

National HIV Surveillance System (NHSS)

OMB # 0920-0573

Supporting Statement Part A

**June 25, 2019
(Change requested August 14, 2020)**

Contact Information

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

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

Table of Contents

Section

A. Justification

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

B. Collections of Information Employing Statistical Methods

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

Exhibits

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

LIST OF ATTACHMENTS

Attachment 1. Authorizing Legislation

Attachment 2. 60 Day Federal Register Notice

Attachment 3. Data collection instruments and data elements

- 3(a) Adult HIV Confidential Case Report Form
- 3(b) Pediatric HIV Confidential Case Report Form
- 3(c) Data Elements for the National HIV Surveillance System
- 3(d) Perinatal HIV Exposure Reporting data collection form
- 3(e) Standards Evaluation Report Form
- 3(f) Initial Cluster Report Form
- 3(g) Cluster Follow-up Form
- 3(h) Cluster Close-out Form

Attachment 4. Form instructions and technical guidance documents

- 4(a) Adult HIV Confidential Case Report Form Technical Guidance
- 4(b) Pediatric HIV Confidential Case Report Form and Perinatal HIV Exposure Report Form Technical Guidance
- 4(c) Technical Guidance for HIV Surveillance Programs: Duplicate Review
- 4(d) Data-to-Care Reporting Guidance for PS18-1802 Recipients
- 4(e) Technical Guidance for HIV Surveillance Programs: Detecting HIV Transmission Clusters
- 4(f) Cluster Investigation Report Form Instructions

Attachment 5. HIV Surveillance Report

Attachment 6. HHS Privacy Impact Assessment

- 6(a) 2019 Privacy Impact Assessment
- 6(b) 2019 Authorization to Operate

Attachment 7. Assurance of Confidentiality, Security Statement and Data Access Packet

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

Attachment 8. Data Security and Confidentiality Guidelines

Attachment 9. Project Determination

Attachment 10. Summary of Proposed Changes in the ICR for the National HIV Surveillance System (NHSS) OMB #0920-0573

- Goal of the NHSS: 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 data: NHSS data are used to estimate HIV incidence and prevalence; monitor patterns in HIV drug resistance and genetic diversity; detect HIV clusters; and describe characteristics of infected persons and perinatally exposed infants. 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 enhancements that will strengthen uses of NHSS data to guide rapid response HIV prevention and control efforts. These enhancements include HIV cluster reporting and surveillance-initiated investigations of persons identified as not-in-care. In 2020, a change was requested to resume data collection and reporting of 6 variables necessary for calculations of HIV incidence using a recent infection testing (RITA) algorithm in selected jurisdictions funded for incidence activities under PS20-2010 Integrated HIV programs for Health departments to support the Ending the HIV Epidemic (EHE) initiative.
- 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 population included: 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 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. 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/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, 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 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; but did not. Therefore, their inclusion does not increase the reporting burden as the burden was previously included.

In 2018, CDC implemented activities under a new funding announcement PS18-1802: Integrated HIV Surveillance and Prevention Programs for Health Departments. The purpose of cooperative agreement PS18-1802 is to implement a comprehensive HIV surveillance and prevention program to prevent new HIV infections and achieve viral suppression among persons living with HIV. This information collection request revision includes activities to continue national surveillance program activities and align with program priorities of PS18-1802. Updating case information, laboratory test results, evaluations of case reports, and deduplication activities are done in the 59 areas and presented separately. Additional data collection for HIV Incidence surveillance has been discontinued and is no longer being conducted as a separate activity and is being replaced by estimation via statistical methods (i.e., by /CD4 depletion model). Reporting of nucleotide sequences as part of molecular HIV surveillance activities have been incorporated into routine reporting (i.e., case report and laboratory updates). Perinatal HIV Exposure Reporting (PHER) is conducted by a subset of 16 of the 59 areas. Beginning in 2021, HIV Incidence Surveillance (HIS) will be resumed using a recent HIV infection testing algorithm (RITA) and reported in a subset of 7 of the 59 reporting areas funded for HIV Incidence surveillance activities under [PS20-2010: Integrated HIV Programs for Health Departments to Support Ending the HIV Epidemic in the United States.](#)

HYPERLINK

"<https://www.cdc.gov/hiv/funding/announcements/ps20-2010/index.html>" Annual reporting for the Standards Evaluation Report (SER) is required by the 59 NHSS grantees has been updated to include some additional elements to better monitor required activities under cooperative agreement PS18-1802.

