**National HIV Surveillance System (NHSS)**

**OMB # 0920-0573**

**Supporting Statement Part A**

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## A. Justification

- Goal of the NHSS: CDC in collaboration with state and local health departments in the 50 states, the District of Columbia, and U.S. dependent areas, conducts national surveillance for cases of HIV infection that provides critical data across the spectrum of HIV disease from HIV diagnosis, to AIDS, the end-stage disease caused by infection with HIV, and death. In addition, this national system provides essential data to estimate HIV incidence and monitor patterns in HIV drug resistance and genetic diversity, as well as provide information on perinatal exposures. Data reported as part of NHSS are the primary population-based information on persons living with HIV in the United States.
- Intended use of data: HIV surveillance data are used to monitor the extent and characteristics of the HIV burden in the United States. These data are used to describe trends in HIV incidence and prevalence and characteristics of infected persons (e.g., demographics, modes of exposure to HIV, clinical and laboratory markers of HIV disease, manifestations of severe HIV disease, and deaths among persons with HIV). HIV surveillance data are used widely at the federal, state, and local levels for planning prevention programs and health-care services, and to allocate funding for prevention and care.
- Methods to be used to collect: laboratories and care providers are required to report cases of HIV, AIDS and related clinical and laboratory data in accordance with local disease reporting laws, rules and regulations. Data are collected on persons who meet the laboratory and clinical criteria published in the CDC HIV surveillance case definition. Laboratories and providers collect data using standard report forms and report to health departments in both paper and electronic formats. Health departments also actively follow up with providers and laboratories to review medical records to complete case reports. Data are then reported electronically from health departments to CDC via the secure access management system (SAMS) after names are removed.
- The population included: the NHSS includes adults/adolescents and children with HIV infection that meets the laboratory or clinical criteria for HIV in 50 states, the District of Columbia, and eight U.S. dependent areas. In addition, where reportable by law rule or regulation, information on infants born to HIV infected mothers is also reported.
- How data will be analyzed: local health departments routinely review and analyze their data to monitor 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, updated fact sheets based on demographic and risk group, periodic supplemental surveillance reports, and also 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.

**1. Circumstances Making the Collection of Information Necessary**

The Centers for Disease Control and Prevention (CDC) requests a 3-year approval for revision to previously OMB approved ICR#0920-0573, expiration 02/29/2016, entitled “National HIV Surveillance System (NHSS)“. Since the first human immunodeficiency virus (HIV) cases were recognized in the United States in 1981, CDC has collected national surveillance data on this important infectious disease. 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). 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 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 HIV transmission and drug resistance patterns and HIV genetic diversity of HIV among infected persons, and monitor perinatal exposures. These data have been collected, maintained and reported using standard report forms and software.

HIV surveillance data collection by CDC is authorized under Sections 317(k) (2) and 318(c) of the Public Health Service Act [42 U.S.C. Sections 247b (k) (2) and 247c(c)], as amended and Sections 304 and 306 of the Public Health Service Act (42 USC 242b and 242k) (**Attachment 1**).

Background

Currently, 59 areas, including all 50 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 the 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 Islands and Micronesia were anticipated to report during the last OMB approval period in 2012; but did not. Therefore, their inclusion does not increase the reporting burden as the burden was previously included. 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 nucleotide sequences as part of molecular HIV surveillance (MHS), and Perinatal HIV Exposure Reporting (PHER) are conducted by a subset of the 59 areas. Annual reporting for the Standards Evaluation Report (SER) and Annual Performance Report (APR) is required by the 59 NHSS grantees, including health departments in the 50 states, 6 independently funded local health departments (Chicago, Houston, Los Angeles, New York City, the City of Philadelphia, and San Francisco), D.C., Puerto Rico, and U.S. Virgin Islands.

