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

OMB # 0920-0573

Supporting Statement Part A

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Supporting Statement

Section
A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention requests approval for revisions to a previously approved project 0920-0573 expiration 02/28/2010 called “Adult and Pediatric HIV/AIDS Confidential Case Reports for National HIV/AIDS Surveillance” for a period of 3 years. Since the beginning of the HIV 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 Division of HIV/AIDS Prevention (DHAP), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), CDC in collaboration with health departments in the states, the District of Columbia, and U.S. dependent areas, conducts national surveillance for cases of human immunodeficiency virus (HIV) infection that includes critical data across the spectrum of HIV disease from HIV diagnosis, to acquired immunodeficiency syndrome (AIDS), the end-stage disease caused by infection with HIV, and death. In addition, the data collection provides the essential data used to calculate population-based HIV incidence estimates and well as monitor patterns in variant, atypical, and resistant strains of HIV among infected persons in the U.S. These data have been maintained and reported through the HIV/AIDS reporting system (HARS) software since 1993. In 2010, the enhanced electronic HIV/AIDS reporting system (eHARS) will be fully deployed, allowing for increased functionality and tracking of all documents related to case reports (e,g. case report forms, laboratory reports) in one system. The revisions requested in this application for renewal include additional data elements that will allow better tracking of documents and flow of previously approved currently collected surveillance data. In addition, we are requesting approval of a new data collection form for Enhanced Perinatal Surveillance (EPS). These revisions are non-substantial changes primarily aimed at improving the format and usability of the form.

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 1). Notification of the request for OMB clearance was published in the Federal Register on September 3,2009 (Attachment 2).Currently, 59 areas (states/territories/U.S. dependent areas) and six U.S cities within those areas are funded to collect HIV/AIDS surveillance data. As of April 2008, 56 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 and report those cases to CDC. Therefore, the estimated burden for the next three years is based on HIV case reporting in 59 areas. Because both HIV and AIDS cases are reported using the same adult and pediatric case report forms the burden estimates are combined for HIV and AIDS cases for each form. Burden estimates for reporting of HIV incidence, variant and atypical, and resistant viral sequences, and enhanced perinatal surveillance data elements are based on the subset of areas reporting those data.

HIV surveillance data are collected to monitor trends in HIV and describe the characteristics of infected persons (e.g., demographics, risk behaviors, clinical and laboratory markers of HIV disease, manifestations of severe HIV disease (AIDS), and deaths among persons with HIV). The eHARS system when fully implemented will enable better tracking of all the documents and data elements associated with collecting this information in one system and ultimately assist in effectively monitoring the epidemic both locally and nationally. Since AIDS was first recognized in 1981, a total of 1,030,832 AIDS cases have been reported through December 31, 2007 in the United States, D.C. and U.S. dependent areas through the national reporting system. In addition, 337,590 cases of HIV that have not progressed to AIDS have been reported to CDC through December 31, 2007. With the advent of highly active antiretroviral therapies that delay the progression of HIV to AIDS, and of AIDS to death, and changes in the AIDS case definition to include an immunologic diagnosis, earlier back-calculation methods from the 1990s for estimating HIV prevalence based on the number of reported AIDS cases are no longer reliable. With 80% of states reporting name-based HIV

diagnoses as of January 2006, an extended back-calculation method now can be used to estimate HIV prevalence more accurately. Based on this method, CDC estimates that 1.1 million adults and adolescents (prevalence rate: 447.8 per 100,000 population) were living with diagnosed or undiagnosed HIV infection in the United States at the end of 2006 (CDC,2008). In 2008, CDC also published the first national estimate of HIV incidence in the United States based on incidence data elements (Hall et al., 2008). This estimate was for the year 2006, and was followed by subpopulation estimates based on the same dataset (CDC, 2008). An estimated 56, 300 new infections occurred in the U.S. and the District of Columbia in 2006. Data from pediatric case reports and enhanced perinatal surveillance have documented declines in perinatal HIV infections in the United states in the beginning of the 21st century and have provided important data on the success of perinatal prevention efforts in the U.S. (McKenna et al. 2007; CDC, 2008)(See Attachment 5 for listing of recent publications).

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 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 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 surveillance system provide the sole source of comprehensive, complete national HIV statistics collected in a timely and standardized manner. If HIV data are not collected, reliable and consistent information will not be available on the extent and distribution of the HIV 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. These surveillance data, together with behavioral data and other scientific information are the primary data used by state and local health departments in their community prevention planning processes to make informed decisions about where and how to target resources locally. Effective assessment of federal, state, and local HIV 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

in the United States cannot be achieved without a national HIV surveillance system.

Currently, HIV and 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 HIV/AIDS Treatment Modernization Act of 2006 which funds treatment and care for persons who could not otherwise afford expensive, life-saving therapies. While in the past funding was based on AIDS case counts, the 2006 re-authorization provides for funding to be based on HIV as well as AIDS data, which better reflect the burden of disease in local areas. Eligibility of jurisdictions for funding is still based on AIDS case counts. A compilation of the 2006 RWCA re-authorization is provided by Health Resources and Services Administration (HRSA) at http://hab.hrsa.gov/law/reauth06.htm. The continued use of HIV disease data to guide funding of these important care programs make the continued collection of high quality data on both HIV and AIDS through the national HIV surveillance system critical.

Privacy Impact Assessment

The data collection for the electronic HIV/AIDS Reporting System (eHARS) has been previously assessed. The privacy impact assessment (PIA) for eHARS has already been done and was submitted March 26, 2009.

Overview of the data collection system

CDC provides funding through cooperative agreements to all U.S. States, District of Columbia and U.S. Dependencies to conduct surveillance for HIV and AIDS. AIDS Surveillance data collections are supported in 59 areas (the 50 states (including 6 separately funded cities), 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 forms (Note the Marshall Islands, Palau and Federated State of Micronesia are in the process of establishing these systems). Currently 56 reporting areas collect confidential HIV data using the same methods for both HIV and AIDS reporting (Note Marshall Islands, Palau, and Federated States of Micronesia have not yet established these HIV reporting systems). It is anticipated that

HIV reporting will be fully implemented in all 59 jurisdictions over the next three years. 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. Additionally, case reports may be abstracted from medical records by health department staff. Often, laboratory reports are forwarded to the health departments initially who then follow up with providers to complete the case report information. Updates to case reports are done as additional information may be received from laboratory reports, vital statistics, or reports received from additional providers. The database is checked for duplicates and deduplicated as part of routine data quality assurance activities. Increasingly, health departments utilize electronic laboratory methods and electronic laboratory medical records for reporting of case information and eHARS will facilitate management and use of these electronic records. Data are combined from a variety of sources and entered and stored in eHARS. Data without identifiers are encrypted and reported monthly to CDC via the secure data network (SDN) where they are added to reports from other areas to form the national database. All state and local health departments have records retention policies in place.