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. At year-end 2016, an estimated 1,140,400 persons aged ≥ 13 years were living with HIV infection (prevalence), including 162,500 (14.2%) persons whose infection had not been diagnosed; the prevalence rate was 421.4 (Table 7). The percentage of diagnosed infections among persons living with HIV at year-end 2016 (85.8%), compared with 2010 (82.8%), increased. (Centers for Disease Control and Prevention. Estimated HIV incidence and prevalence in the United States, 2010–2016. *HIV Surveillance Supplemental Report* 2019;24(No. 1).

<https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-24-1.pdf> . Published February 2019.)

At the end of 2016, an estimated 1,008,929 persons in the United States and 6 dependent areas were living with diagnosed HIV infection,

with an estimated death rate of 4.8 per 100,000. From 2012 through 2016, the annual number and the rate of infections classified as stage 3 (AIDS) in the United States decreased. Through 2017, 1,281,787 persons with HIV, had their infection ever classified as stage 3-AIDS in the United States and 6 dependent areas. From 2012 through 2016, the rate of diagnoses of HIV infection in the United States decreased; the annual number of diagnoses remained stable. In 2017, the rate was 11.8. (Centers for Disease Control and Prevention. *HIV Surveillance Report, 2017*; vol. 29. Published November 2018 <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2017-vol-29.pdf>)

CDC published new incidence and prevalence estimates in 2019 describing trends from 2014-2018. HIV incidence in 2018, compared with 2014, remained stable. In 2018, the estimated number of HIV infections was 36,400; the rate was 13.3. The annual number of HIV infections in 2018, compared with 2014, decreased among persons of multiple races but remained stable for all other race/ethnicities. In 2018, the highest rate was for blacks/African Americans (45.4), followed by the rates for Hispanics/Latinos (22.4) for persons of multiple races (19.3). The annual number of HIV infections in 2018, compared to 2014, remained stable among all transmission categories. Men who have sex with men continued to bear a heavy HIV burden. In 2018, the highest percentages of HIV infections were attributed to male-to-male sexual contact (67% overall and 82% among males). In 2018 among females, the largest percentage of HIV infections was attributed to heterosexual contact (85%). The annual number of HIV infections in 2018, compared with 2014, remained stable in all regions. In 2018, rates were 18.4 in the South, 11.6 in the West, 10.5 in the Northeast, and 8.1 in the Midwest. Estimates of Incidence using CD4 methodology and prevalence for EHE Phase I jurisdictions are provided in the tables A1 and A2 of the surveillance supplemental report. (Centers for Disease Control and Prevention. Estimated HIV incidence and prevalence in the United States, 2014-2018. *HIV Surveillance Supplemental Report 2020*;25(No. 1) <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-25-1.pdf> **HYPERLINK** "<https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-25-1.pdf>")

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 2017 volume 29 (<https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2017-vol-29.pdf>). In 2017, an estimated 99 diagnoses of HIV infection occurred among children <13 years of age in the United States and six dependent areas, of which 73 (74%) were attributed to perinatally acquired infection. Jurisdictions must have appropriate legal authority in place to conduct Perinatal HIV Exposure

Reporting (PHER). At this time, 16 jurisdictions are required to conduct PHER under PS18-1802. These jurisdictions were identified as having $\geq 3,000$ females aged 15-44 years living with diagnosed HIV infection at year-end 2014 or a rate of ≥ 200 females living with diagnosed HIV infection at year-end 2014 per 100,000 females aged 15-44 years (<https://www.cdc.gov/hiv/pdf/funding/announcements/ps18-1802/CDC-HIV-PS18-1802-Attachment-I.pdf>). HIV exposure reporting under PS18-1802. We estimate that the number of perinatal exposures in these 16 jurisdictions would represent approximately 63% 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 National HIV prevention 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 the National HIV prevention goals and defines objectives for measuring progress in reducing the burden of HIV in the United States. In February 2019, the President announced a new initiative "Ending the HIV Epidemic: A Plan for America." The bold initiative will work to reduce new infections by 75% in the next five years and by 90 percent in the next ten years (www.hiv.gov). It is anticipated that HIV surveillance data will continue to play a critical role in monitoring progress towards reaching these important goals.

