**National HIV Surveillance System (NHSS)**

Attachment 10.

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

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**Summary of Changes**

We are requesting continuation of the information collection request (ICR) for the National HIV Surveillance System (NHSS) OMB #0920-0573 with some changes to accommodate activities under our new funding announcement PS18-1802: Integrated HIV Surveillance and Prevention Programs for Health Departments. The changes requested for this ICR include minor modifications to currently collected data elements and forms (including the Adult Case Report Form (ACRF) and the Pediatric Case Report Form (PCRF)), modifications to data system variables used to summarize geocoded address data collected as part of the geocoding activities, addition of a new cluster report form for health departments to report on progress for HIV cluster investigations and addition of investigation reporting and evaluation activities required under PS18-1802 (e.g., data-to-care not in care investigations of persons identified to be not-in-care and cluster investigations). No changes are being requested to data elements collected on the Perinatal HIV Exposure Reporting (PHER) form, but the number of jurisdictions (respondents) completing the form has changed. Requested changes for forms and data elements have been developed with input of state and local HIV surveillance coordinators and the CSTE HIV subcommittee, are non-substantive and are intended to improve usability and data collection and create efficiencies for conducting and evaluating surveillance program activities. Finally, we have updated our burden calculations 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) and incorporated those changes into our burden estimates.

A detailed description of changes are outlined below. The specific changes to the ACRF and PCRF are summarized below and described in detail in Table 1. The revised ACRF and PCRF that include the proposed changes are included in Attachments 3(a) and 3(b). The PHER form, with no proposed changes, is included in Attachment 3(d). In addition, minor modifications to existing data systems variables and two new data systems variables that may be used by health departments for geocoding activities are described in Table 2. The changes in estimated burden hours are described below and revised burden provided in table 12.A

**Changes to the ACRF and PCRF**

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) and 3(b) of our previously approved ICR. The Patient Identification sections of the ACRF and PCRF have been revised to include two additional response options for the "Address Type" field ("Military" and "Other"). This was done to meet the needs of the geocoding activities required under cooperative agreement PS18-1802: Integrated HIV Surveillance and Prevention Programs for Health Departments. In the Residence at Diagnosis sections of the ACRF and PCRF, the field labeled "Address Type" was updated to "Address Event Type" to better reflect that the response options for this field indicate the event associated with the address (e.g., residence at HIV diagnosis); the response options were not changed. In the Residence at Diagnosis sections of the ACRF and PCRF, a new field labeled "Address Type" was added. The response options for "Address Type" in the Residence at Diagnosis sections align with the "Address Type" options collected in the Patient Identification sections of the ACRF and PCRF. These changes were also made to meet geocoding activity requirements.

Finally, a modification was made to the instruction provided under the Documentation of Tests heading in the Laboratory Data sections of the ACRF and PCRF. The wording of the instruction was updated to clarify when

the field "Did documented laboratory test results meet approved HIV diagnostic algorithm criteria?" needs to be completed.

Technical guidance documents including instructions for completing the forms have been revised to align with the changes in the case report forms. Both Attachment 4(a) Technical Guidance for HIV Surveillance Programs - Adult HIV confidential Case Report form and Attachment 4(b) Technical Guidance for HIV Surveillance Programs- Pediatric HIV Confidential Case Report Form and Perinatal HIV Exposure Reporting Form will replace Attachments 4(a) and 4(b) in our ICR.

**Changes to the PCRF Only**

A revised PCRF is provided in Attachment 3(b) Y and changes to the form are outlined in Table 1. Within the Birth History section of the PCRF, a new field labeled "Address Type" was added. The response options for "Address Type" in the Birth History section aligns with the "Address Type" options collected in the Patient Identification sections of the ACRF and PCRF. This update was made to be consistent with how other address information on the form is collected. The designation of the address variables collected in the Birth History section (Street Address, City, County, State/Country, and Zip Code) was changed from optional (i.e., variables that programs may or may not choose to collect) to required (i.e., variables that must be collected by all programs) to align with the designations already in place for collecting address variables in other sections of the form.

An editorial change was made within the second footnote at the bottom of page 1 of the PCRF to remove the comma after the word "maintained." This update was made to align with the formatting of the same footnote that is present on page 4 of the ACRF. In the Treatment/Services Referrals section, the formatting for the label for "This child's primary caretaker is" was modified to have the entire label on a single line rather than spanning two lines.

