National HIV Surveillance System (NHSS)

Attachment 10.

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

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

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. We are requesting to extend data collection on the currently approved data collection instruments through December 31, 2022 (expiration November 30, 2022), and then implement collection that includes the changes described within this document starting in January 2023. The changes requested for this ICR include modifications to currently collected data elements on the Adult HIV Confidential Case Report Form (ACRF), combining information collected for perinatal HIV exposures on two forms (the Perinatal HIV Exposure Reporting [PHER] form and the Pediatric HIV Confidential Case Report Form [PCRF]) to collect on one form (PCRF), and modifications to data system tables and variables as a result of the revisions. Requested changes for forms and data elements have been developed with input of state and local HIV surveillance coordinators and the Council of State and Territorial Epidemiologists (CSTE) HIV subcommittee and are intended to improve usability and data collection and create efficiencies for conducting and evaluating surveillance program activities. In addition, modifications to the Standards Evaluation Report (SER) are requested in order to better align with needed information to assess program performance in January 2023. This information will be captured via REDCap, a secure web application for building and managing online surveys and databases.

An overview of the form changes is provided below. The specific changes to the ACRF and PCRF are 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).

Changes to the ACRF and PCRF (Table 1A)

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. Existing collection of gender identity was updated in the Patient Demographics sections of the ACRF and PCRF to revise the existing response option labels and to collect one additional gender identity response option and the date associated with the gender identity to more accurately summarize a person's gender identity. We revised the designation of the collection of gender identity from recommended to required to be able to more accurately release information about gender categories. With this revision we have proposed to begin collecting information about a person's sexual orientation, including the date associated with the sexual orientation, so that data can be reported by sexual orientation rather than by using information collected in the Patient History section as a proxy. In the Patient History section, we updated the language to align with the Division of HIV Prevention terminology guide, which recommends the use of 'person who injects drugs' instead of 'injection drug user'.

The Laboratory section of the ACRF and PCRF was reformatted. Format changes included combining sections, revising the order for collecting certain test types and the number of test results collected by test type to better align data collection with the recommended HIV testing algorithm and to limit the length of the section on the form. We updated some wording in the Laboratory Data section to reflect current terminology. We added two new test types, HIV-1/HIV-2 RNA NAAT and HIV-1 RNA NAAT (Qualitative and Quantitative), and revised response options on some existing test types to

accommodate changes in HIV testing technology. For test types under the subsections HIV Immunoassays and HIV Detection Tests, we added two new response options: "Self-test, result directly observed by a provider" and "Lab test, self-collected sample" to the variable to collect testing options to be able to summarize documented self-testing activity and self-collected specimens among persons with diagnosed HIV. We have designated the collection of information about self-testing and specimen self-collection in this section as required. We have updated information collection designations of facility name and lab name from optional to required. We updated the information collection designation of result so that all portions (including interpretation) are required. Previously, the interpretation portion of the result had been designated as optional. The designations were changed to improve collection of completed information and ensure consistency of collection across all test types and because this laboratory information is crucial for data-to-care activities. We do not anticipate that changing these designations will increase data collection burden because this information is typically provided through electronic laboratory reporting.

Overall, we made some formatting changes to the ACRF and PCRF. We added roman numerals to each section name to assist staff with referencing a particular section of the form. We removed the State/Local Use section of the form to accommodate room for other form changes; information collected in this section could duplicate information collected elsewhere on the form and state and local HIV surveillance coordinators expressed no concerns with removing this section. We revised the confidentiality statement in the footer of the ACRF and PCRF to remove the words “on file at the local health department” to remove ambiguity about whether the assurance is specific to the local health department or is managed by CDC. We removed the word “please” from the Patient Demographics, Patient History, Clinical, and Treatment/Services Referrals sections to align wording with other instructions throughout the ACRF and PCRF. We updated question labels and instructions so that the language no longer reflects that a test is positive or negative but that the test result is positive or negative.

Changes to the ACRF only (Table 1B)
In the Laboratory Data section of the ACRF we updated the labels for collecting information about HIV diagnoses documented by a physician to clarify instructions for when these field should be completed.

In the HIV Testing History section we added three new fields to collect information about self-testing associated with the first positive test result, the last negative test result, and previous negative test results to be able to summarize self-testing activity among persons with diagnosed HIV.

Changes to the PCRF and PHER Form (Table 1C)
Information about perinatal HIV exposures was previously collected across two forms, the PCRF and PHER form, and information about pediatric HIV infection was also collected on the PCRF. We received feedback from state and local HIV surveillance coordinators and other partners in CDC involved with perinatal HIV elimination efforts that the PCRF and PHER form should be combined to reduce redundancy across the forms and better reflect the information necessary to assess progress with perinatal HIV elimination efforts and to support HIV prevention activities; we concurred with the feedback and consolidated the information to be collected into a single form still called the PCRF as part of this revision. We retained the name of the PCRF because prior to this revision some information about perinatal HIV exposures was collected on the form. However, we revised the instruction associated with the form name from indicating the form was for “patients aged <13 years at time of diagnosis” to “patients aged <13 years at time of perinatal exposure or patients aged <13 years at time of diagnosis.” We worked closely with the perinatal HIV surveillance workgroup, which includes state

and local HIV surveillance coordinators and other partners in CDC, while consolidating the collection of information to a single form. Combining the form reduced the total number of pages for collecting the information on the hard copy forms; we reduced from two forms with four pages each to one form with six pages.

As part of combining the forms into a single PCRF, we identified some variables that collected the same or similar information on both the existing PCRF and PHER form and consolidated the variables to collect the information only one time. In total, we consolidated seven questions on the PHER form with existing variables on the PCRF form; this sometimes included some minor changes in question meaning, question wording, or the available response options. This included consolidating the collection of identifier numbers, the timing of when prenatal care began, and antiretroviral information for the birthing person and child.

We incorporated some key information collected on the PHER form by moving 13 numbered questions from the PHER form to the PCRF. As part of moving the information to the PCRF, there were sometimes minor changes made to the question meaning, question wording, or the available response options. We moved information associated with the birth (e.g., onset of labor, reason for cesarean section, and toxicology screening for the infant after birth) and information associated with the history of the birthing person (e.g., reproductive history, reason birthing person did not receive antiretrovirals, toxicology screening for the birthing person).

As part of the revision, we proposed to stop collecting 10 numbered questions previously collected on the PHER form and two variables on the existing version of the PCRF. We proposed to stop collecting most variables because similar information can be collected through other existing fields or the information was no longer necessary to collect given changes in HIV testing requirements. For example, we proposed to no longer collect whether the biological mother was counseled about HIV testing during this pregnancy, labor, or delivery because routine opt-out HIV testing has been established in the majority of jurisdictions and counseling is not required.

We added five new questions to the PCRF. Two new questions are related to breastfeeding/chestfeeding and premastication by the birthing person to improve the ability to correctly attribute infection to perinatal transmission and to identify when breastfeeding/chestfeeding or premastication by the birthing person occurred. We added two new questions related to breastfeeding/chestfeeding and premastication by a non-birthing person to improve the ability to correctly attribute infection to non-perinatal transmission when child's infection was determined to occur during breastfeeding by a non-birthing person or through receipt of premasticated food from the non-birthing person. We added one question to the Birthing Person History section to collect whether a CD4 and quantitative NAAT test results were documented in the birthing person's labor and delivery record to identify whether medical providers were aware of recent HIV test results during labor and delivery to make clinical decisions about medical care provided during labor and delivery.