Some areas also conduct supplemental surveillance activities and report data elements specific to those efforts. Areas conducting HIV incidence surveillance S*upplemental Activity 1: HIV Incidence Surveillance* (See Attachment 3(d) and 4(b))report additional information used to derive population-based estimates of incidence, including testing frequency, prior testing, and use of HIV-related medicines. Areas conducting variant, atypical and resistant HIV surveillance (*Supplemental Activity 2: Variant, Atypical and Resistant HIV Surveillance* Attachments 3(e) and 4(c))report genotyping test results for drug resistance and HIV-1 subtypes for individuals newly diagnosed with HIV. This information can be obtained from existing data sources, that is from medical record reviews or these data are provided by the testing laboratories to health departments. Additional data on specimen quality are reported for specimens tested. As part of ongoing surveillance activities CDC is conducting enhanced data collection on HIV-infected mothers and their infants in 15 states to maximally reduce perinatal HIV transmission (*Supplemental Activity 3: Enhanced Perinatal Surveillance (EPS)* Attachments 3(f) and 4(d)). Data elements are collected through linking of mother infant pairs, review of supplemental medical records and abstraction of mother and infant medical records. Information collection focuses on HIV testing, use of Zidovudine (ZDV) and

other antiretroviral medications to prevent perinatal HIV transmission, and HIV treatment and care.

Items of Information to be collected

The core HIV/AIDS data collection consists of two forms: (1) Adult HIV/AIDS Case Report Form (CDC 50.42a) and (2) Pediatric HIV/AIDS Case Report Form (CDC 50.42b) (see Attachments 3(a)). 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 pediatric form is 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 surveillance staff in the State or local health departments in accordance with their State or local HIV reporting requirements and then de-identified case data are forwarded to CDC for inclusion in the national database. 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.

HIV/AIDS cases are reported to State and local health departments with some Information in Identifiable Form (IIF) including name, date of birth, address, and phone number and de-identified before being sent to CDC. Other potential IIF include date of death. Date of birth and date of death information are forwarded to CDC together with other case information after names are removed. Demographic information such as sex, age at diagnosis, vital status, country of birth, residence at diagnosis and race and ethnicity are also collected. Patient history information including risk factor information is collected. In addition, information on facility of diagnosis for HIV and AIDS and clinical and laboratory data related to HIV and AIDS are also reported, such as HIV antibody tests, HIV detection tests, CD4 t-lymphocyte tests and viral load tests result. Information on treatment and referral for services data are also collected. These data elements are listed on the current Adult/adolescent and Pediatric HIV/AIDS case report forms and eHARS variable list (Attachments 3(a)(b)(c)). eHARS system stores information in tables reflected in the variable list in Attachment 3(c). The variable list in Attachment 3(c) identifies whether a variable is transmitted to CDC or not, and whether a variable is a program requirement for collection (Required) or if collection is optional (Optional), which may include variables that are CDC

recommended for collection but collection is optional; or whether a variable is generated by the eHARS system from the entered values of other variables. Variables that are not on the current case report form but on the eHARS variable list consist of the following 1) additional variables required for reporting in the new eHARS system 2) additional optional variables which may be of use primarily for local purposes; and 3) system and surveillance process variables for enhanced tracking of surveillance documents. All new variables are within the previously approved categories of data elements listed above or modifications of existing variables. For example, facility type allows additional coded options. Surveillance method (surv_method) is an example of a new surveillance process related field which will allow tracking of the method by which a report was obtained (e.g., Active, Follow-up, Passive, Reabstraction) and can be used for evaluation purposes. In sum, these variables will not substantially increase response burden since they primarily are non-substantive modifications to existing variables, recorded as part of the surveillance process, or calculated by the system. We estimate any burden for these modified data elements are balanced against the efficiencies gained in using the eHARS to streamline data management. CDC will complete deployment of eHARS to all jurisdictions by the end of 2009 and is requesting OMB approval for data elements reportable in eHARS.

We are in the process of consulting with state and local HIV surveillance coordinators on modifications to both the Adult/Adolescent and Pediatric HIV/AIDS confidential case report forms and will be proposing modified versions of the forms in the near future (anticipated for implementation in 2010) based on the data elements included in this request. The data elements required and recommended for collection will be reflected on the case report form. The case report form will be finalized after a consultation with surveillance partners in July of 2009 and will reflect variables from the eHARS variable list in Attachment 3.c.

Data elements for supplemental surveillance activities conducted in a subset of areas include: 1) testing and treatment history for improved monitoring of HIV incidence including information on testing frequency, prior testing, and use of HIV-related medicines. These data elements on testing and treatment are listed in Attachment 3(d); 2) specimen quality and sequence information for improved monitoring of drug resistance and HIV-1 subtypes (Attachment 3(e)); and 3) enhanced information on HIV infected mothers and their infants to maximally reduce perinatal transmission. We are proposing revisions to the Enhanced

