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

Summary of Changes

We are requesting changes to the information collection request (ICR) for the National HIV Surveillance System (NHSS) OMB #0920-0573. 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)), additional data system variables for management and evaluation of health department investigations, and a reduction of some information collected as part of HIV incidence surveillance. In addition, we are requesting update to contact information in the HIV Surveillance Coordinator and Data Managers listing (**Attachment 6**). Requested changes for forms and data elements have been developed with input of state and local HIV surveillance coordinators and the CSTE HIV subcommittee and are intended to improve data collection and create efficiencies for conducting and evaluating surveillance program activities. Together, the requested changes create opportunities for reductions in data collection through reduced reporting and efficiencies of data collection that balance potential increases in burden that may be associated with the additional data elements requested and will result in no change to the estimated burden hours.

Requested form revisions are non-substantive and will serve to enhance efficiency of data collection. Form revisions include changes in categories to accommodate new tests and testing algorithms, updates to allow HIV surveillance programs to identify acute HIV infections for urgent follow-up and persons with non-laboratory evidence of HIV medical care, and other non-substantial editorial changes aimed to improve format and usability of the ACRF and PCRF. The specific changes to the ACRF and PCRF are summarized below and described in detail in Table 1. Revised forms that include the proposed changes are included in **Attachments 3a and 3b**.

This request also includes the addition of data system variables that may be used by health departments to assist with data management and evaluation of their surveillance activities related to investigations of transmission clusters and persons not in care. Specific variables for cluster transmission investigations are listed in Table 2 and variables for investigations of persons not in care are described in Table 3.

Beginning in 2018, the 25 areas conducting HIV Incidence Surveillance will no longer be required to report recent seroconversion (STARHS) test results to CDC, but may continue to collect STARHS information for local purposes. All areas will continue to collect other information such as testing and treatment (TTH) history obtained as part of HIV Incidence Surveillance activities. Since, information for STARHS results will still be reported by some areas, no changes in the currently approved data elements is requested at this time and these variables will remain in the enhanced HIV/AIDS Reporting System (eHARS).

Finally, we received a request from a member of the public (Ms. Tania Bechtel) to remove her contact information since she is no longer in that position in the Louisiana Health Department in Louisiana and **Attachment 6**, has been updated to remove her contact information.

Changes to the ACRF and PCRF

A revised version of the ACRF is provided in **Attachment 1** and revised PCRF is provided in **Attachment 2**. These forms will replace **Attachments 3a and 3b** of our previously approved ICR. The Residence at Diagnosis sections of the ACRF and PCRF have been revised to update one of the response options for the address type variable from "Residence at AIDS diagnosis" to "Residence at stage 3 (AIDS) diagnosis". This was done to align with the

terminology used in the HIV surveillance case definition and other HIV Incidence and Case Surveillance Branch (HICSB) publications. Similarly, one of the response options for the diagnosis type variable was updated from "AIDS" to "Stage 3 (AIDS)" in the Facility of Diagnosis section to align with the terminology that is used in the case definition and other HICSB publications. In addition, the address date variable associated with residence at diagnosis was removed to be consistent with how information is collected in the current enhanced HIV/AIDS Reporting (eHARS) software (i.e., eHARS version 4.9.1).

On both the ACRF and the PCRF, the Clinical section was moved from page 3 to page 2 of the form to allow more space to capture information in the Laboratory Data section on page 3. Within the Clinical section "If TB selected above, indicate RVCT Number" was updated to "If a diagnosis date is provided for either tuberculosis diagnosis above, provide RVCT Number" to clarify when information is requested. The old wording was likely left over from the time when there was a field on the form to select each diagnosis. This is no longer relevant now that the only field associated with each opportunistic illness is the diagnosis date.