HIV surveillance data are collected to monitor trends in HIV and describe the characteristics of persons with diagnosed 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. CDC estimates that approximately 1.2 million adults and adolescents were living with HIV in the United States at the end of 2012. (http://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillancereport_vol20_no2.pdf) At the end of 2013, an estimated 953,245 persons in the U.S. and 6 dependent areas were living with diagnosed HIV infection, with an estimated death rate of 5.2 per 100,000. Through 2014, an estimated 1,246,981 persons with infection ever classified as AIDS have been diagnosed in the U.S. and 6 dependent areas. (http://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-us.pdf)

Using incidence data elements, CDC published an HIV surveillance supplemental report in 2012: HIV incidence in the United States, 2007 – 2010. During this period, incidence remained stable with about 47,500 new infections in 2010. Men who have sex with men continued to bear a heavy HIV burden, as HIV incidence among MSM increased 12% from 2008 to 2010. ((Centers for Disease Control and Prevention. Estimated HIV incidence in the United States, 2007–2010. HIV Surveillance Supplemental Report 2012;17; 17(No. 4). http://www.cdc.gov/hiv/topics/surveillance/resources/reports/#supplemental. Published December 2012.)

Data from pediatric case reports and the enhanced Perinatal Surveillance Project 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. HIV Surveillance Report 2013 volume 25 (http://www.cdc.gov/hiv/library/reports/surveillance/2013/surveillance_Report_vol_25.html). In 2013, an estimated 187 diagnoses of HIV infection occurred among children <13 years of age in the United States and six dependent areas, of which 107 (57%) were attributed to perinatal infection. Jurisdictions must have appropriate legal authority in place to be eligible for Perinatal HIV Exposure Reporting

funding. At this time, we expect a maximum of 35 jurisdictions (34 states and 1 dependent area) with the authority to conduct exposure reporting to collect and report exposure data to CDC. We estimate that the number of perinatal exposures in these 35 jurisdictions would represent approximately 47-50% of the total estimated perinatal HIV exposure cases in the United States and territories.

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 was updated to 2020 in 2015. The Strategy outlines 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 objectives for measuring progress in reducing the burden of HIV in the United States.

Data collected as part of the NHSS are 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 November 2014. HIV Surveillance Supplemental Report 2014 volume 19 no 3 http://www.cdc.gov/hiv/pdf/surveillance_Report_vol_19_no_3.pdf. 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 disease burden 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 funded under the Ryan White HIV/AIDS Program of 2009 which funds treatment and care for persons with HIV who could not otherwise afford expensive, life-saving therapies. 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 data to guide funding of these important care, services, and housing programs make the continued collection of high quality data through the NHSS critical.

**2. Purpose of Use of the Information Collection**

CDC maintains the NHSS to monitor the scope of the HIV disease burden in the United States. These data are the primary population-based 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 towards the goals of the National HIV/AIDS Strategy. 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. 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 2014 (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1.htm). Following extensive consultation and peer review, CDC and the Council of State and Territorial Epidemiologists (CSTE) revised and combined the surveillance case definitions for human immunodeficiency virus (HIV) infection into a single case definition for persons of all ages. Laboratory criteria for defining a confirmed case now accommodate new multi-test algorithms, including criteria for differentiating between HIV-1 and HIV-2 infection and for recognizing early HIV infection. Clinical (non-laboratory) criteria for defining a case for surveillance purposes have been made more practical by eliminating the requirement for information about laboratory tests. The surveillance case definition is intended primarily for monitoring the HIV infection burden and planning for prevention and care on a population level, not as a basis for clinical decisions for individual patients. CDC and CSTE recommend that all states and territories conduct case surveillance of HIV infection using this revised surveillance case definition. With the revised case report forms submitted with this application (**Attachments 3a, b, and d**), it is anticipated that the burden time to complete for adult and pediatric case report data collection will not change because the modifications are minimal.

As our understanding of HIV disease 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. The electronic reporting system used allows jurisdictions flexibility in collecting information from multiple sources and for repeated events required for monitoring the current HIV disease burden. The data elements of the software system are indicated in the variable list in **Attachment 3c**. The revisions to the case report form proposed in this revision will be incorporated into the electronic reporting system and the variable listing in **Attachment 3c** 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 5**), updated fact sheets based on demographic and risk group, periodic supplements to the surveillance reports, and periodically special analyses in peer-reviewed scientific journals to further describe and interpret national HIV data. 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 posted on the DHAP web site at http://www.cdc.gov/hiv/library/reports/surveillance/index.html. The NCHHSTP Atlas is a publically available interactive tool that provides CDC an effective way to disseminate data, while allowing users to observe trends and patterns by creating detailed reports, maps, and other graphics. The Atlas provides interactive maps, graphs, tables, and figures showing geographic patterns and time trends of HIV, AIDS, chlamydia, gonorrhea, primary and secondary syphilis surveillance data, TB and viral hepatitis. 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 the 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 Ryan White HIV/AIDS Program administered by HRSA and the Housing Opportunities for Persons with AIDS program administered by HUD which provides housing assistance and related supportive services for persons with HIV and AIDS.