Perinatal Surveillance (EPS) data collection form. The draft EPS form with the proposed revisions is included in Attachment 3(f) and specific revisions are itemized in the Listed Changes to the EPS Form in Attachments 4(d). The proposed revisions to the Enhanced Perinatal Surveillance (EPS) form are primarily editorial and formative. Specifically, these include changes to the title of the form from the "Enhanced HIV/AIDS Surveillance to Maximally Reduce Perinatal HIV Transmission" to "Enhanced Perinatal Surveillance (EPS)". Format of the form is changed to include check boxes and clear delineation of sections. In addition, the designation of HARS or M-HARS was removed throughout the form. Changes to specific questions include minor editorial or wording revisions, punctuation, and clarification of questions. Unknown options were added to questions that included a yes/no/not documented or record not available option to be consistent with all questions. An "other" option was included for drug names to accommodate new testing algorithms or FDA approved drugs. Crack cocaine and expedited EIA options were included with certain substance abuse questions to maintain consistency. Newer antiretroviral drugs were added to the list of antiretroviral drugs at the end of the form. No substantive changes were made to the number, type, or intent of the questions on this revised EPS form. Corresponding updates to accommodate the Enhanced Perinatal Surveillance System (EPSS) have been made to the draft EPS User's guide provided in Attachment 4(d). Since the changes requested on the revised form are primarily editorial and do not change the number or complexity of the items we estimate that these changes will not significantly increase the overall burden to complete the form. However, we are increasing the estimated time to complete the revised form to be 60 minutes based on input from surveillance coordinators on actual time required to complete the data elements in the currently approved form.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age.

This Information Request (IC) does not involve any web-based data collection methods or refer respondents to websites.

2. Purpose of Use of the Information Collection

CDC maintains the national HIV surveillance system to monitor the scope of the HIV 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 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 morbidity. These modifications address changes in the surveillance case definition as well as changes in the data collection system. The most recent case definition was published in 2008 (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5710a1.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 expanded 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. The current case definition combines the prior definitions for HIV and AIDS into one definition for HIV disease.

As our understanding of the epidemic has increased and the surveillance system has been modified to better monitor the full spectrum of disease, it has become necessary to also expand and refine data collection elements and methods. CDC will complete deployment of a new data collection software system (eHARS) to all jurisdictions by the end of 2009. This system allows jurisdictions more flexibility in collecting information from multiple sources and for repeated events required for monitoring the current epidemic. The data elements of the software system are indicated in the variable list in Attachment 3(c). The eHARS software and corresponding variables represent another step toward modernization of the existing reporting system to better align it with current technologies for exchange of electronic health information. We will also be proposing modifications to both the Adult/Adolescent and Pediatric HIV/AIDS confidential case report forms based on the variables in Attachment 3(c) in the near future (anticipated for implementation in 2010) that will reflect the data elements required and recommended for collection. A consultation on revisions to the case report forms was held at the 2009 HIV Surveillance Workshop on July 14, 2009. After the consultation a workgroup was assembled to draft revised

forms which will be finalized in 2010. It is anticipated that the burden of data collection will not change as the number and type of data elements to be collected are expected to be similar.

Reporting areas routinely review and analyze their data to monitor local HIV trends, evaluate program success, and assist in focusing resources to reduce the burden of HIV. CDC publishes annual surveillance reports summarizing national HIV statistics (see Attachment 6), 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 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 control and prevention. The surveillance report, accompanying slide sets, and other important publications from the HIV surveillance system are also posted on the DHAP web site at http://www.cdc.gov/hiv/topics/surveillance/index.htm . CDC also uses national surveillance data to respond to special data requests to assist other government agencies, Congress, and organizations with HIV control and prevention activities.

HIV 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 HIV morbidity helps determine resources required for federal prevention efforts, including support of state and local HIV programs. These data are also used in DHAP materials for training and education of health care providers, the general public, and the media. HIV 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.

Supplemental data collection activities complement the core data collected as part of Adult/Adolescent and Pediatric HIV surveillance and provided uniquely useful information and are described separately.

Supplemental Activity 1: HIV Incidence Surveillance

(Attachments 3(d) and 4(b))
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 data include testing and treatment history (TTH) such as testing frequency, prior testing, and use of HIV-related medicines. These data elements on testing and treatment are listed in Attachment 3(d) HIV incidence surveillance received a CDC/NCHSTP non-research determination in 2005 (Attachment 8).

As of January 2008, the CDC has funded 25 jurisdictions (18 states, 6 separately funded cities, and the District of Columbia) to conduct HIV incidence surveillance through cooperative agreement who will report data during the next three years. Those areas receive funding to track and ensure shipment of remnant HIV-1 diagnostic specimens to a central laboratory conducting STARHS and to collect testing and antiretroviral treatment history (TTH) information on individuals newly diagnosed with HIV. Data are reported to CDC on a monthly basis via the SDN. All funded areas have begun reporting STARHS results and TTH data to CDC. In August 2008, CDC published the first national estimate of HIV incidence in the United States based on a biological marker of recent infection (Hall et al., 2008). This estimate was for the year 2006, and was followed by subpopulation estimates based on the same dataset (CDC, 2008). Following publication of the national HIV incidence estimate CDC provided training, technical assistance, and statistical programming to state and local health department partners to allow them to develop their own HIV incidence estimates. In 2010 CDC will publish the HIV incidence estimate for 2007 and will continue to report on HIV incidence annually thereafter. (See Attachment 5 for listing of publications)

Supplemental Activity 2: Variant, Atypical and Resistant HIV Surveillance (Attachments 3(e) and 4(c))
For individuals with newly diagnosed HIV, genotyping test results for drug resistance and HIV-1 subtypes are collected as part of variant, atypical and resistant HIV surveillance (VARHS). This

information can be obtained from existing data sources, that is from medical record reviews or laboratory reporting from testing for routine medical care or these data are provided by the surveillance testing laboratory to health departments. Additional data on specimen quality are reported for specimens tested for surveillance. VARHS received a CDC/NCHSTP non-research determination (Attachment 10) and the data elements for VARHS are listed in Attachment 3(e). 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.

As of January 2008 the CDC has funded 11 jurisdictions (8 states and 3 separately funded cities) to conduct Variant, Atypical, and Resistant HIV Surveillance (VARHS) and will incorporate VARHS data into their case reporting activities during the next three year period. The states receive funding to track and ensure shipment of remnant HIV-1 diagnostic specimens to a central laboratory for genotype testing, to maintain a specimen tracking database which ensures compliance with VARHS procedures, and to ensure the reporting of commercially conducted genotype testing results to the state or local health department. Funded jurisdictions submit data to CDC monthly. CDC has recently developed a mutation list for surveillance of transmitted drug resistance for use in the United States (based on the World Health Organization’s HIV-1 Surveillance List [Bennett et al, 2009]), and in 2010 CDC will publish results from VARHS for cases diagnosed in 2006. We will follow that publication with results for 2007, and will publish results from VARHS annually thereafter (See Attachment 5 for publications).

