National HIV Surveillance System (NHSS)

OMB # 0920-0573

Supporting Statement Part A

August 31, 2022

Contact Information

Project Officer: Patricia Sweeney, MPH
HIV Surveillance Branch
Division of HIV Prevention
National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention
1600 Clifton Road NE, Mailstop MS US 8-2
Atlanta, GA 30329

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

Table of Contents

LIST OF ATTACHMENTS

Goal of the Project: The NHSS is the primary source of population-based information on persons living with HIV in the United States and U.S. dependent areas. The NHSS collects information across the spectrum of HIV disease from HIV diagnosis, to AIDS, the end-stage disease caused by infection with HIV, and death.

Intended use of resulting data: NHSS data are used to monitor HIV trends, estimate HIV incidence and prevalence; examine patterns in HIV drug resistance and genetic diversity; detect HIV clusters; and describe characteristics of infected persons and perinatally exposed infants. Data are also used for surveillance-initiated investigations of persons identified as not-in-care to provide linkage to needed HIV medical care and services. NHSS 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. In this Revision, CDC proposes updates to the adult case report form and pediatric case report forms used for reporting cases and exposures that will strengthen uses of NHSS data to guide HIV prevention, care and control efforts.

Methods to be used to collect: Laboratories and health care providers collect data using standard report forms and submit reports to health departments in both paper and electronic formats as required by their jurisdictions. Data are collected on persons who meet CDC's laboratory and clinical criteria for HIV surveillance case definition. De-identified data are then reported electronically from health departments to CDC via the secure access management system (SAMS).

The subpopulation to be studied: The NHSS includes adults/adolescents and children with HIV infection who meet 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 the data will be analyzed: Local health departments routinely review and analyze their data to monitor HIV trends, evaluate program success, monitor HIV clusters 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 and tailored prevention and treatment strategies. Data is publicly available for analysis at CDC NCHHSTP AtlasPlus which is an interactive tool that gives users the ability to create customized tables, maps, and charts using more than 15 years of CDC's surveillance data on HIV, viral hepatitis, sexually transmitted diseases (STDs), and tuberculosis (TB) and also provides access to indicators on social determinants of health allowing users to view social and economic data in conjunction with surveillance data for each disease.

A. Justification

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 No. #0920-0573, expiration 11/30/2022, 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 Prevention (DHP), National Center for HIV, 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 and prevalence estimates, describe the geographic distribution of disease, monitor HIV transmission and drug resistance patterns and genetic diversity of HIV among infected persons, detect and respond to HIV clusters of concern, and monitor perinatal HIV exposures. These data have been collected, maintained, and reported using standard report forms and software. Continued collection of NHSS data is necessary to monitor the impact of HIV disease and guide HIV prevention efforts in the United States. NHSS data are widely used at all government levels to assess the HIV infection morbidity and its impact on mortality, to allocate medical care resources and services, to guide prevention and disease control activities, and monitor progress toward achieving national prevention goals of the ending the HIV epidemic in the U.S. initiative (Ending the HIV Epidemic in the U.S. (EHE) | CDC).

NHSS data collection activities are currently supported through cooperative agreements with health departments under CDC Cooperative Agreements PS18-1802: Integrated HIV Surveillance and Prevention Programs for Health Departments and PS20-2010 Integrated HIV Programs for Health Departments to Support Ending the HIV Epidemic in the United States, PS18-1801 Accelerating the Prevention and Control of HIV/AIDS, Viral Hepatitis, STDs, and TB in the U.S. – Affiliated Pacific Islands and PS23-2302 Accelerating the Prevention and Control of HIV, Viral Hepatitis, STDs, and TB in the U.S. Affiliated Pacific Islands. This information collection request revision includes activities to continue national surveillance program activities and align with program priorities of PS18-1802,PS20-2010, PS18-1801, PS23-2303 and any continuation of CDC funding or new CDC funding announced

for HIV surveillance or surveillance related activities over the next three years.

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 national prevention 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.

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**).

2. Purpose and Use of the Information Collection

The purpose of the information collected by NHSS is to monitor the scope of the HIV disease burden in the United States. Surveillance data are used to monitor HIV trends, estimate HIV incidence and prevalence; examine patterns in HIV drug resistance and genetic diversity; detect HIV clusters; and describe characteristics of persons with HIV infection diagnoses and perinatally exposed infants. Data are also used for surveillance-initiated investigations of persons identified as not-in-care to provide linkage to needed HIV medical care and services. 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. Data collected in the NHSS are critical for monitoring progress towards the goals of the *National HIV/AIDS Strategy for the United States* (NHAS) and Ending the HIV Epidemic in the United States (EHE) initiative. 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 address health inequities by eliminating racial and ethnic disparities.

