

National HIV Surveillance System (NHSS)

OMB # 0920-0573

**Supporting Statement
Part A**

Contact Information

**Project Officer: Patricia Sweeney, MPH
HIV Incidence and Case Surveillance Branch
Division of HIV/AIDS Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention
1600 Clifton Road NE, Mailstop E-47
Atlanta, GA 30333**

**Voice: (404) 639-2047
Fax: (404) 639-2980
Email: pas3@cdc.gov**

February 5, 2013

National HIV Surveillance System(NHSS)
OMB # 0920-0573

Table of Contents

Section

A. Justification

1. Circumstances Making the Collection of Information Necessary
2. Purpose and Use of the Information Collection
3. Use of Improved Information Technology and Burden Reduction
4. Efforts to Identify Duplication and Use of Similar Information
5. Impact on Small Businesses or Other Small Entities
6. Consequences of Collecting the Information Less frequently
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
9. Explanation of Any Payment or Gift to Respondents
10. Assurance of Confidentiality Provided to Respondents
11. Justification for Sensitive Questions
12. Estimates of Annualized Burden Hours and Costs
13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers
14. Annualized Cost to the Government
15. Explanation for Program Changes or Adjustments
16. Plans for Tabulation and Publication and Project Time Schedule
17. Reason(s) Display of OMB Expiration Date is Inappropriate
18. Exceptions to Certification for Paperwork Reduction Act Submissions

B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods
2. Procedures for the Collection of Information
3. Methods to Maximize Response Rates and Deal with Nonresponse
4. Tests of Procedures or Methods to be Undertaken
5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Exhibits

- | | |
|--------------|-----------------------------------|
| Exhibit 12.A | Estimated Annualized Burden Hours |
| Exhibit 12.B | Estimated Annualized Burden Costs |
| Exhibit 14.A | Estimated Cost to the Government |
| Exhibit 16.A | Project Time Schedule |

LIST OF ATTACHMENTS

Attachment 1. Authorizing Legislation

Attachment 2. 60 Day Federal Register Notice

Attachment 3. Data collection instruments and data elements

- 3(a) Adult HIV Confidential Case Report Form
- 3(b) Pediatric HIV Confidential Case Report Form
- 3(c) Supplemental Activity 1: eHARS Data Elements for Adult and Pediatric HIV Confidential Case Reports and HIV Incidence Surveillance (HIS)
- 3(d) Supplemental Surveillance Activity 2: Molecular HIV Surveillance (MHS) Data Elements
- 3(e) Supplemental Surveillance Activity 3: Perinatal HIV Exposure Reporting (PHER) data collection form
- 3(f) Summary of Proposed Changes in the ICR for the National HIV Surveillance System(NHSS) OMB #0920-0573

Attachment 4. Form instructions and technical guidance documents

- 4(a) Adult HIV Confidential Case Report Form Technical Guidance
- 4(b) Pediatric HIV Confidential Case Report Form Technical Guidance Including Supplemental Activity 3: Perinatal HIV Exposure Reporting (PHER)
- 4(c) Supplemental Surveillance Activity 1: HIV Incidence Surveillance Technical Guidance
- 4(d) Supplemental Surveillance Activity 2: Molecular HIV Surveillance (MHS) Technical Guidance

Attachment 5. HIV Incidence and Case Surveillance Branch Publications List for 2009, and 2010, 2011, 2012

Attachment 6. HIV/AIDS Surveillance Report

Attachment 7. HIV Surveillance Coordinators List and 2011 and 2012 HIV Surveillance Workshop and 2012 CSTE Pre-conference Meeting Agenda

- 7(a) HIV Surveillance Coordinators & Data Managers' List
- 7(b) 2011 HIV Surveillance Workshop Agenda
- 7(c) 2012 CSTE Pre-conference Meeting Agenda

Attachment 8. Assurance of Confidentiality, Security Statement and Data Access Packet

- 8(a) Assurance of Confidentiality for HIV/AIDS Surveillance
- 8(b) HIV/AIDS Security Statement and Data Access Packet

Attachment 9. Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis

Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action. Centers for Disease Control and Prevention; 2011

Attachment 10. Statistical Consultation Agenda and Participant list

10(a) Statistical Consultation Agenda

10(b) Statistical Consultation Participant List

Supporting Statement

Section

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests a 3-year approval for revisions to previously OMB approved ICR#0920-0573, expiration 01/31/2013, entitled "Adult and Pediatric HIV/AIDS Confidential Case Reports for National HIV/AIDS Surveillance", which is being changed to "National HIV Surveillance System (NHSS)". Since the beginning of the HIV epidemic in the United States in 1981, 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 NHSS. 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, monitor patterns in variant, atypical, and resistant strains of HIV among infected persons, and monitor perinatal exposures in the U.S. These data have been maintained and reported through the enhanced HIV/AIDS reporting system (eHARS) which was fully deployed in 2010.

