less than 200 CD4+ T-lymphocytes/µl or a CD4+ T-lymphocyte percent of total lymphocytes less than 14, or who have been diagnosed with pulmonary tuberculosis, invasive cervical cancer, or recurrent pneumonia. In 1999, the CDC recommended that all states adopt an integrated

HIV/AIDS reporting system and expand the HIV surveillance case definition to include positive HIV results or reports of a detectable quantity of HIV nucleic acid or plasma HIV RNA. When viral load testing became available and CDC incorporated viral load into the surveillance case definition, this information was added into the case report form cleared by OMB in 2000. The expansion of the surveillance system to include all persons who have been diagnosed with HIV greatly enhanced the knowledge of the scope and impact of the epidemic at State and local levels.

As our understanding of the epidemic has increased and the surveillance system has been expanded to better monitor the full spectrum of disease, it has become necessary to also expand and refine data collection elements and methods. For example, CDC provides supplemental guidance to state and local health departments on how best to obtain accurate information for existing data elements. Some activities may have occurred without explicit approval under the current OMB clearance. However, we believe these additional data elements are an extension of the currently approved data collected on testing and clinical care of persons with HIV infection. These data elements have been collected as part of ongoing evaluation activities to monitor and improve the surveillance system. They have added minimal increases in burden and were directly related to variables on the currently approved forms. In this renewal, we have incorporated these data elements formally into our burden estimates and revised our methods for calculating burden to more accurately reflect the variety of respondent activities related to data collection. Specifically, this renewal request includes additional data elements on recently infected persons (i.e., “incident” cases), who are identified by using the serologic testing algorithm for recent HIV seroconversion

(STARHS) (see **Attachment F**). The ability to estimate the number of incident infections will allow CDC programs to better target HIV testing services and prevention efforts. Another important supplemental surveillance activity is the collection of laboratory data on drug resistance and HIV-1 subtypes; as widespread antiretroviral treatment has been implemented, it is important to monitor the emergence of resistance to these drugs. This supplemental activity will provide population-based data on trends in transmission of drug resistant strains of HIV and the geographic distribution of these resistant strains in the U.S. (See **Attachment G**). These data will also support selection of diagnostic and clinical tests appropriate for use with various HIV-1 subtypes and ultimately inform the development of vaccines nationally. Finally, this renewal request includes expansion of behavioral and clinical data elements collected on mothers and infants as part of supplemental enhanced perinatal surveillance activities (see **Attachment H**) to better monitor the impact of antiretroviral treatment and HIV testing efforts. These supplemental surveillance activities are described below.

The national HIV/AIDS surveillance system is the only source of these types of data on population-based level. The burden of collecting these additional data elements is minimal because related clinical and testing data are already part of case report data under the currently approved data collection. These additional data elements will be incorporated into routine case reporting activities and provide critical data that will be used at both the local and national levels for better targeting prevention and care services for persons with HIV.

AIDS data are collected by 59 reporting areas (the 50 states, the District of Columbia, Puerto

Rico, the U.S. Virgin Islands, Guam, American Samoa, the Republic of Palau, the Republic of the Marshall Islands, the Commonwealth of the Northern Marianna Islands, and the Federates states of Micronesia) using a standard HIV/AIDS case report form. Currently 50 reporting areas collect confidential HIV data using the same methods for both HIV and AIDS reporting. The HIV/AIDS data collection form consists of two forms: (1) Adult HIV/AIDS Case Report Form (CDC 50.42a), (2) the Pediatric HIV/AIDS Case Report Form (CDC 50.42b) **(see Attachments C and D).** Instructions for completing the forms are included in **Attachment E**. Separate case report forms are used for pediatric patients (patients less than 13 years of age at the time of diagnosis) and adult/adolescent patients (13 years of age or older at the time of diagnosis). Although the forms are similar to the adult form, the pediatric form includes behavioral risk and medical history information on the child's mother. These forms are completed by the health care provider or by the HIV/AIDS surveillance staff in the State or local health department in accordance with their State or local HIV reporting requirements. In addition, a laboratory report of an HIV test or AIDS-defining condition sent to health departments may initiate a case report. In these events, follow up with the health care provider is required to obtain complete information. A separate case report form is completed for each reported HIV case as well as each reported AIDS case and contains demographic, clinical, and laboratory information. The data collection forms adhere to OMB Directive 15, collecting race and ethnicity separately, collecting multiple races and disaggregating Asian/Pacific Islander into two categories: Asian and Native Hawaiian/Other Pacific Islander.

Supplemental Activity 1: HIV Incidence Surveillance (**Attachment F**)

Because of the success of antiretroviral therapy in delaying progression to AIDS, methods that have been used to estimate the number of new infections based on AIDS data are no longer adequate. New testing technologies are now available to identify new infections. Specifically, use of the serologic testing algorithm for recent HIV seroconversion (STARHS) allows surveillance systems to determine how many among a group of new HIV diagnoses are from new infections. However, in order to derive a population-based estimate of HIV incidence based on data from those individuals who choose to have an HIV antibody test and who test positive (those reported to HIV surveillance systems) additional data are needed for statistical weighting of STARHS results. These additional data include information on testing, frequency, location, dates, prior positive and negative tests, and use of HIV-related medicines. These data elements on testing and treatment are listed in **Attachment F**. HIV incidence surveillance received a CDC/NCHSTP non-research determination in 2005. DHAP anticipates 30 of the 59 health departments will incorporate reporting of additional data elements on testing and treatment history during the next three years.