Over the last forty years, the NHSS has been modified to respond to changes in the epidemiology of HIV and advances and improvements in surveillance practices, HIV testing technology, care, and treatment, incorporating reporting of HIV diagnoses, clinical indicators of disease progression, such as opportunistic infections, CD4 T-lymphocyte counts and percentages, HIV nucleotide sequences and HIV detection tests (e.g., quantitative viral load) and antiretroviral treatment history. These modifications have addressed changes in the surveillance case definition as well as changes in the data collection system to adjust for programmatic priorities. For example, changes proposed in this revision include additions of response options related to self-testing and HIV testing history variables to better characterize use of recently available self-testing technologies that have particularly increased in use during the COVID-19 pandemic. In addition, modification of the gender identity response options and collection of a new variable on sexual orientation proposed in this revision will allow CDC to better address HIV prevention needs of sexual minority populations(e.g., lesbian, gay, bisexual and transgender (LGBT)). Collection of information on antiretroviral use history allows for monitoring of pre-exposure prophylaxis (PrEP) among persons with diagnosed HIV, whereas HIV nucleotide sequence data allows determining transmission patterns, monitoring HIV drug resistance, and determine the geographic distribution of virus subtypes in the United States. These data will continue to support selection of diagnostic and clinical tests appropriate for use with various HIV-1 subtypes, and ultimately will inform the development of vaccines nationally. In addition, HIV nucleotide sequence data are being used to promptly detect recent, ongoing or rapidly growing transmission clusters to target prevention interventions. Health departments also use surveillance data to identify persons who may be in need of HIV medical care or services and link them to those services to ensure persons with HIV receive needed treatment and achieve viral suppression to ultimately prevent new infections.

Adult and Pediatric Case Reports, Perinatal Exposure Reports and Related Activities

Reporting of Adult and Pediatric cases are fundamental components of NHSS. Health departments compile clinical, behavioral, antiretroviral treatment history and laboratory test information (e.g., HIV tests, CD4) information reported from laboratories and care providers using standard forms, case definitions, and reporting software and report this information to CDC. HIV incidence is estimated by CDC using a statistical model (i.e., a CD4 Depletion model) without the need for additional data collection and will continue to be published in supplemental surveillance reports and other data products. Currently, 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 and current case definition (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1.htm). 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 including these jurisdictions.

In addition to adult and pediatric case reports, infants known to be HIV-exposed are monitored after birth up to 18 months of age to determine HIV infection status and progression to HIV, stage 3 (AIDS). The goals of perinatal HIV exposure reports are to continue to monitor and evaluate perinatal HIV transmission and evaluate prevention efforts in jurisdictions that have laws and regulations that allow for perinatal exposure reporting. Surveillance data collected as part of perinatal exposure reporting are critical for evaluating strategies to prevent perinatal transmission and ultimately improving the health of infants. NHSS has successfully monitored changes in perinatal transmission and treatment successes. 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 40 in recent years.

Data collection for perinatal HIV exposure reporting has become integrated with routine HIV case surveillance and includes medical record reviews of mother-infant pairs and follow-up of HIV exposed children. In this revision, we have discontinued the use of the previously approved Perinatal HIV Exposure Report (PHER) form and will continue data collection of perinatal exposures on the modified Pediatric HIV Confidential Case Report Form (PCRF). The PHER form has been consolidated with the PCRF to reduce redundancy across forms and include some new and revised data elements needed to assess progress with perinatal elimination efforts and support HIV prevention activities.

Surveillance programs routinely update case report information, conduct case report evaluations, and conduct ongoing deduplication activities to ensure the accurate and high-quality data are reported to the national system and burden associated with these activities is included in the burden estimate. Case report forms include necessary elements for the surveillance definition and evaluation of HIV prevention and care programs. The revised forms submitted with this revision include changes to selected currently collected data elements on the Adult HIV Confidential Case Report form (ACRF) (**Attachment 3a**) and a consolidated PCRF (**Attachment 3b**). Detailed description of the form changes are described in the Summary of Changes Document (**Attachment 10**) and **Section 15 Explanation for Program Changes or Adjustments**. The electronic reporting system 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 data elements proposed in this revision will be incorporated into the electronic reporting system (i.e. enhanced HIV/AIDS reporting system (eHARS) v4.13 to be released in 2023). The technical guidance for HIV Surveillance Programs has been revised to support the use of the new forms and the integration of case surveillance and perinatal exposure reporting activities. (**Attachments 4 a,b,c**)

Investigation Reporting and Evaluation

Health departments use the absence of reported test results to HIV surveillance programs to identify persons who may not be in HIV medical care and who may be in need of other services and to link those individuals to needed care and services. This revision includes estimated burden for health departments reporting of these variables, and for interventions to link people to care. This information is primarily imported electronically from other data systems used to manage these activities in the health departments. A logic model for the Data to Care strategy of identifying persons with diagnosed HIV who are not in HIV medical care and linking them to care and guidance for reporting and evaluation of Data to Care not-in-care investigations is included in **Attachment 4(d)**. More information on the Data to Care strategy can be found at Data to Care | Treat | Effective Interventions | HIV/AIDS | CDC.

