

National HIV Surveillance System (NHSS)

Attachment 11.

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

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National HIV Surveillance System (NHSS) OMB #
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Summary of Revisions

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

CDC monitors data quality and implementation of HIV surveillance programs and health departments report on their progress twice a year using process and outcome standards. Findings from these reports are used to improve data quality, interpretation, usefulness, and efficiency, as well as to monitor performance and progress in achieving both state and national HIV surveillance program objectives. The SER consists of a brief set of questions specific to data evaluation standards and laboratory reporting that minimizes the reporting burden on health departments. CDC provides standard SAS programs that can be run on state and local surveillance databases to extract the needed evaluation data in the report. Laboratory reporting questions are used to characterize the completeness and quality of data reported from laboratories in each jurisdiction. The information collected on laboratory data and data quality measures are used to ensure the accuracy, timeliness, and

completeness of the national HIV surveillance data which are widely used and disseminated and critical for monitoring and evaluating the objectives of the National HIV/AIDS Strategy (NHAS). In addition, health departments annually provide a narrative report describing their progress towards achieving program objectives including an implementation plan and timeline as part of the APR. The project narratives, implementation plans and timelines of the APR are critical for ensuring funded programs are making adequate progress toward meeting program objectives outlined in the cooperative agreement for the NHSS. See attachments 3(e) and 3(f) for information collected for the SER and the APR.

Form revisions requested in this ICR will generally enhance efficiency of data collection and not increase the burden of current data collection. Form revisions include necessary changes related to advances in testing technologies (e.g., categories to accommodate new tests and testing algorithms) and advances in antiretroviral (ARV) treatments (e.g. differentiating reasons for treatment such as pre-exposure prophylaxis) and other non-substantial editorial changes aimed to improve format and usability of the ACRF, PCRF, and PHER forms (e.g., standardization of date variables). The specific changes to the ACRF, PCRF, and PHER form are summarized below and described in Table 1 at the end of this document.

Summary of Revisions to the ACRF and PCRF

New categories of diagnostic tests have become available. The first category can detect and distinguish between HIV-1 antigen and HIV-1/2 antibody. The second category can detect and distinguish among HIV-1 antigen, HIV-1 antibody, and HIV-2 antibody. However, the current versions of the ACRF and PCRF do not include the new categories of tests or result options that are necessary to accurately capture the results of these tests. Also, some test categories on the current ACRF and PCRF refer to "type-differentiating tests", but the newly available tests can distinguish between antigen and antibody, which are analytes, not "types" (HIV-1 vs. HIV-2). The ACRF and PCRF have been updated to include the new tests and result options.

The Patient Identification and Residence at Diagnosis sections of the ACRF and PCRF have been updated to add the address date associated with the current street address and the residence at diagnosis street address. "Address Date" has been added after "Current Address, Street" in the Patient Identification section. The phone, city, county, state/country and zip code has been shifted to account for the addition of the address date and "Address Date" has been added after "Street Address" in the Residence at Diagnosis section. Health departments need this information to accurately capture the date associated with the patient's current address and address at diagnosis in the NHSS. Assessment of the most recent location of residence is critical for areas that are providing

assistance in linking patients to care and for retention in care activities as well as more accurate data on the number of persons currently living with HIV in a jurisdiction to better focus care and preventions services and target funding.

The Patient Identification and Health Department Use Only sections of the ACRF and PCRF have been updated to add instructions "(record all dates as mm/dd/yyyy)" to be consistent with all other sections of the forms with dates that have guidance to inform the user how to accurately record dates.

The facility type associated with the child's facility of birth was added to the Treatment/Services Referrals section on the ACRF and the Birth History section on the PCRF. Health departments currently capture facility type of birth in the NHSS. The form was updated to allow a location for health departments to capture the information for entry into the NHSS. Finally, the notation indicating if a variable is transmitted to CDC (i.e., "**") was corrected for several variables. Medical record number and person completing the form were removed from the State/Local Use Only section of both the ACRF and PCRF because this information is captured in the Patient Identification section and Facility Providing Information section. The OI check boxes were removed for opportunistic illnesses (OI) in the Clinical section on the ACRF and PCRF to streamline format. Minor label edits are specified in Table 1.

Summary of Revisions to the ACRF only

The HIV Testing and Antiretroviral Use History section of the ACRF currently includes questions that capture whether a person has ever taken antiretrovirals (ARVs) (for any purpose), the names of the ARVs taken, the dates ARVs first began, and the dates of last use. This section is being revised to collect information to monitor and differentiate the reasons for ARV use: for HIV treatment, for pre-exposure prophylaxis (PrEP), for post-exposure prophylaxis (PEP), to prevent mother to child transmission during pregnancy, for hepatitis B treatment, and, if needed, for other reason (reason to be specified by surveillance staff completing the ACRF). The changes to this section include separating out the questions related to HIV testing and the questions related to ARV use to improve clarity and readability. Response options in this section that previously differentiated "Refused" from "Don't Know/Unknown" have been combined into a single response option with the label "Unknown" as changes in data collection and analysis practices no longer require differentiation between the two response options.