Supplemental Activity 2: Variant, atypical and resistant HIV surveillance (**Attachment G**)

For individuals with newly diagnosed HIV, information on specimen quality and genotyping test results for drug resistance and HIV-1 subtypes as part of variant, atypical and resistant HIV surveillance (VARHS) will be reported. VARHS received a CDC/NCHSTP non-research determination and additional data elements for VARHS are listed in **Attachment G**. These data are provided by the testing laboratory to health departments. Twenty-four of the 59 currently reporting areas are now funded and will incorporate VARHS data into their case

reporting activities during the next three year period. These data will be reported to CDC by participating health departments for the purpose of calculating population-based estimates of prevalence of HIV drug resistance and HIV-1 subtypes among individuals with newly diagnosed HIV. Additional analysis of data on HIV drug resistance will provide information on trends in transmission of resistance and support evaluation of first-line HIV antiretroviral drug treatment and prophylaxis strategies in participating geographic areas by providing information to clinicians, pharmaceutical researchers, and public health authorities making treatment recommendations and developing new treatments. Importantly, these surveillance data of various HIV-subtypes will help inform the selection of appropriate clinical tests and contribute important information for vaccine development and for the understanding of the evolution of HIV in the U.S. and worldwide. Through timely data provided by the national HIV/AIDS surveillance system, CDC is able to determine the variability by region, State, risk group, and by racial/ethnic groups, more accurately track new infections and use that information to better evaluate and target prevention programs and direct resources for care services.

Supplemental Activity 3: Enhanced Perinatal Surveillance (**Attachment H**)

The national HIV/AIDS surveillance system has successfully monitored changes in the epidemic and gauged prevention and treatment successes over the last two decades. For example, in the United States mother-to-child HIV transmission has been drastically reduced, from a high of 2,500 new perinatal HIV infections in 1992 to an estimated 200 to 300 annual new infections in recent years. This reduction is due to the widespread adoption of routine HIV counseling and voluntary testing of pregnant women and the availability of zidovidine

(ZDV) and other drugs to interrupt transmission from the pregnant woman to her baby. As part of ongoing surveillance activities CDC is proposing to enhance data collection on HIV-infected mothers and their infants in 15 states to maximally reduce perinatal HIV transmission. Proposed data collection for enhanced perinatal surveillance (EPS) will supplement information already collected on both the adult and pediatric case report form. These clinical and behavioral data will be used to better monitor the effect of HIV testing, prevention, and treatment guidelines. The overall goals of EPS are to (a) monitor the implementation of the United States Public Health Service (USPHS) recommendations for counseling and voluntary testing of pregnant women, the use of Zidovudine (ZDV) and other antiretroviral medications to prevent perinatal HIV transmission, and the effect of implementation on the trends of HIV disease among children; (b) to establish a surveillance system to collect data that enable states to respond to selected requirements of the Ryan White CARE Act; and (c) to assist in timely evaluation of perinatal prevention efforts. Enhanced perinatal surveillance has received a CDC/NCHSTP non-research determination. Data abstraction forms, instructions, and procedural guidance are provided in **Attachment H**.

Reporting areas routinely review and analyze their data to monitor local HIV/AIDS trends, evaluate program success, and assist in focusing resources to reduce the burden of HIV/AIDS. CDC publishes annual surveillance reports summarizing national HIV/AIDS statistics (see **Attachment I),** updated fact sheets based on demographic and risk group, periodic supplements to the surveillance reports, and also periodically conducts special analyses for publication in peer-reviewed scientific journals to further describe and interpret national HIV/AIDS data. Special analyses describe key trends, identify high risk groups, and

assist in developing new prevention and treatment strategies. The annual report is disseminated to the public, state and city health officers, infectious disease experts, and others concerned with HIV/AIDS control and prevention. The surveillance report, accompanying slide sets, and other important publications from the HIV/AIDS surveillance system are also posted on the DHAP web site at http://www.cdc.gov/hiv/topics/surveillance/index.htm . A public-use version of the AIDS surveillance data set is also available at www.cdc.gov/hiv/software/apids.htm. CDC also uses national surveillance data to respond to special data requests to assist other government agencies, Congress, and organizations with HIV/AIDS control and prevention activities.

HIV/AIDS surveillance data assist federal, state, and local public health officials and policy makers in program planning, evaluation, and resource allocation. The collection of information on AIDS morbidity helps determine resources required for federal prevention efforts, including support of state and local HIV/AIDS programs. These data are also used in DHAP materials for training and education of health care providers, the general public, and the media. HIV/AIDS surveillance data are used to guide the distribution of funds for several federal programs that assist persons living with HIV, including the funding of care and treatment programs under the RWCA and the Housing Opportunities for Persons with AIDS (HOPWA) program administered by the Department of Housing and Urban Development (HUD) which provides housing assistance and related supportive services for persons with HIV and AIDS.