HIV sequence data that are generated from drug resistance testing performed as part of routine HIV medical care are routinely reported to health departments. Using methodology developed by CDC, HIV surveillance data can be analyzed to identify clusters of likely recent and rapid transmission, and ultimately guide the implementation of prevention efforts. Clusters can be identified through analysis of surveillance data including HIV sequence data (e.g., molecular clusters) or diagnosis data (e.g., time-space clusters represent an increase in the number of diagnoses of HIV infection in a particular geographic area above levels expected given previous patterns). In addition, clusters can also be identified via notification by partner services staff, or notification by astute clinical providers or frontline staff at health departments. Cluster investigation variables may be electronically imported from other systems that may be used by health departments and will assist in the overall monitoring and evaluation of cluster investigations. We have included burden of reporting for the estimated subset of persons identified as part of clusters. The additional estimated burden for both cluster investigations and data to care investigations are included in the burden table under Investigation reporting and evaluation. Guidance for Detecting HIV transmission clusters is provided in **Attachment 4 (e).** Additional information and guidance on HIV cluster and detection

response is available at: https://www.cdc.gov/hiv/programresources/guidance/cluster-outbreak/index.html

Cluster Reports

Clusters of HIV are groups of persons related by recent, rapid transmission, for which rapid response is needed in order to intervene to interrupt ongoing transmission and prevent future HIV infections. Health departments may detect clusters through multiple means, as described above. Data on clusters of recent and rapid HIV transmission in the United States will be collected to monitor situations necessitating public health intervention, assess health department response, and evaluate outcomes of intervention activities. It is necessary and important for CDC to collect this information to monitor cluster detection and response activities that are required of all 59 jurisdictions funded under an Integrated HIV Surveillance and Prevention Programs for Health Departments cooperative agreement.

These data will be collected through quarterly cluster report forms **(Attachments 3e,3f,3g)** that will be completed by jurisdictions for clusters that they have identified and for which they are actively conducting response activities. The 'initial cluster report form' **(Attachment 3(e))** will be completed in the quarter a cluster is first identified. This form includes questions about the means of cluster detection, data reviewed to assess the cluster, the size of the cluster and outcomes of routine public health investigations ('partner services'), key findings about the cluster from existing data review, and the jurisdiction's assessment of their level of concern for the cluster. The 'cluster follow up form'**(Attachment 3(f))** will be completed each quarter in which the cluster response remains active. This form includes questions about the current cluster size, outcomes of HIV testing conducted in response to the cluster, and the jurisdiction's updated assessment of their current level of concern for the cluster. The 'cluster close-out form' **(Attachment 3(g))** will be completed when cluster response activities are closed, or at annual intervals while cluster response remains active. This form includes questions on summary outcome measures of response activities, including HIV testing conducted in response to the cluster, PrEP referral, and linkage-to-care efforts. It includes additional questions on activities conducted in response to the cluster, and key findings and impacts of the response. Data from individual cluster report forms will be aggregated at the national level to summarize activities and assess outcomes of cluster response activities at a national level.
Completion of forms will be determined by the number of clusters detected. Jurisdictions without any identified clusters will not complete any, while jurisdictions that may detect multiple clusters will complete multiple cluster report forms. Health departments will

transmit these forms to CDC using CDC's Secure Access Management System (SAMS). Instructions for completing the cluster forms are provided in **Attachment 4(f).**

Standards Evaluation Report (SER)

The annual information collected on laboratory data and data quality measures as part of the SER (**Attachment 3(d)**) 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 program objectives of PS18-1802, PS20-2010 and the national prevention goals. Minor non-substantial edits in wording for clarity and deletion of several questions that are no longer needed are proposed in this revision which will be used for reporting in 2023.

Data Use and Dissemination

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 indicators (see **Attachment 5**), updated fact sheets based on demographic and priority populations, 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 priority populations, 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 DHP website at: HIV Surveillance | Reports| Resource Library | HIV/AIDS | CDC. The NCHHSTP Atlas Plus is a publicly 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. Surveillance data are also used to track progress of the EHE indicators aimed at having greatest effect on the HIV in the United States and is available on The America's HIV Epidemic Analysis Dashboard (AHEAD). Data collected as part of the NHSS are essential for monitoring the progress toward achieving these national objectives in the coming years. A supplemental report illustrating how data from the NHSS can be used to assess progress on selected national care

objectives was published in May 2022. (Centers for Disease Control and Prevention. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2020. *HIV Surveillance Supplemental Report* 2022;27(No. 3). http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html). Published May 2022. Accessed [June 2, 2022]). 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.

The surveillance report published in 2022, shows the overall number of HIV diagnoses in the United States in 2020 (30,403) was 17% lower than in 2019 (36,585). The steep reduction in diagnoses in 2020 is likely due to disruptions in clinical care services, patient hesitancy in accessing clinical services and shortages in HIV testing reagents/materials, which causes concerns regarding underdiagnosis. In 2020, there were 30,692 diagnoses of HIV infection in the United States and 6 dependent areas. At the end of 2020, 1,072,051 persons in the United States and 6 dependent areas were living with diagnosed HIV infection, whereas 18,493 persons with HIV died for an overall death rate of 5.6 per 100,000. A total of 32 children born during 2019 in the United States, received a diagnosis of HIV infection attributed to perinatal transmission. (Centers for Disease Control and Prevention. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2020. *HIV Surveillance Supplemental Report* 2022;27(No. 3). http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. Published May 2022. Accessed [June 2, 2022]). From 2016 through 2019 in the U. S. and Puerto Rico, among the 11,757 children born who were exposed but not perinatally infected with HIV, 82% were born to mothers who were tested before pregnancy and 15% were born to mothers who were tested during pregnancy. (Centers for Disease Control and Prevention. *HIV Surveillance Report, 2020*; vol. 33. https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. Published May 2022. Accessed [June 2, 2022])
The COVID-19 pandemic impacted the HIV surveillance activities and HIV testing in the United States during 2020 making 2020 data unsuitable for trends assessment. CDC most recent publication of HIV incidence and prevalence estimates in the United States describing trends from 2015-2019 is available at: Centers for Disease Control and Prevention. Estimated HIV incidence and prevalence in the United States, 2015–2019. HIV Surveillance Supplemental Report 2021;26(No. 1). http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. Published May 2021. Accessed [June 2, 2022].