Summary of Changes

The revisions requested in this ICR, in addition to the title change, include minor modifications of data elements and forms to better align with anticipated changes in the case definitions to be published in 2013 and continuation of HIV surveillance activities funded under the new funding announcement CDC-RFA- PS13-1302. These include elimination of some variables and minor modifications to testing categories to accommodate new testing algorithms, modifications to staging criteria and non-substantial editorial changes in format. Additional revisions include reducing the number of data elements for two supplemental surveillance activities and changes to the number of areas reporting those data. Specifically, the number of data elements from the former enhanced perinatal surveillance (EPS) was reduced and the form was modified for continuation in 2013 as Perinatal HIV Exposure Reporting (PHER). Additionally, the number of reporting areas will increase from 15 areas conducting EPS to 35 areas that will conduct PHER.

Surveillance data collection on variant and atypical strains (formerly variant, atypical and resistant HIV surveillance (VARHS)) will be continued as Molecular HIV Surveillance (MHS) with a reduced number of data elements previously approved under VARHS and an increase in the number of reporting areas from 11 to 53. We also refined our burden calculations for Case Reports and Laboratory Updates, HIV Incidence Surveillance (HIS), and Molecular HIV Surveillance (MHS) to more accurately reflect the burden of these activities. These changes are described in detail in the section 15 "Explanation for Program Changes or Adjustments", of this supporting statement and **Attachment 3f**.

Background

HIV 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 August 10, 2012 (Vol.77, No. 155, pages 47848-47849)(**Attachment 2**).Data collection instruments, data elements and a listing of the specific modifications in the ICR since the last OMB revision are provided. (See **Attachments 3(a-f)**)

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, all states, D.C., Puerto Rico, U.S. Virgin Islands, American Samoa, Guam, Northern Mariana Islands, and the Republic of Palau mandate and collect confidential name-based surveillance data on HIV cases in adults/adolescents and children using the HIV confidential case report forms. Over the next three years we anticipate that Marshall Islands and the Federated States of Micronesia will also 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. The Marshall Island and Micronesia were anticipated to report during the last OMB approval period in 2009; but did not. Therefore, their inclusion does not increase the reporting burden as the burden was previously included. 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. Updating case information, laboratory test results, and evaluations of case reports are done in the 59 areas and presented separately. Reporting of supplemental data elements for HIV incidence surveillance (HIS), reporting of variant, atypical, and resistant viral sequences as part of Molecular HIV surveillance (MHS), and Perinatal HIV Exposure Reporting (PHER) are reported by a subset of the 59 areas.

HIV surveillance data are collected to monitor trends in HIV and describe the characteristics of persons who have been diagnosed with HIV infection (e.g., demographics, risk behaviors, clinical and laboratory markers of HIV disease, manifestations of severe HIV disease (AIDS), and deaths among persons with HIV). Since AIDS was first recognized in 1981, an estimated 1,163,575 persons have been

diagnosed with AIDS through December 31, 2010 in the United States, D.C. and six U.S. dependent areas and reported to the NHSS. An estimated 803,771 persons were living with a diagnosis of HIV infection at the end of 2009 in 46 states and five U.S. dependent areas with confidential name-based reporting systems in place since at least January 2007. CDC estimates that approximately 1.2 million adults and adolescents were living with HIV in the United States at the end of 2008 (prevalence rate: 469.4 per 100,000 population). Using incidence data elements in 2011, CDC updated the 2006 HIV incidence estimate and subpopulation estimates and calculated incidence overall and for subpopulations for 2007-2009 using improved methodology (Prejean et al., 2011). Overall, HIV incidence in the United States was relatively stable at about 50,000 new infections per year during 2006-2009; however, among young MSM, particularly black/African American MSM, incidence increased.

Data from pediatric case reports and Enhanced Perinatal Surveillance (EPS) 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, CDC 2011) In 2010, an estimated 219 diagnoses of HIV infection occurred among children <13 years of age in the 46 states and five U.S. dependent areas with confidential name-based HIV infection reporting as of January 2007, of which 164 (75%) were attributed to perinatal exposure. As of December 31, 2009, a total of 8,054 singleton births to HIV-infected women had been reported from the 15 areas that conduct EPS activities from 2005 to 2009. These data were used to better describe the population of HIV infected women giving birth in the U.S. and have been used to further focus HIV prevention efforts. (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 NHSS are an integral part of CDC's disease surveillance efforts contributing invaluable data toward CDC's overarching goals of health promotion and disease prevention. In July 2010, the White House released the *National HIV/AIDS Strategy for the United States* (NHAS), which outlined three goals for a coordinated national response to HIV in the United States. These goals are (1) reduce the number of people who become infected with HIV, (2) increase access to care and improve health outcomes for people living with HIV, and (3) reduce HIV-related health disparities. In response, the DHAP of the CDC developed a strategic plan that aligns with NHAS and defines 15 objectives for

measuring progress in reducing the burden of HIV in the United States. Data collected as part of the NHSS will be essential for monitoring the progress toward achieving these objectives in the coming years. A supplemental report illustrating how data from the NHSS can be used to assess progress on selected key objectives was published in June 2012. The data CDC collects through the NHSS 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, nor monitor success toward achieving NHAS goals. These surveillance data, together with behavioral data and other scientific information are the primary data used by state and local health departments in their 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 NHSS.