Supplemental Activity 3: Enhanced Perinatal Surveillance
(Attachments 3(f) and 4(d))
The national HIV 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 fewer than 200 in recent years. Data on the number of perinatal HIV infections suggests ongoing declines throughout the early years of the 21st century from 277 (95% CI, 224-346) in 2001 to 138 (95% CI, 96-186) in 2004 (McKenna and Hue (2007). 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 conducting enhanced data collection on HIV-infected mothers and their infants in 15 states to maximally reduce perinatal HIV transmission.

The 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; and to evaluate efforts to b) reduce perinatal HIV transmission; c) reduce prevention failures for perinatal transmission; d) assess efficacy of antiretroviral medications in preventing perinatal HIV transmission; e) assess potential adverse outcomes of perinatal/postnatal antiretroviral therapy; and f) assess implementation of Public Health Service recommendations for opportunistic infection prophylaxis; and g) to establish a surveillance system to collect data that enable states to respond to selected requirements of the Ryan White CARE Act. To accomplish these goals, project staff and grantees conduct medical records reviews of mother-infant pairs and longitudinal follow-up of all HIV-exposed children to collect pertinent data elements and analyze these data to assess progress toward the aforementioned goals. EPS addresses the CDC Health Protection goal for infants and toddlers ("Start Strong") and the Healthy People 2010 focus area of the Advancing HIV Prevention initiative for further decrease perinatal HIV transmission. Surveillance data collected as part of EPS are critical for evaluating strategies to prevent perinatal transmission and ultimately improving the health of infants. Enhanced perinatal surveillance has received a CDC/NCHSTP non-research determination (Attachment 10).

We are proposing minor revisions to the EPS data collection form to clarify wording and responses to previously approved data elements. Draft data abstraction forms, and user’s Guide instructions are provided in Attachment 3(f) and 4(d). The proposed revisions to the EPS form are primarily editorial and related to formatting of the form. Newer antiretroviral drugs were added to the list of antiretroviral drugs at the end of the

form to help keep up with currently available treatments. Changes to the form were described in the previous section titled “Items of Information to be collected” and are detailed in the listing of changes provided in Attachment 4(d). Corresponding updates to accommodate the Enhanced Perinatal Surveillance System (EPSS) have been made to the draft EPS User’s Guide provided in Attachment 4(d). No substantive changes were made to the number, type, or intent of the questions on this revised EPS form. Since the changes requested on the revised form are primarily editorial and do not change the number or complexity of the items completed, we estimate that these changes will not significantly increase the overall burden to complete the form. However, we are increasing the estimated time to complete the revised form to be 60 minutes based on input from surveillance coordinators on actual time required to complete the data elements in the currently approved form.

Privacy Impact Assessment Information

The information collected as part of the national HIV surveillance system is collected to monitor the scope of the HIV 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 morbidity and mortality in the United States, increasing HIV testing, and eliminating racial and ethnic disparities in new HIV infections and AIDS diagnoses. As our understanding of the epidemic has advanced the national system has evolved to increase our understanding of the epidemic in the United States. Aggregate data are used by state and local health departments for prevention and care planning. HIV and AIDS surveillance data used as the basis for funding formulas for care and treatment programs under the federal Ryan White Treatment Modernization Act of 2006 and Housing and Urban Development assistance programs. CDC provides summary statistics in a variety of surveillance reports, peer reviewed papers, slide sets, fact sheets and resource materials describing the HIV epidemic in the United States. These resources are available on the CDC website at http://www.cdc.gov/hiv/topics/surveillance/index.htm and recent publications are listed in Attachment 5. Without the data from this national system, we would not be able to accurately track the epidemic in the U.S or effectively target prevention and care resources.

Data obtained from supplemental HIV incidence surveillance activities are used to provide national estimates of the annual number of new infections. Monitoring trends in HIV incidence will allow CDC and state and local programs to better focus and evaluate prevention efforts for the populations at greatest risk and ultimately reduce the number of new infections.

Data from supplemental Variant, Atypical and Resistant HIV Surveillance (VARHS) activities are collected to monitor resistant strains of HIV in U.S that are used to describe trends in transmission of drug resistance and HIV subtypes and support evaluation of first-line HIV antiretroviral drug treatment providing important information to clinicians, pharmaceutical researchers, and public health authorities as they make treatment recommendations and develop new treatments.

Data from Enhanced Perinatal Surveillance (EPS) activities are being collected to improve the public's health by maximally reducing the number of new perinatally-acquired HIV infections in the U.S. The intended uses of EPS data are to evaluate the impact of efforts to: reduce perinatal HIV transmission; reduce prevention failures for perinatal transmission; assess efficacy of antiretroviral medications in preventing perinatal HIV transmission; assess potential adverse outcomes of perinatal/postnatal antiretroviral therapy; and assess implementation of Public Health Service recommendations for opportunistic infection prophylaxis.

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 discourages this practice) or secure electronic transfer. Health department staff also conduct medical record abstractions and complete the forms themselves. Data are then compiled by health departments who serve as the respondents for the HIV surveillance system and data are forwarded to CDC. A privacy impact assessment for data collection for the enhanced electronic HIV/AIDS reporting system (eHARS) has been previously completed. Data elements considered to be IIF are collected and maintained by state and local health departments in eHARS and those data are de-identified before being reported to CDC. Data on date of birth, date of death and soundex codes are shared with CDC. CDC uses soundex, date of birth, state of residence, and sex for deduplication of the national data. CDC disseminates summary data and does not share

IIF outside of the HIV surveillance program. State and local health departments follow local schedules for archival and destruction of paper copies of case reports. Case information including personal identifiers is retained in the eHARS system indefinitely in a cumulative database.