3. Use of Improved Information Technology and Burden Reduction

To reduce burden for respondents, the HIV/AIDS surveillance system is based on electronic data management and transmission systems. Since the first cases of AIDS were recognized and states began to report cases through standard case reporting methods, the surveillance system has been modified to support changing needs for data and to improve the efficiency of data collection. DHAP has encouraged the use of electronic reporting methods and provided state health departments with data management software to reduce reporting burden. In 1993, DHAP developed and distributed software for expanded HIV/AIDS surveillance (HIV/AIDS Reporting System [HARS]), a computerized HIV/AIDS database system with which state and local HIV/AIDS programs could collect and manage HIV/AIDS surveillance data from both the HIV and AIDS case report forms. Previously, the AIDS Reporting System (ARS) was used to collect and manage AIDS case report data, and the HIV Reporting System (HRS) was used to collect and manage HIV case report data. As more states began collecting HIV case report data, it became obvious that a single system for both, where possible, was less burdensome for the state and local health departments. The HARS system was primarily designed to facilitate the use of combined HIV and AIDS surveillance data at the state and local levels, but also enabled HIV/AIDS programs to transfer HIV/AIDS case reports electronically simultaneously, rather than in separate transfers to DHAP. Since that time, major improvements in available computer and software technologies together with growing data needs particularly related to electronic reporting, necessitated another modification of the software system.

The newest modification of the HIV/AIDS reporting system, eHARS, aims to ease electronic

reporting and electronic messaging and streamline use of alternate databases that may be used by health departments to manage incoming reports from various sources. For example, health departments may maintain a separate alternate database for managing laboratory reports which will be managed through eHARS once implemented. As of October 2006, the eHARS system as been implemented in six areas (New Jersey, New York State, Louisiana, Michigan, Georgia, and Indiana) with full national deployment scheduled for calendar year 2007. Following the pilot deployment efforts, areas will be prioritized based on a variety of factors such as familiarity with document-based surveillance, participation in incidence surveillance and laboratory reporting efforts, centralized access to the system within a state, and prerequisite hardware availability.

The current system provides flexibility and options for managing data reported from local health departments. DHAP provides the option for States to either delegate maintenance of electronic HARS data to the local health department level or maintain a central system of collecting and managing HIV/AIDS data, depending on the State's surveillance practices. Where local health departments are involved, the local health department collects, enters, and manages HIV/AIDS data in their 'satellite' HARS system and then periodically transmits data via an encrypted electronic data file to the state level master HARS database. The new eHARS system will facilitate use of a central, secure database with controlled access from remote sites via a secure network connection. This functionality provides the option to local users of a tool to electronically manage and use their HIV/AIDS surveillance data. In addition, CDC has developed specific guidelines for State and local surveillance programs to enhance their use of electronic reporting technologies for both case reporting and reporting

from laboratories aimed at reducing data entry burden and increasing the capability to receive and process electronic laboratory data. For example, these guidelines will assist areas in establishing electronic reporting mechanisms with laboratories which will increase efficiency and reduce data management burden at the health department. CDC also now requests that reporting areas send their data electronically on a monthly basis through the secure data network (SDN) to ensure secure and efficient transfer of data.

4. Efforts to Identify Duplication and Use of Similar Information

The data collected by the national HIV/AIDS surveillance system provide the sole source of comprehensive, complete national HIV/AIDS statistics collected in a timely and standardized manner. Through literature searches, attendance at national HIV/AIDS meetings/conferences, discussions with officials from State and local health departments and ongoing consultations with HIV/AIDS experts nationwide, DHAP has determined that these data are unique and are not available from any other source within the federal government or from non-federal sources. In fact, AIDS surveillance has come to be relied on as the only nationally representative data source on which to base the equitable distribution of resources for patient care and management.

5. Impact on Small Businesses or Other Small Entities

Data collection and electronic submissions to CDC from the reporting areas are done by HIV/AIDS surveillance programs in State and local health departments funded by CDC to conduct these activities. Laboratories and care providers are required to report cases of HIV and AIDS in accordance with local disease reporting laws, rules and regulations. Health

departments compile reported information and are the respondents for this surveillance system. No small businesses or small entities are part of the respondent universe.

6. Consequences of Collecting the Information Less Frequently

CDC now requests that reporting areas send their data electronically on a monthly basis through the secure data network (SDN). The goal of this transfer schedule is to finalize annual data within several months after the close of the calendar year. Monthly transmissions have been the norm since initiation of surveillance system in 1981. This transfer schedule has facilitated keeping the reporting area and CDC databases up to date, to ensure timely and accurate assessments of trends. Through timely data provided by the national HIV/AIDS surveillance system, CDC is able to determine the variability by region, state, risk group, and by racial/ethnic groups, more accurately track new infections and use that information to better evaluate and target prevention programs and direct resources for care services.

This reporting schedule has also enabled DHAP to evaluate data quality on an ongoing basis in order to efficiently detect, investigate, and resolve data issues with the reporting areas. DHAP periodically discusses the frequency of electronic data transmission with reporting areas to determine the optimum frequency in order to keep respondent burden low while still allowing prompt identification of changes in HIV/AIDS trends. Less frequent transmission would impede the ability of CDC to maintain an accurate and timely database. There are no legal obstacles to reduce the burden.

7. Special Circumstances Related to the Guidelines of 5 CFR 1320.5

Collection of HIV/AIDS data is conducted in a manner consistent with the guidelines in 5 CFR 1320.6. DHAP requests that reporting areas send encrypted data via the SDN on a monthly basis as justified under section A.6.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. Notification of the request for OMB clearance was published in the *Federal Register* on August 18, 2005, Volume 70, Number 159, Page 48551-48553 **(Attachment B).** No public comments were received.