HIV surveillance data assists federal, state, and local public health officials and policy makers in program planning, evaluation, and resource allocation. Currently, HIV and AIDS case data 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 which funds treatment and care for persons with HIV who could not otherwise afford expensive, life-saving therapies. HIV surveillance data provided for the Ryan White HIV/AIDS Program for fiscal year 2021 is summarized in supplemental report Centers for Disease Control and Prevention. HIV and AIDS data through December 2019 provided for the Ryan White HIV/AIDS Program, for fiscal year 2021. HIV Surveillance Supplemental Report 2022;27(No. 1:[1-17].http://www.cdc.gov/hiv/library/reports/hivsurveillance.html. Published January 2022. Accessed [June 2, 2022]. 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.

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. DHP has encouraged the use of electronic reporting methods and provided state health departments with data management software to reduce reporting burden.

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 enhanced HIV/AIDS reporting System (eHARS), first deployed in 2005 and updated periodically, 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 local and national levels. 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. The next release of the enhanced HIV/AIDS reporting system (eHARS) v4.13 which will align with case report form changes in this revision is anticipated for release in 2023. DHP is joining agency wide data modernization efforts aimed at modernizing data systems and anticipates taking steps toward updating HIV surveillance systems to align with agency efforts over the next 3 years.

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. Information for the Standards Evaluation Report(SER)and Cluster Report Forms are also entered and reported in electronic format to reduce reporting burden. All data are reported securely to CDC via the Secure Access Management System (SAMS). The Division of HIV Prevention is engaged in CDC Data Modernization Initiative (DMI) and plans to align the HIV surveillance systems with DMI goals.

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. Literature searches, attendance at national HIV meetings/conferences, discussions with officials from state and local health departments and ongoing consultations with HIV experts nationwide, continue to support that these data are unique and are not available from any other source within the federal government or from non-federal sources. 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 HIV patient care and management. HIV surveillance data is the primary source for identifying priority geographic locations to focus cross agency resources to end HIV and to monitor progress on the Ending the HIV Epidemic initiative (see the America's HIV Epidemic Analysis Dashboard

(AHEAD). In addition, HIV surveillance data is a primary source for detection of molecular and time space HIV clusters and CDC has collaborated with health departments and health partners to develop guidance and resources for use of data for HIV cluster detection and response activities.

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 directly involved in reporting these data collection to CDC.

6. Consequences of Collecting the Information Less Frequently

CDC requests that reporting areas send their adult, pediatric and perinatal exposure report data electronically on a monthly basis. While the other data collection forms in this ICR are requested less frequently (e.g., SER is reported annually, cluster forms are reported quarterly). The goal of the monthly transfer schedule is to finalize quality 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 can 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 DHP to evaluate data quality on an ongoing basis to efficiently detect, investigate, and resolve data issues with the reporting areas. DHP 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 Guidelines 5 CFR 1320.6

Collection of HIV data is conducted in a manner consistent with the guidelines in 5 CFR 1320.6. DHP 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

A. The 60-Day FRN was published in the *Federal Register* on April 1, 2022, Volume 87, Number 63, Pages 19097-19100 (**Attachment 2a**). CDC received two public comments in support of proposed changes. (**Attachments 2b,c**). The Williams Institute at the UCLA School of Law wrote in support of the additional measure of sexual orientation and maintaining the measure of gender identity (as proposed). They stated that the proposed changes are 1) consistent with the mission and purposes of CDC and NHSS; 2) needed to provide better quality data to achieve prevention goals of ending the HIV epidemic initiative and provide information to better focus research and prevention efforts for LGBT people living with HIV; and 3) consistent with existing research on sexual orientation and gender identity (SOGI) measurement. The additional comment received also wrote in support of the changes proposed citing that the proposed changes would better meet current data needs related to SOGI and to rapid development of test technologies and the associated test history. In addition, the changes would improve the formatting and usability of surveillance forms that would serve to ease the data collection process and would ultimately provide more comprehensive data to monitor the burden of HIV in the United States. Both comments emphasized the need for continued privacy protections and related training for staff involved in surveillance activities. CDC acknowledged the comments and provided letters of response. No actions by the agency were necessary and no changes to the burden hours or costs were required in response to the comments received.

B. Consultation with state, local, and territorial HIV surveillance coordinators, and other HIV specialists occurs on a regular basis through national HIV surveillance monthly calls and webinars, routine site visits, periodic conference calls with HIV surveillance coordinators, CSTE HIV subcommittee leadership and members, 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. During these meetings data collection and evaluation activities are discussed and training offered on aspects of surveillance data collection and use. In July 2021, proposed changes to the data collection forms and software were reviewed with partners and HIV surveillance coordinators during national calls and changes were incorporated as needed based on feedback received. An NHSS HIV Technical Assistance Meeting was held June 12-13, 2019. During 2020 no in-person technical assistance meeting was scheduled due to Covid-19 restrictions. However, during 2020 the HIV Surveillance Branch

continued with monthly national NHSS support and NHSS data systems and laboratory support calls with state and local HIV surveillance staff. Technical assistance meetings resumed in 2021 and were conducted in a series of virtual meetings held in 2021 (8 sessions March through May 3/30, 4/6,4/13,5/4, 5,11,5/18) and 2022 (7 sessions May through June 5/3, 5/10,5/17, 5/24,5/31,6/7,6/14). CDC plans to continue to sponsor these national technical assistance meetings on an annual or biannual basis.