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 June 2018. 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, 2016. *HIV Surveillance Supplemental Report* 2018;23(No. 4). <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published June 2018. 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 to adjust for programmatic priorities. For example, the most recent case definition was published in 2014 (<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1.htm>). 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. Currently approved case report forms

include necessary elements for the surveillance definition and revised forms submitted with this application (**Attachments 3a, b, and d**) include only minor changes such as changes to existing variables (e.g., additional response options) and editing of instructions to improve readability of the form. 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. In addition, the estimated burden includes updates to more accurately reflect current data collection practices (e.g., adjusting the average burden per response for electronic laboratory updates and including a separate line item for deduplication activities previously included with case report evaluations and including new cumulative deduplication activities)(**Attachment 4c**).

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 data elements proposed in this revision will be incorporated into the electronic reporting system i.e. enhanced HIV/AIDS reporting system 4th revision or eHARS4.11. and the variable listing in **Attachment 3c** has been updated to reflect those changes. No changes to the reporting system are required to resume reporting of HIS data elements.

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 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. 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.

Improvements in HIV surveillance that resulted in complete and readily available data for all states has allowed the use of routinely reported CD4 data to estimate HIV incidence. Beginning in 2018, health departments participating in HIV Incidence Surveillance activities were no longer required to collect information on serologic testing algorithm for recent HIV seroconversion (STARHS) results (i.e., recency results from biomarker tests that distinguish recent from long-standing infection) and report that information to CDC for the purpose of estimating HIV incidence. Consequentially this activity is removed from our burden estimate. Health departments may continue to collect and enter recency results to describe recency of infection in their jurisdictions. Although, health departments will no longer be required to collect STARHS-related information, they will continue to collect information on testing and treatment history and antiretroviral use. 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**. These data are reported monthly with other case report information to CDC via secure electronic methods and they are added to reports from other areas to form the national database. HIV incidence is now being estimated nationally via statistical methods (i.e., incidence estimation using a CD4 Depletion model) by CDC and will continue to be published in supplemental surveillance reports and other data products. In 2021 data collection and reporting of HIS data elements will resume in 8 EHE funded jurisdictions (Alabama, Florida, Michigan South Carolina, Texas, Houston, New York City and the District of Columbia). These jurisdictions will also be estimating incidence using a recent infection testing (RITA) algorithm.

Molecular HIV Surveillance (MHS) has been incorporated into routine surveillance activities and no longer funded as a separate activity. The burden of HIV sequence data collection is now reflected under laboratory updates and other case report updates in our burden estimate. HIV sequence data collected will continue to be used for 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 (i.e. clusters) and antiretroviral drug treatment and prophylaxis strategies in participating surveillance areas.

Investigation Reporting and Evaluation

Health departments are now using 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 additional estimated burden for health departments reporting of monitoring and evaluation variables for surveillance-initiated investigations of persons identified as not in care and interventions to link them to care. We anticipate that information will primarily be 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 of using HIV surveillance to facilitate linkage to care can be found at <https://effectiveinterventions.cdc.gov/en/HighImpactPrevention/PublicHealthStrategies/DatatoCare.aspx>.

The surveillance data collected through NHSS are used to monitor and characterize trends in HIV to guide public health action at the federal, state, and local levels, to identify growing HIV clusters, and to identify people for engagement in care efforts to improve health outcomes and prevent transmission. 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 recent and rapid transmission (including molecular clusters), 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. We are including burden for reporting and monitoring of cluster investigations using the variables approved in 2018 in eHARS. We anticipate that these variables will create efficiencies in management of transmission cluster investigations and will be electronically importable from other systems that may be used by health departments. 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 PS18-1802.