On both the ACRF and the PCRF, page 3 of the forms was updated to dedicate the entire page to the Laboratory Data section. Within the Laboratory Data section, variables were added to capture lab name, ordering facility, and ordering provider for each test type. This change will streamline recording of information on the form and entry of information in eHARS. The layout of the section is now more consistent with organization of data entry screens in in eHARS 4.9.1. Variables to capture test brand name/manufacturer for all test types were also added, as the 2016 version of the form only captured test brand name/manufacturer for the immunoassays. The variables lab name, ordering facility, ordering provider, and brand name/manufacturer are currently approved to be collected for all test types. The requested revision is simply to provide dedicated space to capture the information on the ACRF and PCRF. Throughout the Laboratory Data section, the "Rapid Test (check if rapid)" label was changed to "Point-of-care rapid test" to align with the HIV testing data collection form and to clarify that rapid, in this context, refers to a CLIA-waived test performed outside a laboratory.

Under the HIV-1/2 Type-Differentiating Immunoassay test type, a variable was added to capture the role of the test in the HIV diagnostic algorithm, with the response options, "Screening/initial test" and "Confirmatory/supplemental test" to define the role of the test in the diagnostic algorithm. A second update was made under the HIV-1/2 Type-Differentiating Immunoassay test type to capture both the overall test interpretation and the individual analyte results (qualitative). This update was made to allow for the collection of results from all analytes for tests of this type (e.g., the Geenius). Similarly, an update was also made under the HIV-1/2 Ag/Ab and Type-Differentiating Immunoassay test type to capture both the overall test interpretation and the individual analyte results (qualitative result and index value) to be consistent with how information is collected in eHARS 4.9.1. The changes described for the HIV-1/2 Type-Differentiating Immunoassay test type and the HIV-1/2 Ag/Ab and Type-Differentiating Immunoassay test type do not change the data collection burden as this information was already being reported by laboratories for tests of these types. The current revision was made to allow a dedicated space to capture the information on the ACRF and PCRF. Under the HIV-1/2 Ag/Ab and Type-differentiating Immunoassay test type, the symbol after "Result" was changed from an asterisk (*) to a superscript value of the number 2 to ensure consistency throughout the form and avoid confusion. In every other place on the form, the asterisk is used to represent variables that are not transmitted to CDC; however, it was used here to indicate special instructions.

Within the Laboratory Data section, a new subsection was created to capture drug resistance tests (genotypic) in a format similar to other test types. This was done to allow HIV surveillance programs to report if there was evidence that drug resistance testing was performed. It is not practical to collect the results from the genotype test on the case report form. This variable can be used as part of quality assurance to ensure that if drug resistance testing was ordered that a genotype type result with a sequence is also reported. The NHSS has

already been approved to collect drug resistance tests (genotypic), so this change allows a dedicated space for this information to be captured on the ACRF and PCRF.

Finally, minor formatting changes [e.g., updating instructions from "(Check all that apply)" to "(check all that apply)"] were made throughout the ACRF and PCRF to make formatting consistent throughout the forms. The horizontal perforation on the form was also removed as it is no longer necessary to separate the Patient Identification section from the remainder of the form.

Technical guidance documents including instructions for completing the new 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 ACRF Only

A revised ACRF is provided in **Attachment 1** and changes to the form are outlined in Table 1. New information was added to the Clinical section of the ACRF to allow HIV surveillance programs to identify acute HIV infections for urgent follow-up. Questions were added to capture if acute HIV infection was suspected and if yes, to document if clinical signs/symptoms of acute infection or other evidence suggestive of acute infection were present. In this section, the "Clinical" heading was also updated to "Clinical: Acute HIV Infection and Opportunistic Illnesses" to reflect the expanded content of this section. A sub-header of "Opportunistic Illnesses" was also added to separate the fields to distinguish the fields related to acute HIV infection from the fields related to opportunistic illnesses.

Within the Treatment/Services Referrals section, questions were added to collect information on if there is any evidence of receipt of HIV medical care other than laboratory test result. The response options include "1-Yes, documented "or "2-Yes, client self-report, only" along with the date of medical visit or prescription. These questions were added for use in care continuum analyses and working of lists of persons not in care. In addition, the variable "Child's Coded ID" was removed from the Treatment/Services Referrals section, as it is no longer necessary to have a place on the form to collect this information as sites no longer have code-based reporting. It will still be possible to enter this information in eHARS, if needed.