A series of virtual meetings and community engagement webinars were conducted in 2018 and 2019 to discuss implementation of cluster detection and response activities with community members, public health departments, community-based organizations, academics, and public health partners. These meetings focused on engaging communities, of providing information on proposed cluster response activities, discussion of ethical implementation, discussion of the impact of laws and policies, and discussion of data sharing and release issues. In addition, CDC participated in or hosted at least 5 engagements in 2021 and 18 in 2022 to discuss implementation of cluster detection and response activities with public health partners, providers, and community-based organizations, including one 1.5 day-long session hosted by the Presidential Advisory Committee on HIV/AIDS (PACHA) Stigma and Disparities Subcommittee. Other engagements included audiences of HIV care providers, health departments, and other partners and ranged from 7 to over 350 attendees. Overall goals for these discussions were aimed at increasing understanding of community concerns, increasing awareness of HIV surveillance and cluster detection and response activities, and assisting in the development of implementation guidance.

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 for the electronic reporting system was approved May 18, 2020 (**Attachment 6(a)**) and **Attachment 6 (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 7(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, sexual orientation(proposed), 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 software 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 8**). 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 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 7(b)).**

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

HIV surveillance data including data collected for adult/adolescent and pediatric case reporting, surveillance evaluations and cluster detection and response, and perinatal exposure reporting have been determined to be non-research, routine disease surveillance activities/public health program activities by NCHHSTP/CDC and IRB approval is not required (see **Attachment 9**).

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 and ethnicity data are also collected as part of HIV surveillance and may be considered sensitive, but are critical for describing epidemiologic trends, focusing prevention efforts and to monitor and

ensure health equity. 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.

Information on sexual orientation and gender identity may also be considered sensitive but are critical for monitoring the impact of HIV on sexual minorities and focusing prevention efforts. Collection of sexual orientation information is supported by organizations specializing in addressing the needs of sexual minorities and supported by Health People 2030, and the National Academy of Medicine. Further, the data collected is consistent with existing practices of CDC and other federal agencies, reflects recommendations from health departments collecting these data and other data collection systems.

The pediatric case report form used for pediatric 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 antiretroviral medicines affects the health outcomes, 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 and to achieve HIV perinatal transmission elimination goals.

Finally, some clinical and laboratory markers of HIV infection may also be considered sensitive. Fears remain regarding potential stigma associated with HIV infection and its potential impact on employability or insurability and the potential for release for non-public health purposes under state HIV criminal laws. 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. In addition, HIV sequence data is increasingly being used to identify clusters of recent and rapid transmission and prompt follow-up by health departments. The collection of clinical and laboratory data are the cornerstone of our surveillance system and central to monitoring the HIV disease burden and evaluating progress towards national HIV prevention goals.

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 the 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 current 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 7(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 789 responses (HIV and AIDS cases) each for a total of 46,551 responses. We estimate an average of 20 minutes per response for a total of 15,517 burden hours.

Pediatric cases will be reported by 59 health departments using the **Pediatric HIV Confidential Case Report Form** (**Attachment 3b**) and a subset of 47 health departments will also use the **Pediatric HIV Confidential Case Report Form** (**Attachment 3b**) for reporting of perinatal HIV exposures for a combined estimated 57 responses for a total of 3,363 annual responses. We estimate an average of 35 minutes per response for a total of 1,962 annual burden hours using the new consolidated PCRF (**Attachment 3b**).

The fifty-nine health departments will also conduct case report evaluations, reporting an estimated 85 responses each, for a total of 5,015 annual responses. We estimate an average 20 minutes per response for a total of 1,672 annual burden hours.

The annual burden hours for adult case reports decreased from the last revision from 16,795 hours to 15,517. Changes in reports are due to decreases in diagnoses and incidence and subsequent decreases in reports. Minor changes to the adult case reports described in detail in the changes document, will not result in changes to the estimated time per response for the adult HIV case reports or evaluations of HIV case reports. The burden estimate for the new pediatric HIV case report form reflects the inclusion of consolidated information from the previously approved Perinatal Exposure Report form together with the pediatric case report form. Specific changes are described in the accompanying changes document (**Attachment 10**). The number of responses and average time per response are revised to reflect the form changes and use for both perinatal exposure reporting and pediatric reporting.

The fifty-nine health departments also will process an average of 2,519 case report updates involving non-electronic methods each, totaling 148,621 responses annually. We estimate an average 2 minutes per response for a total of 4,954 burden hours. This is an increase from 4,628 burden hours to 4,954 This increase is due to an estimated

increase in the number of responses (from 138,827 to 148,621) to account for increased number of updates for CD4 and viral load test results among persons living with HIV.