Supplemental data collection activities complement routine case surveillance the data 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 serologic testing algorithm for recent HIV seroconversion (STARHS). STARHS result and HIV surveillance data allow the HIV surveillance system to estimate the annual number of HIV infections 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) HIV Surveillance Report Supplemental Report Volume 17 Number 4 (http://www.cdc.gov/hiv/pdf/statistics_hssr_vol_17_no_4.pdf).

To derive a population-based estimate of HIV incidence, HIV testing history 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 history, antiretroviral use and laboratory data have been incorporated into the case report forms and the electronic reporting system and are included with the data elements in **Attachment 3c**. HIV incidence surveillance received a CDC/NCHHSTP non-research determination in 2005 and has received a new non-research determination.

As of January 2013, CDC has funded 25 jurisdictions (18 states, 6 separately funded cities, and the District of Columbia) to conduct HIV incidence surveillance through cooperative agreements. These areas will report data through the end of 2017. All currently funded areas are expected to continue conducting incidence surveillance 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 testing history and antiretroviral use information on individuals with newly diagnosed HIV infection as part of routine case reporting. Testing history, antiretroviral use information and laboratory data are entered and stored in the electronic reporting system. 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 refined the methodology for estimating HIV incidence (Prejean et al., 2011 available at http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0017502)and provided training, technical assistance, and statistical programs to state and local health department partners to allow them

to develop their own HIV incidence estimates. Ongoing technical assistance is provided during national conference calls, one on one technical assistance calls and guidance documents. CDC expects to publish estimates routinely based on the improved methodology to provide updated data on trends in incidence.

*Supplemental Activity 2: Molecular HIV Surveillance (MHS)* (**Attachments 3c and 4d**)

Data for molecular HIV surveillance can be obtained from existing data sources, that is, from laboratories that report HIV genotype test results to health departments. Activities related to monitoring transmission and drug resistance patterns and HIV genetic diversity received a CDC/NCHHSTP non-research determination in 2005. Data is 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 and understanding the spread of HIV. These data can 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.

There are 53 areas eligible to conduct molecular surveillance activities; CDC currently funds 27 jurisdictions (20 states, five separately funded municipalities, the District of Columbia, and Puerto Rico). The surveillance jurisdictions presently receive funding to ensure the reporting of HIV nucleotide sequence data (i.e., an intermediate product of HIV genotype testing) obtained as a part of initial and ongoing care of HIV-infected individuals to the state or local health department. Although dependent of availability of funds, it is anticipated that MHS data collection will be conducted by all 53 eligible areas when a new funding opportunity begins in January 2018. When laboratories submit HIV nucleotide sequences from new diagnoses of HIV, areas will need to investigate and submit antiretroviral use 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 (Wheeler et al, 2010). CDC presented additional years of data and will publish results from analysis for cases diagnosed in 2010-2012 in 2015.

*Supplemental Activity 3: Perinatal HIV Exposure Reporting (PHER)* (**Attachments 3d and 4b**)

The NHSS has successfully monitored changes in the HIV disease burden and gauged prevention and treatment successes over the last two decades. 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. This reduction is thought to be largely due to the use of antiretroviral drugs.

Through 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). 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. Surveillance data collected as part of PHER will be critical for evaluating strategies to prevent perinatal transmission and ultimately improving the health of infants. 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 HIV disease burden in the United States.

Jurisdictions must have appropriate legal authority in place to conduct perinatal exposure reporting. At this time, a maximum of 35 jurisdictions (34 states and 1 dependent area) have the authority to conduct exposure reporting to collect and report PHER data to CDC over the 2013-2017 funding cycle. We estimate that the number of perinatal exposures in these 35 jurisdictions is representative of approximately 47-50% of the total estimated perinatal HIV exposure cases in the United States and territories.