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 include programs Care Act funded under the Ryan White HIV/AIDS Treatment Extension Act of 2009 which funds treatment and care for persons with HIV who could not otherwise afford expensive, life-saving therapies. The legislation was first enacted in 1990 as the Ryan White CARE (Comprehensive AIDS Resources Emergency) Act. It has been amended and reauthorized four times: in 1996, 2000, 2006, and 2009. The Ryan White legislation has been adjusted with each reauthorization to accommodate new and emerging needs, such as an increased emphasis on funding of core medical services and changes in funding formulas. More information about these programs are available from the Health Resources and Services Administration (HRSA) at <http://www.hab.hrsa.gov/>. 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. HIV surveillance data are also provided to the office of Housing and Urban Development (HUD) for allocations for HIV services under the Housing Opportunities for Persons with AIDS (HOPWA) program. 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 NHSS critical.

The data collection and reporting tool, eHARS, has been previously assessed. The privacy impact assessment (PIA) for eHARS was submitted in January 2012.

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. Ongoing HIV 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 Mariana Islands, and the Federated states of Micronesia) using standard HIV/AIDS case report forms. Cases are reported to state/local/territorial 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. Case report updates include updates of clinical indicators and laboratory test data including CD4 counts and viral load test results, and other updates to forms, death matching, monthly intrastate de-duplication, running edit checks and correcting entry errors. The database is checked for duplicates and de-duplicated as part of routine data quality assurance activities. Increasingly, health departments utilize electronic laboratory reporting methods and electronic 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 *Supplemental Activity 1: HIV Incidence Surveillance* (HIS) (See **Attachment 3c and 4c**) report additional information used to derive population-based estimates of incidence. As an integrated component of the NHSS, HIS incorporates into routine case reporting the collection of HIV testing and antiretroviral use history (i.e. Testing and Treatment History [TTH]) and Serologic Testing Algorithm for Recent HIV Seroconversion (STARHS) result to determine recency of infection. These data include testing frequency,

prior testing, use of HIV-related medicines and STARHS specimen information and results (laboratory data). This information can be obtained from existing data sources, including medical record reviews, provider reports, records of partner notification and referral services, other databases, or by testing laboratories to health departments. As part HIV surveillance practice, private/ commercial laboratories send remnant samples of HIV diagnostic tests to the STARHS laboratory for recency testing along with a shipping manifest. Areas conducting Molecular HIV Surveillance, formerly variant, atypical and resistant HIV surveillance (VARHS) (*Supplemental Activity 2: Molecular HIV Surveillance (MHS) Attachments 3d and 4d*) report genotyping test results for drug resistance and HIV-1 subtypes for individuals newly diagnosed with HIV. This activity will be an optional surveillance activity funded in the revised FOA for HIV Surveillance activities beginning in 2013. Information for MHS is provided by HIV genotype testing laboratories to health departments. As part of ongoing surveillance activities CDC is supporting data collection on perinatally exposed infants through Perinatal HIV Exposure Reporting (PHERS) with data collection on HIV-infected mothers and their infants to reduce perinatal HIV transmission and evaluate prevention programs (*Supplemental Activity 3: Perinatal HIV Exposure Reporting (PHER) Attachments 3e and 4b*). PHER data collection is based on the former EPS activity and will be an optional surveillance activity funded in the revised FOA for HIV Surveillance activities beginning in 2013. In PHER, infants known to be HIV-exposed are monitored after birth up to 18 months of age to determine HIV infection status of the child and progression to HIV, stage 3 (AIDS). PHER, along with pediatric case surveillance and in partnership with the FIMR-HIV Prevention Methodology (FHMP) program would allow CDC to better characterize the perinatal epidemic in the U.S. Data elements are collected through 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.

Description of Information to be collected

The core HIV data collection consists of two forms: (1) Adult HIV Case Report Form (CDC 50.42a) and (2) Pediatric HIV Case Report Form (CDC 50.42b) (see **Attachments 3a and b**). 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 and 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 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 results of HIV antibody tests, HIV detection tests, CD4 T-lymphocyte tests and viral load tests. Information on treatment and referral for services are also collected. These data elements are listed on the current Adult and Pediatric HIV Confidential Case Report Forms and eHARS variable list (**Attachments 3a, b, and c**). eHARS system stores information in tables reflected in the variable list in **Attachment 3c**. The variable list in **Attachment 3c** 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. Some variables are not on the current case report form but on the eHARS variable list, including some optional variables which may be of use primarily for local purposes and system and surveillance process variables for enhanced tracking of surveillance.

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, use of HIV-related medicines, and STARHS specimen information and results. These data elements on testing and treatment are listed on the case report form and included with eHARS variable list in (**Attachment 3a&c**); 2) specimen quality and sequence information for improved monitoring of drug resistance and HIV-1 subtypes (**Attachment 3e**); and 3) information on HIV infected mothers and their infants for PHERS. Similar to EPS, PHER will collect data on exposed infants as well as infants who are infected, and their HIV-infected mothers. EPS was funded in 15 areas from 2006-2011. Data collection included extensive information on exposed and infected infants and their mothers. EPS was discontinued for calendar year 2012. PHER differs from EPS in that information collected will focus on fewer key data elements. The data elements were identified by a perinatal working group made up of DHAP and state surveillance

stakeholders and determined to be "critical" to maintain a standard report form. In PHER, infants known to be HIV-exposed will be monitored after birth up to 18 months of age to determine HIV infection status of the child and progression to HIV, stage 3 (AIDS). PHER, along with pediatric case surveillance and in partnership with the FIMR-HIV Prevention Methodology (FHPM) program will allow CDC to better characterize the perinatal epidemic in the U.S.