We estimate 10,130 responses for laboratory updates through electronic methods in the 59 reporting areas for total of 597,668 responses annually. We estimate an average of 0.5 minute per electronic response for a total burden of 4,981 hours.

The fifty-nine jurisdictions also conduct deduplication activities including both routine interstate deduplication activities (RIDR) and cumulative interstate deduplication activities (CIDR). We estimate 59 areas complete deduplication activities will report 3,032 responses per respondent for an estimated 178,888 annual responses. We estimate 10 minutes per response based on published analyses and feedback from health departments on time to resolve duplicates for a total of 29,815 total burden hours.

Various investigations are routinely conducted by health departments as part of funded surveillance activities. Burden for investigations reporting and evaluation accounts for burden associated with reporting of cluster and data-to-care investigation variables reported through the NHSS. We estimate 59 areas will transmit data on investigation activities including 929 responses per respondent for an estimated 54,811 annual responses. We estimate 1 minute per response for a total of 914 total burden hours.

Three cluster report forms are used to monitor progress on cluster response **(Attachments 3e, 3f,3g).** We estimate 59 areas will report on the initial cluster report form, reporting on average 2.5 responses per respondent for an estimated 148 annual responses. We estimate 1 hour per response for a total of 148 burden hours for the initial cluster report form. We estimate 59 areas will report on the cluster follow-up form collecting 5.0 responses per respondent for an estimated 148 annual responses. We estimate 30 minutes per response for a total of 148 burden hours for the cluster follow-up form. We estimate 59 areas will report on the cluster close-out form, reporting on average 2.5 responses per respondent for an estimated 148 annual responses. We estimate 1 hour per response for a total of 148 burden hours for the cluster close-out report form.

Fifty-nine jurisdictions will report on the quality of HIV Surveillance data using process and outcome standards once a year using the Standards Evaluation Report (SER) form (see **Attachment 3 d)**. The 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 information collected for the annual SER includes a brief set of questions about evaluation outcomes, the collection of laboratory data for HIV surveillance and security and confidentiality practices 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. Laboratory reporting questions are used to characterize the completeness and quality of data reported from laboratories in each jurisdiction. Information collected on the SER is essential for establishing the accuracy and reliability of the national HIV surveillance data. There is no change in the estimated burden for SER. We estimate 8 hours per response for the SER for a total burden of 472 hours.

The total estimated burden in hours for this ICR is 60,731.

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 (ACRF) (att 3a,4a)	59	789	46551	20/60	15517
Health Departments	Perinatal Exposure and Pediatric HIV Case Report (PCRF) (att 3b,4b)	59	57	3363	35/60	1962
Health Departments	Case Report Evaluations (att 3a,b,c)	59	85	5015	20/60	1672
Health Departments	Case Report Updates (att 3a,b,c)	59	2519	148621	2/60	4954
Health Departments	Laboratory Updates (att 3a,b,c)	59	10130	597670	0.5/60	4981
Health Departments	Deduplication Activities (att 4c)	59	3032	178888	10/60	29815
Health Departments	Investigation Reporting and Evaluation (att 4 d,e)	59	929	54811	1/60	914

Health Departments	Initial Cluster Report Form (att 3e,4f)	59	2.5	148	1	148
Health Departments	Cluster Follow-up Form(att 3f,4f)	59	5	295	0.5	148
Health Departments	Cluster Close-out Form (att 3g,4f)	59	2.5	148	1	148
Health Departments	Annual Reporting: Standards Evaluation Report (SER) (att 3d)	59	1	59	8	472
Total						**60731**

B. Estimates of Annualized Cost

The estimated total cost to respondents is $1,821,863. This is based on an estimated hourly wage of $30/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 $18.00/hr. and one epidemiologist at $42/hr. for an estimated $30/hr. The salary estimates were based on U.S. Department of Labor estimated mean hourly rates in the United States in 2017 for one data entry person (data entry keyer) at $17.28/hr. and one epidemiologist at $41.70/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	No. of Respon-dents	Total No. of Annual Responses	Avg. Burden per Response (in hours)	Hourly Wage Rate	Total Burden Cost
Health Departments	Adult HIV Case Report (ACRF)(att 3a,4a)	59	46551	20/60	$30	$465,510
Health Departme	Perinatal HIV	59	3363	35/60	$30	$58,853

nts	Exposure and Pediatric HIV Case Report (PCRF)(att 3b,4b)					
Health Departments	Case Report Evaluations (att 3a,b,c)	59	5015	20/60	$30	$50,150
Health Departments	Case Report Updates (att 3a,b,c)	59	148621	2/60	$30	$148,621
Health Departments	Laboratory Updates (att 3a,b,c)	59	597670	0.5/60	$30	$149,418
Health Departments	Deduplication Activities (att 4c)	59	178888	10/60	$30	$894,440
Health Departments	Investigation Reporting and Evaluation (att 4 d,e)	59	54811	1/60	$30	$27,406
Health Departments	Initial Cluster Report Form (att 3e,4f)	59	148	1	$30	$4,440
Health Departments	Cluster Follow-up Form (att 3f,4f)	59	295	30/60	$30	$4,425
Health Departments	Cluster Close-out Form (att 3g,4f)	59	148	1	$30	$4,440
Health Departments	Annual Reporting Standards Evaluation Report (SER) (att 3d)	59	59	8	$30	$14,160
Total						$1,821,863

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 2 Analysts: 1 @ $124,863 1 @ $123,769	$248,632
	Printing	$4,500
	Software development, deployment, and maintenance*	$1,697,188
	HIV Surveillance Branch Intramural, Including Personnel	$6,669,480
	Subtotal	$8,619,800
Cooperative Agreements with States	HIV Surveillance**	$57,423,703***
	Total	$66,043,503

* Note presented as average of FY22, FY23, FY24 costs.
** 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 2022 HIV surveillance activities program costs. Estimates include annualized costs for HIV surveillance in U.S. affiliated pacific islands.