PHER was implemented in 2013; however surveillance jurisdictions were never separately funded for exposure surveillance activities. Although PHER funding is still not available, some jurisdictions conduct exposure reporting as resources allow (e.g., by using HIV case surveillance funds). Data are collected through medical records reviews of mother-infant pairs and follow-up of all HIV-exposed children. Case surveillance collects information on HIV-infected women and infants who are perinatally infected with HIV. PHER collects information on exposed infants, as well as infants who are infected, and their HIV-infected mothers. Data collection for perinatal HIV exposure has become integrated with routine HIV case surveillance and data collection tools (the pediatric case report form and data collection system), and the technical guidance has been revised to support the integration of case surveillance and PHER activities. For example, the surveillance software was updated in July of 2014 to include a module specific to the collection of the PHER data elements. Surveillance data collected as part of PHER will be critical for evaluating strategies to prevent perinatal HIV transmission and ultimately improving the health of infants.

The PHER form is included in **Attachment 3d** and a list of changes are provided in **Attachment 11.** Revisions to the PHER form are primarily editorial and formatting and will not affect the estimated burden.

The annual information collected on laboratory data and data quality measures as part of the SER (**Attachment 3(e)**) are used to ensure the accuracy, timeliness, and completeness of the national HIV

surveillance data which are widely used and disseminated and critical for monitoring and evaluating the objectives of the National HIV/AIDS Strategy. The project narratives, implementation plans and timelines of the APR (**Attachment 3 (f)**) are critical for ensuring funded programs are making adequate progress toward meeting program objectives outlined in the cooperative agreement for the NHSS.

**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 and AIDS surveillance (HIV/AIDS Reporting System [HARS]), a computerized HIV database system with which state and local HIV programs could collect and manage HIV surveillance data from the 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 electronic reporting system currently used is an application for collecting, storing, and sending data to CDC and is necessary to monitor the HIV disease burden and to conduct systematic evaluations of HIV surveillance programs. The system, first deployed in 2005, 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 entered into the electronic reporting system. The electronic reporting system works with SQL to enable powerful data manipulation. Using ad hoc reporting, SAS, and other tools, NHSS data can be queried, filtered, joined, and then exported to Excel, Access, or other software applications for additional reporting and analysis. The electronic reporting system application enables project areas to collect, manage, analyze, disseminate, and report to CDC the data needed to monitor and track the HIV disease burden on both a local and a national level. The electronic reporting system provides project areas with the tools needed to follow CDC technical guidance for HIV surveillance. Since full deployment of the electronic reporting system CDC’s emphasis has been on assisting the project areas in maximizing the use of the surveillance data, through provision of SAS programs and other tools and technical guidance. Updates to the software are made one to two times per year, usually to reflect updated business requirements for surveillance practices, updated HIV case definition,

new laboratory testing algorithms, or other enhancements or problem solving improvements.

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. Most surveillance programs import electronic laboratory test results into the reporting system. The electronic reporting system 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 the electronic reporting system, and data are reported to CDC in encrypted electronic format via the Secure Access Management System (SAMS).

**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 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 Access Management System (SAMS). The goal of this transfer schedule is to finalize quarterly data sets

within four to six weeks 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 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 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 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 Guidelines5 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 secure access management system (SAMS) 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**

The 60-Day FRN was published in the *Federal Register* on 7/13/2015, Volume 80, Number 133, Pages 40067-40068 (**Attachment 2**). No public comments were received.

Consultation with state, local, and territorial HIV surveillance coordinators, and other HIV specialists occurs on a regular basis through national HIV surveillance workshops, routine site visits, periodic conference calls with HIV surveillance coordinators, and national conferences. A listing of HIV Surveillance Coordinators is provided in **Attachment 6**. 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. Surveillance coordinators attended the national meetings of the Council of State and Territorial Epidemiologists (CSTE) (June 2013 and 2014) where surveillance practices and guidelines were discussed. National HIV Surveillance System Grantees' Meetings were held in Atlanta April 2013 and December 2014. During the meetings data collection and evaluation activities were discussed and training was offered on aspects of surveillance data collection and

use. CDC plans to continue to sponsor these meetings on an annual or biannual basis and the next meeting planned for December 2015. A position statement on modification of the HIV surveillance case definition was discussed and adopted in April 2014.