These data will be collected through quarterly cluster report forms (**att 3f, 3g, 3h**) 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' (**att 3f**) 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' (**att 3g**) 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' (**att 3h**) 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 that do not identify recent and rapid clusters of HIV transmission will not complete any cluster report forms, while some jurisdictions will detect multiple recent and rapid clusters of HIV transmission, necessitating the completion of 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)**.

Perinatal HIV Exposure Reporting (PHER)

Perinatal HIV Exposure Reporting (PHER) (**Attachments 3d and 4b**) will be conducted by a minimum of 16 jurisdictions under PS18-1802. These jurisdictions were identified as having $\geq 3,000$ females aged 15-44 years living with diagnosed HIV infection at year-end 2014 or a rate of ≥ 200 females living with diagnosed HIV infection at year-end 2014 per 100,000 females aged 15-44 years (<https://www.cdc.gov/hiv/pdf/funding/announcements/ps18-1802/CDC-HIV-PS18-1802-Attachment-I.pdf>).

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 100 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 will allow CDC to better characterize the perinatal HIV disease burden in the United States.

Data are collected through medical record reviews of mother-infant pairs and follow-up of HIV-exposed children. Case surveillance collects information on women and children <13 year of age with diagnosed HIV infection, including infants with perinatally acquired

transmission. PHER collects information on women with diagnosed HIV infection and HIV-exposed infants, including infants who become infected. Data collection for perinatal HIV exposure reporting has become integrated with routine HIV case surveillance, as the data collection tools (the PCRF, the PHER Form and the data collection system) and the technical guidance have been revised to support the integration of case surveillance and PHER activities. Surveillance data collected through PHER will be critical for evaluating strategies to prevent perinatal HIV transmission and ultimately improving the health of infants and their mothers. The PHER form is included in **Attachment 3(d)** and there are no changes requested for this form in this revision.

HIV Incidence Surveillance (HIS)

In 2018, HIV Incidence surveillance activities were scaled and CDC began using a CD4-based statistical model for incidence estimation back. In 2021, a subset of jurisdictions previously conducting HIS activities funded under PS20-2010 Integrated HIV Programs for Health Departments to Support Ending the HIV Epidemic in the United States, will begin conducting HIS activities again and estimating HIV incidence using a recent infection testing algorithm (RITA) based on test results, testing history, and clinical information that have continued to be reported as part of routine surveillance and collection of previously approved variables for specimen tracking and estimation (Attachments 3(a) and 3(c)). Since the goals of EHE are to reduce new HIV infections, accurate calculation of incidence is critical for measuring the success of prevention efforts. This incidence surveillance activity will help CDC and state health departments address whether potential increases in HIV diagnoses represent new infections or diagnoses of longstanding chronic infections finally being identified, as well as enable comparison of the currently used statistical methods using the CD4-based model and identification of best practices for incidence estimation.

Standards Evaluation Report (SER)

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 program objectives of PS18-1802 and the national prevention goals.

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 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.

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 Guidelines 5 CFR 1320.6

Collection of HIV data is conducted in a manner consistent with the guidelines in 5 CFR 1320.6. DHAP requests that reporting areas send encrypted data via the 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 April 23, 2019, Volume 84, Number 78, Pages 16868-16870 (**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 monthly calls and workshops, routine site visits, periodic conference calls with HIV surveillance coordinators, and national conferences. These discussions allow CDC to obtain information on the availability of data, frequency of data collection, clarity of instructions, and record keeping, reporting format, and key data elements. A PS18-1802 Recipients' Meeting was held in Atlanta June 5-8, 2018 for both prevention and surveillance staff and a technical assistance meeting for surveillance staff is scheduled for June 12-13, 2019. 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 technical guidance meeting for HIV surveillance is planned for June 2019.

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, a similar session on community engagement

regarding implementation of cluster response was also conducted at the U.S. Conference on AIDS in September 2018. Overall goals for these discussions were aimed at increasing understanding of community concerns 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 April 10, 2019 by the CDC privacy officer (**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, 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 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 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 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 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.