Data that may be considered sensitive, such as certain information on sexual and drug using behaviors that may be related to transmission is collected as part of HIV surveillance. These data are critical for monitoring patterns of transmission and describing risks associated with HIV infection. This information is used by CDC to describe epidemiologic trends by risk behavior and also used locally in development of epidemiologic profiles used to target community based prevention programs. Questions collected as part of the pediatric case report and as part enhanced perinatal surveillance EPS include important information on maternal history including mother's drug use behavior, prenatal and treatment during pregnancy which are critical for monitoring and evaluation of HIV prevention and treatment programs at the state, local, and national levels. Some clinical and laboratory markers of HIV infection may also be considered sensitive. However, these data are critical for monitoring trends in HIV diagnosis and describing the full spectrum of HIV morbidity in the United States and locally.

Because these sensitive data are collected as part of HIV surveillance, steps are taken at every stage of data collection, storage, and use to ensure that confidentiality and privacy is maintained. Various state laws and regulations protecting data collected and stored by health departments as part of public health surveillance exist. In addition, policies delineating security and confidentiality practices and data release exist at the state and local health department and CDC levels serving to further protect HIV surveillance data. As a condition of funding under the HIV 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 9. 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, and secure 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. These policies and procedures include steps that would be taken if a breach were to occur. In addition, staff sign non-disclosure agreements or confidentiality statements annually that outline staff responsibilities and possible penalties if a breach were to occur. CDC reviews procedures for protecting the confidentiality and security of HIV surveillance data through periodic site visits and as part of the annual renewal of cooperative agreements for HIV surveillance.

HIV surveillance data are collected and held at CDC under an Assurance of Confidentiality under Section 308(d) of the Public Health Service Act (42 USC 242m(d)) (see Attachments 1 and 8). 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 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)). In addition, authorization is required to access the national HIV surveillance data. Each person granted access to the data must sign a non-disclosure agreement, agree to abide by CDC data release policies, and complete annual security and confidentiality training.

3. Use of Improved Information Technology and Burden Reduction

To reduce burden for respondents, the HIV 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 programs could collect and manage HIV surveillance data from both the HIV and AIDS case report forms in a single system. 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 enhanced electronic HIV/AIDS Reporting System (eHARS) is an application for collecting, storing, and retrieving the data the CDC has identified as necessary to monitor the epidemic and to conduct systematic evaluations of HIV surveillance programs and prevention policies and will assist with evaluation activities both locally and nationally. The system aims to ease electronic reporting 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. eHARS replaces HARS (HIV/AIDS Reporting System), maintains much of its functionality, and extends its capabilities. Importing of electronic files is more robust, and data reporting and analysis is executed more quickly. eHARS works with SQL to enable powerful data manipulation. Using ad hoc reporting and other tools, eHARS data can be queried, filtered, joined, and then exported to Excel and Access for additional reporting and analysis. The eHARS application enables project areas to collect, manage, analyze, disseminate, and report to CDC the data needed to monitor and track the HIV epidemic on both a local and a national level. eHARS provides project areas with the tools needed to follow CDC technical guidance for HIV/AIDS Surveillance. The eHARS system was fully deployed in all areas using electronic systems in September 2009. We then moved into a maintenance and support phase for the system, where updates, fixes, etc., will be issued and project areas supported in use of the system and especially in the use of the data collected and maintained in the system. CDC's emphasis will be on assisting the project areas in maximizing the utilization of the surveillance data.

Data is increasingly obtained from electronic data sources to complete cases reports, particularly from laboratories. However, a laboratory report alone does not typically contain all of the required data elements to complete a case report and usually requires additional follow-up activities such as medical record review, telephone contact, or local database abstraction. It is estimated that over 60% of case reports involve some receipt of

electronic data to complete the report based on information obtained by the Council of State and Territorial Epidemiologists (CSTE) from HIV Surveillance Coordinators. eHARS provides tools to facilitate the import and use of electronic data sources and enhance the use of electronic health information for case reporting thereby decreasing burden on health departments. Data elements available in eHARS on the surveillance method used, report medium, and facility type will enable better tracking of this information in the future as areas begin using eHARS. All case reports (100%) are entered and reported by health departments (who serve as the respondents for this data collection) using the electronic reporting system eHARS and reported in encrypted electronic format to CDC via the secure data network (SDN).

4. Efforts to Identify Duplication and Use of Similar Information

The data collected by the national HIV surveillance system provide the sole source of comprehensive, complete national HIV statistics collected in a timely and standardized manner. Through literature searches, attendance at national HIV meetings/conferences, discussions with officials from state and local health departments and ongoing consultations with HIV 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, HIV and 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 Business or Other Small Entities

Data collection and electronic submissions to CDC from the reporting areas are done by HIV 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 involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

CDC 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 quarterly data sets within several months after the close of the quarters. This transfer schedule has facilitated keeping the reporting area and CDC databases up to date, and ensured timely and accurate assessments of trends. Through timely data provided by the national HIV 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 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 relating to the Guidelines 5 CFR 1320.6

Collection of HIV 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 for adequate and timely tracking of disease trends. Further description of this process and justification are described in A.6.

A. 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 September 3, 2009 (Attachment 2). No public comments were received.

B. Consultation with State, local, and territorial HIV surveillance coordinators, and other HIV/AIDS specialists

occurs on a regular basis through national HIV surveillance workshops, routine site visits, 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 in December 2007 and during the National Meetings of the Council of State and Territorial Epidemiologists (CSTE) in June 2007 and 2008 where surveillance practices and guidelines were discussed. A national HIV surveillance workshop for surveillance coordinators was held in Atlanta July 13-16, 2009. During this meeting we discussed revisions to data collection forms in addition to training on aspects of surveillance data collection and use. We plan to continue to sponsor these meetings on a biannual basis in the future. Two position statements were discussed at the 2009 CSTE meeting involving HIV surveillance activities. The first addresses data reported as part of VARHS activities and describes required reporting of HIV genetic information resulting from HIV drug resistance testing. The second addresses the standard case definition used for notifiable disease reports of HIV.

Since 2006, DHAP has sponsored consultations on HIV incidence estimation where invited experts discussed various statistical approaches for calculating incidence. The agenda and participant list for the consultation in June 2006 was provided in our last renewal and the agenda and participant list for is the February 2007 consultation is included in Attachment 11. Sessions at the national 2009 HIV Surveillance Workshop in July 2009 discussed 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 EPS sessions conducted at the 2007 Joint Perinatal Hepatitis B and HIV Grantees Meeting, Atlanta, April 30- May 2, 2007. An Enhanced Perinatal Surveillance (EPS) Surveillance Coordinator’s Meeting was held in conjunction with the 2009 HIV Surveillance Workshop. Contact information for surveillance coordinators in state and local health departments and consultants providing input over the last three years are provided in Attachment 7.