Jurisdictions must have appropriate legal authority in place to be eligible for PHER funding. At this time, we are aware of 34 states and 1 dependent area who stated in a 2008 CSTE survey they had the authority to conduct exposure reporting. These areas are: Alaska, Arkansas, Arizona, Connecticut, Delaware, Florida, Georgia, Hawaii, Iowa, Illinois, Indiana, Kansas, Louisiana, Maryland, Michigan, Minnesota, Missouri, Mississippi, Montana, North Carolina, North Dakota, Nebraska, New Hampshire, New Jersey, New Mexico, New York, Ohio, Pennsylvania, Rhode Island, Puerto Rico, South Carolina, Texas, Utah, Virginia, and Washington. We estimate these 34 states and territory would represent approximately 47-50% of the total estimated perinatal HIV exposure cases.

We anticipate that over the next several years, data collection for PHER will become more integrated with routine HIV case surveillance. This integration will entail using the same data collection tools (the Pediatric HIV Confidential Case Report Form and PHER form), data collection system (eHARS), and revision of current technical guidance to support further the integration of case surveillance and PHER staff and activities. Funding will be based on case load of the number of perinatal HIV exposures for each area.

The PHER form is included in **Attachment 3e** and a list of changes are provided in **Attachment 3f**. The proposed revisions primarily include reducing the number of data elements and minor changes to wording or format to improve data collection. Specific instructions for completing the new PHER form are planned for development in 2012.

2. Purpose of Use of the Information Collection

CDC maintains the NHSS 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. These data are critical for monitoring progress on the NHAS. 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 periodically to better monitor and respond to changes in HIV morbidity, advances in testing technologies, and care and treatment for persons with HIV. These modifications address changes in the

surveillance case definition as well as changes in the data collection system. For example, the most recent case definition was published in 2008 (<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5710a1.htm>). In 2011, CDC held another consultation to consider changes to the case definition to update testing categories to accommodate new testing algorithms and modify the staging criteria. The proposed changes were vetted at the annual meeting of the Council of State and Territorial Epidemiologists (CSTE) in June 2012 and adopted as a position statement (12-ID-05 Committee Infectious Diseases Title: Revisions Proposed for the Surveillance Case Definition for HIV infection see CSTE website for more information at <http://www.cste.org/dnn/AnnualConference/PositionStatements/tabid/191/Default.aspx>) An updated case definition is planned for publication by CDC in 2012. With the revised case report forms submitted with this application (**Attachments 3a, b, and e**), it is anticipated that the burden time to complete for adult and pediatric case report data collection will not change as the number and type of data elements to be collected are expected to be similar. However, the reduced number of variables collected for PHER will result in fewer burden hours for supplemental perinatal exposure reporting.

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, methods, and data management. Full deployment of eHARS has allowed 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 3c**. 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. The revisions to the case report form proposed in this revision will be incorporated into eHARS reporting system in the coming year and the variable listing in **attachment 3** will be updated to reflect those changes.

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, supplemental

reports on various topics of interest, accompanying slide sets, fact sheets, 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>. In 2011, CDC launched the [NCHHSTP Atlas](#) which was created to provide an interactive platform for accessing HIV, viral hepatitis, sexually transmitted disease (STD), and tuberculosis (TB) data collected by CDC's NCHHSTP. This interactive tool provides CDC an effective way to disseminate data, while allowing users to observe trends and patterns by creating detailed reports, maps, and other graphics. This Atlas will replace previously published AIDS Public Information Dataset (APIDS). Currently, the Atlas provides interactive maps, graphs, tables, and figures showing geographic patterns and time trends of HIV, AIDS, chlamydia, gonorrhea, and primary and secondary syphilis surveillance data. TB and viral hepatitis are slated to be included in 2012. 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 assists 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 routine surveillance the data collected as part of Adult/Adolescent and Pediatric HIV surveillance in some areas and are described separately. *Supplemental Activity 1: HIV Incidence Surveillance (HIS)* (**Attachments 3c and 4c**)

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. Testing technologies are used to identify recent HIV infections using STARHS. STARHS result and HIV surveillance data, allow the HIV surveillance system to estimate the total number of diagnosed and undiagnosed HIV infections in a single year in the population. HIV incidence estimation is based on the observed number of new HIV diagnoses classified as recent infections using STARHS and the estimated probability that a new HIV infection would be diagnosed within the STARHS recency period (and thus classified as a recent infection) (Prejean et al., 2011).

However, in order to derive a population-based estimate of HIV incidence TTH data such as testing frequency, prior testing, and use of HIV-related medicines are needed for statistical weighting of STARHS recency results. These data elements on HIV testing and treatment and laboratory data have been incorporated into the case report forms and eHARS and are included with eHARS data elements in **Attachment 3c**. HIS received a CDC/NCHHSTP non-research determination in 2005 and has received a new non-research determination. (**Attachment 4c, page 21-22**).