Finally, the "HIV Antiretroviral Use History" section header was changed to "Antiretroviral Use History" on the ACRF to provide a more accurate description, as this section also captures information about hepatitis B treatment.

Changes to the PCRF Only (Attachment 3B)

A revised PCRF is provided in **Attachment 2** and changes to the form are outlined in Table 1. Within the Birth History section of the PCRF, six date variables (i.e., "Date: _ _/_ _/_ _ _ _") were added to capture the "Date began" and "Date of last use" for the three variables pertaining to the mother's antiretroviral (ARV) use. This update was made to be consistent with how information is collected in eHARS 4.9.1. The response option of "Refused" was also added to "Did mother receive any ARVs during this pregnancy?" and "Did mother receive any ARVs during labor and delivery?" to mirror how data are collected in eHARS 4.9.1. Finally, the response option "3->2" was changed to "3-More than two" for the Type variable in the Birth History section for clarity.

In the Clinical section of the PCRF, the "Clinical" heading was updated to "Clinical: Opportunistic Illnesses" to be more consistent with the ACRF heading.

Within the Services Referrals section, the format was updated for capturing the neonatal ARVs for HIV prevention and the antiretroviral therapy for HIV treatment variables to align with how treatment information is captured on the ACRF and to mirror how data are collected in eHARS 4.9.1. This required the addition of a field for the drug reason associated with both variables and adding a place to capture the drug name for ARVs associated with HIV treatment. In addition, the "Service Referrals" heading was updated to "Treatment/Services Referrals" to match the heading within eHARS and align with the ACRF.

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: Residence at Diagnosis, Variable: Address Type	Updated one of the response options from "Residence at AIDS diagnosis" to "Residence at stage 3 (AIDS) diagnosis".	To align with terminology used in the case definition and HICSB publications.
Page 1, Section: Residence at Diagnosis, Variable: Address Date	Removed this variable associated with the residence at diagnosis.	This information is redundant with HIV test date information already collected in the laboratory data section of the form. This change on the form is consistent with how HIV diagnosis dates are calculated and used in eHARS 4.9.1 for the date of the address at HIV diagnosis. This change will have a minimum decrease in burden. (See description in changes in burden section below.)
Page 2, Section: Facility of Diagnosis, Variable: Diagnosis Type	Updated one of the response options from "AIDS" to "Stage 3 (AIDS)".	To align with terminology used in the case definition and HICSB publications.
Page 2, Section: Clinical, Variable: N/A	Moved the Clinical section from page 3 to page 2 of the form.	To allow more room to capture information in the Laboratory Data section on page 3.
Page 2, Section: Clinical, Variable: RVCT Number	Changed from "If TB selected above, indicate RVCT Number" to "If a diagnosis date is provided for either tuberculosis diagnosis above, provide RVCT Number".	To clarify when information is requested. This wording was likely from when there was a field on the form to select each diagnosis and is no longer relevant now that the only field associated with each opportunistic illness is the diagnosis date.
Page 3, Section: Laboratory Data, Variable: N/A	Dedicated page 3 of the form to the Laboratory Data section.	To allow more room to capture information in the Laboratory Data section.
Page 3, Section: Laboratory Data, Variables: Lab name, Facility name, Provider name, Test brand name/manufacturer	The variables lab name, ordering facility, ordering provider, and brand name/manufacturer have already been approved to be collected for all test types. The current revision was made to allow a dedicated space to capture the information	To be consistent with how the information is collected in eHARS 4.9.1.