We revised the response options for the existing variable to collect the delivery method in the Birth History section on the PCRF to align with current medical practice for delivery methods. We also updated the designation for collecting information for the delivery method from optional to required to align with the designation on the current PHER form that indicators for a cesarean delivery is a required field.

Overall, we made some formatting and wording changes to the PCRF to improve clarity. In the Laboratory Data section of the PCRF, we updated the labels for collecting information about HIV diagnoses documented by a physician to clarify instructions for when these field should be completed. Throughout the Patient History section, we updated references from "biological mother" to "birthing person" to better reflect that information should be collected for the birthing person regardless of gender identity or parental status. We updated the instruction in the section titled "Birth History (for Perinatal Cases only)" to "Birth History (for patients exposed perinatally with or without consequent infection)" to clarify instructions for when this section of the form should be completed. In the Birth History Section, we revised the label for a variable from "Birth Defects" to "Congenital Disorders" to align with current preferred terminology. We added the Birthing Person History section to the PCRF to limit the length of the existing Birth History information as information from the previous PHER form was incorporated into the PCRF; this also included moving some information previously collected in the Birth History section to the Birthing Person History section (e.g., birthing person last name soundex). The addition of this section creates a more focused area for collecting the majority of data that are related to the birthing person rather than the child. We added the gender identity variable to the Patient History section of the hard copy PCRF for the first time; this information had been captured previously in the electronic reporting system (i.e., enhanced HIV/ADS reporting system (eHARS)) on the PCRF document, but not on the hard copy form. Refer to "Changes to the ACRF and PCRF" section of this document above for other changes related to collecting gender identity that were shared across the forms.

eHARS Only Changes (Table 2)

We proposed two changes that would be made only in eHARS but would not be reflected on the hard copy forms. These include addition of 5 types of patient identifiers from other data collection systems that can be entered or imported into eHARS to improve the ability to link with other data collection systems. In addition, we also created new variables that summarize information submitted for each person (i.e., person view summary variable) to summarize information associated with suspected acute HIV infection.

SER Changes (Table 3)

We are requesting a non-substantial change to the Standards Evaluation Report (SER) as provided in Attachment 3(d) and the specific changes are outlined in Table 3. The proposed form will be provided to jurisdictions in January 2023 to report their outcomes. Most of the changes are minor edits for clarity and consistency, and deletion of questions that are no longer needed. The word document format of the SER will be provided to jurisdictions as a guide, but data collection will occur via REDCap.

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

Table 1A. Changes to the ACRF and PCRF

Section, Variable	Change Proposed	Reason for Change Proposed
Section IV (ACRF & PCRF): Patient Demographics, Variable: Gender Identity	Revised label from "Current Gender Identity" to "Gender Identity"	To reflect that the gender identity collected might not reflect the gender identity at the time the form was completed.
Section IV (ACRF & PCRF): Patient Demographics, Variable: Gender Identity	On ACRF, relabeled response options from “Male” to “Man," "Female" to “Woman,” “Transgender male-to-female (MTF)” to “Transgender woman,” and “Transgender female-to-male" to “Transgender man" on the ACRF. On the PCRF, relabeled response options from "Male" to "Boy," "Female" to "Girl," "Transgender male-to-female" to "Transgender girl," and "Transgender female-to-male" to "Transgender boy." Updated order of response options so that "Transgender woman" (ACRF) and "Transgender girl" (PCRF) is the last of these four response options.	To improve differentiation between “sex assigned at birth” (e.g., male, female) and gender identity (e.g., man, woman, transgender man, transgender woman). Similar terms for gender have been used in HIV surveillance reports by other city health departments (e.g., 2018 Annual HIV Epidemiology Report for San Francisco Department of Public Health and the 2019 HIV Surveillance Annual Report for New York City Department of Health and Mental Hygiene). Updated to align gender identity terms on the PCRF with terms used for this age group on the CDC's Youth Risk Behavior Survey.
Section IV (ACRF & PCRF): Patient Demographics, Variable: Gender Identity	Added one new gender identity response option: Declined to answer.	To better differentiate between when a person declined to provide their gender identity and when gender identity was not collected.
Section IV (ACRF & PCRF): Patient Demographics, Variable: Gender Identity	Added variable in eHARS to collect the response to the "(specify)" option associated with "Additional Gender Identity" on the hard copy form. No changes to the hard copy form.	To allow place in eHARS to capture information collected on the hard copy form for consistency.

Section IV (ACRF & PCRF): Patient Demographics, Variable: Gender Identity	Added a field to collect "Date Identified" associated with the gender identity collected. Assigned designation of this field for collection as required.	To be able to monitor changes in gender identity over time and accurately summarize a person's gender identity at specific points in time presented in state/local and national surveillance products.
Section IV (ACRF & PCRF): Patient Demographics, Variable: Gender Identity	Updated designation for collecting this information from recommended to required.	To more accurately release information about gender categories.
Section IV (ACRF & PCRF): Patient Demographics, Variable: Sexual Orientation	Added question and response options to collect sexual orientation. □ Straight or heterosexual □ Lesbian or gay □ Bisexual □ Additional sexual orientation (specify)_____ □ Declined to answer □ Unknown Associated with the sexual orientation response added the field "Date Identified" to collect sexual orientation over time. Assigned designation of these fields for collection as required.	To allow for future release of aggregate data by reported sexual orientation rather than by using information collected in the Patient History section as a proxy.
Section IV (ACRF & PCRF): Patient Demographics, Variable: Country of Birth Section VII (ACRF & PCRF): Patient History, Variable: Other documented risk Section VII (ACRF): Patient History, Variable: Pediatric Risk Section VIII (ACRF): Clinical, Variable: If YES, describe	Removed "please" from question label and response options.	To align wording with other instances where a free text option is provided to record other response options.

Section XII (PCRF): Treatment/Services Referrals, Variable: This child's primary caretaker is		
Section VII (ACRF & PCRF): Patient History, Variable: Heterosexual contact with intravenous/injection drug user	Updated language to: "Heterosexual contact with person who injected drugs"	To align with Division of HIV Prevention terminology guide.
Section IX (ACRF & PCRF): Laboratory Data, Variable: Subheading	Combined subsection headings for "HIV Immunoassays (Nondifferentiating)" and "HIV Immunoassays (differentiating)" into a single subsection heading titled "HIV Immunoassays." Revised order of the test types collected in this subsection. Removed space to collect information about a second test of the same test type (i.e., TEST 2). Updated label from TEST 1 to TEST.	To better align collection of the information with the recommended HIV testing algorithm and to limit the length of the section.
Section IX (ACRF & PCRF): Laboratory Data, Variable: HIV-1/2 Ag/Ab differentiating immunoassay, Result	Updated to collect an overall result for the test with response options of "Reactive" and "Nonreactive". Update to collect analyst results for HIV-1 p24 antigen with response options of "Reactive" and "Nonreactive" and HIV-1/2 antibody with response options of "Reactive" and "Nonreactive."	To accommodate result options available with new FDA-approved test and align with changes made to eHARS 4.12.
Section IX (ACRF & PCRF): Laboratory Data, Variable: HIV-1/2 Ag/Ab differentiating immunoassay , HIV-1/2 Ag/Ab and type-differentiating immunoassay , HIV-1/2 type-differentiating immunoassay	Added label "TEST" in front of test type option.	To make consistent across the Laboratory Data section.
Section IX (ACRF & PCRF): Laboratory Data, Variable: Role of test in diagnostic algorithm	Removed from hard copy form. Updated label from "HIV-1/2 type-differentiating immunoassay" to "HIV-1/2 type-differentiating immunoassay (supplemental)."	HIV-1/2 type-differentiating immunoassay should only be used as the supplemental test with current FDA approved tests. Updated form to limit routine collection of information on the