Sessions at the national HIV Surveillance Workshop in April 2013 and December 2014 discussed both incidence and molecular surveillance activities and data collection. HICSB organized a consultation via a series of 6 webinars between October of 2013 and February of 2014 to assess factors associated with the statistical method used to calculate HIV incidence. National and international consultants participated in three webinars that focused on reviewing the validity of the assumptions of the Stratified Extrapolation Approach (SEA) that is used to estimate HIV incidence in the United States and the possible effects of violating the assumptions on the incidence estimate. All assumptions were examined and discussed in the four webinars. It was concluded that the effects of violating these assumptions are minimal or counterbalance one another.

**9. Explanation of Any Payment or Gift to Respondents**

The respondents for this ICR are health departments that are funded through CDC cooperative agreements to conduct HIV surveillance activities. There are no other provisions for payments or gifts to respondents.

**10. Protection of the Privacy and Confidentiality of Information Provided by Respondents**

The NCHHSTP PRA Coordinator has determined that the Privacy Act applies to this information collection. Personally identifiable information (PII) is being collected. A Privacy Impact Assessment was renewed and updated for the electronic reporting system in 2015 (**Attachment 7(a)**) and **Attachment 7 (b)** provides the authorization to operate. The applicable system of records notice (SORN) is 09-20-0136.

Reporting of HIV case data is required under state laws and regulations for notifiable disease reporting. These data are reported without consent of the individual by health care providers and laboratories to state or local health departments or through abstraction of medical records by health department personnel. Data are reported voluntarily by state and local health departments to CDC and these activities are supported through cooperative agreements.

HIV surveillance data are collected under an Assurance of Confidentiality under Section 308(d) of the Public Health Service Act (42 USC 242m(d))(**Attachment 8(a)**). 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 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)).

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 complete the forms. Data are then compiled by health departments that serve as the respondents for the HIV surveillance system and forwarded to CDC. Although identifiable patient-level case report data are collected by local health departments the case report data are de-identified before they are transmitted to CDC.

The Adult and Pediatric HIV Confidential Case Report Forms include a header that contains patient identifiers (e.g., 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. Other PII include date of death. Date of birth and date of death information are forwarded to CDC together with other case information after names and street addresses are removed. Demographic information such as sex, age at diagnosis, vital status, country of birth, residence, race and ethnicity are also collected.

Upon receipt of the case report forms, the health department assigns 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. Case information including personal identifiers is retained in the health departments' local electronic reporting system indefinitely in a cumulative database.

Areas use a microcomputer system developed by CDC 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. The current method is the Secure Access Management System (SAMS). The SAMS uses digital certificate technology to create a Secure Sockets Layer (SSL) or encrypted tunnel through which data are transmitted to CDC.

Because sensitive data are collected as part of HIV surveillance, steps are taken at every stage of data collection, storage, and use to ensure that data are secured and confidentiality and privacy are 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 (**Attachment 9**). The 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.

NCHHSTP Data security and confidentiality guidelines specify data are required to be kept in a physically and technically secure environment, with limited access by a minimum number of authorized individuals. Paper documents related to case reports are required to be kept in locked filing cabinets within a secure area. State and local health departments follow local schedules for archival and destruction of paper copies of case reports. 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. 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.

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. These and additional steps taken by CDC to secure the data are described in detail in the Confidentiality Security Statement for the National Human Immunodeficiency Virus (HIV) Surveillance System (NHSS) and Surveillance-related Data (including surveillance information, case investigations, supplemental surveillance projects, research activities, and evaluations (**Attachment 8(b)**)

## 11. Institutional Review Board (IRB) and Justification for Sensitive Questions

HIV surveillance data including data collected for surveillance evaluations, HIV incidence, molecular surveillance, and perinatal exposure reporting have been determined to be non-research surveillance activities by NCHHSTP/CDC and IRB approval is not required (see **Attachment 10**).

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.

Race ethnicity data are also collected as part of HIV surveillance and may be considered sensitive, but are critical for describing epidemiologic trends and focusing prevention efforts. The data collection forms adhere to OMB standards for the classification of federal data on race and ethnicity, collecting race and ethnicity separately, collecting multiple races and disaggregating Asian/Pacific Islander into two categories: Asian and Native Hawaiian/Other Pacific Islander.

The pediatric case report form and perinatal HIV exposure reporting 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 affects 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 disease burden 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 HIV disease burden and evaluating progress towards the goals of the National HIV/AIDS Strategy.

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 Council of State and Territorial Epidemiologists revised data re-release agreements with states that specify the geographic level at which their data can be released. The revised data release policy and agreements to abide by restrictions on data release for CDC staff are included with the Assurance of Confidentiality Security Statement and access packet (**Attachment 8(b)**).