	on the ACRF and PCRF.	
Page 3, Section: Laboratory Data, Variable: HIV-1/2 Type-Differentiating	Added a variable to capture the role of the test in the HIV diagnostic algorithm, update to capture both an overall test interpretation and individual analyte results (qualitative). These updates do not change the data collection burden as this information was already being reported by laboratories for tests of these types. The current revision was made to allow a dedicated space to capture the information on the ACRF and PCRF.	To allow collection of results from all analytes for tests of this type (e.g., Geenius) and to define the role of the test in the diagnostic algorithm.
Page 3, Section: Laboratory Data, Variable: HIV-1/2 Ag/Ab and Type-Differentiating Result	Updated to capture an overall test interpretation and individual analyte results (qualitative result and index value). These updates do not change the data collection burden as this information was already being reported by laboratories for tests of these types. The current revision was made to allow a dedicated space to capture the information on the ACRF and PCRF.	To be consistent with how the information is collected in eHARS 4.9.1.
Page 3, Section: Laboratory Data, Variable: Drug Resistance Tests	Created a new subsection to capture drug resistance tests (genotypic) in a format similar to other test types. Drug Resistance Tests (Genotypic) TEST □ HIV-1 Genotype (Unspecified) Test brand name/manufacturer Lab name Facility name Provider name Collection Date __ __ /__ __ /__ __ __ ___ The NHSS has already been approved to collect drug resistance tests (genotypic), so this change allows a dedicated space for this information to be captured on the ACRF and PCRF.	To allow HIV surveillance programs to report if there was evidence that drug resistance testing was performed. It is not practical to collect the results from the genotype test on the case report form. This variable can be used as part of quality assurance to ensure that if drug resistance testing was ordered that a genotype type result with a sequence is also reported. This new variable will not be used as part of any calculated variables in eHARS associated with the case definition (e.g., hiv_dx_dt).
Page 3, Section: Laboratory Data, Variable: Rapid Test	Updated label from "Rapid Test (check if rapid)" to "Point-of-care rapid test".	To align with the HIV testing data collection form and clarify that rapid refers to a CLIA waived test performed outside a laboratory.
Page 3, Section: Laboratory Data, Variable: HIV-1/2 Ag/Ab and Type-differentiating Result	Changed the symbol used after RESULT* from an asterisk (*) to a different symbol.	Updated to a new symbol to avoid confusion. In every other place in the document the * is used to represent variables that are not transmitted to CDC. Here is it used after the variable to indicate special instructions.

All	Removed horizontal perforation on the form that separates the Patient Identification section from the remainder of the form.	It is no longer necessary to separate the Patient Identification section from the remainder of the form.
All	Made minor formatting changes (e.g., update instructions from "(Check all that apply)" to "(check all that apply)".	To make formatting consistent throughout the form.
ACRF only		
Page 2, Section: Clinical, Variable: Suspect acute HIV infection	Added the following questions and responses: Suspect acute HIV infection? □ Yes □ No □ Unknown *If YES, complete the two items below; enter documented negative HIV test data in Laboratory Data section, and patient or provider report of previous negative HIV test in HIV Testing History section.*Clinical signs/symptoms consistent with acute retroviral syndrome (e.g., fever, malaise/fatigue, myalgia, pharyngitis, rash, lymphadenopathy)? □ Yes □ No □ Unknown Date of sign/symptom onset __ __ /__ __ /__ __ __ ___ Other evidence suggestive of acute HIV infection? □ Yes □ No □ Unknown *If YES, please describe:* _____ Date of evidence __ __ /__ __ /__ __ __ ___	To allow HIV surveillance programs to identify acute HIV infections for urgent follow-up. This will have a minimal increase in burden. (See description in changes in burden section below.)
Page 2, Section: Clinical, Variable: N/A	Updated the section label from "Clinical" to "Clinical: Acute HIV Infection and Opportunistic Illnesses". Added a sub-header of "Opportunistic Illnesses" to separate the fields to capture information about acute HIV infection from the fields to capture opportunistic illnesses.	To provide further description in the section label to reflect the expanded content of this section.
Page 4, Section: Treatment/Services Referrals, Variable: Child's Coded ID	Removed this variable from the hard copy form.	It is no longer necessary to have a place on the form to collect this information as states no longer have code-based reporting. The child's state number, which is also on the form, is used by all jurisdictions now for this purpose. It will still be possible to enter this information in eHARS, if needed This change will represent a minimum decrease to no impact on burden since collection is no longer required and states have not been collecting or reporting this optional information in recent years.