		hard copy form about this test type to approved use as a supplemental test.
Section IX (ACRF & PCRF): Laboratory Data, Variable: HIV-1/2 type-differentiating immunoassay, Result, Overall Interpretation	Added response option of "HIV-1 positive with HIV-2 cross-reactivity." Update response option order: □ HIV positive, untypable □ HIV-1 positive with HIV-2 cross-reactivity □ HIV-2 positive with HIV-1 cross-reactivity □ HIV negative □ HIV indeterminate □ HIV-1 indeterminate □ HIV-2 indeterminate □ HIV-1 positive □ HIV-2 positive	To account for a result option available with new FDA-approved test and group similar test results together in response option order.
Section IX (ACRF & PCRF): Laboratory Data, Variable: HIV Detection Tests (Qualitative) and HIV Detection Tests (Quantitative viral load)	Combined subsection headings for "HIV Detection Tests (Qualitative)" and "HIV Detection Tests (Quantitative viral load)" into a single subsection heading titled HIV Detection Tests." Removed space to collect information about a second test of the same test type (i.e., TEST 2). Updated label from TEST 1 to TEST. Removed instruction "(Note: Include earliest test at or after diagnosis) associated with "HIV Detection Tests (Quantitative viral load)" subsection heading.	To limit the length of the Laboratory Data section. To reflect the fact that when reporting quantitative test results on the form that it does not always have to be the earliest test at or after diagnosis.
Section IX (ACRF & PCRF): Laboratory Data, Variable: HIV-1 RNA/DNA NAAT and HIV-2 RNA/DNA NAAT	Updated label associated with each test type option from "(Quantitative viral load)" to "(Quantitative)." Update Result response options from "Detectable" and "Undetectable" to "Detectable above limits," "Detectable within limit," and "Detectable below limit," and "Not detected."	To reflect current terminology and test result reporting options for FDA approved tests of this type.
Section IX (ACRF & PCRF): Laboratory Data, Variable: HIV-1/HIV-2 RNA NAAT	Created space to capture information associated with HIV-1/HIV-2 RNA NAAT tests in a format to similar test types. TEST □ HIV-1/2 RNA NAAT (Qualitative) Test brand name/Manufacturer	To accommodate collection of information associated with new FDA-approved tests and align with changes made to eHARS 4.12. These updates do not change the data collection burden

	Lab name Facility name Provider name Result □ HIV-1 □ HIV-2 □ Both (HIV-1 and HIV-2) □ HIV, not differentiated (HIV-1 or HIV-2) □ Neither (negative) Collection Date __ __ / __ ___ / __ __ __ __	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.
Section IX (ACRF & PCRF): Laboratory Data, Variable: HIV-1 RNA NAAT (Qualitative and Quantitative)	Created space to capture information associated with HIV-1 RNA NAAT (Qualitative and Quantitative) tests in a format to similar test types TEST □ HIV-1 RNA NAAT (Qualitative and Quantitative) Test brand name/Manufacturer Lab Name Facility name Provider name Result Qualitative: □ Reactive □ Nonreactive Analyte results: HIV-1 Quantitative: □ Detectable above limit □ Detectable within limits □ Detectable below limit Copies/mL Log Collection Date __ __ / __ ___ / __ __ __ __	To accommodate collection of information associated with new FDA-approved test and align with changes made to eHARS 4.12. 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.
Section IX (ACRF & PCRF): Laboratory Data, Variable: Immunologic Tests (CD4 count and percentage)	Reduced number of CD4 test results to be collected from three at specific points in time (at or closest to diagnosis, <200 cells/uL or 14%, and other) to a single CD4 count without a specified point in time.	To limit the length of the Laboratory Data section. To reflect the fact that a CD4 test result at any point in time can be reported.
Section IX (ACRF & PCRF): 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 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	To reflect current terminology for FDA approved tests of this type.

	sequence" to "Complete the above only if none of the following were positive for HIV-1: Western blot, IFA, culture, quantitative NAAT (RNA or DNA), qualitative NAAT (RNA or DNA), HIV-1/2 type-differentiating immunoassay (supplemental test), stand-alone p24 antigen, or nucleotide sequence."	
Section IX (ACRF & PCRF): Laboratory Data, Variable: HIV-1/2 type-differentiating immunoassay, Result and HIV-1/2 Ag/Ab and type-differentiating immunoassay, Result	Renumbered footnote. Moved footnote from area specific to the test result to the end of the Laboratory Data section.	To accommodate additional footnote added. To limit the length of the Laboratory Data section.
Section IX (ACRF & PCRF): Laboratory Data, Variable: If YES, provide specimen collection date of earliest positive test for this algorithm (existing label)/ If YES, provide specimen collection date of earliest positive test result for this algorithm Section VIII (ACRF): Clinical, Variable: Suspect acute HIV infection Section IX (ACRF): Laboratory Data, Variable: Date of last documented negative HIV test result Section XII (ACRF): HIV Testing History, Variable: Ever had previous positive HIV test result?, Date of first positive HIV test result, Ever had a negative HIV test result, Date of last negative HIV test result, Number of negative HIV test results within the 24 months before the first positive test result Section VII (PCRF): Patient History, Variable: Date of birthing person's first positive test result to confirm infection	Revised label from "test" to "test result(s)."	To clarify that only the test results can be positive or negative, not the test itself.

Section IX (ACRF & PCRF): Laboratory Data, Variable: Test brand name/manufacturer	Designated test brand name/manufacturer as an optional field for the two new test types (HIV-1 RNA NAAT (Qualitative and Quantitative) and HIV-1/HIV-2 RNA NAAT.	To align designation for collecting test brand name/manufacturer for the new test types with the designation for all other laboratory test types already collected.
Section IX (ACRF & PCRF): Laboratory Data, Variable: Facility name	Designated facility name as a required field for the two new types. Updated the designation of facility name from optional to required for all other laboratory test types already collected.	Facility name is crucial for conducting data to care activities.
Section IX (ACRF & PCRF): Laboratory Data, Variable: Lab name	Designated lab name as a required field for the two new types. Updated the designation of lab name from optional to required for all other laboratory test types already collected.	Lab name is crucial for conducting data to care activities.
Section IX (ACRF & PCRF): Laboratory Data, Variable: Provider name	Designated provider name as an optional field for the two new test types (HIV-1 RNA NAAT (Qualitative and Quantitative) and HIV-1/HIV-2 RNA NAAT.	To align designation for collecting provider name for the new test types with the designation for all other laboratory test types already collected.
Section IX (ACRF & PCRF): Laboratory Data, Variable: Collection date	Designated collection date as a required field for the two new test types (HIV-1 RNA NAAT (Qualitative and Quantitative) and HIV-1/HIV-2 RNA NAAT.	To align designation for collecting collection date for the new test types with the designation for all other laboratory test types already collected.
Section IX (ACRF & PCRF): Laboratory Data, Variable: Result (all portions)	Designated result as a required field for the new HIV-1/HIV-2 RNA NAAT. Designated the result qualitative and analyte result as required fields for the new HIV-1 RNA NAAT (Qualitative and Quantitative) test type. Revised the designation for HIV-1 RNA/DNA NAAT (Quantitative) and HIV-2 RNA/DNA NAAT (Quantitative) so that all portions of the result are required; previously the interpretation portion of the result was designated as optional.	To ensure that the designation of result was consistent across all laboratory test types collected.
Section IX (ACRF & PCRF): Laboratory Data, Variable: Trend Branch	Updated so that the first letter in each word of the following labels is capitalized: Test Brand	To improve consistency in capitalization of labels throughout the Laboratory Data section.