As of January 2008, CDC has funded 25 jurisdictions (18 states, 6 separately funded cities, and the District of Columbia) to conduct HIV incidence surveillance through cooperative agreement. These areas will report data through the end of 2012. A new funding cycle will start in 2013 that will allow incidence data collection during the next five years. All currently funded areas are expected to continue conducting HIS activities.

Those areas receiving funding are required to track and ensure shipment of remnant HIV-1 diagnostic specimens to a central laboratory conducting STARHS and to collect TTH information on individuals newly diagnosed with HIV as part of routine case reporting. TTH information and laboratory data are entered and stored in eHARS. These data are reported monthly to CDC via secure electronic methods and they are added to reports from other areas to form the national database.

In 2011, CDC updated the 2006 HIV incidence estimate and calculated incidence for 2007-2009 using improved methodology (Prejean et al., 2011). CDC provided training, technical assistance, and statistical programs to state and local health department partners to allow them to develop their own HIV incidence estimates during the 2011 workshop (**Attachment 7 b** - 2011 HIV Incidence Surveillance Workshop: Data Quality and Estimation). CDC expects to annually publish four year estimates based on the improved methodology in order to provide updated data on trends in incidence as the data are available. (See **Attachment 5** for listing of publications)

Supplemental Activity 2: Molecular HIV Surveillance (MHS) (formerly known as *Variant, Atypical and Resistant HIV Surveillance*) (**Attachments 3d and 4d**)

For individuals with newly diagnosed HIV, genotype test results were collected as part of Variant, Atypical and Resistant HIV Surveillance (VARHS). With changes in the activity to include the collection of HIV nucleotide sequences from all available genotype test results, VARHS will be renamed to Molecular HIV Surveillance (MHS) in 2013. Similar to VARHS, data for MHS can be obtained from existing data sources, that is, from laboratories that report HIV genotype test results to health departments. VARHS received a CDC/NCHHSTP non-research determination in 2005 and we are in the process of reviewing

this determination. 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 HIV-infected individuals. Additional analysis of data on HIV drug resistance will provide information on trends in HIV drug resistance and subtype distribution, and support evaluation of HIV phylogenetic networks and antiretroviral drug treatment and prophylaxis strategies in participating surveillance areas

As of January 2012 CDC funded 11 jurisdictions (eight states and three separately funded municipalities) to conduct VARHS. The surveillance jurisdictions presently receive funding to ensure the reporting of HIV nucleotide sequence data, an intermediate product of HIV genotype testing, to the state or local health department. VARHS will be replaced by MHS in 2013 with 53 areas eligible to conduct this optional activity. MHS will expand the HIV nucleotide sequence collection from only genotype tests performed on individuals newly diagnosed with HIV infection to any genotype tests done as a part of initial and ongoing care of HIV-infected individuals. When laboratories submit HIV nucleotide sequences from new diagnoses of HIV outside of the CDC HIS activity that collects antiretroviral treatment history, areas will need to investigate and submit that information to CDC along with HIV nucleotide sequence data. Funded jurisdictions submit HIV nucleotide sequence data to CDC monthly. CDC has developed a mutation list for surveillance of transmitted drug resistance for use in the United States and first published 2006 VARHS data in 2010 (Wheeler et al, 2010). CDC presented additional years of VARHS data and will publish results from VARHS data analysis for cases diagnosed in 2006-2010 in 2012 (See **Attachment 5** for publications).

Supplemental Activity 3: Perinatal HIV Exposure Reporting (PHER) formerly Enhanced Perinatal Surveillance (Attachments 3e and 4b)

The NHSS 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 zidovudine (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 PHER are to continue to monitor and evaluate perinatal HIV transmission and evaluate prevention efforts in states that have laws and regulations that allow for perinatal exposure reporting.

Case surveillance collects information on HIV infected women and infants who are perinatally infected with HIV. PHER, and its precursor, EPS, collect information on exposed infants, as well as infants who are infected, and their HIV-infected mothers. EPS was funded in 15 areas from 2006-2011. Data collection included extensive information on exposed and infected infants and their mothers. EPS was discontinued for calendar year 2012. PHER differs from EPS in that information collected will focus on fewer key data elements to be collected on the standard case report form (see **Attachment 3e** for proposed data collection form). In PHER, infants known to be HIV-exposed are monitored after birth up to 18 months of age to determine HIV infection status of the child and progression to HIV, stage 3 (AIDS). PHER, along with pediatric case surveillance and in partnership with the FIMR-HIV Prevention Methodology (FHPM) program would allow CDC to better characterize the perinatal epidemic in the U.S.

Jurisdictions must have appropriate legal authority in place to be eligible for PHER funding. At this time, we are aware of 34 states and 1 dependent area who stated in a 2008 CSTE survey they had the authority to conduct exposure reporting. These areas are: Alaska, Arkansas, Arizona, Connecticut, Delaware, Florida, Georgia, Hawaii, Iowa, Illinois, Indiana, Kansas, Louisiana, Maryland, Michigan, Minnesota, Missouri, Mississippi, Montana, North Carolina, North Dakota, Nebraska, New Hampshire, New Jersey, New Mexico, New York, Ohio, Pennsylvania, Rhode Island, Puerto Rico, South Carolina, Texas, Utah, Virginia, and Washington. We estimated 8700 perinatal HIV exposures in the United States during 2006. These 34 states and territory would represent approximately 47-50% of the total estimated perinatal HIV exposure cases.