Page 4, Section: Treatment/Services Referrals, Variable: Evidence of receipt of HIV medical care (other than laboratory test result)	Added the following questions and response options: Evidence of receipt of HIV medical care other than laboratory test result (select one; record additional evidence in Comments) □ 1-Yes, documented □ 2-Yes, client self-report, only Date of medical visit or prescription __ __ /__ __ /__ __ __ ___	To be used for care continuum analyses and working of lists of person who are not in care This will relate to a minimum increase in burden because it will be optional for areas to collect and when collected will be imported from other systems. (See description in changes in burden section below.)
Page 4, Section: HIV Antiretroviral Use History, Variable: N/A	Changed the label for the section to "Antiretroviral Use History".	To provide a more accurate description since this section also captures information about hepatitis B treatment.
PCRF only		
Page 4, Section: Birth History, Variable: Type	Changed one of the response options from "3->2" to "3-More than two".	To clarify the response option.
Page 4, Section: Birth History, Variable: Did mother receive any ARVs prior to this pregnancy?	Added the following questions and responses: Date began __ __ /__ __ /__ __ __ ___ Date of last use __ __ /__ __ /__ __ __ ___	To be consistent with information collected in eHARS 4.9.1. There is a minimum to no increase in burden for these dates since they are already collected for adult women with diagnosed HIV infection on the ACRF and can be transferred from that form. Additionally, since the question of ARV use is already collected on the PCRF there would be only a minimal burden to record the corresponding dates on the PCRF for the very small number abstracted from medical records. Adding this to the PCRF ensures standardization across the two data collection instruments. (See description in changes in burden section below.)
Page 4, Section: Birth History, Variable: Did mother receive any ARVs during this pregnancy?	Added option of "Refused". Add the following questions and responses: Date began __ __ /__ __ /__ __ __ ___ Date of last use __ __ /__ __ /__ __ __ ___	To be consistent with information collected in eHARS 4.9.1.
Page 4, Section: Birth History, Variable: Did mother receive any ARVs during labor and delivery?	Added option of "Refused". Added the following questions and responses: Date began __ __ /__ __ /__ __ __ ___ Date of last use __ __ /__ __ /__ __ __ ___	To be consistent with information collected in eHARS 4.9.1.

Page 2, Section: Clinical, Variable: N/A	Updated the section label from "Clinical" to "Clinical: Opportunistic Illnesses".	To be more consistent with ACRF heading.
Page 4, Section: Service Referrals, Variable: Neonatal ARVs for HIV prevention and antiretroviral therapy for HIV treatment	Updated format to align with how treatment information is captured on the ACRF. This required adding a) a field for the drug reason associated with both variables and b) a place to capture the drug name for ARVs associated with HIV treatment.	To be consistent with how the information is collected in eHARS 4.9.1.
Page 4, Section: Service Referrals, Variable: Heading	Updated heading from "Service Referrals" to "Treatment/Services Referrals".	To match the heading within eHARS and align with the ACRF.

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

Additional Data System Variables to Assist with Investigations of Transmission Clusters

The National HIV Surveillance System (NHSS) is the primary source for monitoring HIV infection in the United States. 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. Through Molecular HIV surveillance (MHS), a component of the NHSS, surveillance jurisdictions collaborate with laboratories to collect genetic sequences that are generated from drug resistance testing performed as part of routine HIV medical care. Using methodology developed by CDC, 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 proposing the addition of variables to assist health departments with monitoring clusters systematically and evaluating cluster investigation activities. Health department surveillance investigation activities are separate from case reporting and therefore it is not necessary to include these new variables on the paper-based case report forms. Inclusion of the following variables in eHARS in 2018 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. Because these variables will only apply to the small subset of persons identified and investigated as part of transmission clusters identified, we do not anticipate a change in burden associated with these new variables.