Summary of Revisions to the PCRf only

Within the Patient History section, the numbers preceding the response options for the question "Child's biological mother's HIV infection status" were removed. This change was made to minimize potential errors when entering the information into the reporting system. Three opportunistic infections (i.e., Carcinoma, invasive cervical, M. tuberculosis, pulmonary X, and Pneumonia, recurrent in

a 12 mo. period) were added to the Clinical section of the PCRf to reflect the current HIV Surveillance Case Definition. In addition, three date variables (i.e., "Date: __/__/____") were removed from the Services Referrals section and replaced with "Date began: __/__/____" and "Date of last use: __/__/____". This change was made to mirror what is planned for data collection in the next reporting software update.

Summary of Revisions to the PHER Form

The top of the PHER form currently includes a space to write a State Number; however it is not clear if this State Number belongs to the infant or the mother. This section is being revised to collect the infant and the mother's state number to prevent confusion and allow the user to link data from the PHER Form to the ACRF and the PCRf. The City Number of the infant and the mother was also added as this is the primary case identifier in some separately funded cities.

Two questions on the PHER form were revised to correct skip patterns. Question 8 was revised to capture any available toxicology screen results on the mother (question 9) regardless of the answer to question 8. A toxicology screen could have been done even if evidence of substance use was omitted from the medical or social work records. Question 15 was also revised to capture any available birth information in question 17, regardless of whether the mother was referred for HIV care post-delivery (question 15).

The Antiretroviral Drugs section was entirely removed from the PHER form, as the list of current ARVs is constantly evolving and we are not able to keep up with the changes in real time. In addition, we do not provide a list of drugs on the ACRF or PCRF and we want these forms to be as consistent as possible.

Finally, the changes to the PHER form include revisions to the formatting (e.g., inserted page numbers and corrected spacing issues) to improve clarity and readability. The changes also include minor modifications to update typographical errors (e.g., replaced the reference to page 8 with a reference to page 4).

The previous burden associated with this ICR was 53,700 hours. The total requested burden for this ICR is 50,504 hours. This represents a reduction of 3,194 hours or 6% decrease overall. The decrease is largely due to decreases in the number of stage 3 (AIDS) case reports nationally which is accounted for in our burden calculations. Additionally, since the last ICR, CDC has made improvements in national data processing resulting in improved data quality and deduplication of cases which also contributes to reduction in case counts used in our burden calculations. These factors are counterbalanced by anticipated increases in laboratory and case report updates among persons living with HIV and the burden included for annual reporting of the SER and Laboratory Report and APR. Together these factors result in a small overall change in the burden requested in this ICR.

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

Location in Document	Modifications to the ACRF Attachment 3(a), the PCRF form Attachment 3(b) and PHER Attachment 3(d)
Location in Document	Modifications made only to the ACRF
Attachment 3a: Top half of page 4; Treatment/Services Referrals section	<ul style="list-style-type: none"> Removed the words "the" and "section" from the "For Children of Patient" header.
Attachment 3a: Top half of page 4; Treatment/Services Referrals section	<ul style="list-style-type: none"> Changed the variable label from "Child Soundex" to "Child's Last Name Soundex".
Attachment 3a: Top half of page 4; Treatment/Services Referrals section	<ul style="list-style-type: none"> Added formatting to designate the date format to be used for "Child's Date of Birth" variable. Inserted _ _/_ _/_ _.
Attachment 3a: Top half of page 4; Treatment/Services Referrals section	<ul style="list-style-type: none"> Updated the variable label "Hospital of Birth (if child was born at home, enter "home birth")" to "Facility Name of Birth (if child was born at home, enter "home birth")".
Attachment 3a: Top half of page 4; Treatment/Services Referrals section	<ul style="list-style-type: none"> Changed the variable label from "Hospital Name" to "Facility Type". Added selected facility type categories and values. Included the category "Inpatient" with the values of "Hospital" and "Other, specify". Included the category "Outpatient" with the value of "Other, specify". Included the category "Other Facility" with the values of "Emergency Room", "Corrections", "Unknown", and "Other, specify".
Attachment 3a: Top half of page 4; Treatment/Services Referrals section	<ul style="list-style-type: none"> Moved the variable label "Phone" up one line to come after "Facility Name of Birth...". Added the standard designation for the phone number format (i.e., Phone ()_____).
Attachment 3a: Top half of page 4; HIV Antiretroviral Use History section and HIV Testing History section	<ul style="list-style-type: none"> Separated out the HIV testing-related questions from the antiretroviral use-related questions in the "HIV Testing and Antiretroviral Use History" section and created two separate sections. In the "HIV Antiretroviral Use History" section: <ul style="list-style-type: none"> Created section header "HIV Antiretroviral Use History (record all dates as mm/dd/yyyy)". Deleted "testing and treatment history" from the first question, replacing with "antiretroviral (ARV) use" and added a colon (:) at the end of the first question, "Main source of testing and treatment history information (select one)". Removed "/PEMS" from the "NHM&E/PEMS" choice in the first question.