Name/Manufacturer, Lab Name, Facility Name, Provider Name, Index Value	Name/Manufacturer, Lab Name, Facility Name, Provider Name, Index Value.	
Section IX (ACRF & PCRF): Laboratory Data, Variable: Testing Option	For tests under the subsections HIV Immunoassays and HIV Detection Tests, added label to designate the testing option. Updated wording for response option from "Point-of-care rapid test." Added two new response options: " Self-test, result directly observed by a provider" and "Lab test, self-collected sample." Added associated footnote below the Laboratory Data section. Testing Option (if applicable) □ Point-of-care test by provider □ Self-test, result directly observed by a provider1 □ Lab test, self-collected sample [1]Results not directly observed by a provider should be recorded in HIV Testing History. Assigned designation of this field for collection as required.	To be able to summarize documented self-testing activity and self-collected specimens among persons with diagnosed HIV.
Section IX (ACRF & PCRF): Laboratory Data, Variable: Testing Option	Associated with the last documented negative HIV test under the Documentation of Tests subsection, added label to designate the testing option and three response options. Testing Option (if applicable) □ Point-of-care test by provider □ Self-test, result directly observed by a provider1 □ Lab test, self-collected sample [1]Results not directly observed by a provider should be recorded in HIV Testing History. Assigned designation of this field for collection as required.	To be able to summarize documented self-testing activity and self-collected specimens among persons with diagnosed HIV.
Section (ACRF & PCRF): All, Variable: N/A	Added roman numerals to designate each section.	To assist staff with referencing a particular section of the form.
Section (ACRF & PCRF): State/Local Use (deleted), Variable: N/A	Removed section from the hard copy form.	To accommodate room for other form changes.

Section (ACRF & PCRF): Footer, Variable: Confidentiality Statement	Removed the words “on file at the local health department” from the confidentiality statement.	To remove ambiguity about whether the assurance is specific to the local health department or is managed by CDC.

Table 1B. Changes to the ACRF Only

Section, Variable	Change Proposed	Reason for Change Proposed
Section IX (ACRF): Laboratory Data, Variable: Is earliest evidence of HIV infection diagnosis documented by a physician rather than by laboratory test results?	Updated label from "If HIV laboratory tests were not documented, is HIV diagnosis documented by a physician?" to "Is earliest evidence of HIV infection diagnosis documented by a physician rather than by laboratory test results?"	To clarify instructions for when this field should be completed.
Section IX (ACRF): Laboratory Data, Variable: If YES, provide date of diagnosis by physician	Updated label from "If YES, provide date of diagnosis" to "If YES, provide date of diagnosis by physician."	To clarify which date should be used to complete the field.
Section XII (ACRF): HIV Testing History, Variable: Was the first positive test result from a self-test performed by the patient?	Added the following question and responses after "Date of first positive HIV test result" question: Was the first positive test result from a self-test performed by the patient? □ Yes □ No □ Unknown Assigned designation of this field for collection as required.	To be able to summarize self-testing activity among persons with diagnosed HIV.
Section XII (ACRF): HIV Testing History, Variable: Was the last negative test result from a self-test performed by the patient?	Added the following question and responses after "Date of last negative HIV test result" question: Was the last negative test result from a self-test performed by the patient? □ Yes □ No □ Unknown Assigned designation of this field for collection as required.	To be able to summarize self-testing activity among persons with diagnosed HIV.
Section XII (ACRF): HIV Testing History, Variable: How many of these negative test results were from self-tests performed by the patient?	Added the following question and responses after "Number of negative HIV test results within the 24 months before the first positive test result " question:	To be able to summarize self-testing activity among persons with diagnosed HIV.

	How many of these negative test results were from self-tests performed by the patient? __ __ □ Unknown Assigned designation of this field for collection as required.	

Table 1C. Changes to the PCRF and PHER Form

Variables Consolidated Across the PCRF and PHER Form

Section, Variable	Change Proposed	Reason for Change Proposed
Section II (PCRF): Health Department Use Only Header, Variable: State Number	Consolidated collection of PHER form "Infant's State Number" into PCRF Health Department Use Only section field "State Number" with change in question wording on the PHER form, but with no change to existing PCRF field label or response options.	To consolidate data collection into a single form for persons <13 years at time of HIV perinatal exposure or HIV diagnosis.
Section II (PCRF): Health Department Use Only Header, Variable: City/County Number	Consolidated collection of PHER form "Infant's City Number" into PCRF Health Department Use Only section field "City/County Number" with change in question wording on the PHER form, but with no change to existing PCRF field label or response options.	To consolidate data collection into a single form for persons <13 years at time of HIV perinatal exposure or HIV diagnosis.
Section XI (PCRF): Birthing Person History, Variable: Birthing Person State ID Number	Consolidated collection from PHER form "Mother's State Number." Moved from Birth History section to newly created Birthing Person History section with change to question wording and no change to the response options. Changed wording from "Maternal" to "Birthing Person."	To limit the length of the Birth History section. To consolidate data collection into a single form for persons <13 years at time of HIV perinatal exposure or HIV diagnosis.
Section XI (PCRF): Birthing Person History, Variable: Prenatal Care—Month of Pregnancy Prenatal Care Began	Consolidated collection from PHER form Q3 with change in question meaning from collecting weeks' gestation to months' gestation and no change in response options. Moved from Birth History section to newly created Birthing Person History section with no changes to existing PCRF field label or response options.	To consolidate data collection into a single form for persons <13 years at time of HIV exposure or diagnosis. To limit the length of the Birth History section. Updated designation to align with