The proposed variables for are described in Table 2.
Table 2. Proposed Variables for Transmission Clusters

Variable Name	Description	Valid Values
cluster_uid	Cluster ID alphanumeric identifier	A-Z, 0-9,-,_, blank

cluster_ident_method	Method of cluster identification	01 - State/local molecular cluster analysis 02 - National molecular cluster analysis 03 - State/local time-space cluster analysis 04 - National time-space cluster analysis 05 - Provider notification 06 - Partner services notification 88 - Other
person_ident_method	Method the person was identified as part of this cluster	1 - Through analysis/notification 2 - Through investigation
person_ident_dt	Date the person was identified as part of this cluster	YYYYMMDD
invest_cluster_seq	System generated sequence number	Numeric values
invest_type_cd	Type of investigation	0 – Transmission cluster

Additional Data System Variables to Assist with Investigations of Persons Not in Care

Health departments are increasingly using data from HIV surveillance to monitor care outcomes of persons diagnosed with HIV. HIV viral load and CD4 test results routinely reported as part of HIV surveillance can be used as a proxy for care visits and be used to estimate the proportion of persons with diagnosed HIV infection who have been linked to care or retained in care over time. Additionally, health departments may use 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. 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 proposed new variables will assist health departments in monitoring and evaluation of 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 from other data systems used to manage these activities in the health departments. Although these variables will be available in eHARS in 2018, we anticipated that jurisdictions will be in various stages of implementation and not be reporting this information until 2019. Therefore, there is no change in burden associated with the inclusion of these variables at this time.

The proposed variables for are described in Table 3.

Table 3. Proposed Variables for Not-in-Care Investigations

Variable name	Description	Valid Values
invest_case_seq	Sequence number to make the record unique	System-generated numeric values

invest_type_cd	Type of investigation	1 – Not in care
invest_ident_method	How person was first identified as needing investigation	01 – Health department HIV surveillance system (e.g., eHARS) 02 – Health department integrated data system 03 – Provider report 04 – Transmission cluster investigation 05 – Elevated viral load investigation 06 – Partner services investigation 07 – Medical Monitoring Project (MMP) 88 – Other
invest_ident_dt	Date first identified as needing investigation	YYYYMMDD
invest_incl	Included in investigation	Y – Included in investigation N – Excluded from investigation
invest_start_dt	Date investigation opened	YYYYMMDD
invest_dispo	Investigation disposition	1 – Deceased 2 – Resides out of jurisdiction 3 – In care 4 – Not in care (confirmed) 5 – Unable to determine
invest_dispo_dt	Investigation disposition date	YYYYMMDD
invest_dispo_method	Basis of investigation disposition	1 – Database/record search, only 2 – Patient contact/field investigation, only 3 – Database/record search and patient contact/field investigation
int_dispo	Intervention disposition	1 – No intervention initiated 2 – Linkage/re-engagement intervention declined by client 3 – Returned to care before linkage/re-engagement intervention was initiated 4 – Linkage/re-engagement intervention initiated, not successfully linked to/re-engaged in care 5 – Linked to/re-engaged in care, documented 6 – Linked to/re-engaged in care, client self-report, only 7 – Linkage/re-engagement status unknown
int_dispo_dt	Intervention disposition date	YYYYMMDD

Change in HIV Incidence Surveillance Data Collection

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. Therefore, beginning in 2018, health

departments participating in HIV Incidence Surveillance activities will no longer be required to collect information on STARHS results (i.e., recency results from biomarker tests that distinguish recent from long-standing infection) for the purpose of estimating HIV incidence. However, health departments may continue to collect and enter recency results in eHARS for purposes of describing recency of infection in their jurisdictions and will continue to collect information on testing and treatment history. We anticipate that some areas will scale down the collection of STARHS results over the next year and these jurisdictions will still have some burden associated with this scale down of their data collection resulting in no change in burden hours. Because data collection and entry will continue, the data management system (eHARS) will continue to allow data entry and management of the currently OMB approved variables associated with STARHS results and TTH and no deletion of data elements are required.

Update to the HIV Surveillance Coordinator Contact Information in Attachment 6.
We received a request from a member of the public (Ms. Tania Bechtel) to remove her contact information since she is no longer in that position in the Louisiana Office of Public Health. We removed her contact information from page 18 of **Attachment 6**.