It is anticipated that future data collection for perinatal HIV exposure will become more integrated with routine HIV case surveillance and data collection tools (the pediatric case report form), data collection system (eHARS), and technical guidance will be revised to support further the integration of case surveillance and PHER staff and activities.

Data will be collected through medical records reviews of mother-infant pairs and follow-up of all HIV-exposed children to collect pertinent data elements. Surveillance data collected as part of PHER will be critical for evaluating strategies to prevent perinatal transmission and ultimately improving the health of infants. EPS has received a CDC/NCHHSTP non-research determination and this determination is in the process of being reviewed.

We are proposing a reduced number of data elements be retained from the EPS data collection form on the PHER form. For the retained questions, some minor changes were made to the formatting of the questions on the new form. The data collection form is included in **Attachment 3e**. The form instructions and user's guide is currently under development. Based on previous experience with the EPS and discussion with surveillance coordinators, we estimate that the changes will reduce the burden time required for this form to 30 minutes.

Privacy Impact Assessment Information

The information collected as part of the NHSS 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 are used as the basis for funding formulas for care and treatment programs under the Ryan White HIV/AIDS Treatment Extension Act of 2009 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 HIS 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 MHS optional activities are collected to monitor resistant strains of HIV in the U.S. The information is 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 PHER 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 PHER 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 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 de-duplication 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 eHARS 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 of 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 Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action. Centers for Disease Control and Prevention; 2011 available at: <http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf>

These data security and confidentiality 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, and guidance on development of data sharing plans. 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 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 works with SQL to enable powerful data manipulation. Using ad hoc reporting, SAS, 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. Since full deployment of eHARS CDC's emphasis has been on assisting the project areas in maximizing the utilization of the surveillance data, through provision of SAS programs and other tools and technical guidance on import of electronic laboratory data into the system.

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. In 2011, approximately 57% of surveillance programs stated they imported electronic laboratory test results into eHARS. eHARS provides tools to facilitate the import and use of electronic data sources and enhance the use of electronic health information for case reporting. All case reports (100%) are entered and reported by health departments (who serve as the respondents for this data collection) using 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 NHSS 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 NHSS, 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.

8. Comments in Response to the [Federal Register](#) Notice and Efforts to Consult Outside the Agency

Notification of the request for OMB clearance was published in the *Federal Register* on August 10, 2012, Volume 77, Number 155, Pages 47848-47850 (**Attachment 2**). No public comments were received.

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 July 2011 and during the National Meetings of the Council of State and Territorial Epidemiologists (CSTE) in June 2012 and 2010 where surveillance practices and guidelines were discussed. A national HIV surveillance workshop for surveillance coordinators was held in Atlanta July 18-22, 2011. During this meeting we discussed data collection and evaluation activities 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. A position statement on modification of the HIV surveillance case definition was discussed and adopted in June 2012. The HIV Incidence and Case surveillance Branch sponsored in collaboration with the Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB), sponsored a *Consultation on Monitoring and Use of Laboratory*

Data Reported to HIV Surveillance, March 9-10, 2011, in Atlanta, Georgia. The purpose of the consultation was to explore science, program, and ethical considerations for collection and use of laboratory indicators in HIV surveillance for public health action and monitoring. Approximately 40 external consultants including state and local HIV surveillance staff, ethicists, HIV community advocates, care providers, and representatives from laboratories and relevant national organizations participated in the 2 day meeting with CDC and HRSA staff. A CDC HIV Surveillance Case Definition Consultation was held February 7-8, 2012 with experts and stakeholders to consider proposed revisions to the CDC case definition for public health surveillance of HIV infection.

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 the September 2011 consultation is included in **Attachment 10**. Sessions at the national HIV Surveillance Workshop in July 2009 and in July 2011 discussed both incidence and viral resistance surveillance activities and data collection. During the 2011 workshop we discussed improving incidence data quality, conversion to eHARS and data management, as well as areas' approaches to receive electronic HIV nucleotide sequence data from HIV genotype testing laboratories were discussed in anticipation of VARHS transition to MHS.

In 2011, DHAP sponsored a consultation to obtain input on the potential effects of the new algorithm and recency assays on specimen and data collection for HIV incidence surveillance, to solicit considerations for integrating other HIV surveillance laboratory data into incidence estimation methods, and to discuss other possible methods that may be used to estimate incidence in the United States. The agenda, participant list and summary of the consultation are included in **Attachment 10**.

Contact information for surveillance coordinators in state and local health departments and consultants providing input over the last three years, meeting agendas and meeting summaries are provided in **Attachment 7a**.

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 again in January 2012. The Privacy Act System of Records Notice (SORN) number is 09-20-0136.

The Adult and Pediatric HIV Confidential Case Report Forms include a header that contains patient identifiers (e.g., 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.

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 last name 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 eHARS indefinitely in a cumulative database.