	Updated designation of this field for collection from optional to required.	current designation for this field when collected on the PHER form.
Section XI (PCRF): Birthing Person History, Variable: Did birthing person receive any ARVs during this pregnancy?	Consolidated collection of PHER form Q12 into existing PCRF Birthing Person History section field "Did mother receive any ARVs during pregnancy?" with changes in question wording, and response options. Moved to the PCRF Birthing Person History section. Although the question wording was updated from "prescribed" to "receive" the information collected will reflect whether there is any evidence of ARVs received, which includes documentation that ARVs were prescribed. Changed the question wording to state "birthing person" instead of "mother". Revised question wording from "Drug name" to "If YES, specify all ARVs", "Date drug started" to "Date began" and "Date stopped" to "Date of last use." Removed response options "Not documented" and "Record not available." No longer collect "Gestational age drug started," "Drug stopped," or "Stop codes." No longer collect "Drug refused" separately from other response options. Updated designation of this field for collection from recommended to required.	To retain more frequently used practice in existing National HIV Surveillance System data collection to collect information on antiretrovirals. To better reflect that information should be collected for the birthing person regardless of gender identity or parental status. To align with document-based surveillance. To consolidate data collection into a single form for persons <13 years at time of HIV perinatal exposure or HIV diagnosis. Updated designation to align with current designation for this field when collected on the PHER form.
Section XI (PCRF): Birthing Person History, Variable: Did birthing person receive any ARVs during labor/delivery?	Consolidated collection of PHER form Q14 into existing PCRF Birthing Person History section field "Did mother receive any ARVs during labor and delivery?" with changes in question wording, and response options. Moved to the PCRF Birthing Person History section. Although the question wording was updated from "prescribed" to "receive" the information collected will reflect whether there is any evidence of ARVs received, which includes documentation that ARVs were	To retain more frequently used practice in existing National HIV Surveillance System data collection to collect information on antiretrovirals. To better reflect that information should be collected for the birthing person regardless of gender identity or parental status. To align with document-based surveillance. To consolidate data collection into a single

	prescribed. Changed the question wording to state "birthing person" instead of "mother. Revised question wording from "Drug name" to "If YES, specify all ARVs", "Date received" to "Date began." Removed response options "Not documented" and "Record not available." No longer collect "Time received" or "Type of administration." No longer collect "Drug refused" separately from other response options. Updated designation of this field for collection from recommended to required.	form for persons <13 years at time of HIV perinatal exposure or HIV diagnosis. Updated designation to align with current designation for this field when collected on the PHER form.
Section XII (PCRF): Treatment/Services Referrals, Variable: This child ever taken any ARVs?	Consolidated collection of PHER form Q20 into PCRF Treatment/Services Referrals section "This child ever taken any ARVs?" with changes in question meaning, question wording, and response options. Changed question meaning from collecting antiretrovirals prescribed to antiretrovirals received. Revised question wording from "Drug name" to "ARV medication", "Date drug started" to "Date began" and "Stop Date" to "Date of last use." Removed response options "Not documented" and "Record not available." No longer collect "Drug Refused," "Time started," "Drug stopped," or "Stop codes." Modified layout of response options to change from collecting all ARV medications received for a specific reason in one row to allowing up to five ARV medications to be documented on separate rows along with the reason for use. Additional ARV medications can be recorded in the Comments section.	To retain more frequently used practice in existing National HIV Surveillance System data collection to collect information on antiretrovirals received rather than prescribed. To reduce data collection burden while consolidating data collection into a single form for persons <13 years at time of HIV perinatal exposure or HIV diagnosis.

Variables Moved from the PHER Form to the PCRF

Section, Variable	Change Proposed	Reason for Change Proposed
Section X (PCRF): Birth History, Variable: If Cesarean delivery, mark all the following indications that apply	Moved from PHER form Q18 to PCRF Birth History section with no change in question meaning or question wording, but changes to response options. Removed "Not applicable" response option. Changed the response option wording to state "birthing person" instead of "mother."	To better reflect that information should be collected for the birthing person regardless of gender identity or parental status. To consolidate data collection into a single form for persons <13 years at time of HIV perinatal exposure or HIV diagnosis.
Section X (PCRF): Birth History, Variable: Birth information	Moved from PHER form Q17 to PCRF Birth History section with no changes to question wording, but changes in question meaning and response options. Question meaning changed by no longer collecting the date and time associated with the "Onset of labor" or "Admission to labor and delivery." Removed response options "Birth not in hospital" and "Record not available."	To consolidate data collection into a single form for persons <13 years at time of HIV exposure or diagnosis.
Section X (PCRF): Birth History, Variable: Was a toxicology screen done on the infant at birth?	Moved from PHER form Q10 to PCRF Birth History section with no change in question meaning, but changes in question wording and response options. Updated label from "at birth" to "after birth." Updated response options to include results for three additional substances (fentanyl, K2, and PCP). Removed "Toxicology screening not documented" response option. Added "Unknown" response option. Revised question wording and collection of response options to collect information about each specific substance screened and whether the result of the screening was "Positive," "Negative," "Unknown," or "Not screened" for each substance. Added field to collect date screened for each substance. Added instruction to clarify how to complete the form is	To reflect that information should be collected on any infant toxicology screening done within a time period after birth rather than just a toxicology screening done only at time of birth. To update current list of substances to include substances with a growing frequency of use so that they are systematically collected rather than captured through the "Other" response option. To differentiate which substances were included in the toxicology screening and the toxicology screening result for each specific substance. To consolidate data collection into a single form for persons

	the same substance is screened for more than one time.	<13 years at time of HIV perinatal exposure or HIV diagnosis.
Section XI (PCRF): Birthing Person History, Variable: Birthing Person City/County ID Number	Moved collection of PHER form "Mother's City Number" to PCRF Birthing Person History section with change in question wording, but no change in question meaning or response options. Changed question wording from "Mother's City Number" to "Birthing Person City/County ID Number."	To consolidate data collection into a single form for persons <13 years at time of HIV perinatal exposure or HIV diagnosis. To better reflect that information should be collected for the birthing person regardless of gender identity or parental status.
Section XI (PCRF): Birthing Person History, Variable: Has the birthing person ever been pregnant before this pregnancy? Include previous pregnancies that ended in a live birth, miscarriage, stillbirth, or induced abortion	Moved from PHER form Q6 to PCRF Birthing Person History section with no change in question meaning, but changes in question wording and response options. Changed the question wording to state "birthing person" instead of "mother." Changed sub-question wording from "No. of previous pregnancies" to "If YES, specify how many previous pregnancies." Revised response options from collecting the number of previous live births, previous miscarriages or stillbirths, and previous induced abortion to collect pregnancy outcome and year of outcome for each individual previous pregnancy. No longer collect total previous abortions.	To better reflect that information should be collected for the birthing person regardless of gender identity or parental status. To improve quality assurance activities associated with reporting of HIV status of previous pregnancies. To consolidate data collection into a single form for persons <13 years at time of HIV perinatal exposure or HIV diagnosis.
Section XI (PCRF): Birthing Person History, Variable: If NO, select reason (Associated with “Did birthing person receive any ARVs during this pregnancy?)	Moved from PHER form Q12a to PCRF Birthing Person Information section with changes in question meaning, question wording, and response options. Updated question meaning by changing to respond if antiretrovirals were not received instead of not prescribed. Updated question wording from "If no antiretroviral drug was prescribed during pregnancy, check reason." to "If NO, select reason." Removed response option "Not documented." Updated wording in	To retain more frequently used practice in existing National HIV Surveillance System data collection to collect information on antiretrovirals received rather than prescribed. To better reflect that information should be collected for the birthing person regardless of gender identity or parental status. To align with document-based surveillance. To consolidate data collection into a single form for persons