**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 Confidential Case Report Form** (**Attachment 3a**) and report an estimated 1,061 responses (HIV and AIDS cases) each for a total of 62,599 responses. We estimate an average of 20 minutes per response for a total of 20,866 burden hours. The same 59 health departments will also report using the **Pediatric HIV Confidential Case Report Form** (**Attachment 3b**) with an estimated 5 responses for a total of 295 responses. We estimate an average of 20 minutes per response for a total of 98 annual burden hours using the PCRF (**Attachment 3b**). The fifty-nine health departments will also conduct case report evaluations, reporting an estimated 107 responses each, for a total of

6,313 annual responses. We estimate an average 20 minutes per response for a total of 2,104 annual burden hours. The annual burden hours for adult case reports decreased from the last revision from 24,780 hours to 20,866 hours and decreased for pediatric case reports from 118 hours to 98 hours. We estimate that AIDS cases will continue to decrease as more individuals start and continue therapy (i.e., fewer total annual responses due to AIDS reports). 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.

The fifty nine health departments will process an average of 1,576 case report updates involving non-electronic methods each, totaling 92,984 responses annually. We estimate an average 2 minutes per response for a total of 3,099 burden hours. This is an increase from 2,889 burden hours to 3,099. This increase is due to an estimated increase in the number of responses (from 86,671 to 92,984) to account for increased number of updates for CD4 and viral load test results among persons living with HIV.

We estimate 6,303 responses for laboratory updates in the 59 reporting areas for total of 371,877 responses annually. We estimate an average of 1 minute per electronic response for a total burden of 6,198 hours.

Twenty-five of the 59 areas will conduct HIV incidence surveillance and provide data elements for incidence in the electronic reporting system (**Attachment 3c)**. We estimate these 25 areas will report 2,288 responses each for a total of 57,200 annual responses. We estimate 10 minutes per response for a total of 9,533 burden hours. The total burden hours for incidence surveillance in this revision decreased from 11,371 to 9,533 because the total responses decreased. The total number of responses was calculated using the number of annual HIV and AIDS cases reported in 25 funded 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).

We estimate 53 areas will report molecular HIV surveillance data elements (**Attachment 3c**). Each area will report 829 responses for a total of 43,937 annual responses. We estimate 5 minutes per response for a total of 3,661 burden hours. The total number of responses decreased from 51,251 to 43,937. The total number of burden hours decreased from 4,271 to 3,661. This decrease is mostly due to decreases in case reports in jurisdictions conducting molecular surveillance.

In this revision, we estimate 35 areas with specific laws in place will conduct Perinatal HIV Exposure Reporting (see **Attachment 3d**). 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. The total burden hours as requested for this data collection has not changed and is the same as that requested in the last renewal.

Fifty-nine jurisdictions including 50 states, 6 separately funded cities (Chicago, Houston, Los Angeles, New York City, City of Philadelphia, San Francisco), D.C., Puerto Rico and U.S. Virgin Islands will report on the quality of HIV Surveillance data and progress of their surveillance programs using process and outcome standards twice a year. The Standards Evaluation Report (SER) is used to improve data quality, interpretation, usefulness, and surveillance system efficiency, as well as to monitor progress toward meeting surveillance program objectives. The proposed information collected for the annual SER includes a brief set of questions about evaluation outcomes and the collection of laboratory data for HIV surveillance that minimizes the reporting burden on health departments (see **Attachment 3 (e).** CDC provides standard SAS programs that can be run on state and local surveillance databases to extract the needed evaluation data. Laboratory reporting questions are used to characterize the completeness and quality of data reported from laboratories in each jurisdiction. Information of the annual SER is essential for establishing the accuracy and reliability of the national HIV surveillance data. In the APR, jurisdictions provide a narrative description of progress towards achieving program objectives including an implementation plan and timeline (**see Attachment 3 (f)**). The project narratives, implementation plan and timeline of the APR are critical for ensuring funded programs are making adequate progress toward meeting program objectives outlined in the cooperative agreement for the NHSS. All 59 areas will report 1 response per respondent for each report for an estimated 59 total annual responses per report. We estimate 8 hours per response for the SER for a total burden of 472 hours. We estimate an average of 42 hours for the APR for a total burden of 2,478 hours. The addition of these two annual reporting items represents a change in our burden requested in the last renewal.