Areas use a microcomputer system developed by CDC eHARS 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 a secure encrypted process, currently referred to as 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 Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action. Centers for Disease Control and Prevention; 2011 available at: <http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf> These guidelines include standards 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))(Attachments 1 & 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. We are in the process of renewing these determinations and these new certifications will include the MHS and PHERS activities.

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 (**Attachment 8 & 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 2011 included sessions and presentations on surveillance practices and procedures as well as security and confidentiality (**Attachment 7b** for 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 standards outlined in the Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action. Centers for Disease Control and Prevention; 2011 available at: <http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf> These guidelines include detailed standards 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)) (**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. Information will be shared in accordance with the provisions outlined in the assurance and security statement. Data requests are handled as outlined in the security statement and security access packet with the Assurance of Confidentiality (**Attachment 8**). Data re-release agreements with state health departments were revised in 2011. 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. The security statement including the access packet materials for employees and contractors, data release policy, and assurance of confidentiality are included in **Attachment 8**.

The security statement outlines steps to maintain physical security and 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.

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 PHER data collection asks for maternal history, including questions about the mother's drug use behavior, prenatal care, receipt of antiretroviral treatment during pregnancy, and other antiretroviral treatment. These questions are asked in part because the mother's medical history/receipt of antiretrovirals 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 their 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 person's 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. The 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 revise data re-release agreements with states that specify the geographic level at which their data can be released. A document summarizing the revised policy and agreements will be included in the revised data access packet in the next extension of the Assurance of Confidentiality in 2012.

12. Estimates of Annualized Burden Hours and Costs

A. Estimate of annualized burden hours

Fifty-nine health departments will serve as respondents for the Adult HIV Case Report form (**Attachment 3a**) and report an estimated 1,260, responses (HIV and AIDS cases) each for a total of 74,340 responses. We estimate an average of 20 minutes per response for a total of 24,780 burden hours. The same 59 health departments will also report using the Pediatric HIV Case Report Form an estimated 6 responses for a total of 354 responses. We estimate an average of 20 minutes per response for a total of 118 annual burden hours using the Pediatric Case Report form (**Attachment 3b**). The fifty-nine health departments will also conduct case report evaluations, reporting an estimated 127 responses each, for a total of 7,493 annual responses. We estimate an average 20 minutes per response for a total of 2,498 annual burden hours. The annual burden hours for adult case reports decreased from the last revision from 36,167 hours to 24,780 hours and decreased for pediatric case reports from 157 hours to 118 hours because fewer cases (i.e., fewer total annual responses) will be reported as newer HIV surveillance systems mature and prevalent cases are reported into those systems. In addition, previous estimated burden for adult and

pediatric HIV case reports included estimated burden for evaluations which are now presented separately in the burden table. The estimated time per response did not change from the previous OMB request for the adult HIV case reports, pediatric HIV case reports or evaluations of HIV cases reports.

Updates are now presented in two separate categories as case report updates (primarily paper- 2 minutes average burden per response) and laboratory updates (primarily electronic- 1 minute average response). The fifty nine health departments will process an average of 1,469 Case Report Updates involving non-electronic methods each, totaling 86,671 responses annually. We estimate an average 2 minutes per response for a total of 2,889 burden hours. This is an increase from 477 burden hours to 2,889. This increase is due to an estimated increase in the number of responses (from 5,723 to 86,671) to account for increased number of updates for CD4 and viral load test results. We also decreased the response time from five minutes to two minutes for updates which involve paper reports.

We estimate 5,876 responses for Laboratory Updates in the 59 reporting areas for total of 346,684 responses annually. We estimate an average of 1 minute per electronic response for a total burden of 5,778 hours.

Twenty-five of the 59 areas will conduct HIV Incidence Surveillance (HIS) and provide data elements for incidence in eHARS (**Attachment 3c**). We estimate these 25 areas will report 2,729 responses each for a total of 68,225 annual responses. We estimate 10 minutes per response for a total of 11,371 burden hours. The total burden hours for HIS in this revision increased from 10,154 to 11,371 because the total responses increased. This increase is because we updated the calculation to reflect new performance requirements. The total number of responses was calculated using the number of annual HIV and AIDS cases reported in 25 HIS areas adjusted for the percentage of cases estimated to meet the necessary outcome standard for completeness (85% completeness of testing and treatment history data and 60% completeness for laboratory data).

In the last OMB approval, Molecular HIV Surveillance (MHS) was called Variant, Atypical and Resistant HIV Surveillance (VARHS) and was only done in areas with HIV Incidence Surveillance. We estimate 53 areas will report MHS data elements (**Attachment 3d**). Each area will report 967 responses for a total of 51,251 annual responses. We estimate 5 minutes per response for a total of 4,271 burden hours. The total number of responses increased from 22,209 to 51,251. The total number of burden hours increased from 1851 to 4271. This increase is mostly due to the increase in anticipated reporting areas from 11 to 53.