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. 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 Council of State and Territorial Epidemiologists revised data 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 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 854 responses (HIV and AIDS cases) each for a total of 50,386 responses. We estimate an average of 20 minutes per response for a total of 16,795 burden hours. The same 59 health departments will also report using the **Pediatric HIV Confidential Case Report Form (Attachment 3b)** with an estimated 3 responses for a total of 177 responses. We estimate an average of 20 minutes per response for a total of 59 annual burden hours using the PCRFB (**Attachment 3b**). The fifty-nine health departments will also conduct case report evaluations, reporting an estimated 86 responses each, for a total of 5,074 annual responses. We estimate an average 20 minutes per response for a total of 1,691 annual burden hours. The annual burden hours for adult case reports decreased from the last revision from 20,866 hours to 16,795 hours and decreased for pediatric case reports from 98 hours to 59 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) and HIV diagnoses may also decrease as incidence decreases. 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 2,353 case report updates involving non-electronic methods each, totaling

138,827 responses annually. We estimate an average 2 minutes per response for a total of 4,628 burden hours. This is an increase from 3,099 burden hours to 4,628. This increase is due to an estimated increase in the number of responses (from 92,984 to 138,827) to account for increased number of updates for CD4 and viral load test results among persons living with HIV.

We estimate 9,410 responses for laboratory updates through electronic methods in the 59 reporting areas for total of 555,190, responses annually. We estimate an average of 0.5 minute per electronic response for a total burden of 4,627 hours. We have reduced the average response time from 1 minute to 0.5 minute to account for improvements in electronic laboratory reporting capacity and maturity of reporting systems used by health departments.

In this revision, we are including a new separate burden item for deduplication activities previously included as part of case report evaluations to better account for both routine interstate deduplication activities (RIDR) and cumulative interstate deduplication activities (CIDR). We estimate 59 areas complete deduplication activities will report 2,741 responses per respondent for an estimated 161,719 annual responses. We estimate 10 minutes per response based on reported feedback from health departments on time to resolve duplicates for a total of 26,953 total burden hours.

We are including a new burden line item for investigation reporting and evaluation to account 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 901 responses per respondent for an estimated 53,159 annual responses. We estimate 1 minute per response for a total of 886 total burden hours.

In this revision we are including a new burden lines item for reporting of three cluster report forms to monitor progress on cluster response (**Attachments 3f, 3g, 3h**). 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.

In this revision, we have reduced the number of health departments collecting information on the Perinatal HIV Exposure Report (PHER)

form from 35 to 16 to reflect the 16 areas required to report under the new funding announcement (see **Attachment 3d**). 2019 PHER burden was calculated based on the estimated number of HIV-infected women giving birth that would be reported from 16 areas funded to conduct PHER under PS18-1802. Sixteen areas will collect 197 responses per respondent for an estimated 3,152 total annual responses. We estimate 30 minutes per response for a total burden of 1,576 hours. This reduction in the total burden hours is due to the reduction of the number of respondents (from 35 to 16).

The following 8 jurisdictions were funded to resume HIV Incidence Surveillance (HIS) in 2021: **.Alabama, District of Columbia, Florida, Michigan, New York City, South Carolina and Texas and Houston**It is anticipated that reporting for both Houston and the rest of the state of Texas will be done through the state health department, therefore burden calculations include 7 jurisdictions:Alabama, District of Columbia, Florida, Michigan, New York City, South Carolina and Texas (including). Houston**These jurisdictions estimate HIV incidence using a recent infection testing algorithm (RITA) based on test results, testing history, and clinical information that have continued to be reported as part of routine surveillance and resume collection of 6 previously approved variables for specimen tracking and estimation. (see Attachments 3a,3c, 4a). Seven areas will collect 2,282 responses per respondent for an estimated 15,974 total responses. We estimate 5 minutes per response for a total burden of 1,331 burden hours.**

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. 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 and includes some revised items to align with the activities required under PS18-1802 (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 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 58,131. This burden estimate is approximately 21% higher than our previous burden estimate of 48,026 approved in 2018 (approved July 17, 2018). The

higher burden is due to changes in program activities required to be carried out by grantees under the PS18-1802 and refinements made to our burden calculations.