B. Consultation with State, local, and territorial HIV/AIDS surveillance coordinators, and other HIV/AIDS specialists occurs on a regular basis through HIV/AIDS national surveillance workshops, routine site visits, and periodic conference calls with HIV/AIDS surveillance coordinators, and national conferences. These discussions allow CDC to obtain information on the availability of data, frequency of data collection, clarity of instructions, and record keeping, reporting format, and key data elements. Meetings of surveillance coordinators occurred during the National Meetings of the Council of State and Territorial Epidemiologists (CSTE) in June 2005 and June 2006 where surveillance practices and guidelines were discussed. We plan to hold additional meetings with surveillance coordinators where revisions to data collection forms will be discussed, and we plan to sponsor meetings in conjunction with other national meetings in the future. Five regional workshops were

> conducted in 2006 for trainings in surveillance practices using our revised technical guidance and trainings related to deployment of eHARS are currently underway. In 2005, consultations were held on both the adult and pediatric case definitions, where potential revisions to both the adult and pediatric HIV classification systems were discussed with expert consultants including HIV care providers, data consumers and state and local surveillance staff.

Since 2001, DHAP has sponsored a variety of consultations with expert consultants, local stakeholders and state and local surveillance staff on various aspects of HIV incidence and viral resistance surveillance. In 2004, CDC with the Forum for Collaborative HIV Research conducted a consultation on HIV viral resistance surveillance in North America to obtain input from a variety of expert consultants on issues of HIV resistance surveillance including data collection. Between 2001 and 2005, five consultations on HIV incidence surveillance were held covering a variety of topics including ethical considerations, statistical methods, and the development and implementation of surveillance methods and protocols. One consultation specifically addressed what data would be needed to estimate incidence. In addition, input on data was obtained from the Cognitive Lab at the National Center for Health Statistics. In 2006 a statistical consultation to evaluate methods was held. Additional feedback and revision of data collected on testing history were obtained through pilot testing in a health department clinic and from feedback from participating health departments. In April 2005, a training of trainers for HIV incidence surveillance coordinators on the collection of HIV testing history data was conducted. In addition, since 2004, annual meetings have been conducted with state and local incidence surveillance coordinators to

discuss both incidence and viral resistance surveillance activities and data collection. Consultations and meetings were also conducted for enhanced perinatal surveillance that included discussion of specific variables needed at both the State and federal levels, data collection and reporting procedures, form development, types of data available in medical charts, and quality assurance procedures. These included a meeting with enhanced perinatal surveillance grantees in June 2003, a conference call with perinatal surveillance and prevention grantees in November 2004, and a perinatal executive workgroup meeting was held in January 2006. Contact information for surveillance coordinators in state and local health departments and consultants providing input over the last three years are provided in **Attachment J**.

9. Explanation of Any Payment or Gift to Respondents

There are no provisions for payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The CDC Privacy Act Officer has reviewed this OMB application and has determined that the Privacy Act is not applicable. Local authority for investigation and reporting of cases of HIV infection and AIDS is provided by State regulations for follow-up of persons with notifiable diseases, as defined in each jurisdiction. Case reports are completed by local health care service providers and laboratories and transmitted to state and local health departments by U.S. mail, secure fax (CDC security and confidentiality guidance now discourages this practice) or secure electronic transfer. In some instances, health department staff go out and complete the forms themselves Data are then compiled by health

departments that serve as the respondents for the HIV/AIDS surveillance system and data are forwarded to CDC. Although identifiable patient-level case report data are collected by local health care providers and laboratories the case report data are de-identified before they are transmitted to CDC. Therefore, the data collection does not meet the definition of a Privacy Act system of records.

The data collection forms include a header that contains patient identifiers (complete name, address, and telephone number). The header feature allows health department personnel to verify the identity of each patient (and associated patient-level information) reported to the surveillance system, and to conduct public health follow-up. An additional security feature to assist health departments is planned to modify the form to include the addition of a blank space in both the header and the bottom portion of the form that can be used locally to assign a form number (that will not be sent to CDC). This will enable the top portion of the form to be detached and mailed separately from the bottom portion of the form and linked via the assigned number at the health department.

Upon receipt of the case report forms, the health department is responsible for assigning one or two unique codes to each case report: the State Patient Number and/or the City/County Patient Number. Names entered into HARS are converted by the software to a soundex code. The data files submitted electronically to CDC contain only the soundex code and state assigned patient numbers and not the directly identifiable information contained in the header. Paper documents related to case reports are required to be kept in locked filing cabinets within a locked roomed. Areas use a microcomputer system developed by CDC (the

HIV/AIDS Reporting System [HARS]) to store and analyze data, as well as transmit de-identified encrypted data to CDC. A revised HIV reporting system (eHARS) is currently in the final stages of development and beginning deployment. eHARS is scheduled to replace HARS in 2007. Since April 2004, all health departments have been required to forward data to CDC electronically through the Secure Data Network (SDN). The SDN uses digital certificate technology to create a Secure Sockets Layer (SSL) or encrypted tunnel through which data are transmitted. The SSL is broken once the client browser loses connectivity with the CDC Web server, which is located outside its firewall. The microcomputer software program includes a procedure to double encrypt the data before transmission to CDC, and the data are then de-encrypted on receipt at CDC.