- o Retained in first row "Date patient reported information __ /__ /__ __".
- o In the second row, retained the question "Ever taken any ARVs?". Combined the response options "Refused" and "Don't Know/Unknown" into a single response labeled "Unknown".
- o Added a third row of the "HIV Antiretroviral Use History" section that modified the collection of antiretroviral medications to include the reason for antiretroviral use:
 - "If yes, reason for ARV use (select all that apply):"
 - HIV Tx ARV medications:_____
 - Date began: __ /__ /__ __
 - Date of last use: __ /__ /__ __
 - PrEP ARV medications:_____
 - Date began: __ /__ /__ __
 - Date of last use: __ /__ /__ __
 - PEP ARV medications:_____
 - Date began: __ /__ /__ __
 - Date of last use: __ /__ /__ __
 - PMTCT ARV medications:_____
 - Date began: __ /__ /__ __
 - Date of last use: __ /__ /__ __
 - HBV Tx ARV medications:_____
 - Date began: __ /__ /__ __
 - Date of last use: __ /__ /__ __
 - Other _____ ARV medications:_____
 - Date began: __ /__ /__ __
 - Date of last use: __ /__ /__ __
- In the "HIV Testing History" section below the "HIV Antiretroviral Use History" section:
 - o Revised existing section header "HIV Testing and Antiretroviral Use History" (if required by Health Department) (record all dates as mm/dd/yyyy)" and deleted "and Antiretroviral Use" and "(if required by Health Department)".
 - o Deleted "and treatment" from the first question and added a colon (:) at the end of the first question, "Main source of testing and treatment history information (select one)".
 - o Removed "/PEMS" from the "NHM&E/PEMS" choice in the first question.
 - o Combined the response options "Refused" and "Don't Know/Unknown" into a single response option labeled "Unknown" for the questions "Ever had previous positive HIV test", "Ever had a negative HIV test", and "Number of negative HIV tests within 24 months before first positive test".

Location in Document	Modifications made only to the PCRf
Attachment 3b: Bottom half of page 2; Patient History section	<ul style="list-style-type: none"> Removed the number and hyphen (-) at the beginning of each check box option associated with the variable label "Child's biological mother's HIV infection status (select one):".
Attachment 3b: Bottom half of page 2; Patient History section	<ul style="list-style-type: none"> Removed extra space between "had" and "HETEROSEXUAL" in the "Biological Mother had HETEROSEXUAL relations with any of the following:" header.
Attachment 3b: Bottom half of page 3; Clinical section	<ul style="list-style-type: none"> Added the following three OI's to the section: "Carcinoma, invasive cervical", "M. tuberculosis, pulmonary", and "Pneumonia, recurrent in a 12 mo. period".
Attachment 3b: Bottom half of page 3; Clinical section	<ul style="list-style-type: none"> Removed columns 1 and 2 of the last row of the section (i.e., Removed the variable label "Has this child been diagnosed with pulmonary tuberculosis?" along with the variable label "Date").
Attachment 3b: Bottom half of page 3; Clinical section	<ul style="list-style-type: none"> Shifted the text in column 3 of the last row of this section (i.e., "If TB selected above, indicate RVCT Case Number") to the left and put the text on one line as on the ACRF.
Attachment 3b: Top half of page 4; Birth History (for Perinatal Cases only) section	<ul style="list-style-type: none"> Added a header (in green) for "Residence at Birth".
Attachment 3b: Top half of page 4; Birth History (for Perinatal Cases only)section	<ul style="list-style-type: none"> Removed "Residence at Birth" variable label and shifted the text "Check if SAME as Current Address" to the left.
Attachment 3b: Top half of page 4; Birth History (for Perinatal Cases only)section	<ul style="list-style-type: none"> Changed the header (in green) from "Hospital of Birth" to "Facility of Birth".
Attachment 3b: Top half of page 4; Birth History (for Perinatal Cases only)section	<ul style="list-style-type: none"> Changed the variable label "Facility Name" to "Facility Name of Birth (if child was born at home, enter "home birth")".
Attachment 3b: Top half of page 4; Birth History (for Perinatal Cases only)section	<ul style="list-style-type: none"> Added new variable "Facility Type" for consistency with the revised ACRF.
Attachment 3b: Top half of page 4; Birth History (for Perinatal Cases only)section	<ul style="list-style-type: none"> Added an asterisk (*) at the beginning of "ZIP Code".