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	854	50,386	20/60	16,795
Health Departments	Pediatric HIV Case Report (att 3b, 3c, 4b)	59	3	177	20/60	59
Health Departments	Case Report Evaluations (att 3a, 3b, 3c)	59	86	5,074	20/60	1,691
Health Departments	Case Report Updates (att 3a, 3b, 3c, 4a, 4b)	59	2,353	138,827	2/60	4,628
Health Departments	Laboratory Updates (att 3a, 3b, 3c, 4a, 4b)	59	9,410	555,190	0.5/60	4,627
Health Departments	Deduplication Activities (att 4c)	59	2,741	161,719	10/60	26,953
Health Departments	Investigation Reporting and Evaluation (att 4d, e)	59	901	53,159	1/60	886
Health Departments	Initial Cluster Report	59	2.5	148	1	148

	Form (att 3f, 4f)					
Health Departments	Cluster Follow-up Form(att 3g, 4f)	59	5	295	30/60	148
Health Departments	Cluster Close-out Form (att 3h, 4f)	59	2.5	148	1	148
Health Departments	Perinatal HIV Exposure Reporting (PHER)(att 3d, 4b)	16	197	3,152	30/60	1,576
HIV Incidence Surveillance (HIS)	Adult HIV Case 3a, 3c, 4a) attReport(7	2,282	15,974	5/60	1,331
Health Departments	Annual Reporting: Standards Evaluation Report (SER)(att 3e)	59	1	59	8	472
Total						59,462

B. Estimates of Annualized Cost

The estimated total cost to respondents is \$1,605,466. This is based on an estimated hourly wage of \$27/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 \$16/hr. and one epidemiologist at \$37/hr. for an estimated \$27/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 \$16/hr. and one epidemiologist at \$37/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 Respondents	Total No. of Annual Responses	Avg. Burden per Response (in hours)	Hourly Wage Rate	Total Respondent Costs
Health Departments	Adult HIV Case Report (att 3a)	59	50,386	20/60	\$27	\$453,474
Health Departments	Pediatric HIV Case Report (att 3b)	59	177	20/60	\$27	\$1,593
Health Departments	Case Report Evaluations (att 3c)	59	5,074	20/60	\$27	\$45,666
Health Departments	Case Report Updates (att 3a, b, c)	59	138,827	2/60	\$27	\$124,944
Health Departments	Laboratory Updates (att 3a, b, c)	59	555,190	0.5/60	\$27	\$124,918
Health Departments	Deduplication Activities (att 4c)	59	161,719	10/60	\$27	\$727,736
Health Departments	Investigation Reporting and Evaluation (att 4 d, e)	59	53,159	1/60	\$27	\$23,922
Health Departments	Initial Cluster Report	59	148	1	\$27	\$3,996

	Form (att 3f, 4f)					
Health Departme nts	Cluster Follow- up Form (att 3g, 4f)	59	295	30/60	\$27	\$3,983
Health Departme nts	Cluster Close- out Form (att 3h, 4f)	59	148	1	\$27	\$3,996
Health Departme nts	Perinata l HIV Exposure Reportin g (att 3d, 4b)	16	3,152	30/60	\$27	\$42,552
Health Departme nts	HIV Incidenc e Surveill ance (HIS) (att3a, 3c, 4a)	7	15,974	5/60	\$27	\$35,942
Health Departme nts	Annual Reportin g - Standard S Evaluati on Report (SER) (att 3e)	59	59	8	\$27	\$12,744
Total						\$1,605,466

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 data managers: 1 @ \$103,849 @ \$89,050	\$192,899
	Printing	\$4,500
	software development, deployment, and maintenance	\$1,172,476
	HIV Incidence and Case Surveillance Branch Intramural, Including Personnel	\$7,402,556
	Additional intramural staff for HIV Incidence Surveillance	\$474,539
	Laboratory Branch Intramural funding for HIV Incidence Surveillance	\$1,477,600
	Subtotal	\$10,724,570
Cooperative Agreements with States	HIV Surveillance**	\$58,097,984***
Cooperative Agreements with States	HIV Incidence Surveillance Activities	\$4,770,400
Contract	Commercial Reference Laboratories for HIV Incidence Activities	\$600,000
	Total	\$74,192,954

* Note amount based on allocated funding.