As a condition of funding under the HIV/AIDS surveillance cooperative agreements, health departments must certify annually that they comply with security and confidentiality program requirements outlined in the *Technical Guidance for HIV/AIDS Surveillance Programs, Volume III: Security and Confidentiality Guidelines, Atlanta Georgia, Centers for Disease Control and Prevention, 2006*. (**Attachment K**. Also available at http://www.cdc.gov/hiv/surveillance.htm). These guidelines include detailed requirements to address areas of physical and electronic security, development of policies, training, data access controls, data security, data transfer and storage. Surveillance data are required to be kept in a physically and technically secure environment, with limited access by a minimum number of authorized individuals. Persons with authorized access are required to attend local security training annually and be individually responsible for protecting their own workstations. Confidential surveillance data must be encrypted before electronic transfer and

ancillary databases or other electronic files containing confidential data also need to be encrypted when not in use. Additionally, areas must have written policies and procedures. CDC reviews procedures for protecting the confidentiality and security of HIV/AIDS surveillance data through periodic site visits and as part of the annual renewal of cooperative agreements for HIV/AIDS surveillance.

HIV/AIDS surveillance data are currently collected under an Assurance of Confidentiality under Section 308(d) of the Public Health Service Act (42 USC 242m(d)) (see **Attachments A and L**). The Assurance applies both to individual patients who are the subject of this data collection, and to the organizational respondents that support the surveillance system by collecting data. Information collected in the HIV/AIDS surveillance system that would permit direct or indirect identification of any individual or establishment is collected with a guarantee that it will be held in strict confidence, that it will be used only for purposes stated in the Assurance, and that it will not otherwise be disclosed or released without the consent of the individual or the establishment in accordance with Section 308(d) of the Public Health Service Act (42 USC 242m(d)). HIV/AIDS surveillance data including data collected for surveillance evaluations, HIV incidence, VARHS, and EPS have been determined to be non-research surveillance activities by NCHSTP/CDC. Institutional Review Board review where required may be conducted at the local level.

11. Justification of Sensitive Questions

Sensitive information, including information on sexual or drug using behaviors that may be related to HIV transmission is collected as part of HIV/AIDS surveillance. Risk factors for transmission of HIV include behaviors which are sensitive and, in some cases, illegal (e.g., substance abuse). However, these data are critical for monitoring patterns of transmission and are important for understanding and describing risk behaviors associated with HIV infection. CDC uses these data to describe epidemiologic trends by risk behavior. These data are also used extensively by community prevention planning groups to help target prevention activities at the local level. For example, these data may be used to target community-based HIV testing programs or HIV-related care services. The value of HIV/AIDS surveillance data is greatly diminished without sufficient information to determine whether persons have engaged in recognized or potential risk behaviors, including sexual behaviors and illicit use of drugs.

The Pediatric HIV/AIDS Confidential Case Report and EPS data collection asks for maternal history, including questions about the mother's drug use behavior, prenatal care, receipt of antiretroviral treatment (zidovudine or ZDV) during pregnancy, and other antiretroviral treatment. These questions are asked in part because the mother's medical history/receipt of ZDV impacts upon the medical care and treatment the infant should receive. Collection of medical history and behavioral information on mothers and their exposed infants is critical for continued monitoring and refinement of HIV prevention and treatment guidelines for pregnant women and children.

Finally, some clinical and laboratory markers of HIV infection may also be considered sensitive. Fears still remain regarding potential stigma associated with HIV infection. However, laboratory test data related to a persons HIV positive status or tests indicative of disease progression are needed to monitor trends in HIV diagnosis and describe the spectrum of HIV- related morbidity over time. CDC uses these core data elements to profile the HIV epidemic in the United States and local areas use these data extensively to monitor local disease trends. These collection of clinical and laboratory markers of HIV disease are the cornerstone of our core surveillance data central to monitoring the epidemic.

CDC and State health departments have data release policies that restrict the release of information that could indirectly or directly identify an individual. Data released by CDC are typically in aggregate format with cell size restrictions. CDC in collaboration with CSTE worked with states to specify the geographic level at which their data can be released. The AIDS Public Use Dataset manual available at http://www.cdc.gov/hiv/SOFTWARE/apids/apidsman.htm describes the data release policy. Additionally, CDC *Security and Confidentiality Guidelines* require that data release policies must incorporate provisions to protect against public access to raw data or data tables that include small denominator populations that could be indirectly identifying and outline additional considerations for developing data release policies (**Attachment K**).

12. Estimates of Annualized Burden Hours and Costs

A. Estimate of annualized burden hours:

The total estimated burden in hours for this project is 57,774. This burden is considerably higher than in the published *Federal Register* notice (**Attachment B**) and previous burden estimates for this system. This increase is to differences in the way the burden estimate is calculated for the case reports (these differences are described below) and also to the addition of three supplemental surveillance activities described previously. The estimated burden includes that for case reports and evaluations of HIV/AIDS surveillance based on these reports, and collection of additional data for HIV incidence, VARHS, and EPS data. This figure includes 59 areas (states/territories) each completing HIV and AIDS case reports and a subset of those areas completing additional data elements for incidence, VARHS and EPS. Detailed estimates for the burden of collection of these additional data elements are provided in Table A.1.

In previous OMB packages, the burden estimate was based on 10 minutes per completed case report form; this included only the time required by an average person completing a case report form if all information were readily available. In this package, a more realistic and complete burden estimate is presented which includes time for the activities State and local health departments must conduct to collect the data. We estimate each Adult and Pediatric HIV or AIDS case report will take approximately 20 minutes for the health departments to complete. This estimate is based on information obtained from surveillance experts regarding the average length of time involved in the range of follow-up activities to compile and complete missing information on case reports, including medical record review (10-45 minutes), phone follow-up with providers (15-25 minutes), abstraction from local databases (5-15 minutes), and electronic data transfer (<5 minutes) and the proportion each of these activities contributes to their overall follow-up activities. Information from surveillance staff suggest that approximately 50% of

follow-up activities involve medical record review, 30% by phone, 10% from local database abstraction, and 10% by electronic data transfer.