Attachment 3b: Top half of page 4; Birth History (for Perinatal Cases only)section	<ul style="list-style-type: none"> Replaced the colon (:) with a question mark (?) at the end of the variable label "Did mother received any antiretrovirals (ARVs) prior to this pregnancy:".
Attachment 3b: Top half of page 4; Birth History (for Perinatal Cases only)section	<ul style="list-style-type: none"> Changed "Maternal Soundex" to "Maternal Last Name Soundex".
Attachment 3b: Top half of page 4; Birth History (for Perinatal Cases only)section	<ul style="list-style-type: none"> Removed the colon (:) at the end of the variable label "*Other Maternal ID - List Type:".
Attachment 3b: Top half of page 4; Birth History (for Perinatal Cases only)section	<ul style="list-style-type: none"> Removed the colon (:) at the end of the variable label "Number".
Attachment 3b: Bottom half of page 4; Services Referrals section	<ul style="list-style-type: none"> Removed the three date variables (i.e., "Date: _ _/_ _/_ _ _") and replaced with "Date began: _ _/_ _/_ _ _" and "Date of last use: _ _/_ _/_ _ _".
Attachment 3b: Bottom half of page 4; Services Referrals section	<ul style="list-style-type: none"> Shifted the "Yes" checkbox to the left for "Neonatal ARVs for HIV prevention".
Attachment 3b: Bottom half of page 4; Services Referrals section	<ul style="list-style-type: none"> Shifted the "Yes" checkbox to the left for "Anti-retroviral therapy for HIV treatment".
Location in Document	Modifications to the ACRF and PCRF
Attachment 3a: Bottom half of page 1, 2, 3, and 4; Footer Attachment 3b: Bottom half of page 1, 2, 3, and 4; Footer	<ul style="list-style-type: none"> Updated the revision date of the form from 3/2013 to 9/2015.
Attachment 3a: Top half of page 1; Patient Identification section Attachment 3b: Top half of page 1; Patient Identification section	<ul style="list-style-type: none"> Removed the text "*Patient Name". Shifted remaining variables in the row to the left.

<p><u>Attachment 3a:</u> Top half of page 1; Patient Identification section</p> <p><u>Attachment 3b:</u> Top half of page 1; Patient Identification section</p>	<ul style="list-style-type: none"> Added vertical lines to separate the variable labels "First Name", "Middle Name", and "Last Name" for the primary and alternate names collected in the first two rows of the section.
<p><u>Attachment 3a:</u> Top half of page 1; Patient Identification section</p> <p><u>Attachment 3b:</u> Top half of page 1; Patient Identification section</p>	<ul style="list-style-type: none"> Removed the asterisk (*) from the beginning of the variable label "Alternate Name Type".
<p><u>Attachment 3a:</u> Top half of page 1; Patient Identification section</p> <p><u>Attachment 3b:</u> Top half of page 1; Patient Identification section</p>	<ul style="list-style-type: none"> Added text at the top of the section "(record all dates as mm/dd/yyyy)".
<p><u>Attachment 3a:</u> Top half of page 1; Patient Identification section</p> <p><u>Attachment 3b:</u> Top half of page 1; Patient Identification section</p>	<ul style="list-style-type: none"> Changed variable label from "*Current Street Address" to "*Current Address, Street".
<p><u>Attachment 3a:</u> Top half of page 1; Patient Identification section</p> <p><u>Attachment 3b:</u> Top half of page 1; Patient Identification section</p>	<ul style="list-style-type: none"> Added new variable "Address Date" after "Current Address, Street". Shifted "Phone", "City", "County", "State/Country" and "ZIP Code" to account for the addition of the "Address Date" variable.

<p><u>Attachment 3a:</u> Top half of page 1; Patient Identification section</p> <p><u>Attachment 3b:</u> Top half of page 1; Patient Identification section</p>	<ul style="list-style-type: none"> Removed the colon (:) at the end of the variable labels "Other ID Type" and "Number".
<p><u>Attachment 3a:</u> Top half of page 1; Patient Identification section</p> <p><u>Attachment 3b:</u> Top half of page 1; Patient Identification section</p>	<ul style="list-style-type: none"> Added an asterisk (*) at the beginning of the variable label "Number".
<p><u>Attachment 3a:</u> Top half of page 1; Health Department Use Only section</p> <p><u>Attachment 3b:</u> Top half of page 1; Health Department Use Only section</p>	<ul style="list-style-type: none"> Added text at the top of the section "(record all dates as mm/dd/yyyy)".
<p><u>Attachment 3a:</u> Top half of page 1; Facility Providing Information section</p> <p><u>Attachment 3b:</u> Top half of page 1; Facility Providing Information section</p>	<ul style="list-style-type: none"> Added an asterisk (*) at the beginning of the variable label "ZIP code".
<p><u>Attachment 3a:</u> Bottom half of page 1; Patient Demographics section</p> <p><u>Attachment 3b:</u> Bottom half of page 1; Patient Demographics section</p>	<ul style="list-style-type: none"> Removed the asterisks (*) before the variable labels "Expanded Ethnicity" and "Expanded Race".

<p><u>Attachment 3a:</u> Bottom half of page 1; Residence at Diagnosis section</p> <p><u>Attachment 3b:</u> Bottom half of page 1; Residence at Diagnosis section</p>	<ul style="list-style-type: none"> Added text at the top of the section "record all dates as mm/dd/yyyy)".
<p><u>Attachment 3a:</u> Bottom half of page 1; Residence at Diagnosis section</p> <p><u>Attachment 3b:</u> Bottom half of page 1; Residence at Diagnosis section</p>	<ul style="list-style-type: none"> Added new variable "Address Date" after "Street Address".
<p><u>Attachment 3a:</u> Top half of page 2; State/Local Use Only section</p> <p><u>Attachment 3b:</u> Top half of page 2; State/Local Use Only section</p>	<ul style="list-style-type: none"> Removed the text "-Provider identifier information is not transmitted to CDC!-".
<p><u>Attachment 3a:</u> Top half of page 2; State/Local Use Only section</p> <p><u>Attachment 3b:</u> Top half of page 2; State/Local Use Only section</p>	<ul style="list-style-type: none"> Changed variable label from "Physician's Name (Last, First, M.I.)" to "Provider Name (Last, First, M.I.)" and removed the colon (:) from the end of the variable label. Added an asterisk (*) before the variable label "Provider Name (Last, First, M.I.)".
<p><u>Attachment 3a:</u> Top half of page 2; State/Local Use Only section</p> <p><u>Attachment 3b:</u> Top half of page 2; State/Local Use Only section</p>	<ul style="list-style-type: none"> Changed the variable label from "Phone No" to "Phone" and removed the colon (:) from the end of the variable label. Added an asterisk (*) before the variable label "Phone".