15. Explanation for Program Changes or Adjustments

Data collection instruments, data elements and a listing of specific changes to instrument content are provided. (See **Attachments 3a,3b,3c,3d,3e,3f,3g and Attachment 10.)**

The total estimated burden in hours for this ICR is 60,731 approximately 2% higher than our previous burden estimate of 59,462 approved in 2020 (non-substantial changes approved September 22, 2020, December 13, 2021). The small increase in burden overall is due to the decrease in burden from the removal of HIV incidence data collection balanced by increases in burden for reporting of laboratory and case updates, deduplication activities, and case investigations due to increases in prevalence and anticipated increases in reporting of perinatal exposures.

Specifically, changes in this revision include: 1) Discontinuation of one information collection activity (HIV incidence surveillance). The previously approved incidence program activity was not implemented. Incidence estimation will be continuing using statistical model without the need for additional data collection; 2)Program-initiated modifications to approved forms (both ACRF and PCRF) that improve usability and consolidation of the PCRF and PHER forms which were combined to reduce redundancy across the forms and better reflect the information necessary to assess progress with perinatal HIV elimination efforts and to support HIV prevention activities; 3) Minor decreases in new adult case reports using the ACRF due to decreases in HIV diagnoses; 4) Increased burden for case and laboratory updates, deduplication activities and case investigations due to the increasing number of persons living with HIV for which additional laboratory and case information is reported and linkage to care activities may be conducted; in addition, adjustments to the estimate of laboratory updates to account for reporting of perinatal exposed children who subsequently had negative test results reported also contributed to the increase. Exhibit A.15-A provides an overview of all changes proposed in this Revision request.

Exhibit A.15-A. Overview of Changes

Form Name	Approved Burden Hours as of Septemer 2020	Burden Hours Requested in this Revision	Net Change in Burden Hours	Overview of Changes to Burden and Forms
Adult HIV Case Report (ACRF) (att 3a,3c,4a)	16,795	15,517	-1,278	**DECREASE** in burden due to revised estimated number of responses per respondent(1); **MODIFIED** content of the ACRF with no change in average burden time per response.
Pediatric HIV Case Report (PCRF) (att 3b,3c,4b)	59	1962	+1903	**INCREASE** in burden due to revised estimated number of responses per respondent that includes burden moved from PHER form together with pediatric case reports on this revised form(1);

				MODIFIED content of the PCRF to include Pediatric Exposure information from PHER Form. PHER form no longer used.
Perinatal HIV Exposure Reporting (PHER)	1,576	0	-1,576	**DISCONTINUED form. MODIFIED** PCRF form now includes burden of perinatal exposures reports;
Case Report Evaluations (att 3a,3b,3c)	1691	1672	-19	**INCREASE** in burden due to revised estimated number of responses per respondent;[1]
Case Report Updates (att 3a,3b,3c,4a,4b)	4628	4954	+326	**INCREASE** in burden due to revised estimated number of responses per respondent;[1]
Laboratory Updates (att 3a,3b,3c,4a,4b)	4627	4981	+354	**INCREASE** in burden due to the revised estimated number of responses per respondent;[2]
Deduplication Activities (att 4c)	26,953	29815	+2,862	**INCREASE** in burden due to the revised estimated number of responses per respondent;[2]
Investigation Reporting and Evaluation (att 4 d,e)	886	914	+28	**INCREASE** in burden due to the revised estimated number of responses per respondent;[2]
Initial Cluster Report Form (att 3e,4f)	148	148	0	**NO CHANGE** in burden;
Cluster Follow-up Form (att 3f,4f)	148	148	0	**NO CHANGE** in burden;
Cluster Close-out Form (att 3g,4f)	148	148	0	**NO CHANGE** in burden;
Annual Reporting: Standards Evaluation Report (SER) (att 3d)	472	472	0	**NO CHANGE** in burden;
	59,462	60,731	+1,269	**NET INCREASE IN TOTAL BURDEN**

(1) Reflects reduction in case reports (diagnoses) due to improvements in prevention

(2) Reflects increases in prevalence due to improvements in medical care for persons with HIV.

Discontinued Information Collections

HIV incidence surveillance was not implemented and is being discontinued as a separate activity. HIV Incidence continues to be

estimated via statistical methods (i.e., incidence estimation using a CD4 Depletion model) by CDC, lifting the burden off the grantees.