A total of 52,510 responses are estimated for the Adult Case Report form for AIDS and 177 responses are estimated for the Pediatric Case Report form for AIDS. These estimates are based on the annual number of AIDS cases reported to CDC from these areas. Additionally, a total of 54,988 responses are estimated for Adult HIV case reports and 649 for pediatric HIV reports. Theses annual estimates are based on the number of HIV cases reported to CDC from these areas. We adjusted these estimates to allow for a 5% increase in reporting of AIDS and 10% increase in reporting of HIV reports due to anticipated increases as additional states implement confidential name-based HIV reporting and increases in HIV testing activities. We also included in these estimates an adjustment for anticipated evaluations based on these forms. This included 6000 additional responses for evaluation activities conducted in 10 moderate morbidity areas at 600 cases each that we distributed among the total responses for adult and pediatric reports. The resulting burden is 17,503 hours for the Adult AIDS case reports and 59 for the Pediatric AIDS case reports. The total estimated burden hours are 18,329 for adult HIV case reports and 216 for pediatric case HIV reports.

Table A1. also includes the estimated burden of providing updated information on previously reported cases. This additional burden results largely from updates of clinical and laboratory indicators of HIV infection such as CD4 counts and viral load test results. Because laboratory reporting practices vary across states according to their various disease reporting rules and regulations the resulting burden will also vary. Based on discussions with surveillance staff, we

estimate approximately 1% of living HIV/AIDS cases will be updated at least one time annually, resulting in an estimated 5,015 responses distributed among all 59 reporting jurisdictions for a total of 418 burden hours.

Approximately 30 of the 59 states conducting HIV/AIDS surveillance also provide data elements for *Supplemental Surveillance Activity 1: Incidence Surveillance*. We estimate an additional ten minutes to complete these data elements in addition to the case report form follow-up activities. Information is obtained from medical records, records of partner notification and referral services, counseling and testing sites, provider reports, and testing laboratories. We estimated the additional time for collecting these data would be 5 minutes for data collected either through record abstraction activities (medical record, prevention services records) or phone updates for provider reports, or electronic download of local databases, plus an additional 5 minutes or less for the electronic download of laboratory data. Therefore, the average response time for the testing data and laboratory data for incidence is estimated to be 10 minutes. The total responses are estimated based on the number of annual HIV and AIDS cases reported in these areas. There will be an estimated 2,833 responses per respondent. The total burden hours for incidence data elements will be 14,165 hours.

Twenty-four states of the 59 states conducting HIV/AIDS surveillance have also been funded to submit data for *Supplemental Surveillance Activity 2: Variant, Atypical and Resistant HIV Surveillance (VARHS).* Selection of areas was tied to eligibility for incidence data collection and based on a minimum number of AIDS cases to allow population-based surveillance with statistical methods. We estimated that the average burden per response is 5 minutes. This

estimate was based on the majority of data coming from the health department through their own public health laboratories which provide efficient mechanisms of reporting to the surveillance unit by both hard copy, access to laboratory databases, and electronic transfer. The eHARS system will facilitate the electronic management of these data resulting in minimum burden per response. A total of 70,008 responses are estimated based on the number of annual HIV and AIDS cases reported in the 24 areas. There will be an estimated 2,917 responses per respondent and it will take approximately 5 minutes to download the data for a total burden of 5,834 for VARHS.

Fifteen states will also conduct *Supplemental Surveillance Activity 3: Enhanced Perinatal Surveillance (EPS)*. These areas were funded using resources available for this activity. Areas were selected through a competitive process and had to be receiving prevention program funds. Based on current experience with data abstraction for mother and infant pairs and current average estimates for medical record review, we estimate additional data collection for EPS will take approximately 25 minutes. These data are based on estimated number of HIV infected women giving birth. There will be an estimated 200 responses per respondent and it will take approximately 25 minutes to complete for a total burden of 1250 hours to complete the EPS data elements.

A.1 Estimates of Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden Per Response (in hours)	Total Burden (in hours)
State Health Departments	Adult Case Report:AIDS	59	890	52,510	20/60	17,503
	Adult Case Report:HIV	59	932	54,988	20/60	18,329
State Health Departments	Peds Case Report:AIDS	59	3	177	20/60	59
	Peds Case Report:HIV	59	11	649	20/60	216
State Health Departments	Case Report Updates	59	85	5,015	5/60	418
State Health Departments	Incidence	30	2,833	84,990	10/60	14,165
State Health Departments	VARHS	24	2,917	70,008	5/60	5,834
State Health Departments	EPS	15	200	3,000	25/60	1,250
Total				271,337		57,774

* The estimate of annualized burden hours are based on the average total number of cases (i.e., shown under Total Responses) expected to be reported by State and local health departments each year.

B. Estimates of Annualized Cost

The estimated total cost to respondents is $1,155,480. This is based on an estimated hourly wage of $20 per hour for each Health Department. Since typically the data collection is a collaborative effort, we used an average of an estimated salary of one data entry person at $12.00/hr and one epidemiologist at $28/hr for an estimated $20/hr. The salary estimates were based on U.S. Department of Labor estimated hourly rates in the U.S. in 2005 for one data entry person (data entry keyer) at $12.29 per hour and one medical scientist (as a proxy for an epidemiologist) at

$28.18 per hour. Note this estimated cost is subsumed in the cooperative agreement costs outlined in section 14. below and should not be considered as additional costs.