<p><u>Attachment 3a:</u> Top half of page 2; State/Local Use Only section</p> <p><u>Attachment 3b:</u> Top half of page 2; State/Local Use Only section</p>	<ul style="list-style-type: none"> Removed the variable "Medical Record No".
<p><u>Attachment 3a:</u> Top half of page 2; State/Local Use Only section</p> <p><u>Attachment 3b:</u> Top half of page 2; State/Local Use Only section</p>	<ul style="list-style-type: none"> Removed the colon (:) from the "Hospital/Facility" variable label.
<p><u>Attachment 3a:</u> Top half of page 2; State/Local Use Only section</p> <p><u>Attachment 3b:</u> Top half of page 2; State/Local Use Only section</p>	<ul style="list-style-type: none"> Removed the variable "Person Completing Form".
<p><u>Attachment 3a:</u> Top half of page 2; Facility of Diagnosis section</p> <p><u>Attachment 3b:</u> Top half of page 2; Facility of Diagnosis section</p>	<ul style="list-style-type: none"> Moved the text "(check all that apply to the facility below)" to be directly after the variable label before starting the checkboxes. Capitalized the "C" in "check". That is, updated to "(Check all that apply to the facility below)".
<p><u>Attachment 3a:</u> Top half of page 2; Facility of Diagnosis section</p> <p><u>Attachment 3b:</u> Top half of page 2; Facility of Diagnosis section</p>	<ul style="list-style-type: none"> Added an asterisk (*) at the beginning of the variable label "ZIP code".

<p><u>Attachment 3a:</u> Top half of page 2; Facility of Diagnosis section</p> <p><u>Attachment 3b:</u> Top half of page 2; Facility of Diagnosis section</p>	<ul style="list-style-type: none"> Removed the asterisk (*) from the beginning of the variable label "Specialty".
<p><u>Attachment 3a:</u> Bottom half of page 2; Patient History section</p> <p><u>Attachment 3b:</u> Bottom half of page 2; Patient History section</p>	<ul style="list-style-type: none"> Removed the word "section" from the variable label "Received transfusion of blood/blood components (other than clotting factor) (document reason in Comments section)" to update to "Received transfusion of blood/blood components (other than clotting factor) (document reason in Comments)".
<p><u>Attachment 3a:</u> Bottom half of page 2; Patient History section</p> <p><u>Attachment 3b:</u> Bottom half of page 2; Patient History section</p>	<ul style="list-style-type: none"> Removed the word "section" from the variable label "Other documented risk (please include detail in Comments section)" to update to "Other documented risk (please include detail in Comments)".
<p><u>Attachment 3a:</u> Top half of page 3; Laboratory Data section</p> <p><u>Attachment 3b:</u> Top half of page 3; Laboratory Data section</p>	<ul style="list-style-type: none"> Changed text at the top of the section from "Laboratory Data (record additional tests in Comments section) (record all dates as mm/dd/yyyy)" to "Laboratory Data (record additional tests and tests not specified below in Comments) (record all dates as mm/dd/yyyy)".
<p><u>Attachment 3a:</u> Top half of page 3; Laboratory Data section</p> <p><u>Attachment 3b:</u> Top half of page 3; Laboratory Data section</p>	<ul style="list-style-type: none"> Changed the name of the first test category from "HIV Antibody Tests (Non-type-differentiating)" to "HIV Immunoassays (Non-differentiating)".
<p><u>Attachment 3a:</u> Top half of page 3; Laboratory Data section</p> <p><u>Attachment 3b:</u> Top half of page 3; Laboratory Data section</p>	<ul style="list-style-type: none"> Removed the block for TEST 3 and its result in the first test category "HIV Immunoassays (Non-differentiating)".