The total estimated burden in hours for this ICR is 50,504. This burden estimate is approximately 6% lower than our previous burden estimate (53,700 in 2012). This decrease is largely due to a decrease in the number of persons diagnosed and reported with AIDS which is used as part of the burden calculation. Because of success of antiretroviral therapies, people with HIV are living longer and healthier lives and not developing stage 3 (AIDS). Additionally, the NHSS has improved national data processing and deduplication procedures which also contributes to the decreased number of cases nationally.

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(att 3a,3c,4a) | 59 | 1,061 | 62,599 | 20/60 | 20,866 |
| Health Departments | Pediatric HIV Case Report (att 3b,3c,4b) | 59 | 5 | 295 | 20/60 | 98 |
| Health Departments | Case Report Evaluations (att 3a,3b,3c) | 59 | 107 | 6,313 | 20/60 | 2,104 |
| Health Departments | Case Report Updates (att 3a,3b,3c,4a, 4b) | 59 | 1,576 | 92,984 | 2/60 | 3,099 |
| Health Departments | Laboratory Updates (att 3a,3b,3c,4a, 4b) | 59 | 6,303 | 371,877 | 1/60 | 6,198 |
| Health Departments | HIV Incidence Surveillance (HIS) (att 3a,3c,4c) | 25 | 2,288 | 57,200 | 10/60 | 9,533 |
| Health Departments | Molecular HIV Surveillance (MHS) (att 3a,3b,3c, 4a,4d) | 53 | 829 | 43,937 | 5/60 | 3,661 |
| Health Departments | Perinatal HIV Exposure Reporting (PHER) (att 3c,3d,4b) | 35 | 114 | 3,990 | 30/60 | 1,995 |
| Health Departments | Annual Reporting: Standards Evaluation Report (SER) (att 3e) | 59 | 1 | 59 | 8 | 472 |
| Health Departments | Annual Reporting: Annual Performance | 59 | 1 | 59 | 42 | 2,478 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | Report (APR) (att 3f) | | | | | |
| Total | | | | | | 50,504 |

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 $1,262,600. This is based on an estimated hourly wage of $25/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/hr. and one epidemiologist at $36/hr. for an estimated $25/hr. The salary estimates were based on U.S. Department of Labor estimated mean hourly rates in the U.S. in 2014 for one data entry person (data entry keyer) at $14/hr. and one epidemiologist at $36/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 (att 3a,3c,4a) | 20,866 | $25 | $521,650 |
| Health Departments | Pediatric HIV Case Report (att 3b,3c,4b) | 98 | $25 | $2,450 |
| Health Departments | Case Report Evaluations (att 3a,3b,3c) | 2,104 | $25 | $52,600 |
| Health Departments | Case Report Updates (att 3a,3b,3c,4a,4b) | 3,099 | $25 | $77,475 |
| Health Departments | Laboratory Updates (att 3a,3b,3c,4a,4b) | 6,198 | $25 | $154,950 |
| Health Departments | HIV Incidence Surveillance (att 3a,3c,4c) | 9,533 | $25 | $238,325 |
| Health Departments | Molecular HIV Surveillance (att 3a,3b,3c, 4a,4d) | 3,661 | $25 | $91,525 |
| Health Departments | Perinatal HIV Exposure Reporting (att | 1,995 | $25 | $49,875 |

| | | | | |
|---|---|---|---|---|
| | 3c,3d,4b) | | | |
| Health Departments | Annual Reporting – Standards Evaluation Report (SER) (att 3e) | 472 | $25 | $11,800 |
| Health Departments | Annual Reporting – Annual Performance Report (APR) (att 3f) | 2478 | $25 | $61,950 |
| Total | | | | $1,262,600 |

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 or 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<br>2 data managers:<br>1 @ $87,219<br>1 @ 94,000 | $181,219 |
| | Printing | $6752 |
| | software development, deployment, and maintenance | $3,200,000* |
| | HIV Incidence and Case Surveillance Branch Intramural, Including Personnel | $7,093,033 |
| | Subtotal | $10,481,004 |
| Cooperative Agreements | HIV Surveillance** | $61,635,501*** |

| | | |
|---|---|---|
| with States | | |
| | Total | $72,116,505 |

*Estimated average annual cost based on projected contractual costs for FY2015 through FY 2019 for support and maintenance.
** Note that these costs support the existing infrastructure of HIV surveillance programs in health departments. This includes costs related to data collection, analysis as well as other program costs.
***FY 2015 Case, Incidence, Direct Assistance, MHS, PHER, and Geocoding. Estimates do not include annualized costs for U.S. affiliated pacific islands.