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

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 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 surveillance system and data are forwarded to CDC. Although identifiable patient-level case report data are collected by local health departments from care providers and laboratories the case report data are de-identified before they are transmitted to CDC. A Privacy Impact Assessment was completed for eHARS March 26, 2009. The Privacy Act System of Records Notice (SORN) number is 09-20-0136.

The adult/adolescent and pediatric 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 was approved in the last request for extension but not implemented on the form. The case report form workgroup will consider for the next version of the form (to be finalized in 2010) including 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 the system 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 date of birth 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. State and local health departments follow local schedules for archival and destruction of paper copies of case reports. Case information including personal identifiers is retained in the eHARS system indefinitely in a cumulative database.

Areas use a microcomputer system developed by CDC (the HIV/AIDS Reporting System [HARS] or enhanced electronic HIV/AIDS Reporting System [eHARS] when deployed) to store and analyze data, as well as transmit de-identified encrypted data to CDC. 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. Data maintained at CDC are stored on a secure server with limited access. Steps are taken to limit access to the national database to those authorized by the Chief of the HIV Incidence and Case Surveillance Branch. All staff authorized to access CDC databases must complete annual security and confidentiality training, be familiar with Branch and CDC data release policies and procedures and sign non-disclosure agreements.

As a condition of funding under the HIV 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 9. 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 surveillance data through periodic site visits and as part of the annual renewal of cooperative agreements for HIV surveillance.

HIV 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 1 and 8). 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 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 surveillance data including data collected for surveillance evaluations, HIV incidence, VARHS, and EPS have been determined to be non-research surveillance activities by NCHHSTP/CDC (Attachment 10). Institutional Review Board review where required may be conducted at the local level.

Privacy Impact Assessment Information

A. A privacy impact assessment has been reviewed by ICRO, who determined that the Privacy Act does apply. The applicable system of records notice is 09-20-0136.

B. Information collected as part of HIV surveillance are kept in a physically and electronically secure environment. Steps are taken throughout the surveillance process from data collection through storage and use of the data to ensure data are secured. Policies and procedures for security and confidentiality and data release exist at both the HIV surveillance programs at state or local health departments and at CDC (see Attachment 8 and 9). Technical guidelines for HIV/AIDS surveillance include guidance for health department staff on data collection procedures as well

as security and confidentiality guidelines. Annual security and confidentiality training and signing of confidentiality/nondisclosure agreements are required of both state health department and CDC staff. Additional trainings on data collection procedures are routinely supported by CDC through workshops and regional trainings for surveillance coordinators. The national HIV Surveillance Workshop conducted in July 2009 included sessions on surveillance practices and procedures as well as security and confidentiality (See Attachment 7 for draft 2009 workshop agenda).

As a condition of funding under the HIV 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 9. 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. All records and documents pertaining to the HIV surveillance will be kept in locked file cabinets. Records will not be left uncovered on the desks and rooms will be locked after hours. Access controls to physical locations where HIV data are in place. Health departments use a variety of mechanisms, including the use of identification badges and key cards to control access to physical locations where data are stored. Persons with authorized access to surveillance data 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. Scheduled back-ups of electronic data are made according to health department policies. State and local health departments follow local schedules for archiving and destruction of paper copies of case reports. Case information including personal identifiers is retained in the eHARS system indefinitely in a cumulative database. CDC reviews procedures for protecting the confidentiality and security of HIV surveillance data through periodic site visits and as part of the annual renewal of cooperative agreements for HIV surveillance.

HIV 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 1 and 8). 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 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)) Electronic databases are housed on a secure server with limited access at CDC. In addition, authorization is required to access the national HIV/AIDS surveillance data. Each person granted access to the national data (including contractors and federal employees) must sign a non-disclosure agreement, agree to abide by CDC data release policies, and complete annual HIV/AIDS security and confidentiality training. The security statement including the access packet materials for employees and contractors are included in Attachment 8 together with the assurance of confidentiality. Information will be shared in accordance with the provisions outlined in the assurance. The security statement states all records and documents containing sensitive HIV/AIDS surveillance data will be kept in locked file cabinets. Records will not be left uncovered on the desks and rooms will be locked after hours. Access controls to physical locations where HIV data are kept are in place. Project records will be retained and destroyed in accordance with applicable CDC records retention schedules. The electronic data maintained at CDC is cumulative and will be retained indefinitely. At CDC, access to the buildings is monitored by guards and access granted to CDC employees and escorted guests. At CDC access to the HIV surveillance data is limited to persons authorized by the Chief, HIV Incidence and Case Surveillance Branch. Data requests are handled as outlined in the security statement and security access packet with the Assurance of Confidentiality (Attachment 8). Third party requests for information will be referred to the Office of the CDC Freedom of Information Act Officer in the Office of Communications when applicable.

HIV surveillance data are on the CDC local area network (LAN) and mainframe computers maintained by the Information Technology Service Office (ITSO),CDC comply with several Federal policies,

statutes, regulations, and other directives for the collection, maintenance, use, and dissemination of data, including the Department of Health and Human Services Automated Information Systems Security Program, the Computer Security Act of 1987 (Public Law 100-235), the E-Government Act of 2002 (Public Law 107-347), and the Federal Information Security Management Act (FISMA). Additionally, the LAN is in compliance with CDC's Office of the Chief Information Security Officer (OCISO) ADP Security Policy. Security features implemented include user ID and password protection, mandatory password changes; limited logins; user rights/file attribute restrictions and virus protection.

Data entered into computer files by staff at state and local health departments and transmitted electronically via encrypted files to CDC are uploaded into CDC LAN. DHAP employees or contractors, and any ITSO or other CDC employees or contractors who service or maintain the systems or components necessary to support data management of HIV surveillance program files, are granted access to the files only upon approval by the Chief, HIV Incidence and Case Surveillance Branch. Access rights are removed when staff no longer require them. The list of authorized users is maintained and reviewed annually to ensure persons no longer needing access are removed.

