

**Summary of Proposed Changes in the ICR for the
National HIV Surveillance System (NHSS) OMB # 0920-0573
September 1, 2021**

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 proposed form will be provided to jurisdictions in January 2022 to report their outcomes. Most of the changes are minor edits for clarity and consistency. We will be adding two new outcome indicators to track case and laboratory timelines among Ending the HIV Epidemic (EHE) jurisdictions. However, this will not add to the burden because the new EHE indicators will be generated using the same CDC-provided SAS program that generates all other outcome standards and will not require any additional time for respondents. Jurisdictions currently report the SER results via a Word document. However, we are exploring electronic data collection options such as RedCap that we may implement with the January 2022 submission to facilitate reporting. The final SER form with changes accepted is provided in Attachment 2.

In addition, we are requesting minor changes to the three Cluster Report Forms (Initial, Follow-up, and Close-out) as indicated in Attachments 3, 5, 7 and outlined in Table 2. Changes to the cluster report forms include minor edits to instructions or text of an existing question for clarification. In addition, changes in format of responses to two questions are requested. We are requesting an additional question to be added to better capture information more consistently from an existing field. The proposed forms will be provided to jurisdictions in January 2022 to continue their routine reporting of HIV clusters. In sum, these changes are minor and will not change the response time or burden hours for the Initial, Follow-up, or Closeout Cluster Report forms. The final Cluster report forms with changes accepted are provided in Attachments 4,6, and 8.

We estimate the burden to complete the SER and Initial, Follow-up and Closeout Cluster Reports will remain unchanged and take the same time 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)

Form, Page, Section, Question/Field	Change Proposed	Reason for Change Proposed
SER Form Pages 1-9	All evaluation periods are updated to reflect the 2022 report.	To ensure that jurisdictions are reporting on the correct evaluation periods.
SER Form Page 1	Added a field for the jurisdiction to enter the name of the jurisdiction, the primary and secondary surveillance contact, and the overall responsible party.	Added administrative fields to capture the current points of contact in the jurisdiction.
SER Form Pages 2-9	Minor edits in wording were made throughout for consistency and clarity. Examples: Part B. Laboratory <ul style="list-style-type: none"> - Question 1 changed state to jurisdiction to be inclusive for all funded entities - Question 2 changed lab to laboratory for consistency Part C. Pediatric/Perinatal <ul style="list-style-type: none"> - Added "territory" to questions to be inclusive of all funded jurisdictions. Part D. Geocoding and Data Linkage <ul style="list-style-type: none"> - Edited "CDC guidance" to "Geocoding and Data Linkage Technical Guidance for HIV Surveillance Programs" to be specific on what guidance it is referring to. Part F. Outcome Standards <ul style="list-style-type: none"> - Edited questions to use the phrase "cases" throughout for consistency. Part I. Security and Confidentiality <ul style="list-style-type: none"> - Made edits to define acronyms (e.g., D2C and MMP) 	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 2. Section B. Laboratory, Question 2	Updated the timeframe and added a question to specify the specific years: 2. Since 2018, 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, such as types of tests performed and LOINC usage, by all laboratories that report to your jurisdiction. <input type="checkbox"/> Yes • What year(s)? Click here to enter text. <input type="checkbox"/> No	This activity is required to be completed once in a 5-year funding cycle. Therefore, the question was edited to include the time frame of the NOFO. If they answer yes, then a follow up question asks them to specify which years.
SER Form Page 4. Section E. Cluster Detection and Response, Question 1	The following sentence was edited to: 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?	Updated the question to ask about the final plan instead of the draft plan that was due the year prior.
SER Form Pages 4-5. Section F. Submission of Required Outcome Standards with SAS Tables	Edited the list of SAS tables that should be included with the SER submission to match the names of the SAS output files. This was done for consistency and clarity. One table was deleted, "Viral Suppression for Cluster Members", because it is included within the Lab Reporting Tables. Two tables were added: "PS20_2010 HIV case report timeliness tables" and "PS20_2010 Laboratory results report timeliness tables". These are two new output SAS tables that produce the results for the two new indicators that are described below.	Edited the names of the SAS tables for clarity.
SER Form Pages 5-6. Section F. Submission of Required Outcome Standards with SAS Tables	Added two indicators to assess enhanced case and lab reporting timeliness. These were added to Part F Outcome Standards. Did ≥75% of all HIV cases whose diagnoses were first entered into eHARS during 2021, get first entered within 30 days after the date of diagnosis? Did ≥75% of all laboratory test results entered into eHARS during 2021, get entered within 14 days after the date of specimen collection?	These two indicators were added to evaluate the Respond Pillar for PS20-2010. They evaluate enhanced case and lab reporting timeliness within the Ending the HIV Epidemic in the US (EHE) jurisdictions. They will be calculated via a CDC-provided SAS program.
SER Form Page 7. Section G. Submission of Required Outcome Standards without SAS Tables	The following note was deleted from this section: <u>Note: This section is optional since cluster detection activities were not required for all of 2019.</u>	Cluster detection activities were required throughout 2020, so this note was deleted.
SER Form Page 7. Section I. Security and Confidentiality Q4	Question 4 in the Security and Confidentiality section was deleted and questions renumbered accordingly.	Response to Q4 is no longer needed. Q3 will provide the necessary information for this reporting year.