	response options to state "birthing person" instead of "mother."	<13 years at time of HIV perinatal exposure or HIV diagnosis.
Section XI (PCRF): Birthing Person History, Variable: If NO, select reason (Associated with Did birthing person receive any ARVs during labor/delivery?)	Moved from PHER form Q14a to PCRF Birthing Person Information section with changes in question meaning, question wording, and response options. Updated question meaning by changing to respond if antiretrovirals were not received instead of not prescribed. Updated question wording from "If no antiretroviral drug was prescribed during pregnancy, check reason." to "If NO, select reason." Removed response option "Not documented." Updated wording in response options to state "birthing person" instead of "mother."	To retain more frequently used practice in existing National HIV Surveillance System data collection to collect information on antiretrovirals received rather than prescribed. To better reflect that information should be collected for the birthing person regardless of gender identity or parental status. To align with document-based surveillance. To consolidate data collection into a single form for persons <13 years at time of HIV perinatal exposure or HIV diagnosis.
Section XI (PCRF): Birthing Person History, Variable: Was the birthing person screened for any of the following conditions during this pregnancy?	Moved from PHER form Q4 to PCRF Birthing Person Information section with changes in question wording, question meaning, and response options. Changed the question wording to state "birthing person" instead of "mother." Changed question meaning by updating instructions from "Check test(s) performed before birth, but closest to date of delivery or admission to labor and delivery" to "Check test(s) performed before birth." Removed "Not documented" and "Record not available" from response options for specific diagnoses.	To better reflect that information should be collected for the birthing person regardless of gender identity or parental status. To align with document-based surveillance. To consolidate data collection into a single form for persons <13 years at time of HIV perinatal exposure or HIV diagnosis.
Section XI (PCRF): Birthing Person History, Variable: Were any of the following conditions diagnosed for the birthing person during this pregnancy or at the time of labor and delivery?	Moved from PHER form Q5 to PCRF Birthing Person Information section with no change in question meaning, but changes in question wording and response options. Changed the question wording to state "birthing person" instead of "mother" and to state as a question rather than a statement. Updated abbreviation in	To better reflect that information should be collected for the birthing person regardless of gender identity or parental status. To make HBsAg terminology consistent throughout the form. To align with document-based surveillance. To consolidate data

	one of the diagnoses collected from "HbSAg+" to "HBsAg." Removed instruction "See instructions for data abstraction for definitions." Removed "Not document" and "Record not available" from response options.	collection into a single form for persons <13 years at time of HIV perinatal exposure or HIV diagnosis.
Section XI (PCRF): Birthing Person History, Variable: Were substances used by the birthing person during this pregnancy?	Moved from PHER form Q8 to PCRF Birthing Person History section with no change in question meaning, but changes in the question wording and response options. Changed the question wording from "Was substance use during pregnancy noted in the medical or social work records?" to "Were substances used by the birthing person during this pregnancy?" Removed the overall "Record Not Available" response option; updated wording of response option from "No (Go to 9)" to "No."	To align with document-based surveillance. To consolidate data collection into a single form for persons <13 years at time of HIV perinatal exposure or HIV diagnosis.
Section XI (PCRF): Birthing Person History, Variable: Collection of whether specific substances were used or injected (Associated with Were substances used by the birthing person during this pregnancy?)	Moved questions from PHER form Q8a and 8b to PCRF Birthing Person History section with no change in question meaning, but changes in question wording and response options. Update question wording from "If yes, indicate which substances were used during pregnancy" and “If substances used, were any injected?" to collect whether each substance was used and injected. Updated response options to include results for three additional substances (fentanyl, K2, and PCP). Updated to record response options of "Used and injected," "Used and did not inject," "Used and unknown if injected," "Did not use," and "Unknown if used" for each specific substance rather than just selecting substance if "Yes."	To update current list of substances to include substances with a growing frequency of use so that they are systematically collected rather than captured through the "Other" response option. To differentiate between when a specific substance was not used or injected versus when there's not sufficient documentation to indicate whether a specific substance was used or injected. To consolidate data collection into a single form for persons <13 years at time of HIV perinatal exposure or HIV diagnosis.
Section XI (PCRF): Birthing Person History, Variable: Was a toxicology screen done on the birthing person (either during this pregnancy or at the time of delivery)?	Moved from PHER form Q9 to PCRF Birthing Person History section with no change in question meaning, but changes in question wording and response options. Changed the question wording	To consolidate data collection into a single form for persons <13 years at time of HIV perinatal exposure or HIV diagnosis.

	to state "birthing person" instead of "mother." Updated response options to include results for three additional substances (fentanyl, K2, and PCP). Removed "Toxicology screening not documented" response option. Added "Unknown" response option. Revised question wording and collection of response options to collect information about each specific substance included in the toxicology screening and whether the result of the screening was "Positive," "Negative," "Unknown," or "Not screened" for each substance. Added field to collect date screened for each substance. Added instruction to clarify how to complete the form is the same substance is screened for more than one time.	

Variables on PHER Form No Longer Collected

Section, Variable	**Change Proposed**	**Reason for Change Proposed**
Section VII (PCRF): Patient History, Variable: Was the biological mother counseled about HIV testing during this pregnancy, labor, or delivery?	No longer collect.	To reduce burden given implementation of routine opt-out testing without requirements for counseling in the majority of jurisdictions.
Section XII (PCRF): Treatment/Services Referrals, Variable: Was this child breastfed?	No longer collect.	Important to differentiate whether breastfeeding was by the birthing person or a non-birthing person. New fields proposed to add to the Patient History section to collect information about breastfeeding by birthing person and non-birthing person.
Section (PHER): Comments, Variable: Comments	No longer collect.	Existing Comments section on the PCF can be used to collect the information.
Section (PHER): Q1, Variable: If information on the mother is not	No longer collect.	Existing field "This child's primary caretaker is" in the PCRF

available, was the child adopted, or in foster care?		Treatment/Services Referrals section with no changes to the existing question or response option can be used to collect similar information.
Section (PHER): Q2, Variable: Records abstracted	No longer collect.	Existing field "Document Source" in the PCRF Health Department Use only section with no changes can be used to collect similar information.
Section (PHER): Q7, Variable: Complete the chart for all siblings. (DOB, age, HIV serostatus)	No longer collect.	Information can be collected by completing separate PCRFs for each sibling and linking with the birthing person's record.
Section (PHER): Q11, Variable: Was the mother's HIV serostatus noted in her prenatal care medical records?	No longer collect.	Field "Birthing person's 's HIV infection status" in the PCRF Patient History section can be used to collect similar information.
Section (PHER): Q13, Variable: Was mother's HIV serostatus noted in her labor and delivery records?	No longer collect.	Field "Birthing person's 's HIV infection status" in the PCRF Patient History section can be used to collect similar information.
Section (PHER): Q15, Variable: Was mother referred to HIV care after delivery?	No longer collect.	Information about referrals to medical care are not well documented. Existing fields in the Laboratory Data section of the birthing person's ACRF can be used to assess receipt of HIV care after delivery.
Section (PHER): Q16, Variable: First CD4 or first viral load after discharge	No longer collect.	Existing fields in the Laboratory Data section of the birthing person's ACRF can be used to collect this information.
Section (PHER): Q19, Variable: Was mother's HIV serostatus noted on the child's birth record?	No longer collect.	Field "Birthing person's 's HIV infection status" in the PCRF Patient History section can be used to collect similar information.