New or Modified Information Collection and Processing Activities
We have discontinued the use of the PHER form but will continue data collection of perinatal exposures on a the modified PCRF form. The modified PCRF form includes both changes to key pediatric report variables as well as incorporation of previously approved and new variables for perinatal exposure reports. (See form changes description below and the summary of changes (Attachment 10.) for specific changes). We also revised the average time per response of the PCRF form to account for both reporting of perinatal exposure and pediatric case information and revised the number of responses in our burden calculation to account for an anticipated increased number of jurisdictions reporting perinatal exposure information using the revised PCRF form (i.e., 47 jurisdictions are expected to report perinatal exposure data on the revised PCRF compared to 16 jurisdictions reporting using the previously approved (now discontinued) PHER form).

Our calculations include a smaller number of adult and pediatric case reports that account for fewer people receiving HIV diagnoses. This reduction is likely attributed to improvements in prevention efforts. In addition, the burden calculations for case report and laboratory updates, deduplication activities, and investigation reporting and evaluation activities account for increases in the number of persons living with HIV due to successes in treatment (increasing prevalence) and subsequent increased reporting for those burden line items.

Form Changes
The form changes requested for this ICR include modifications to currently collected data elements on the Adult HIV Confidential Case Report Form (ACRF), the consolidation of information collected from two forms (the Perinatal HIV Exposure Reporting [PHER] form and the Pediatric HIV Confidential Case Report Form [PCRF]) to one form (the PCRF), and modifications to associated data system tables and variables as a result of the revisions. The requested changes for forms and variables have been developed with input of state and local HIV surveillance coordinators and the CSTE HIV subcommittee and surveillance partners. We are requesting to continue data collection using our currently approved data collection instruments through December 2022 and implementing the proposed form changes starting in January 2023.

The specific changes to the adult and pediatric case report forms are described in detail in the attached “Summary of Proposed Changes” provided in **Attachment 10**.

A revised version of the ACRF is provided in **Attachment 3(a**) and the revised PCRF is provided in **Attachment 3(b)**. These forms will replace Attachments 3(a), 3(b) of our previously approved ICR.

Some reformatting, reordering and minor changes to wording of instructions were made for clarity and consistency and to improve organization of both the ACRF and revised PCRF forms.

Changes made to both the ACRF and PCRF include addition of two variables to collect sexual orientation information, updated gender identity response options, addition of two new HIV test types to accommodate changes in testing technology, the addition of two new response options related to self-testing, the addition of three new HIV testing history variables to summarize self-testing activities (ACRF only) and formatting changes to improve usability of both forms. In the Patient History section, we updated the language to align with the Division of HIV Prevention terminology guide, which recommends the use of ‘person who injects drugs’ instead of ‘injection drug user’.

The main changes to the PCRF include those related to critical perinatal exposure information that was consolidated across the PHER and PCRF to reduce redundancy across forms and include some new and revised data elements needed to assess progress with perinatal elimination efforts and support HIV prevention activities. Combining the PCRF and PHER forms reduced the information collected from the two forms which will reduce burden of data collection and increase usability of the forms. In all, 10 variables in the PHER form will no longer be collected; 7 variables from the PHER form were combined with existing variables on the PCRF; 13 variables were moved from the PHER form to the new PCRF; 5 new variables were added to the PCRF including 4 related to breastfeeding/chestfeeding and premastication risk behaviors and one variable related to documentation of laboratory results in a person’s labor and delivery record; response options for the existing delivery method variable was revised on the PCRF to align with current medical practices. Health departments will now use the one revised PCRF form to report perinatal exposures and pediatric case reports and the revised burden for both perinatal exposure reporting and pediatric case reporting is now combined and included under the PCRF form line. The number of respondents reporting pediatric case reports is 59 and a subset of those jurisdictions that have perinatal exposure reporting will also report some perinatal exposure information using the revised PCRF form and the PCRF burden estimate has been revised to account for this reporting. The time per response for the PCRF has been revised from 20 minutes to 35 minutes average per response to reflect these changes and increased reporting of perinatal exposure data elements.

Minor modifications to dates and time periods in the Standards Evaluation Report (SER) are requested to better align with needed

information to assess program performance the next report cycle in January 2023. (**Attachment 3d**)

16. Plans for Tabulation and Publication and Project Time Schedule

Collected HIV data are analyzed and published annually in the HIV Surveillance Report with quarterly updates to selected tables and slide sets found at https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. Typically, the surveillance report is completed and published approximately– 18 months after a diagnosis year. Cases reported to CDC by the end of December are used for the annual HIV surveillance report, Supplemental Reports, and the NCHHSTP AtlasPlus and summarized through the end of the previous calendar year. For example, HIV surveillance data for 2020 were finalized in December 2021 and the report were posted on the DHP web site and updated in the AtlasPlus at the end of second quarter 2022. Over the years, data dissemination has increased to provide prompt dissemination of current HIV morbidity trends and timely evidence for decision makers related to program planning, evaluation, and resource allocation. For example, in 2020, DHP began releasing *HIV Surveillance Data Table*s and updating the NCHHSTP Atlas for selected HIV indicators on a quarterly basis for more timely monitoring of the Ending the HIV Epidemic in the U.S. (EHE) initiative. These quarterly data are also published in the Department of Health and Human Services America's HIV Epidemic Analysis Dashboard (AHEAD.)

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 DHP publications and materials for training and education of health care providers, researchers, the 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 priority populations, 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. DHP/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

DHP/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)

There are no exceptions to the certification.