**Table 1. Proposed Modifications to the Adult HIV Confidential Case Report Form (ACRF) and Pediatric HIV Confidential Case Report Form (PCRF)**

| Page, Section, Variable | Change Proposed | Reason for Change Proposed |
|---|---|---|
| **ACRF and PCRF** | | |
| Page 1, Section: Patient Identification, Variable: Address Type | Added two additional response options: "Military" and "Other." | To meet the needs of the geocoding activities required under the cooperative agreement PS18-1802: Integrated HIV Surveillance and Prevention Programs for Health Departments. |
| Page 1, Section: Residence at Diagnosis, Variable: Address Type (previous label)/Address Event Type (new label) | Updated the label from "Address Type" to "Address Event Type." No changes were made to the existing response options. | To better reflect that the response options for this field indicate the event associated with the address (e.g., residence at HIV diagnosis). |
| Page 1, Section: Residence at Diagnosis, Variable: New (Address Type) | Added a new field labeled "Address Type." The response options aligned with the response options for "Address Type" in the Patient Identification section. | To meet the needs of the geocoding activities required under cooperative agreement PS18-1802: Integrated HIV |

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|---|---|---|
| | | Surveillance and Prevention Programs for Health Departments. |
| Page 3, Section: Laboratory Data, Variable: N/A | Modified the instruction provided under the Documentation of Tests heading. Changed from "*Complete the above only if none of the following was positive: HIV-1 Western blot, IFA, culture, viral load, or qualitative NAAT [RNA or DNA]* " to " *Complete the above only if none of the following were positive for* ***HIV-1****: Western blot, IFA, culture, viral load, qualitative NAAT (RNA or DNA), HIV-1/2 type-differentiating immunoassay (supplemental test), stand-alone p24 antigen, or nucleotide sequence.*" | To clarify when the field "Did documented laboratory test results meet approved HIV diagnostic algorithm criteria?" needs to be completed. |
| **PCRF only** | | |
| Page 1, Section: Second footnote, Variable: N/A | Removed the comma after the word "maintained" in the second footnote at the bottom of page 1. | To make the formatting consistent with the same footnote that is present on page 4 of the ACRF. |
| Page 4, Section: Birth History, Variable: Address Type (new label) | Added a new field labeled "Address Type." The response options aligned with the response options for "Address Type" in the Patient Identification sections of the ACRF and PCRF. | To be consistent with how other address information on the form is collected. |
| Page 4, Section: Treatment/Services Referrals, Variable: This child's primary caretaker is | Updated the formatting of the label to have the entire label on a single line rather than spanning two lines. | To make the label easier to read and to be consistent with the formatting used for other labels in this section of the form. |

Footnote. The revised Adult HIV Confidential Case Report Form (ACRF) is provided in Attachment 3(a) and the revised Pediatric HIV Confidential Case Report Form (PCRF) is provided in Attachment 3(b)

**Additional Data System Variables for Geocoding Activities**

The Centers for Disease Control and Prevention (CDC) is committed to reducing health disparities and promoting health equity and has adopted the social determinants of health (SDH) conceptual framework to determine priorities and focus intervention efforts. Recognizing gaps in data regarding SDH and HIV, health departments have incorporated geocoding of HIV surveillance data into routine surveillance practice and analyze and display geocoded HIV surveillance data along with SDH indicators that may affect HIV transmission. Although many jurisdictions have been conducting routine geocoding and data linkage (GDL) as an optional activity and reporting those data to CDC, all funded HIV surveillance programs will be incorporating GDL into routine surveillance activities as part of the new cooperative agreement PS18-1802.

We are proposing modifications of an existing currently OMB approved data system variable and the addition of two new data system variables that may be used by health departments for GDL. Relevant changes are also captured on the paper-based case report forms as described in the section above. However, since GDL

activities occur after case reporting it is not necessary to include some of the information on the case report forms. Inclusion of the following variables in eHARS in 2020 will allow information associated with GDL to be collected in the HIV surveillance system (i.e. the enhanced HIV/AIDS Reporting System (eHARS)). We anticipate that these changes will create efficiencies in management of geocoded data. Because address data already being collected is used for geocoding activities, we do not anticipate a change in burden associated with these variables.