<p><u>Attachment 3a:</u> Top half of page 3; Laboratory Data section</p> <p><u>Attachment 3b:</u> Top half of page 3; Laboratory Data section</p>	<ul style="list-style-type: none"> Removed "Other: Specify Test: _____" from the TEST 1 and TEST 2 lines in the first test category "HIV Immunoassays (Non-differentiating)".
<p><u>Attachment 3a:</u> Top half of page 3; Laboratory Data section</p> <p><u>Attachment 3b:</u> Top half of page 3; Laboratory Data section</p>	<ul style="list-style-type: none"> De-emphasized the Rapid Test checkboxes by moving them further to the right after the "Collection Date" variable label, removing bold font, and making proper case (i.e., "Rapid Test (<i>check if rapid</i>)") in the RESULT lines of the first test category "HIV Immunoassays (Non-differentiating)". Removed the colon (:) at the end of the Rapid Test checkbox labels.
<p><u>Attachment 3a:</u> Top half of page 3; Laboratory Data section</p> <p><u>Attachment 3b:</u> Top half of page 3; Laboratory Data section</p>	<ul style="list-style-type: none"> Changed "Manufacturer _____" to "Test Brand Name/Manufacturer _____" in the first test category "HIV Immunoassays (Non-differentiating)". Moved from the RESULT lines to the TEST lines.
<p><u>Attachment 3a:</u> Top half of page 3; Laboratory Data section</p> <p><u>Attachment 3b:</u> Top half of page 3; Laboratory Data section</p>	<ul style="list-style-type: none"> Changed the name of the second test category from "HIV Antibody Tests (Type-differentiating) [HIV-1 vs. HIV-2]" to "HIV Immunoassays (Differentiating)".
<p><u>Attachment 3a:</u> Top half of page 3; Laboratory Data section</p> <p><u>Attachment 3b:</u> Top half of page 3; Laboratory Data section</p>	<ul style="list-style-type: none"> Changed the TEST line to read "<checkbox> HIV-1/2 Type-differentiating (Differentiates between HIV-1 Ab and HIV-2 Ab) Test Brand Name/Manufacturer _____" in the second test category "HIV Immunoassays (Differentiating)". Also, removed the text "TEST".
<p><u>Attachment 3a:</u> Top half of page 3; Laboratory Data section</p> <p><u>Attachment 3b:</u> Top half of page 3; Laboratory Data section</p>	<ul style="list-style-type: none"> Changed the result options to the following, with a checkbox for each: "HIV-1", "HIV-2", "Both (undifferentiated)", "Neither (negative)", "Indeterminate" for the first test type in the second test category "HIV Immunoassays (Differentiating)". Retained the text "RESULT:", and "Collection Date". Added a Rapid Test checkbox following "Collection Date" to read "<checkbox> Rapid Test (<i>check if rapid</i>)".

<p><u>Attachment 3a:</u> Top half of page 3; Laboratory Data section</p> <p><u>Attachment 3b:</u> Top half of page 3; Laboratory Data section</p>	<ul style="list-style-type: none"> Added a row to capture a second test type to read "<checkbox> HIV-1/2 Ag/Ab-differentiating (Differentiates between HIV Ag and HIV Ab) Test Brand Name/Manufacturer_____ " under the second test category "HIV Immunoassays (Differentiating)".
<p><u>Attachment 3a:</u> Top half of page 3; Laboratory Data section</p> <p><u>Attachment 3b:</u> Top half of page 3; Laboratory Data section</p>	<ul style="list-style-type: none"> Added a row to capture a second result with a checkbox for: "Ag reactive", "Ab reactive", "Both (Ag and Ab reactive)", "Neither (negative)", "Invalid/Indeterminate" for the second test type in the second test category "HIV Immunoassays (Differentiating)". Added the text "RESULT:", the "Collection Date" variable, and Rapid Test checkbox.
<p><u>Attachment 3a:</u> Top half of page 3; Laboratory Data section</p> <p><u>Attachment 3b:</u> Top half of page 3; Laboratory Data section</p>	<ul style="list-style-type: none"> Added a row to capture a third test type to read "<checkbox> HIV-1/2 Ag/Ab and Type-differentiating (Differentiates among HIV-1 Ag, HIV-1 Ab, and HIV-2 Ab) Test Brand Name/Manufacturer_____ " under the second test category "HIV Immunoassays (Differentiating)".
<p><u>Attachment 3a:</u> Top half of page 3; Laboratory Data section</p> <p><u>Attachment 3b:</u> Top half of page 3; Laboratory Data section</p>	<ul style="list-style-type: none"> Added a row to capture a third result in the second type category "HIV Immunoassays (Differentiating)" with the row titled "Result*:". Added two components: "HIV-1 Ag" and "HIV Ab". Response options for "HIV-1 Ag" were "Reactive", "Nonreactive", "Not Reported", with a checkbox for each. Response options for "HIV Ab" were "HIV-1 Reactive", "HIV-2 Reactive", "Both Reactive, Undifferentiated", "Both Nonreactive", with a checkbox for each. Added Collection Date. Added instructions "*Select one result for HIV-1 Ag and one result for HIV Ab".
<p><u>Attachment 3a:</u> Top half of page 3; Laboratory Data section</p> <p><u>Attachment 3b:</u> Top half of page 3; Laboratory Data section</p>	<ul style="list-style-type: none"> Changed the text from "TEST 1:" to "TEST" under the third test category "HIV Detection Tests (Qualitative)".
<p><u>Attachment 3a:</u> Top half of page 3; Laboratory Data section</p> <p><u>Attachment 3b:</u> Top half of page 3; Laboratory Data section</p>	<ul style="list-style-type: none"> Removed the block for TEST 2 and its RESULT under the third test category "HIV Detection Tests (Qualitative)".

