

**Summary of Proposed Changes in the ICR for the
National HIV Surveillance System (NHSS) OMB # 0920-0573
October 28, 2020**

Summary of Changes

We are requesting a non-substantial change to the information collection request (ICR) for the National HIV Surveillance System (NHSS) OMB #0920-0573. Specifically, we are requesting a non-substantial change to the Standards Evaluation Report (SER) as provided in Attachment 1 and the specific changes are outlined in Table 1. The changes were made to simplify language and improve clarity. The proposed form will be used by jurisdictions in January 2021 to report their 2019 outcomes. These changes will result in fewer overall questions. However, we estimate the burden to complete the new SER will remain unchanged and take one workday (approximately eight hours) to complete. Therefore, no changes to the burden table are requested. The current burden table for this ICR (with no changes) is provided in Exhibit 12.A.

Table 1. Summary of Changes to the Standards Evaluation Report (SER)

OMB Form 0920-0573	New Proposed Form	Changed Proposed	Reason for Change Proposed
Pages 1-9	Pages 1-9	All evaluation periods are updated to reflect the 2021 report.	To ensure that jurisdictions are reporting on the correct evaluation periods.
Page 2. Part B. Laboratory	Page 2. Part B. Laboratory	<p>Question 1 was reworded.</p> <p><u>The old version:</u></p> <p>1. In 2019, did your surveillance program do an assessment to identify all laboratories (in state and out of state) that conducted HIV-related testing for providers and facilities in your jurisdiction using a method such as a lab survey, Centers for Medicare and Medicaid Services (CMS) search, or state laboratory licensing office search? This must include more than just counting the number of labs submitting HIV-related test results to the health department.</p> <p><input type="checkbox"/> Yes</p> <ul style="list-style-type: none"> • Number of laboratories? Click here to enter text. <ul style="list-style-type: none"> o Please describe how your program obtained this number. Click here to enter text. <p><input type="checkbox"/> No</p> <ul style="list-style-type: none"> • Based on eHARS data, what is the number of HIV-testing laboratories that reported at least one HIV test result to your program during 2019? <ul style="list-style-type: none"> o Number of laboratories: Click here to enter text. <p><u>The new version:</u></p> <p>1. In 2020, did your surveillance program develop and/or update the list of all laboratories (in state and out of state) that conducted HIV-related testing for persons who reside in your jurisdiction using a method such as Centers for Medicare and Medicaid Services (CMS) search, or evaluation of your electronic laboratory report (ELR) program baseline spreadsheet?</p> <p><input type="checkbox"/> Yes</p> <ul style="list-style-type: none"> • Did you identify new laboratories that conduct HIV testing for persons who reside in your jurisdiction? <ul style="list-style-type: none"> <input type="checkbox"/> Yes <input type="checkbox"/> No • What is the total number of laboratories that report HIV-related test results for persons who reside in your 	Updated to clarify the meaning of and process for determining the number of laboratories reporting in a jurisdiction

		<p>jurisdiction? Click here to enter text.</p> <p><input type="radio"/> Please describe how your program obtained this number. Click here to enter text.</p> <p><input type="checkbox"/> No</p>	
Page 2. Part B. Laboratory	Page 2. Part B. Laboratory	<p>Inserted the following question:</p> <p>2. In 2020, did your surveillance program conduct an assessment on laboratories that conducted HIV-related testing for persons who reside in your jurisdiction? This assessment is to maintain documentation on the types of tests performed and LOINC usage by all laboratories that report to your jurisdiction.</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>	Updated to clarify the meaning of a laboratory assessment
Page 2. Part B. Laboratory	Page 2. Part B. Laboratory	<p>Changed question 3 (formerly 2)</p> <p><u>Old version</u></p> <p>2. Are you aware of any laboratories that conducted HIV-related testing for providers and facilities within your jurisdiction that <u>did not report any results</u> to your program in 2019?</p> <p><input type="checkbox"/> Yes</p> <ul style="list-style-type: none"> Approximately what percentage of your jurisdiction's lab volume is missing because of this? Click here to enter text. <p><input type="checkbox"/> No</p> <p><u>New version</u></p> <p>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 lab data in your December 2020 data transfer? Please include lapses attributed to either the lab not reporting test results or because the HL7 reader/transmitter in the health department did not send the results to HIV surveillance</p> <p><input type="checkbox"/> Yes</p> <ul style="list-style-type: none"> Approximately what percentage of your total jurisdiction's lab volume is missing because of this? Click here to enter text. Approximately what percentage of all CD4 results (<200 and ≥200), or all viral load results (detectable and undetectable) are missing because of this? Click here to enter text. <p><input type="checkbox"/> No</p> <ul style="list-style-type: none"> In 2020, did your program monitor the quality of incoming reports of laboratory test results (including test result volumes) on a quarterly basis or more frequently? <input type="checkbox"/> Yes <input type="checkbox"/> No 	Combined and clarified questions 2 and 3 to determine if all lab test results were transmitted to CDC.
Page 2. Part B. Laboratory	Page 2. Part B. Laboratory	<p>Delete original question 3 -</p> <p>3. Of the laboratory data reported to your program during 2019, are you aware of any issues that prevented your program from receiving all positive/reactive HIV detection test results, all CD4 results (<200 and ≥200), or all viral load results (detectable and undetectable) and resulted in missing lab data in your December</p>	Combined and clarified questions 2 and 3 to determine if all lab test results were transmitted to CDC