Backup copies of HIV surveillance data are made by the LAN tape backup system nightly. Backup services are provided under a separate CDC-wide contract. Contractor facilities and staff are subject to the same Federal policies, statutes, regulations, and other directives, as well as to departmental and CDC security policies, which apply to CDC mainframe and LAN computers and staff. Access to LAN backup tapes is restricted to ITSO staff responsible for maintaining the backup procedures.

The process for handling security incidents is defined in data policies both for state health departments and at CDC. Event monitoring and incident response is a shared responsibility between the system’s team and the office of the Chief Information Security Officer (OCISO). Reports of suspicious security or adverse privacy related events should be directed to the component’s Information Systems Security Officer, CDC helpdesk, or to the CDD Incident Response Team. The CDC OCISO reports to the HHS Secure One Communications Center, which reports incidents to US-CERT as appropriate.

C. Reporting of HIV and AIDS cases is required under state laws and regulations for notifiable disease reporting. These data are reported without consent of the individual by providers and laboratories to state or local health departments or through abstraction of medical records by health department personnel. Data are shared voluntarily by state health departments with CDC for the purpose of compiling standard national HIV surveillance data for monitoring the epidemic at the national level.

D. Reporting of HIV and AIDS cases is required under state laws and regulations for notifiable disease reporting. These data are reported without consent of the individual by providers and laboratories to state or local health departments or through abstraction of medical records by health department personnel. Providers and laboratories report information on the case report forms to state health departments and health departments then voluntarily share these data with CDC. CDC supports and provides funding for HIV surveillance data collection efforts in state and local health departments through cooperative agreements. The data collected for HIV surveillance purposes are protected under an Assurance of Confidentiality as described in this subsection under B. Data collection forms include the following statement regarding this assurance and nature of their reporting: “This report to the Centers for Disease Control and Prevention (CDC) is authorized by law (Sections 304 and 306) of the Public Health Service Act, 42USC 242b and 242k). Response in this case is voluntary for federal government purposes, but may be mandatory under state and local statutes. Your cooperation is necessary for the understanding and control of HIV/AIDS. Information in CDC’s HIV/AIDS surveillance system that would permit identification of any individual on whom a record is maintained is collected with a guarantee that it will be held in confidence, will be used only for the purposes stated in the assurance on file at the local health department, and will not otherwise be disclosed or released without the consent of the individual in accordance with Section 308(d) of the Public Health Service Act (42 USC 242m).”

11. Justification for 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 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 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 and its potential impact on employability or insurability. 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 as well as the security statement provided in Attachment 8. 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 9).

12. Estimates of Annualized Burden Hours and Costs

A. Estimate of annualized burden hours

The total estimated burden in hours for this project is 51,311. This burden is somewhat lower than previous burden estimates for this system (57,774) primarily due to estimated leveling of the number of cases reported over the next three years as surveillance systems mature in areas most recently implementing HIV reporting. To a lesser extent, the reduction in the number of areas conducting supplemental data collection for incidence and VARHS also has contributed to a decrease in over all burden hours. The estimated burden includes that for case reports and evaluations of HIV surveillance based on these reports (including reabstraction/validation activities and routine interstate deduplication), other update functions such as routine updates to forms, death matching, monthly intrastate deduplication running edit checks and correcting entry errors (identified separately as case report updates) 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 exhibit 12.A.

The burden estimate includes time for the activities State and local health departments must conduct to collect the data and has not changed since the last renewal. However, because all areas are anticipated to have both HIV and AIDS reporting, and both HIV and AIDS cases are reported on the same adult and pediatric case report forms, the burden estimates are presented for Adult HIV/AIDS case reports and Pediatric HIV/AIDS case reports. 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 a weighted average 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 (25 minutes on average), phone follow-up with providers (20 minutes on average), abstraction from local databases (15 minutes on average), and electronic data transfer (approximately 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. Although any one case report does not typically involve all these methods, taking this average over all forms results in the 20 minute estimate. The overall average 20 minute burden estimate per report is based on 12.5 minutes for medical record reviews, 6 minutes for phone follow-up with providers and labs, 1.5 minutes for abstraction from local databases, and less than 1 minute for electronic data transfer.

A total of 108,501 responses are estimated for the Adult Case Report form (Attachment 3(a)) for HIV and AIDS cases and 472 responses are estimated for the Pediatric Case Report form (Attachment 3(b))for HIV and AIDS cases. These estimates are based on the annual number of HIV and AIDS cases reported to CDC from these areas. Theses annual estimates are based on the number of HIV and AIDS cases reported to CDC from these areas. For areas without mature HIV reporting systems we estimated the number of HIV cases to adjust for stabilization of the number of HIV reports in those areas. The estimates for adult and pediatric HIV and AIDS reports were up by 10% to account for evaluation activities such as re-abstractions (validation studies), routine deduplication activities, and evaluations of data collection/system performance. The resulting burden is 36,167 hours for the Adult case reports and 157 for the Pediatric case reports.

Exhibit 12.A. also includes the estimated burden of providing updated information on previously reported adult and pediatric cases (Adult and Pediatric case report forms in Attachments 3(a) and 3(b)). This additional burden results largely from routine updates of clinical and laboratory indicators of HIV infection such as CD4 counts and viral load test results, additional separate burden for other update functions such as routine updates to forms, death matching, monthly intrastate deduplication running edit checks and correcting entry errors. 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 5,723 responses distributed among all 59 reporting jurisdictions for a total of 477 burden hours.

Twenty five of the 59 jurisdictions conducting HIV/AIDS surveillance also provide data elements for *Supplemental Surveillance Activity 1: Incidence Surveillance* (see Attachment 3(d) for incidence data elements). 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 25 areas adjusting for the percentage of cases estimated to meet the necessary outcome standard for completeness of critical incidence data elements (85%). An total of 60,925 annual responses and 2,437 responses per respondent are estimated for HIV incidence data elements. The total burden hours for incidence data elements will be 10,154 hours.