**15. Explanation for Program Changes or Adjustments**

Data collection instruments, data elements and a listing of the specific modifications in the ICR since the last OMB revision are provided. (See **Attachments 3a,3b,3c,3d,3e,3f,4a,4b,4c,4d and Attachment 11)**

The revisions to this ICR include the addition of annual reporting hours for completing a Standards Evaluation Report (SER) and an Annual Performance Report (APR). In addition, modifications to currently collected data elements and forms including the Adult Case Report Form (ACRF), Pediatric Case Report Form (PCRF) and the Perinatal HIV Exposure Reporting (PHER) Form are also requested.

CDC monitors data quality and implementation of HIV surveillance programs and health departments report on their progress twice a year using process and outcome standards. Findings from these reports are used to improve data quality, interpretation, usefulness, and efficiency, as well as to monitor performance and progress in achieving both state and national HIV surveillance program objectives. The SER consists of a brief set of questions specific to data evaluation standards and laboratory reporting that minimizes the reporting burden on health departments. CDC provides standard SAS programs that can be run on state and local surveillance databases to extract the needed evaluation data in the report. Laboratory reporting questions are used to characterize the completeness and quality of data reported from laboratories in each jurisdiction. The information collected on laboratory data and data quality measures are used to ensure the accuracy, timeliness, and completeness of the national HIV surveillance data which are widely used and disseminated and critical for monitoring and evaluating the objectives of the National HIV/AIDS Strategy. In addition, health departments annually provide a narrative report describing their progress towards achieving program objectives including an implementation plan and timeline as part of the APR. The project narratives, implementation plans and timelines from the APR are critical for ensuring funded programs are making adequate progress toward meeting program objectives outlined in

the cooperative agreement for the NHSS. (**See Attachments 3(e) and 3(f)**).

Revisions to both the ACRF and PCRF include minor modifications of testing categories to accommodate new testing algorithms, the addition of an address date associated with the current street address and the residence at diagnosis street address, inclusion of additional instructions to record all dates as mm/dd/yyyy on the ACRF and PCRF, modifications to the HIV Testing and Antiretroviral Use History section on the ACRF and non-substantial editorial changes aimed at improving the format and usability of the forms. Revisions to the PHER form included general format edits, clarification of skip patterns of existing questions and removal of the antiretroviral drug listing. The specific changes to the adult and pediatric case report, and PHER forms are described in detail in the "Summary of Proposed Changes" provided in **Attachment 11**.

The requested burden for this project is 50,504 hours. This is approximately 6% percent decrease from our previous burden estimate which was 53,700 hours. This decrease is largely due to a decrease in the number of persons reported with AIDS which is used as part of the burden calculation. Because of the success of antiretroviral therapies, people with HIV are living longer and healthier lives and not developing stage 3 (AIDS). Additionally, NHSS has improved national data processing and deduplication procedures which also contributes to the decreased number of cases nationally. We anticipate increased reporting activities related to laboratory and other updates to case reports. Burden estimates for incidence data collection decreased by approximately 16% for the 25 areas conducting incidence surveillance. This decrease is largely due to decrease in AIDS cases and overall reduction in reported data used in calculation of our estimate. Burden associated with molecular surveillance activities decreased by approximately 14% primarily due to decrease in AIDS cases and overall reduction in reported data used in calculation of our estimate. There was no change in perinatal exposure reporting burden.

**16. Plans for Tabulation and Publication and Project Time Schedule**

Collected HIV data are analyzed and published annually in the HIV Surveillance Report and slide sets found at http://www.cdc.gov/hiv/library/reports/index.html. 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 2013 were finalized in June 2014 and the report was posted on the Division of HIV/AIDS (DHAP) web site and distributed in the first quarter 2015. 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 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 state and local health departments to make standard site-specific tables and figures for use in their epidemiologic profiles for HIV Prevention and Ryan White HIV/AIDS Program community planning. These tools improve use 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.

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**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.