The proposed variables for GDL are described in Table 2. The new variables addr_type_orig_cd and geographic_level will be designated as required variables for collection.

**Table 2. Proposed Variables for GDL**

| Variable Name | Description | Valid Values |
|---|---|---|
| address_type_cd | Existing address type variable in eHARS. Includes categories that represent the address event type. Will be modified to include two new response options for "Military" and "Other."<br><br>Also collected on the paper-based forms. | BAD - Bad address<br>COR - Correctional facility<br>CUR - Current<br>FOS - Foster home<br>HML - Homeless<br>POS - Postal<br>RAD - Residence at death<br>RBI - Residence at birth<br>RES - Residential<br>RHE - Residence at perinatal exposure<br>RSR - Residence at pediatric seroreversion<br>RSA - Residence at diagnosis of stage 3 HIV infection (AIDS)<br>RSH - Residence at diagnosis of HIV infection<br>SHL - Shelter<br>TMP - Temporary<br>To be determined - Military<br>To be determined - Other |
| addr_type_orig_cd | Additional field for address type information when the address_type_cd captures an address event type (i.e., current, residence at death, residence at birth, residence at perinatal exposure, residence at pediatric seroreversion, residence at diagnosis of stage 3 HIV infection (AIDS), and residence at diagnosis of HIV infection)<br><br>Also collected on the paper-based forms. | BAD - Bad address<br>COR - Correctional facility<br>FOS - Foster home<br>HML - Homeless<br>POS - Postal<br>RES - Residential<br>SHL - Shelter<br>TMP - Temporary<br>To be determined - Military<br>To be determined - Other |

| | | |
|---|---|---|
| geographic_level | Geographic level to which the address was geocoded. | 1=Census tract<br>2=Zip code<br>3=County<br>4=Insufficient |

**Additional Estimated Burden Investigation Reporting and Evaluation**

In 2017, additional variables were requested and approved for monitoring and evaluation of data-to-care not in care investigations of persons identified to be not-in-care and cluster investigations and subsequently added to eHARS.

Health departments are now using the absence of reported test results to HIV surveillance programs to identify persons who may be not in care and may be in need of HIV medical care or other services and link those individuals to needed 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. 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 genetic sequence data can be analyzed to identify clusters of recent and rapid transmission, and ultimately guide the implementation of prevention efforts. In addition to using genetic sequence data, transmission clusters can be identified through analysis of HIV surveillance 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), 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 in 2019 will allow results of transmission cluster analyses to be documented for cases 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 reporting for the estimated subset of persons identified and investigated as part of transmission clusters identified. The additional estimated burden for both cluster investigations and data to care investigations are included in the burden table below under Investigation Reporting and Evaluation.

**Cluster Report Form**

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, including through routine analyses of data reported to the National HIV Surveillance System. 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 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' 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' 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' 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.

**Changes in the Standards Evaluation Report (SER)**

The Standards Evaluation Report (SER) is used by CDC and Health Departments 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 SER includes a brief set of questions about evaluation outcomes and the collection of laboratory data that will be reported one time a year by each 59 health departments. A revised Standards Evaluation Report (SER) is provided in Attachment 3(e) and changes from the last version are outlined in Table 3. Changes are related to the transition from cooperative agreement PS13-1302 to cooperative agreement PS18-1802, 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.

Table 3. Summary of Changes to the Standards Evaluation Report (SER)

| Currently approved SER Form | Proposed SER Form | Changed Proposed | Reason for Change Proposed |
|---|---|---|---|
| Page 3, Section C. Pediatric/ Perinatal | Page 3, Section C. Pediatric/ Perinatal | Added outcome measure "Perinatal HIV Exposure Reporting". | Re-alignment with the requirements of the new cooperative agreement PS18-1802. |
| NA | Page 3, Section D, Geocoding and Data Linkage | Added one question with a Yes/No checkbox to determine if geocoded data was sent to CDC per our joint MOU. | CDC is not able to view geocoded data by the time the SER is due so the question is asked of the jurisdiction. |
| Page 4, Section E, Submission of Required SAS Outcome Tables | Page 4, Section F, Submission of Required SAS Outcome Tables | Rows with Yes/No checkboxes indicating whether SAS outcome tables were attached were added in lines 4, 9, and 10, reading "Cumulative Interstate Duplicate Review", "Geocoding", and "Viral suppression for cluster members". | Re-alignment with the requirements of the new cooperative agreement PS18-1802. |
| Page 4, Section E, Table below | Page 5, Section F, Table below | Rows with "Measure", "Standard" and "Result" were added in lines | Re-alignment with the requirements of the new |