<p><u>Attachment 3a:</u> Top half of page 3; Laboratory Data section</p> <p><u>Attachment 3b:</u> Top half of page 3; Laboratory Data section</p>	<ul style="list-style-type: none"> Removed "HIV-1 P24 Antigen" from the TEST row under the third test category "HIV Detection Tests (Qualitative)".
<p><u>Attachment 3a:</u> Bottom half of page 3; Laboratory Data section</p> <p><u>Attachment 3b:</u> Bottom half of page 3; Laboratory Data section</p>	<ul style="list-style-type: none"> Changed "CD4 at or closest to current diagnostic status" to "CD4 at or closest to diagnosis" under the fifth test category "Immunologic Tests (CD4 count and percentage)".
<p><u>Attachment 3a:</u> Bottom half of page 3; Laboratory Data section</p> <p><u>Attachment 3b:</u> Bottom half of page 3; Laboratory Data section</p>	<ul style="list-style-type: none"> Removed "p24 Ag" from the text line "Complete the above only if none of the following was positive..." under the "Documentation of Tests" header.
<p><u>Attachment 3a:</u> Bottom half of page 3; Laboratory Data section</p> <p><u>Attachment 3b:</u> Bottom half of page 3; Laboratory Data section</p>	<ul style="list-style-type: none"> Removed the colon at the end of the last line of the first row under the "Documentation of Tests" heading in the section. The phrase was updated as follows: "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]".
<p><u>Attachment 3a:</u> Bottom half of page 3; Clinical section</p> <p><u>Attachment 3b:</u> Bottom half of page 3; Clinical section</p>	<ul style="list-style-type: none"> Removed the three "OI" columns.
<p><u>Attachment 3a:</u> Bottom half of page 4; Comments section</p> <p><u>Attachment 3b:</u> Bottom half of page 4; Comments section</p>	<ul style="list-style-type: none"> Removed the asterisk (*) at the beginning of header.
<p><u>Attachment 3a:</u> Bottom half of page 4; Comments section</p> <p><u>Attachment 3b:</u> Bottom half of page 4; Comments section</p>	<ul style="list-style-type: none"> Decreased the number of lines allowed for entry in the "Comments" section.

<p><u>Attachment 3a:</u> Bottom half of page 4; Local/Optional Fields section</p> <p><u>Attachment 3b:</u> Bottom half of page 4; Local/Optional Fields section</p>	<ul style="list-style-type: none"> Decreased the number of lines allowed for entry in the "Local/Optional Fields" section.
Location in Document	Modifications to the PHER Form
<p><u>Attachment 3d:</u> Top half of page 1; Header</p>	<ul style="list-style-type: none"> Added "Infant's" before "State Number".
<p><u>Attachment 3d:</u> Top half of page 1; Header</p>	<ul style="list-style-type: none"> Added "Mother's State Number_____".
<p><u>Attachment 3d:</u> Top half of page 1; Header</p>	<ul style="list-style-type: none"> Added "Infant's City Number _____".
<p><u>Attachment 3d:</u> Top half of page 1; Header</p>	<ul style="list-style-type: none"> Added "Mother's City Number _____".
<p><u>Attachment 3d:</u> Top half of page 1; Question 4</p>	<ul style="list-style-type: none"> Changed "test performed" to "test(s) performed".
<p><u>Attachment 3d:</u> Bottom half of page 1; Question 7</p>	<ul style="list-style-type: none"> Changed "State No." to "State Number" and "City No." to "City Number".
<p><u>Attachment 3d:</u> Bottom half of page 1; Question 7</p>	<ul style="list-style-type: none"> Updated the "(See list.)" under HIV serostatus to "(See list below)".
<p><u>Attachment 3d:</u> Bottom half of page 1; Footer</p>	<ul style="list-style-type: none"> Changed the first sentence of the privacy statement to: "Public reporting burden of this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information."
<p><u>Attachment 3d:</u> Bottom half of page 1, 2, 3, and 4; Footer</p>	<ul style="list-style-type: none"> Added page numbers (e.g., Page 1 of 4) to improve the user's ability to locate and reference questions.
<p><u>Attachment 3d:</u> Top half of page 2; Question 8</p>	<ul style="list-style-type: none"> Replaced "No (Go to 10.)" with "No (Go to 9)".