B1. Estimates of Annualized Cost*

Type of Respondent	Form Name	Total Burden (in hours)	Hourly Wage	Total Response Costs
State Health Departments	Adult Case Report:AIDS	17,503	$20	350,060
	Adult Case Report:HIV	18,329		366,580
State Health Departments	Peds Case Report:AIDS	59	$20	1,180
	Peds Case Report:HIV	216		4,320
State Health Department	Case Report Updates	418	$20	8,360
State Health Departments	Incidence	14,165	$20	283,300
State Health Departments	VARHS	5,834	$20	116,680
State Health Departments	EPS	1,250	$20	25,000
Total Annualized Cost to Respondents				$1,155,480

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no capital or maintenance costs to the respondent resulting from the collection of the information.

14. Annualized Cost to the Federal Government

CDC Costs

Data Management Staff	
- 2 data managers at $80,000	$160,000
- 2 Quality control/help desk staff	$120,000
- 1 Support staff person	$40,000
Printing	$5,000
eHARS development and deployment	$1,867,000*
HIV Incidence and Case Surveillance Branch Intramural Including Personnel	$5,074,000
Subtotal	$7,266,000

Cooperative Agreements with States

HIV/AIDS Surveillance **	$50,734,000
Total	$58,000,000

*Estimated average annual cost based on reported OMB IT cost for FY06 $1.4 million, FY07 $2.5 million, FY08 $1.7 million.

** (Note that these costs support the existing infrastructure of HIV surveillance programs in state health departments. This includes costs related to data collection, analysis as well as other program costs).

15. Explanation for Program Changes or Adjustments

The requested burden for this project is 55,774 hours. The previous burden associated with this information collection was 13,191 hours. The requested total burden represents an increase of 338%. This increase is due several factors. First, we have refined and adjusted our methods for calculating burden estimates to better reflect the variety of follow-up activities health departments (respondents) conduct to compile and complete case report forms resulting in a greater than 100% increase in the average burden per response. Second, we have explicitly incorporated estimated burden activities for evaluations and case updates into our estimates. Finally, we have included estimated burden for collection of additional data elements for incidence, VARHS and EPS. Although these activities have been included as ongoing surveillance efforts and the data collected considered an extension of currently approved data elements. The formalization of these data elements and inclusion of these additional data elements in the burden estimates has resulted in an increase in the requested burden. Additionally, since the publication of our 60-day *Federal Register* notice, we have re-evaluated our burden estimate for incidence activities and VARHS. The incidence activities which were listed as pre- and post-test testing history forms are now more accurately reflected under the revised incidence heading. A detailed presentation of the burden changes since the previous approval is presented in Table 15A.

Table 15A. Changes in Burden Since Previous Report*

Form Name	Requested Burden (in hours)	Previous Burden	60 Day FRN Burden	Percent Change (previous)	Percent Change (60Day)
Adult Case Report:AIDS	17,503	7,183	8,004	143%	119%
Adult Case Report:HIV	18,329	5,889	7,955	211%	130%
Peds Case Report:AIDS	59	30	20	97%	195%
Peds Case Report:HIV	216	89	89	143%	143%
Case Report Updates	418	Not Included	Not Included	N/A	N/A
Incidence	14,165	Not Included	1,577	N/A	798%
VARHS	5,834	Not Included	315	N/A	1752%
EPS	1,250	Not Included	Not Included	N/A	N/A

*Current Burden Estimates are not comparable to previous estimates because they have been revised to reflect 1) the more complete burden to respondents in collecting the data and 2) the addition of three supplemental surveillance activities. See Text for full explanation.

16. Plans for Tabulation and Publication and Project Time Schedule

Collected HIV/AIDS data are analyzed and published annually in the HIV/AIDS Surveillance report and slide sets found at http://www.cdc.gov/hiv/topics/surveillance/index.htm. The surveillance report is completed approximately 6 months after the data are finalized. For example, the national HIV/AIDS surveillance data for 2004 were finalized in June 2005 and the final report was posted on the DHAP web site and distributed to state and city HIV/AIDS surveillance coordinators by December 2005. This short time between data finalization and report publication provides

prompt dissemination of current HIV/AIDS morbidity trends and timely evidence for decision makers related to program planning, evaluation, and resource allocation.

For the annual HIV/AIDS surveillance data collection, the following time schedule has been estimated based on the experience of the previous five years of data collection, analyses, and publication. This is an ongoing data collection cycle.

Activity	Time Schedule
Complete/submit forms	1-12 months after OMB approval
Final data validation	13-14 months after OMB approval
Final data analysis	15-17 months after OMB approval
Final annual report publication	18-20 months after OMB approval

The HIV/AIDS data are also included in DHAP materials for training and education of health care providers, the general public, and the media. Numerous publications have resulted and will continue to result from the data. Special analyses are periodically conducted by DHAP staff to summarize key trends, identify high risk groups, and assist in developing new prevention strategies. These analyses are often published in peer-reviewed scientific journals. CDC also has distributed SAS analysis programs for areas to make standard site-specific tables and figures for use in their epidemiologic profiles for HIV Prevention and Ryan White Care Act community planning. These tools improve utilization of HIV/AIDS data at the State and local levels. DHAP/CDC also responds to special data requests to assist other government agencies and organizations in their HIV/AIDS prevention activities.