Eleven jurisdictions conducting HIV/AIDS surveillance have also been funded to submit data for *Supplemental Surveillance Activity 2: Variant, Atypical and Resistant HIV Surveillance (VARHS)*(see Attachment 3(e) for VARHS data elements). 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. It is anticipated that the eHARS system will facilitate the electronic management of these data resulting in minimum burden per response. A total of 22,209 responses are

estimated based on the number of annual HIV and AIDS cases reported in the 11 areas. There will be an estimated 2,019 responses per respondent and it will take approximately 5 minutes to download the data for a total burden of 1,851 for VARHS.

Fifteen states will also conduct *Supplemental Surveillance Activity 3: Enhanced Perinatal Surveillance (EPS)*(see Attachment 4(f) for EPS data abstraction form). 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 60 minutes. This is an increase from 25 minute average burden requested in the last renewal. Based on input from surveillance coordinators, actual data collection is taking longer than anticipated is approximately 60 minutes. The estimated total number of responses is based on estimated number of HIV infected women giving birth (approximately 2500). There will be an estimated total of 2,505 total responses and 167 responses per respondent. Completion of the EPS data abstraction form will take approximately one hour to complete for a total burden of 2,505 hours to complete the collection of EPS data elements.

Exhibit 12.A Estimates of Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Total No. of Annual Responses	Avg. Burden per Response (in hours)	Total Annual Burden (in hours)
Health Departments	Adult HIV/AIDS Case Report	59	1,839	108,501	20/60	36,167
Health Departments	Pediatric HIV/AIDS Case Report	59	8	472	20/60	157
Health Departments	Case Report Updates	59	97	5,723	5/60	477
Health Departments	Incidence	25	2,437	60,925	10/60	10,154

Health Departments	VARHS	11	2,019	22,209	5/60	1,851
Health Departments	EPS	15	167	2,505	1	2,505
Total						51,311

Note: The estimates of total annualized burden hours are based on the estimated total number of case reports (i.e., Total No. Annual Responses) expected to be completed by State and local health departments each year (see narrative for description).

B. Estimates of Annualized Cost

The estimated total cost to respondents is $1,128,842. This is based on an estimated hourly wage of $22 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 $13.00/hr and one epidemiologist at $31/hr for an estimated $22/hr. The salary estimates were based on U.S. Department of Labor estimated mean hourly rates in the U.S. in 2008 for one data entry person (data entry keyer) at $13.04 per hour and one epidemiologist at $31.01 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.

Exhibit 12.B Estimates of Annualized Burden Cost

Type of Respondent	Form Name	Total Burden (in hours)	Hourly Wage Rate	Total Respondent Costs
State Health Departments	Adult HIV/AIDS Case Report	36,167	$22	$795,674
State Health Departments	Pediatric HIV/AIDS Case Report	157	$22	$3,454
State Health Department	Case Report Updates	477	$22	$10,494

State Health Departments	Incidence	10,154	$22	$223,388
State Health Departments	VARHS	1,851	$22	$40,722
State Health Departments	EPS	2,505	$22	$55,110
Total				$1,128,842

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

Exhibit 14 A. Estimates of Annualized Costs to the Federal Government

Expense Type	Expense Explanation	Annual Costs (dollars)
CDC Costs	Data Management Staff 2 data managers: $240,000 1 @ $90,000 1 @ 150,000	$240,000
	2 Quality control/help desk staff 1 @ 90,000 1 @ 53,000	$143,000
	Printing	$5,000 $5,000

	eHARS development and deployment	$900,000*
	HIV Incidence and Case Surveillance Branch Intramural Including Personnel	$5,368,000
	Subtotal	$6,656,000
Cooperative Agreements with States	HIV/AIDS Surveillance**	$54,789,689
	Total	$61,445,689

*Estimated average annual cost based on reported OMB IT cost for FY06 $1.4 million, FY07 $2.5 million, FY08 $1.7 million, FY09 1.2 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 51,311 hours. The previous burden associated with this information collection was 57,774 hours. The requested total burden represents an 11% decrease. This decrease is due several factors in our revision request. First, we adjusted our estimate for anticipated stabilization of case reporting over the next three years as areas newly implementing HIV reporting mature. Secondly, we have reduced the number of areas collecting incidence data from 30 to 25 and areas collecting VARHS data elements from 24 to 11. We have also refined the estimated amount time needed to complete EPS data collection from 25 to 60 minutes based on actual data collection in these states and also reduced the estimate of the number of HIV infected pregnant women anticipated to be eligible for this activity to 2,505 based on current estimates. This resulted in an increase in overall burden hours for EPS from 1,250 to 2,505. While we have proposed minor non-substantive modifications to the EPS form that are primarily editorial and do not increase the number of data elements these changes will not directly effect the burden associated with the data collection.

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. Typically

the surveillance report is completed approximately 6 months after the data are finalized. Cases reported to CDC by the end of June are used for the year end surveillance report summarizing data through the end of the calendar year. For example HIV/AIDS surveillance data for 2007 were finalized in June 2008 and the report was posted on the Division of HIV/AIDS (DHAP) web site and distributed to state and city HIV/AIDS surveillance coordinators in the first quarter 2009. However, it is anticipated that this schedule may be modified as areas begin reporting data through the new eHARS system and we make necessary changes to processing of the national data. We anticipate that this will add an additional 3 months to our reporting schedule. The time between data finalization and report publication even with this additional time still provides prompt dissemination of current HIV morbidity trends and timely evidence for decision makers related to program planning, evaluation, and resource allocation.

For the ongoing HIV surveillance data collection, the following adjusted annual time schedule in presented Exhibit 16 A. This annual estimate is based on the experience of the previous five years of data collection, analyses, and publication. Note this is an ongoing data collection cycle. Data are collected continuously throughout the three year OMB approval period.

The HIV data are also included in DHAP publications and materials for training and education of health care providers, researchers, 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 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 prevention activities.

Exhibit 16.A Project Time Schedule for Each Annual Data Collection*

Activity	Time Schedule

Complete/submit forms 1-12 months after OMB approval	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	18-23 months after OMB approval
Dissemination of results in other formats (e.g., supplemental reports, peer review articles)	23-36 months after OMB approval

*Note this is an annualized estimate; Data are collected continuously throughout the three year period.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

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

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18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions 5CFR 1320.3(h)(1)-(10)

There are no exceptions to the certification.