Section (PHER): Q20a, Variable: If no antiretroviral drug as prescribed, indicate reason.	No longer collect.	To reduce data collection burden while consolidating data collection into a single form for persons <13 years at time of HIV perinatal exposure or HIV diagnosis.

New Variables to Collect

Section, Variable	**Change Proposed**	**Reason for Change Proposed**
Section VII (PCRF): Patient History, Variable: Child breastfed/chestfed by birthing person	Added new field labeled "Child breastfed/chestfed by birthing person" with response options of "Yes," "No," and "Unknown." Assigned designation of this field for collection as required.	To improve the ability to correctly attribute infection to perinatal transmission when child's infection was determined to occur during breastfeeding by the birthing person.
Section VII (PCRF): Patient History, Variable: Child received premasticated/pre-chewed food from birthing person	Added new field labeled "Child received premasticated/pre-chewed food from birthing person" with response options of "Yes," "No," and "Unknown." Assigned designation of this field for collection as required.	To improve the ability to correctly attribute infection to perinatal transmission when child's infection was determined to occur due to receipt of premasticated/pre-chewed food from the birthing person.
Section VII (PCRF): Patient History, Variable: Child breastfed/chestfed by non-birthing person	Added new field labeled "Child breastfed/chestfed by non-birthing person" with response options of "Yes," "No," and "Unknown." Assigned designation of this field for collection as required.	To improve the ability to correctly attribute infection to non-perinatal transmission when child's infection was determined to occur during breastfeeding by a non-birthing person.
Section VII (PCRF): Patient History, Variable: Child received premasticated/pre-chewed food from non-birthing person	Added new field labeled "Child received premasticated/pre-chewed food from non-birthing person" with response options of "Yes," "No," and "Unknown." Assigned designation of this field for collection as required.	To improve the ability to correctly attribute infection to perinatal transmission when child's infection was determined to occur due to receipt of premasticated/pre-chewed food from the non-birthing person.
Section XI (PCRF): Birthing Person History, Variable:	Added new field labeled "Was a test result (with a specimen collection date within the 6 weeks on or before delivery) documented in the birthing person's labor/delivery record" with response	To identify whether medical providers were aware of recent HIV test results during labor and delivery to make

	options of "Yes," "No," and "Unknown" for both CD4 and Quantitative NAAT (RNA or DNA) test types.	clinical decisions about medical care provided during labor and delivery.

Other Changes

Section, Variable	**Change Proposed**	**Reason for Change Proposed**
Section (PCRF): Form Title, Variable: N/A	Changed title of PCRF form from "Pediatric HIV Confidential Case Report Form (Patients aged <13 years at time of diagnosis)" to "Pediatric HIV Confidential Case Report Form (Patients aged <13 years at time of perinatal exposure or patients aged <13 years at time of diagnosis)."	To reflect that the form should be completed for patients exposed perinatally with or without consequent infection along with patients <13 years at time of HIV diagnosis.
Section N/A (PCRF): N/A, Variable: N/A	Increased number of pages of the hard copy PCRF from 4 pages to 6 pages.	To accommodate new variables being collected and the consolidation of the PHER form (4 pages) and existing PCRF (4 pages).
Section IV (PCRF): Patient Demographics, Variable: Gender Identity	Added variable to the hard copy PCRF.	Current gender identity is already collected in eHARS on the PCRF document. Updated for consistency between hard copy form and eHARS.
Section VII (PCRF): Patient History, Variable: All	Changed references from "biological mother" to "birthing person" for all questions in this section.	To better reflect that information should be collected for the birthing person regardless of gender identity or parental status.
Section IX (PCRF): Laboratory Data, Variable: Is earliest evidence of diagnosis documented by a physician rather than by laboratory test results?	Updated label from "If laboratory tests were not documented, is patient confirmed by a physician as" to "Is earliest evidence of diagnosis documented by a physician rather than by laboratory test results?"	To clarify instructions for when this field should be completed.
Section IX (PCRF): Laboratory Data, Variable: Date of diagnosis by physician	Update label from "Date of diagnosis" to "Date of diagnosis by physician" for both fields collected associated with "If laboratory tests were not documented, is patient confirmed by a physician as."	To clarify which date should be used to complete the fields.

Section X (PCRF): Birth History, Variable: N/A	Changed instruction associated with section title from "Birth History (for Perinatal Cases only)" to "Birth History (for patients exposed perinatally with or without consequent infection)."	To clarify instructions for when this section of the form should be completed.
Section X (PCRF): Birth History, Variable: Delivery	Revised response options. Added new response option " Cesarean," removed the numbers from the start of the other remaining response options, and removed response options "2-2-Elective Cesarean," "3-Nonelective Cesarean" and "4-Cesarean, unknown type." Updated designation of this field for collection from optional to required.	To align with current medical practice; cesareans are not an elective procedure. Updated designation to align with the current designation that the indicators for Cesarean delivery is required.
Section X (PCRF): Birth History, Variable: Congenital Disorders	Revised label from "Birth Defects" to "Congenital Disorders." Updated from “If yes, specify types” to “If YES, specify types.”	To align with current preferred terminology and improve consistency of capitalization for “if yes” questions.
Section XI: Birthing Person History, Variable: N/A	Added a new section to PCRF with title "Birthing Person History (for patients exposed perinatally with or without consequent infection)."	To limit the length of the Birth History section.
Section XI (PCRF): Birthing Person History, Variable: Birthing Person Date of Birth, Birthing Person Last Name Soundex, Birthing Person Country of Birth, Other Birthing Person ID (specify type of ID and ID number), Prenatal Care—Total Number of Prenatal Care Visits, Did birthing person receive any antiretrovirals (ARVs) prior to this pregnancy?	Moved from Birth History section to newly created Birthing Person History section with change to question wording and no change to the response options. As applicable, changed wording from "Maternal" to "Birthing Person." Updated label for variable to collect the birthing person’s date of birth from "DOB" to "Date of Birth."	To limit the length of the Birth History section. To better reflect that information should be collected for the birthing person regardless of gender identity or parental status.

Table 2. eHARS Only Changes

Description	Change Proposed	Reason for Change Proposed
ID Type	Added additional types of patient identifiers from other data collection systems that can be entered or imported into eHARS: EvalWeb Client ID EvalWeb Form ID EvalWeb Partner Services Case Number Integrated Disease Surveillance System Person ID Integrated Disease Surveillance System Event ID No changes to the hard copy form.	To improve linkages with other data collection systems.
Person View Hierarchy	Created a person view hierarchy associated with the variables under the heading "Acute HIV Infection" on the Clinical tab.	To summarize information associated with suspected acute HIV infection.