<u>Attachment 3d:</u> Top half of page 2; Question 8, Question 9, and Question 10	<ul style="list-style-type: none"> Removed the extra line under "Specific drug(s) not documented".
<u>Attachment 3d:</u> Top half of page 2; Question 9	<ul style="list-style-type: none"> Moved the checkboxes to the left (so the first one lines up directly under the text as in Q1).
<u>Attachment 3d:</u> Top half of page 2; Question 9 and Question 10	<ul style="list-style-type: none"> Moved the checkbox for "No" under the "Yes, negative result" checkbox and moved "Toxicology screen not documented" under "No".
<u>Attachment 3d:</u> Top half of page 2; Question 10	<ul style="list-style-type: none"> Moved the checkboxes to the left (so the first one lines up directly under the text as in Q1).
<u>Attachment 3d:</u> Bottom half of page 2; Question 11	<ul style="list-style-type: none"> Moved the checkboxes to the left (so the first one lines up directly under the text as in Q1).
<u>Attachment 3d:</u> Bottom half of page 2; Question 12	<ul style="list-style-type: none"> Moved the checkboxes to the left (so the first one lines up directly under the text as in Q1).
<u>Attachment 3d:</u> Bottom half of page 2; Question 12	<ul style="list-style-type: none"> Added "(Go to 13)" after the "Unknown" checkbox.
<u>Attachment 3d:</u> Bottom half of page 2; Question 12	<ul style="list-style-type: none"> Removed the "See list on p.8" under "Drug name".
<u>Attachment 3d:</u> Bottom half of page 2; Question 12	<ul style="list-style-type: none"> Removed the column for "Other (specify)" and merged lines i through vi for the two columns.
<u>Attachment 3d:</u> Bottom half of page 2; Question 12	<ul style="list-style-type: none"> Replaced "Stop codes (See list on p. 8)" with "Stop codes (See list on p. 4)".
<u>Attachment 3d:</u> Top half of page 3; Question 14a	<ul style="list-style-type: none"> Inserted space below questions (similar to Q15).
<u>Attachment 3d:</u> Top half of page 3; Question 14	<ul style="list-style-type: none"> Added "(Go to 15)" after the "Unknown" checkbox.

<p><u>Attachment 3d:</u> Top half of page 3; Question 14</p>	<ul style="list-style-type: none"> Removed the extra space between "Record not available" and "(Go to 15)".
<p><u>Attachment 3d:</u> Top half of page 3; Question 14</p>	<ul style="list-style-type: none"> Removed the "See list on p.8" under "Drug name".
<p><u>Attachment 3d:</u> Top half of page 3; Question 14</p>	<ul style="list-style-type: none"> Removed the column for "Other (specify)" and merged lines i through vi for the two columns.
<p><u>Attachment 3d:</u> Top half of page 3; Question 15</p>	<ul style="list-style-type: none"> Replaced "No (Go to 18.)" with "No (Go to 17)".
<p><u>Attachment 3d:</u> Top half of page 3; Question 15</p>	<ul style="list-style-type: none"> Moved the checkboxes to the left (so the first one lines up directly under the text as in Q1).
<p><u>Attachment 3d:</u> Top half of page 3; Question 16</p>	<ul style="list-style-type: none"> Added "the mother's" to the question: "If yes, indicate first CD4 result or first viral load after discharge from hospital (up to 6 months after discharge)". Example: "If yes, indicate the mother's first CD4 result or first viral load after discharge from hospital (up to 6 months after discharge)".
<p><u>Attachment 3d:</u> Top half of page 3; Question 16</p>	<ul style="list-style-type: none"> Replaced "Viral load" with "Viral load result".
<p><u>Attachment 3d:</u> Top half of page 3; Question 16</p>	<ul style="list-style-type: none"> Inserted space below questions (similar to Q15).
<p><u>Attachment 3d:</u> Bottom half of page 3; Question 18</p>	<ul style="list-style-type: none"> Moved "Not applicable" under "Not specified".
<p><u>Attachment 3d:</u> Bottom half of page 3; Question 18</p>	<ul style="list-style-type: none"> Moved the checkboxes to the left (so the first one lines up directly under the text as in Q1).
<p><u>Attachment 3d:</u> Bottom half of page 3; Question 19</p>	<ul style="list-style-type: none"> Moved the checkboxes to the left (so the first one lines up directly under the text as in Q1).

<u>Attachment 3d:</u> Bottom half of page 3; Question 19	<ul style="list-style-type: none"> • Inserted space below questions (similar to Q15).
<u>Attachment 3d:</u> Top half of page 4; Question 20	<ul style="list-style-type: none"> • Removed the "See list on p.8" under "Drug name".
<u>Attachment 3d:</u> Top half of page 4; Question 20	<ul style="list-style-type: none"> • Removed the column for "Other (specify)" and merged lines i through vi for the two columns.
<u>Attachment 3d:</u> Top half of page 4; Question 20	<ul style="list-style-type: none"> • Updated the spacing so it is consistent between the five responses (e.g., between "Record not available" and "Unknown").
<u>Attachment 3d:</u> Top half of page 4; Question 20	<ul style="list-style-type: none"> • Changed "(See list on p. 4)" under Stop codes to "(See list)".
<u>Attachment 3d:</u> Top half of page 4; Question 20	<ul style="list-style-type: none"> • Moved the checkboxes to the left (so the first one lines up directly under the text as in Q1).
<u>Attachment 3d:</u> Bottom half of page 4	<ul style="list-style-type: none"> • Removed the Antiretroviral drugs section entirely.
<u>Attachment 3d:</u> Bottom half of page 4; List of Abbreviations section	<ul style="list-style-type: none"> • Removed all of the abbreviations from the list except for the five abbreviations that are referenced in the form.
<u>Attachment 3d:</u> Bottom half of page 4; Comments section	<ul style="list-style-type: none"> • Added the text "Comments" to the beginning of the section.
<u>Attachment 3d:</u> Bottom half of page 4; Comments section	<ul style="list-style-type: none"> • Moved the comments to the last section on page. 4.

***Note 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) and the revised Perinatal Exposure Reporting (PHER) form is provided in Attachment 3(d).**