		<p>2019 data transfer? For example:</p> <p>a. Laboratory XYZ usually sends 500 viral load results each month, however, during August, undetectable viral load results were not received from Laboratory XYZ and the problem was not resolved by December 2019; or</p> <p>b. Laboratory XYZ was transmitting all viral load result but the HL7 ELR reader/transmitter in the health department did not send the test results to the HIV program</p> <p><input type="checkbox"/> No</p> <ul style="list-style-type: none"> In 2019, did your program monitor the quality of incoming reports of laboratory test results (including test result volumes) on a quarterly basis or more frequently? <input type="checkbox"/> Yes <input type="checkbox"/> No <p><input type="checkbox"/> Yes</p> <ul style="list-style-type: none"> Approximately what percentage of all test results in a given year is typically reported by this laboratory or laboratories? Click here to enter text. Approximately what percentage of the test results expected from this laboratory or laboratories in 2019 was not received? Click here to enter text. Please describe the expected test results that were not received from this laboratory or laboratories: Click here to enter text. 	
Page 3. Part B. Laboratory	Page 3. Part B. Laboratory	<p>Edit paragraph 4: Deleted columns titled "If "no", what % of results received have been transferred to CDC?"</p> <p>Also edited two headings:</p> <ul style="list-style-type: none"> "CD4 Results" became "CD4 (< 200 and ≥ 200)" "Viral load results" became "Viral load tests (detectable and undetectable)" 	Shortened and clarified this to determine what CD4 and VL are being transmitted to CDC
Page 3. Part C. Pediatric/Perinatal	Page 3. Part C. Pediatric/Perinatal	For the first question on "Birth Ascertainment," deleted "and infants with HIV infection not [reported to surveillance, and enter the results into eHARS]"	Revised so that the question is specific to completing linkage activities. A new question (1C) was added to assess the status of entering the results of the linkage into eHARS. This change allows HICSB to be able to differentiate between jurisdictions who completed the linkage but did not enter the results into eHARS and jurisdictions who did not complete the linkage.
Page 3. Part C. Pediatric/Perinatal	Page 3. Part C. Pediatric/Perinatal	<p>Inserted three follow-up questions to 1A. One is a yes/no question but two require text responses. The three questions include:</p> <p>"1B. If no to 1A, please describe why you did not link with all state/local birth certificate data. [Free text]"</p>	<p>For 1B - To understand why jurisdictions did not link to all state/local birth certificate data so that HICSB can better tailor technical assistance to support conducting this required activity.</p> <p>For 1C - To assess the status of</p>