In the last OMB approval, *Perinatal HIV Exposure Reporting (PHER)* was called *Enhanced Perinatal Surveillance (EPS)* and was conducted in 15 areas. In this revision, we anticipate 35 areas with specific laws in

place will also conduct *Perinatal HIV Exposure Reporting (PHER)* (see **Attachment 3e**). The estimated total number of responses is based on the estimated number of HIV infected women giving birth (approximately 4,000) in these areas. Thirty-five areas will collect 114 responses per respondent for an estimated 3,990 total annual responses. We estimate 30 minutes per response for a total burden of 1,995 hours. This is a decrease in total burden hours compared to the previous revision for EPS (from 2505 to 1995 burden hours). While there was an increase in the number of areas and total responses, the estimated time per response decreased from 60 minutes to 30 minutes because of the reduced number of data elements reported.

The total estimated burden in hours for this ICR is 53,700. This burden estimate is approximately 5% higher than our previous burden estimate (51,311 in 2009) due to changes in the expected number of responses, the number of respondents for some data collection activities, and refinements in our methods for calculating burden for some activities.

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 Case Report	59	1,260	74,340	20/60	24,780
Health Departments	Pediatric HIV Case Report	59	6	354	20/60	118
Health Departments	Case Report Evaluations	59	127	7,493	20/60	2,498
Health Departments	Case Report Updates	59	1,469	86,671	2/60	2,889
Health Departments	Laboratory Updates	59	5,876	346,684	1/60	5,778
Health Departments	HIV Incidence Surveillance (HIS)	25	2,729	68,225	10/60	11,371
Health Departments	Molecular HIV Surveillance (MHS)	53	967	51,251	5/60	4,271
Health Departments	Perinatal HIV Exposure Reporting	35	114	3,990	30/60	1,995

	(PHER)					
Total						53,700

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 \$1,288,800. This is based on an estimated hourly wage of \$24/hr. 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 \$14.00/hr. and one epidemiologist at \$34/hr. for an estimated \$24/hr. The salary estimates were based on U.S. Department of Labor estimated mean hourly rates in the U.S. in 2011 for one data entry person (data entry keyer) at \$14.00/hr. and one epidemiologist at \$34.01/hr. 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 Annual Burden (in hours)	Hourly Wage Rate	Total Respondent Costs
Health Departments	Adult HIV Case Report	24,780	\$24	\$594,720
Health Departments	Pediatric HIV Case Report	118	\$24	\$2,832
Health Departments	Case Report Evaluations	2,498	\$24	\$59,952
Health Departments	Case Report Updates	2,889	\$24	\$69,336
Health Departments	Laboratory Updates	5,778	\$24	\$138,672
Health Departments	HIV Incidence Surveillance (HIS)	11,371	\$24	\$272,904
Health Departments	Molecular HIV Surveillance (MHS)	4,271	\$24	\$102,504
Health Departments	Perinatal HIV Exposure Reporting (PHER)	1,995	\$24	\$47,880
Total				\$1,288,800

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).

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, other than their time.

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: 1 @ \$93,000 1 @ 94,000	\$187,000
	Printing	\$5,000 \$5,000
	eHARS development, deployment, and maintenance	\$2,300,000*
	HIV Incidence and Case Surveillance Branch Intramural Including Personnel	\$6,300,000
	Subtotal	\$8,792,000
Cooperative Agreements with States	HIV/AIDS Surveillance**	\$60,000,000
	Total	\$68,792,000

*Estimated average annual cost based on reported OMB IT cost for FY11 \$3.2 million, FY12 \$2.7 million, FY13 \$1.8 million, FY14 1.6 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 53,700 hours. The previous burden associated with this information collection was 51,311 hours. The requested total burden represents an approximate 5% increase. This small increase reflects reductions in some activities and increases in others and refinements in some of our calculations. First, our estimate now reflects the stabilization of case reporting due to having mature reporting systems in all areas. Burden calculations in this revision were based on reported cases without any additional adjustments for areas without mature reporting systems. This resulted in a decrease in burden for adult and pediatric case reports and evaluations based on those reports. We anticipate increased reporting activities related to laboratory and other updates to cases reports. We refined our estimates for these updates to more accurately reflect the number of updates and considered the burden required for each method of update separately (primarily electronic or other methods). This resulted in a large increase in burden due to updates that more accurately reflects the current burden associated with these activities in health departments. Burden estimates for incidence data collection increased by approximately 12% for the 25 areas conducting incidence surveillance. This increase is due to a slight refinement in our estimate to additionally account for completeness of laboratory data reporting of STARHS results. Burden associated with MHS activities (formerly VARHS) increased primarily due to expansion in the number of areas participating (from 11 to 53). There was an overall decrease in burden attributed to perinatal exposure reporting (PHER) (formerly EPS) which is primarily due to the reduction in data elements and burden time per response (from 60 minutes to 30 minutes) which was not offset by the anticipated increased number of areas conducting exposure reporting (34 areas versus 15 areas previously conducting similar activities in EPS). **Attachment 3(f)** includes a detailed description of changes in this ICR.

16. Plans for Tabulation and Publication and Project Time Schedule

Collected HIV/AIDS data are analyzed and published annually in the HIV Surveillance Report and slide sets found at <http://www.cdc.gov/hiv/topics/surveillance/index.htm>. Typically the surveillance report is completed and published approximately 6-9 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 surveillance data for 2010 were finalized in June 2011 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 2012. 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.

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

There are no exceptions to the certification.