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|---|---|---|---|
| the Yes/No checkboxes | the Yes/No checkboxes | 4, 13, and 15, reading "Cumulative Interstate Duplicate Review", "Geocoding", and "Viral suppression for cluster members". | cooperative agreement PS18-1802. These tables run automatically with CDC developed software thus jurisdiction burden is not impacted. |
| NA | Page 6, Section G, Submission of Required Outcome Standards without SAS Tables | Section G is new. | Re-alignment with the requirements of the new cooperative agreement PS18-1802. |

**Changes in Estimates of Annualized Burden Hours**

We estimate an overall increase in total estimated annualized burden hours for this ICR from 48,026 to 58,131 hours resulting primarily from changes in program activities and refinements made to our burden calculations. This increase is largely due to addition of new surveillance activities that are required to be carried out by grantees under cooperative agreement PS18-1802: Integrated HIV Surveillance and Prevention Programs for Health Departments. Specifically, we have included burden for Investigation Reporting and Evaluation for data to care and cluster investigations. We have also added burden for reporting of a cluster report form to monitor cluster detection and response activities. We also have revised our burden estimate calculations to better estimate the number of electronic laboratory updates resulting in an increased number of responses and reducing time per response to account for improvements in electronic laboratory reporting capacity and computing power and increased efficiencies of established data systems. We have also separated out deduplication activities from case report evaluations to accommodate both Routine Interstate Deduplication Review (RIDR) activities and new Cumulative Interstate Deduplication Review (CIDR), adjusting the time per response to 10 minutes based on feedback from health departments on time for completion of these activities. In addition to these additional data collection activities that increase burden, there are some activities that have been discontinued or changed resulting in reductions in burden. 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 NOFO reducing burden hour for this activity. 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 incorporated into routine surveillance activities and the burden is now reflected under laboratory updates and other case report updates for reporting of the genotype sequence and testing history information. The revised estimate of burden hours is provided in table 12.A.

Exhibit 12.A Estimate of Annualized Burden Hours.

| 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) |
|---|---|---|---|---|---|
| Adult HIV Case Report(att 3a,3c,4a) | 59 | 854 | 50,386 | 20/60 | 16,795 |
| Pediatric HIV Case Report (att 3b,3c,4b) | 59 | 3 | 177 | 20/60 | 59 |
| Case Report Evaluations (att 3a,3b,3c) | 59 | 86 | 5,074 | 20/60 | 1,691 |
| Case Report Updates (att 3a,3b,3c,4a,4b) | 59 | 2353 | 138,827 | 2/60 | 4,628 |
| Laboratory Updates (att 3a,3b,3c,4a,4b) | 59 | 9410 | 555,190 | 0.5/60 | 4,627 |
| Deduplication Activities (att 4c) | 59 | 2741 | 161,719 | 10/60 | 26,953 |
| Investigation Reporting and Evaluation (att 3c,4d,4e) | 59 | 901 | 53,159 | 1/60 | 886 |
| Initial Cluster Report Form (att 3f,4f) | 59 | 2.5 | 148 | 1 | 148 |
| Cluster Follow-up Form (att 3g,4f) | 59 | 5 | 295 | 30/60 | 148 |
| Cluster Close-out Form (att 3h, 4e) | 59 | 2.5 | 148 | 1 | 148 |
| Perinatal HIV Exposure Reporting (PHER) (att 3c,3d,4b) | 16 | 197 | 3,152 | 30/60 | 1,576 |
| Annual Reporting: Standards Evaluation Report (SER)(att 3e) | 59 | 1 | 59 | 8 | 472 |

| | | | | | |
|---|---|---|---|---|---|
| Total Burden | | | | | 58,131 |

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