		<p>“1C. If yes to 1A, did you enter all information identified from the linkage to state/local birth certificate data into eHARS before your final December 2020 data transfer to CDC?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No “</p> <p>“ID. If no to 1C, please describe why you did not enter all information identified from the link to state/local birth certificate data into eHARS. [Free text]”</p>	<p>entering the results of the linkage into eHARS. This change allows HICSB to be able to differentiate between jurisdictions who completed the linkage but did not enter the results into eHARS and jurisdictions who did not complete the linkage.</p> <p>For 1D - To understand why jurisdictions completed the linkage but did not enter the results into eHARS so that HICSB can better tailor technical assistance to support conducting this required activity.</p>
Page 3. Part C. Pediatric/Perinatal	Page 3. Part C. Pediatric/Perinatal	<p>Moved the following question to the “Outcomes Standards for Surveillance”</p> <p>“Did ≥ 85% of perinatally exposed infants born in 2018 have HIV infection status determined by 18 months of age?”</p>	This measure is actually an outcome measure for perinatally exposed infants and so it should be in the “Outcome Standards for Surveillance” section.
Page 3. Part C. Pediatric/Perinatal	Page 3. Part C. Pediatric/Perinatal	<p>With regard to Number of perinatally HIV exposed infants for birth year, inserted the following two questions:</p> <p>Does this match with the number of perinatally exposed infants reported to CDC through your final December 2020 data transfer?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>And:</p> <p>“If this does not match, please describe the reasons the numbers do not match (e.g., X perinatally exposed infants reported to health department that were not in the state/local birth certificate data because the infant was a resident of another jurisdiction).”</p>	Data quality reviews identified discrepancies in the number of perinatally HIV exposed infants reported through the surveillance system versus on the Standards Evaluation Report. This information will help HICSB assess and target assistance to improve the accuracy of the number of perinatally HIV exposed infants. Accurate information is necessary in order to monitor progress eliminating perinatal HIV transmission.
Page 4. Part E. Cluster Detection and Response	Page 4. Part E. Cluster Detection and Response	<p>The following sentence was edited to:</p> <p>In 20192020, did your program develop and submit a written plan for establishing and maintaining capacity for cluster and outbreak detection and response according to CDC guidance?</p>	Updated the year of interest and added ‘written draft’ to reflect the requirement that jurisdictions were expected to submit a written draft cluster and outbreak response plan.
Page 7. Part G. Submission of Required Outcome Standards without SAS Tables	Page 7. Part G. Submission of Required Outcome Standards without SAS Tables	<p>The following note was added to this section:</p> <p><u>Note: This section is optional since cluster detection activities were not required for all of 2019.</u></p>	Add this note to clarify that filling out this section is optional.
Page 7. Part G. Submission of Required Outcome Standards without SAS Tables	Page 7. Part G. Submission of Required Outcome Standards without SAS Tables	<p>The following edit was made to the footnote:</p> <p>For the two Testing/re-testing and PrEP Referral standards above, please briefly discuss what you plan to do in the coming year how you plan to improve testing/re-testing and PrEP referral outcomes for persons in clusters and risk networks. In-2021.</p>	Made minor edits to clarify footnote on table.

Exhibit 12.A Estimate of Annualized Burden Hours.

Form Name	No. of Respondents	No. of Responses per Respondent	Total No. of Annual Responses	Avg. Burden per Response (in hours)	Total Annual Burden (in hours)
Adult HIV Case Report(att 3a, 3c, 4a)	59	854	50,386	20/60	16,795
Pediatric HIV Case Report (att 3b, 3c, 4b)	59	3	177	20/60	59
Case Report Evaluations (att 3a, 3b, 3c)	59	86	5,074	20/60	1,691
Case Report Updates (att 3a, 3b, 3c, 4a, 4b)	59	2353	138,827	2/60	4,628
Laboratory Updates (att 3a, 3b, 3c, 4a, 4b)	59	9410	555,190	0.5/60	4,627
Deduplication Activities (att 4c)	59	2741	161,719	10/60	26,953
Investigation Reporting and Evaluation (att 3c, 4d, 4e)	59	901	53,159	1/60	886
Initial Cluster Report Form (att 3f, 4f)	59	2.5	148	1	148
Cluster Follow-up Form (att 3g, 4f)	59	5	295	30/60	148
Cluster Close-out Form (att 3h, 4e)	59	2.5	148	1	148
Perinatal HIV Exposure Reporting (PHER) (att 3c, 3d, 4b)	16	197	3,152	30/60	1,576
HIV Incidence Surveillance (HIS) (att. 3a, 3c, 4a)	7	2,282	15,974	5/60	1,331
Annual Reporting: Standards	59	1	59	8	472

Evaluation Report (SER)(att 3e)					
Total Burden					59,462

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