** 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 2019 HIV surveillance activities program costs. 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 specific changes to instrument content are provided. (See **Attachments 3a, 3b, 3c, 3d, 3e, 3f, 4a, 4b, 4c, 4d and Attachment 10.**)

The total estimated burden in hours for this ICR is 59,462, approximately 24% higher than our previous burden estimate of 48,026 approved in 2018 (approved July 17, 2018). The higher burden is due to changes in program activities required to be carried out by grantees under the new program announcement PS18-1802, addition of HIV incidence surveillance in a subset of jurisdictions and refinements made to our burden calculations.

Specifically, changes include the discontinuation of two information collection activities; implementation of improved data processing procedures that are reflected in a new line item in the burden table as well as refined estimates for the number of cases and burden; new information collection supporting activities required by the PS18-1802 cooperative agreement; modified content of selected approved forms, also relating to PS18-1802 requirements; and program-initiated modifications to selected approved forms that improve usability. 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 July 2018	Burden Hours Requested in this Revision	Net Change in Burden Hours	Overview of Changes to Burden and Forms
HIV Incidence Surveillance (HIS)	9,533	0	-9,533	DECREASE (DISCONTINUED IC)
Molecular HIV Surveillance	3,661	0	-3,661	DECREASE in burden; DISCONTINUED as a distinct information collection category. Variables have been incorporated into Laboratory Updates and Case Report Updates and are reflected in REVISED estimates for those information collections
Deduplication Activities (att 4c)	0	26,953	+26,953	INCREASE in burden for NEW improved information processing activities that improve data quality and refine the estimated number of responses per respondent
Adult HIV Case Report (att 3a, 3c, 4a)	20,866	16,795	-4,071	DECREASE in burden due to revised estimated number of responses per respondent ⁽¹⁾ ;

				MODIFIED content of the ACRF
Pediatric HIV Case Report (att 3b,3c,4b)	98	59	-39	DECREASE in burden due to revised estimated number of responses per respondent ⁽¹⁾ ; MODIFIED content of the PCRf
Case Report Evaluations (att 3a,3b,3c)	2,104	1,691	-413	DECREASE in burden due to revised estimated number of responses per respondent ⁽¹⁾ ; MODIFIED content of the ACRF and the PCRf
Case Report Updates (att 3a,3b,3c,4a,4b)	3,099	4,628	+1,529	INCREASE in burden due to revised estimated number of responses per respondent; MODIFIED content of the ACRF and the PCRf
Laboratory Updates (att 3a,3b,3c,4a,4b)	6,198	4,627	-1,571	DECREASE in burden; the number of responses per respondent increased and burden per response decreased, resulting in a net decrease
Investigation Reporting and Evaluation (att 4 d,e)	0	886	+886	INCREASE in burden for NEW activities required under NOFO PS18-1802
Initial Cluster Report Form (att 3f,4f)	0	148	+148	INCREASE in burden for NEW activities required under NOFO PS18-1802
Cluster Follow-up Form (att 3g,4f)	0	148	+148	INCREASE in burden for NEW activities required under NOFO PS18-1802
Cluster Close-out Form (att 3h,4f)	0	148	+148	INCREASE in burden for NEW activities required under NOFO PS18-1802
Perinatal HIV Exposure Reporting (PHER) (att 3d, 4b)	1,995	1,576	-419	DECREASE in burden due to reduction in the number of sites required to participate under NOFO PS18-1802
HIV Incidence Surveillance (HIS) (3a,3catt, 4a)	0	1,331	+1331	INCREASE in burden due to resumption of HIV incidence activities in Ending the HIV Epidemic (EHE) funded jurisdictions in 2021.
Annual Reporting: Standards Evaluation Report (SER) (att 3e)	472	472	0	NO CHANGE in burden; updated content to align with the new cooperative agreement
	48,026 ⁽²⁾	59,462	+11,436	NET INCREASE IN TOTAL BURDEN