17. Reasons Display of OMB Expiration Date is Inappropriate

DHAP/CDC is not seeking an exception to the required display of the expiration date for the form. New forms will be printed with the new expiration date for OMB approval when approval is obtained.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to certifications are requested.

B. Collections of Information Employing Statistical Methods

No sampling methods will be used to select respondents. Absolute case count is preferred to sampling for the following reasons: (1) HIV/AIDS is a reportable disease and, therefore, States routinely collect information on each reportable case. Data collected by the HIV/AIDS surveillance system assist local areas by identifying populations that need immediate attention and trends that help focus valuable resources, (2) DHAP's goal is to reduce the burden of HIV/AIDS in the United States and an absolute case count provides the best information on disease burden.

1. Respondent Universe and Sampling Methods

HIV/AIDS surveillance data include all cases reported to the 59 participating health departments. Data collection of new elements for incidence and VARHS will be implemented in fewer areas because areas needed a minimum number of HIV/AIDS cases to apply statistical methods to estimate HIV incidence and limited availability of funds. No sampling method is used to select reported cases.

2. Procedures for Collection of Information

Data collection and electronic submissions to CDC from the reporting areas are done by HIV/AIDS surveillance programs in public health departments. Laboratories and care providers are required to report cases of HIV and AIDS in accordance with local disease reporting laws, rules and regulations. Health Departments compile reported information and serve as respondents for this surveillance system. Health Departments use CDC provided software to manage surveillance data and report data to CDC. The revised system eHARS will enhance health departments' capabilities to implement ongoing and systematic quality control procedures and evaluate system performance. CDC also performs periodic data quality checks and provides reports for areas to use in the investigation of incomplete, inconsistent, and unusual data and provides guidance for evaluating system performance.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Health departments conduct ongoing evaluations of system performance. Minimum performance standards for surveillance programs are outlined in the *Guidelines for National Human Immunodeficiency Virus Case Surveillance Including Monitoring for Human Immunodeficiency Virus Infection and Acquired Immunodeficiency Syndrome. MMWR 1999 (No-13 (11-16*)) available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4813a1.htm. Minimum performance standards include completeness of reporting (>85%), timeliness of reporting (>66% of cases reported within 6 months of diagnosis), accurate case counts (less than or equal to 5% duplicate case reports and less than or equal to 5% incorrectly matched cases) and 85% of cases should be reported with risk information. Evaluations of

completeness of reporting conducted by DHAP and reporting areas have revealed that completeness of AIDS case reporting is high (over 80%). Areas are encouraged to continually identify new report sources and incorporate these into routine case finding procedures to continually enhance completeness of reporting. Areas also complete validation studies where case report information is re-abstracted from medical charts to assess the accuracy of the reported data. Implementation of the eHARS software will assist areas in conducting ongoing evaluations of their document -based surveillance activities and enhance quality control capabilities. Since Federal funding for several large treatment and care programs (e.g., RWCA and HOPWA) rely on HIV/AIDS case counts for funding formulas, respondents maximize case finding activities to provide complete and accurate case counts. Furthermore, critical data elements reported to CDC are quite complete because CDC only includes cases with complete demographic information into the national databases. Completeness of reporting of data elements collected for incidence, VARHS and EPS will be assessed on an ongoing basis.

4. Tests of Procedures or Methods to be Undertaken

Tests for procedures or methods for the proposed modifications included extensive review and consultation with State and local health departments regarding data collection as well as incorporation of previously implemented components of instruments used by State and local agencies. For estimating incidence statistical methods must account for testing and medication use history. Review and testing of statistical methods for incidence surveillance are currently conducted according to the 2006 consultation with statistical experts (see consultation summary in **Attachment M**).

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Local and state health departments are responsible for collecting data on persons eligible to be reported, entering data into the HARS database, and transmitting data to CDC. CDC receives regular input from health departments through annual surveillance coordinator meetings. In addition, local areas analyze and disseminate the data for use in program planning and funding allocation. Outside (non-CDC) individuals or agencies are occasionally consulted on statistical aspects of the design, collection and/or analysis of HIV/AIDS data. Several such consultations were held regarding the statistical methodology used to estimate HIV incidence based on the STARHS technology. The individual consultant or agency from whom we request assistance depends on the problem being addressed and most often takes form as a multi-disciplinary panel. (see **Attachments J and M**)

List of Attachments

A. Public Health Laws Permitting Data Collection

B. *Federal Register* Notice, August 18, 2005, Volume 70, Number 159, Pages 48551-48553

C. Adult HIV/AIDS Confidential Case Report Form

D. Pediatric HIV/AIDS Confidential Case Report Form

E. Form Instructions in Technical Guidance for HIV/AIDS Surveillance Programs Volume II: Data Collection Resources and Reporting. Centers for Disease Control and Prevention; 2006

F. Supplemental Surveillance Activity 1: HIV Incidence Surveillance Data Elements and Procedures

G. Supplemental Surveillance Activity 2: Variant, atypical and Resistant HIV Surveillance (VARHS) Data Elements and Guidance

H. Supplemental Surveillance Activity 3: Enhanced Perinatal Surveillance (EPS) Data Collection Forms and Procedural Guidance

I. *HIV/AIDS Surveillance Report*

J. Listings of Surveillance Coordinators in State Health Departments and Expert Consultants

K. Technical Guidance for HIV/AIDS Surveillance Programs Volume III: Security and Confidentiality Guidelines. Centers for Disease Control and Prevention; 2006.

L. Assurance of Confidentiality for HIV/AIDS Surveillance

M. Statistical Consultation Summary