Table 3. SER Changes

Form, Page, Section, Question/Field	Change Proposed	Reason for Change Proposed
SER Form Pages 1-9	All evaluation periods are updated to reflect the 2023 report.	To ensure that jurisdictions are reporting on the correct evaluation periods.
SER Form Pages 2-9	Minor edits in wording were made throughout for consistency and clarity. Examples: Introduction - Moved key personnel names to table format for improved formatting Part F. Submission of Required Outcome Standards with SAS Tables - Corrected the jurisdictions listed in the EHE footnote to include only the jurisdictions expected to report on the EHE indicators.	These minor edits were made to make the document more consistent and accurate in its language. These changes do not impact the meaning of any questions.
SER Form Page 1	Added a field to capture email addresses of contacts.	Previously we captured the names of the primary surveillance contact, the secondary surveillance contact, and the Overall Responsible Party. We are now going to capture the email addresses for these contacts as well, so we have up to date information on these key staff members.
SER Form Page 2. Section B. Laboratory, Question 2	Updated the timeframe:	In the 2022 SER, jurisdictions were asked if they had completed an assessment up until that point in the NOFO. Now that we have

<table>
<tr>
<td></td>
<td>2. ~~Since 2018,~~ In 2022 did your surveillance program conduct an assessment on laboratories that conduct HIV-related testing for persons who reside in your jurisdiction? This assessment is to maintain documentation, such as types of tests performed and LOINC usage, by all laboratories that report to your jurisdiction.
☐ Yes
• ~~What year(s)? Click here to enter text.~~
☐ No</td>
<td>that information, we only need to ask if an assessment was done in the most recent year, i.e., 2022, in the 2023 SER.</td>
</tr>
<tr>
<td>SER Form Page 2. Section B. Laboratory, Question 3</td>
<td>Edited the follow up questions to Question 3 to capture time frame:

3. Are you aware of any laboratory reporting lapses of HIV-related test results for persons who reside within your jurisdiction that resulted in missing laboratory data in your December 2022 data transfer? Please include lapses in laboratory reporting to CDC, including those attributed to the laboratory not reporting test results or because the HL7 reader/transmitter in the health department did not send the results to HIV surveillance.
☐ Yes
<table>
<tr><th>Year of specimen collection</th><th>Approximately what percentage of your total jurisdiction's laboratory volume is missing for the calendar year indicated?</th><th>Approximately what percentage of your total jurisdiction's CD4 results (< 200 and ≥ 200) and viral load results (detectable and undetectable) are missing for the calendar year indicated?</th></tr>
<tr><td>2022*</td><td></td><td></td></tr>
<tr><td>2021</td><td></td><td></td></tr>
</table>
*At a minimum, lab results through September 2022
• ~~Approximately what percentage of your total jurisdiction's laboratory volume is missing because of this?~~
• ~~Approximately what percentage of all CD4 results (< 200 and ≥ 200) and all viral load results (detectable and undetectable) are missing because of this? Click here to enter text.~~
☐ No
• In 2022, did your program monitor the quality of incoming reports of laboratory test results (including test result volumes) on a quarterly basis or more frequently? ☐ Yes ☐ No</td>
<td>Question 3 was edited in order to capture what year a reporting lapse occurred in. This is important for determining which years a jurisdiction did not have complete laboratory reporting.</td>
</tr>
<tr>
<td>SER Form Page 2. Section B. Laboratory, Question 4</td>
<td>Deleted question 4:

~~4. By December 2021, did your surveillance program transfer to CDC via eHARS all CD4 (<200 and ≥200) and viral load (detectable and~~</td>
<td>Question 4 is no longer needed to determine laboratory reporting completeness. Question 3 is sufficient.</td>
</tr>
</table>

<table>
<tr>
<td></td>
<td>~~undetectable) test results from laboratory reports received from 2019-2021?~~
<table>
<tr><th rowspan="2">~~Year reports were received~~</th><th colspan="3">~~CD4 (<200 and ≥200)~~</th><th colspan="3">~~Viral load test~~</th></tr>
<tr><th>~~Yes~~</th><th>~~No~~</th><th>~~Describe type of CD4 results received~~</th><th>~~Yes~~</th><th>~~No~~</th><th>~~Describe type of viral load results received~~</th></tr>
<tr><td>~~2019~~</td><td>☐</td><td>☐</td><td></td><td>☐</td><td>☐</td><td></td></tr>
<tr><td>~~2020~~</td><td>☐</td><td>☐</td><td></td><td>☐</td><td>☐</td><td></td></tr>
<tr><td>~~2021*~~</td><td>☐</td><td>☐</td><td></td><td>☐</td><td>☐</td><td></td></tr>
</table>
~~*At a minimum, reports received from January 2021 through September 2021~~</td>
<td></td>
</tr>
<tr>
<td>SER Form
Page 4. Section E. Cluster Detection and Response, Question 1</td>
<td>The following question was deleted:

~~Did your program submit a final written plan for establishing and maintaining capacity for cluster and outbreak detection and response according to the guidance in Detecting and Responding to HIV Transmission Clusters: A Guide for Health Departments by July 15, 2021?~~</td>
<td>This question on summiting a final cluster and outbreak detection and response plan is not relevant in the 2023 SER.</td>
</tr>
<tr>
<td>SER Form
Page 4. Section E. Cluster Detection and Response, Follow-up questions</td>
<td>The follow up questions on Cluster and Detection Response was deleted.

~~If you did not meet the standards in 1 - 3 above, please discuss each unmet standard:~~
~~a. Why you did not meet the minimum standard for cluster detection and response in 2021.~~
~~b. Your plan to ensure your program meets this standard in 2022.~~</td>
<td>This information is no longer needed to be captured in the SER. It will be captured in the End of Year report (EOYR), which is where information on all other standards that were not met is currently collected.</td>
</tr>
<tr>
<td>SER Form
Pages 4-5. Section F. Submission of Required Outcome Standards with SAS Tables</td>
<td>Deleted yes/no question for whether each output report was attached.
Deleted the portion of the outcome measure table that required data entry and instead just listed outcome measures for reference.

One table was added, “Outcome indicator summary”.

Moved to Section C. Perinatal:
Provide percentage of perinatally HIV exposed infants born in 2020 who have HIV infection status determined by 18 months of age (Standard: 85%):

Wording of timeliness of laboratory reporting indicator was updated:</td>
<td>All the outcome measures are included in the output reports that are submitted with the SER, so they do not need be entered into the form. The one indicator that was in the outcome table that is not included in any of the output reports (perinatal HIV exposure reporting) was moved to Section C. Perinatal. The language in the timeliness of laboratory reporting indicator was updated to more accurately reflect how the indicator is being measured.</td>
</tr>
</table>

	Of all laboratory test results entered into eHARS ~~with a specimen collection date~~ during 2021 for persons with HIV infection diagnosed during 2021, at least 85% were entered into eHARS within 60 days of the specimen collection date, assessed December 2022	
SER Form Page 6. Section F. Submission of Required Outcome Standards with SAS Tables	Deleted the following question: ~~If you did not meet the Previous Negative HIV Test or Viral Suppression for Cluster Members standard above, please discuss:~~ ~~a. Why you did not meet the minimum standard in 2022.~~ ~~b. Your plan to ensure your program meets the standard in 2023.~~	This information is no longer needed to be captured in the SER. It will be captured in the EOYR, which is where information on all other standards that were not met is currently collected.
SER Form Page 10. Section I. Security and Confidentiality, Question 6	Added a 'Not Applicable' response option and clarified that that the question refers to data sharing with the Medical Monitoring Project. Did your program implement practices that support secure sharing and use of HIV data across necessary programs within the health department~~, including~~ for collaboration with the Medical Monitoring Project (MMP) (if applicable)? ☐Not applicable	Clarified that the question refers to data sharing with MMP, which is only application to sites funded for MMP, so a 'Not applicable' response option was added.