(1) Reflects reduction in cases due to improvements in prevention, and refined estimates due to improvements in data processing and de-duplication

(2) Information collection for the Annual Performance Report (2,478 annualized burden hours) was discontinued under 0920-0573 in July 2018 and is not included in this total; the activity was migrated to OMB No. 0920-1132

Discontinued Information Collections

HIV incidence surveillance has been discontinued as a separate activity and incidence is now being estimated via statistical methods (i.e., incidence estimation using a CD4 Depletion model) by CDC, lifting the burden off the grantees. Finally, Molecular HIV Surveillance has been discontinued as a distinct information collection category. Variables have been incorporated into Laboratory Updates and Case Report Updates and are reflected in revised burden estimates for those information collections.

New or Modified Information Collection and Processing Activities

We have included a separate line item for deduplication activities from case report evaluations to accommodate both routine and cumulative deduplication activities (i.e., RIDR and CIDR), adjusting the time per response to 10 minutes based on feedback from health departments on time for completion of these activities. These adjustments provide a better assessment of the data collection burden related to deduplication activities and assisted us in refining the estimated number of responses per respondent (site) for case reporting. Our estimates for the number of adult and pediatric case reports were further reduced due to fewer people developing AIDS as a result of the success of antiretroviral therapies allowing people with HIV to live longer and healthier lives and not developing stage 3 (AIDS).

Specific content changes to the Adult Case Report Form (ACRF) and the Pediatric Case Report Form (PCRF) include minor modifications to forms and existing fields, such as an additional response option to an existing variable, change in variable label, and modification of a form instruction to improve clarity. Additional modifications to data system variables used to summarize geocoded address data are also proposed as part of the geocoding activities to be conducted under PS18-1802.

Under the new cooperative agreement CDC is estimating additional new burden for Investigation Reporting and Evaluation for cluster and data to care investigations to link persons to care and added burden for reporting of a cluster report form to monitor cluster detection and response activities. We also have revised our calculations to better estimate the number of electronic laboratory updates resulting in an increased number of responses and reduced the time per response to account for improvements in electronic laboratory reporting capacity and computing power and increased efficiencies of established data systems.

As part of the new Ending the Epidemic (EHE) Initiative a subset of jurisdictions are funded in a new cooperative agreement PS20-2010 to resume data collection for HIV Incidence Surveillance (HIS) Data collection for HIS will resume in 7 jurisdictions in 2021 and will contribute to an increase in overall burden.

Finally, the number of health departments collecting information on the Perinatal HIV Exposure Report (PHER) form was reduced from 35 to 16 to reflect the 16 areas required to report under the new notice of funding opportunity (NOFO), i.e., the cooperative agreement, reducing burden hour for this activity.

Minor changes are proposed for the Standards Evaluation Report (SER) form that are necessary for transitioning to the new cooperative agreement PS18-1802 and relate to additional automation of processes and outcome measures that were previously captured manually, and the addition of outcome measures that were not available for Year 1 due to data collection limitations. The proposed form will be provided to jurisdictions in January 2020 to report their 2018 outcomes, and each January thereafter for the following three years. It is anticipated that the burden to complete the new proposed SER will not change.

The specific changes to the adult and pediatric case report and eHARS system variables related to geocoding activities, and SER are described in detail in the "Summary of Proposed Changes" provided in **Attachment 10**.

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

<https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>.

Typically the surveillance report is completed and published approximately 4-6 months after the data are finalized. Cases reported to CDC by the end of June are used for the year end surveillance report summarizing data through the end of the previous calendar year. For example HIV surveillance data for 2017 were finalized in June 2018 and the report was posted on the Division of HIV/AIDS (DHAP) web site and distributed in the last quarter 2018. Over the years, the time between data finalization and report publication has been reduced to provide 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 is presented in 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.

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.