Changes in Estimates of Annualized Burden Hours

We estimate no change in estimated annualized burden hours for this ICR as part of this change request. The requested changes are non-substantial and include formatting changes and modifications to existing approved data elements. A few changes in variables that will have some minimal increase or decrease in burden. Specifically, removal of the date associated with the residence at HIV diagnosis can be considered to be a minimal decrease in burden because eHARS calculates the date of diagnosis elsewhere in the application from the test dates entered in the laboratory data section. The collection of the address date at diagnosis is redundant and removing this from the form decreases burden of recording this date in multiple places. Additional variables for acute infection will have a minimal increase in burden because only a very small percentage of new diagnoses (e.g., less than 4%) will meet the criteria for acute infection due to the very short diagnostic window and will have the necessary information documented in medical records to report acute infection.   It is no longer necessary to have a place on the form to collect information for the variable Child's Coded ID because states no longer have code-based reporting. The child's state number, which is also on the form, is used by all jurisdictions now for this purpose. This change will represent a minimum decrease to no impact on burden since collection is no longer required and states have not been collecting or reporting this optional information in recent years.   The addition of the variable: evidence of receipt of HIV medical care (other than laboratory test result) will have a minimum increase in burden because it will be optional for areas to collect and when collected it will be imported from other data systems and not involve new data collection. However, the use of this variable is likely to result in some reduction in burden over time by enabling jurisdictions to better identify in their surveillance data, persons who may be in care and should not be included in NIC investigations when used. We estimate a minimum increase in burden for the addition of dates to the variable:*"Did mother receive any ARVs prior to this pregnancy?* "since these dates are already collected for adult women with diagnosed HIV infection on the ACRF and can be transferred from that form. Additionally, since the question of ARV use is already collected on the PCRF there would be only a minimal burden to record the corresponding dates on the PCRF for the very small number abstracted from medical records. Adding this to the PCRF ensures standardization across the two data collection instruments. Considered together these changes in burden result in no overall change in the total annual burden hours of data collection for the ACRF and PCRF.

New data elements requested for monitoring and evaluation of health department investigations will have minimal impact on burden hours for this ICR. Specifically, data elements for monitoring and evaluating transmission cluster investigations will be collected on only a small subset of all persons diagnosed and reported through HIV surveillance that are identified as being in transmission clusters and investigated. Data

elements for investigations of persons not in care will be imported from other databases used by health departments for these activities and these data elements will not be reported until areas develop and implement procedures for investigations of persons identified as not in care in their jurisdictions. On balance, these requested changes result in no overall change in burden because the minor increases that may be attributed to new variables is minimal and will be offset by reductions in burden due to scaling down of reporting of STARHS results and efficiencies gained from data element modifications.

Exhibit 12.A provides the current burden table for this ICR indicating there are no changes in burden.

Exhibit 12.A Estimates of Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Total No. of Annual Responses	Avg. Burden per Response (in hours)	Total Annual Burden (in hours)
Health Departments	Adult HIV Case Report(att 3a,3c,4a)	59	1,061	62,599	20/60	20,866
Health Departments	Pediatric HIV Case Report (att 3b,3c,4b)	59	5	295	20/60	98
Health Departments	Case Report Evaluations (att 3a,3b,3c)	59	107	6,313	20/60	2,104
Health Departments	Case Report Updates (att 3a,3b,3c,4a,4b)	59	1,576	92,984	2/60	3,099
Health Departments	Laboratory Updates (att 3a,3b,3c,4a,4b)	59	6,303	371,877	1/60	6,198
Health Departments	HIV Incidence Surveillance (HIS) (att 3a,3c,4c)	25	2,288	57,200	10/60	9,533
Health Departments	Molecular HIV Surveillance (MHS) (att 3a,3b,3c, 4a,4d)	53	829	43,937	5/60	3,661
Health Departments	Perinatal HIV Exposure Reporting (PHER) (att 3c,3d,4b)	35	114	3,990	30/60	1,995
Health Departments	Annual Reporting: Standards Evaluation Report (SER) (att 3e)	59	1	59	8	472

Health Departments	Annual Reporting: Annual Performance Report (APR) (att 3f)	59	1	59	42	2,478
Total						50,504

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