Table 2. Summary of Changes to the Cluster Report Form.

Form, Section, Question/Field	Change Proposed	Reason for Change Proposed
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All three Cluster report forms (Initial, Follow-up, Closeout)	Replaced 'Jurisdiction Name' with 'Reporting Jurisdiction Name'	To clarify that the field should be populated with the reporting jurisdiction name
Initial Cluster Report form, General cluster information Section 5a, 5b	Added fields 5a and 5b, for entry of the county or other geographic area for clusters identified by time-space analysis	To allow for systematic entry for data that was previously entered into a free-text field
Initial Cluster Report form, General cluster information Section 7	Reorganized response format for data entry to replaced free text field containing description with discrete cells for question 7. Removed the instruction : "Had this cluster been identified by any other method? (If yes, please describe the method(s) and date(s) of prior detection, and note other cluster IDs for previously identified clusters using the cell to the right) ", Replaced free-text entry box with discrete cells for data entry, revising question to read: "7.a If the cluster overlaps with another cluster identified by a different method, please select the method of identification, date of detection and cluster ID"	To allow for systematic entry for data that was previously entered into a free-text field
Initial cluster report form, non-molecular clusters Section 9b	Added question 9b: "Please describe the case definition you are using to determine which cases are included in this cluster (i.e., inclusion criteria for person, place, and time)."	To provide a separate field for information that was previously inconsistently entered into a narrative response field
All three Cluster report forms (Initial, Follow-up, Closeout), "Local cluster ID entered into eHARS" field instruction	Added clarifying note of instruction indicating recommended nomenclature: A local cluster ID must be populated on this form and in eHARS. For molecular clusters, please use the following nomenclature: the two-letter jurisdiction abbreviation followed by the year and month in which the cluster was first identified and Secure HIV TRACE cluster ID (e.g., GA_YYYYMM_10-5) For time-space clusters, please use the following nomenclature: the two letter jurisdiction abbreviation followed by the year and month in which the cluster was first identified and cluster ID with the initials 'TS' (e.g., GA_YYYYMM_TS789). Please ensure that cluster IDs do NOT contain personal identifiers.	To provide clarification on entry instructions and nomenclature
All three Cluster report forms (Initial, Follow-up, Closeout)	Edited text changing "HIV positive persons" to "People with HIV" throughout all forms	Non-substantive change to update the terminology to align with current CDC/DHAP terminology
Initial cluster report form, question 20 note	Edited text in note reading 'autopopulated from #18' to autopopulated from #13, #18a, and #13g)	Corrected previous error in note

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

Attachment 1. 2022 Standards Evaluation Report (SER) with changes tracked
Attachment 2 2022 Standards Evaluation Report (SER) with changes accepted
Attachment 3 Cluster Report Forms (Initial) with changes tracked
Attachment 4 Cluster Report Forms (Initial) with changes accepted
Attachment 5 Cluster Report Forms (Follow-up) with changes tracked
Attachment 6 Cluster Report Forms (Follow-up) with changes accepted
Attachment 7 Cluster Report Forms (Closeout) with changes tracked
Attachment 8 Cluster Report Forms (Closeout) with changes accepted