

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

### 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 modifications to the Standards Evaluation Report (SER) (attachment 3d) to align with information needed to assess HIV surveillance program performance in the new NOFO [PS24-0047 High-Impact HIV Prevention and Surveillance Programs for Health Departments](#). These changes in the SER will be implemented in the next report requested in February 2025 based on work conducted through the end of 2024. The edits consist of formatting and wording changes to better capture performance measures, questions to capture newly added process and outcome standards, deletion of questions no longer needed, and opportunities to provide contextual information. These contextual questions were previously answered separately in an end of year report (EOYR) and are being moved to the SER so all information on performance is captured together. These questions will only be answered by health departments that have not met performance standards. Changes are noted in Attachment 1 and the specific changes are outlined in Table 1. The final SER form with changes accepted is provided in Attachment 2. Throughout the form the nomenclature <Year>, <Year-1>, etc. is used to denote text that will be dynamic and will be updated each new reporting year. For example, on the 2025 SER, the <Year> field will be replaced with 2025 and the <Year-1> field will be replaced with 2024. Italicized text has been added to note future changes to the form. These will be included in the document that will be shared with health departments for their awareness but will not be in the electronic form in REDCap, because the electronic form will only include elements relevant for that year's submission. This SER form will continue to be completed in REDCap, a secure web application for building and managing online surveys and databases. Together, the proposed changes are within the scope of the already approved questions, involve both deletion and addition of questions, and modest updates to improve the usability of the form consistent with the process and outcome standards of the new NOFO that will not result in changes to the overall estimated burden hours for reporting the SER.

Attachment included:

Attachment 3d\_Standards Evaluation Report Form (SER)

**Table 1. SER Changes** (Note. Page numbers are based on Track Changes version in the 'All Markup' view)

Form, Page, Section, Question/Field	Change Proposed	Reason for Change Proposed						
SER Form Pages 1-15	<p>All evaluation periods were updated to be in a dynamic format.</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>- In 2023&lt;Year-1&gt;, did you link case reports for persons with diagnosed HIV infection whose assigned sex at birth is not male to the birth certificate data file from the vital records office for all 2022&lt;Year-2&gt; births to identify all perinatally exposed infants with a residence of birth in your jurisdiction?</li> <li>- Of the expected number of persons whose HIV infection was diagnosed during 2022&lt;Year-2&gt;, at least (≥) 95% are reported in eHARS, assessed December 2023&lt;Year-1&gt;</li> </ul>	To avoid annual submission of a change request for the information collection request (ICR) when only a year change is needed, we are now formatting the SER form to have dynamic fields.						
SER Form Page 1-3. Section A. Death Ascertainment	This section was restructured so that the questions are split by data source instead of by intended information to be gathered. The follow up question on unmet standards was split into three separate questions so that the responses about each data source appear in their own text box instead of grouped together. No additional information is being requested. The follow up questions will only be answered if a standard was not met. They will be made available to respond to in REDCap through skip pattern logic.	To better capture the modified death ascertainment process standards.						
SER Form Page 3-4. Section B. Laboratory	<p>Deleted questions 1 and 2</p> <ul style="list-style-type: none"> <li>- 1. In 2023, did your surveillance program develop and/or update the list of all laboratories.....</li> <li>- 2. In 2023 did your surveillance program conduct an assessment of laboratories....</li> </ul>	These questions are no longer needed.						
SER Form Page 3. Section B. Laboratory	Added a table of questions to capture new process standards and a follow up question on why standards were not met. The follow up question will only appear in REDCap if a standard was not met.	To assess the new/modified process standards. The follow up questions are being moved from the EOYR so that all information on performance is captured in the SER form.						
SER Form Page 4. Section B. Laboratory	<p>The format of question 3 was modified slightly.</p> <p>1. <b>Are you aware of any lapses in laboratory reporting lapses of HIV-related test results for persons who reside within your jurisdiction that resulted in missing laboratory data in your December &lt;Year-1&gt;2023 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.</b></p> <p><input type="checkbox"/> Yes</p> <table border="1" data-bbox="594 1222 1350 1414"> <thead> <tr> <th data-bbox="594 1222 730 1369">Year of specimen collection</th> <th data-bbox="730 1222 1024 1369">Approximately what percentage of your total jurisdiction's laboratory volume is missing for the calendar year indicated?</th> <th data-bbox="1024 1222 1350 1369">Approximately what percentage of your total jurisdiction's CD4 results (&lt; 200 and ≥ 200) and viral load results (detectable and undetectable) are missing for the calendar year indicated?</th> </tr> </thead> <tbody> <tr> <td data-bbox="594 1369 730 1414">&lt;Year-1&gt;-2023*</td> <td data-bbox="730 1369 1024 1414"></td> <td data-bbox="1024 1369 1350 1414"></td> </tr> </tbody> </table>	Year of specimen collection	Approximately what percentage of your total jurisdiction's laboratory volume is missing for the calendar year indicated?	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?	<Year-1>-2023*			To clarify the intent of the question.
Year of specimen collection	Approximately what percentage of your total jurisdiction's laboratory volume is missing for the calendar year indicated?	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?						
<Year-1>-2023*								

	<div style="border: 1px solid black; padding: 2px; display: inline-block;"> <p style="color: red; margin: 0;">&lt;Year-2&gt; 2022</p> </div> <p>*At a minimum, lab results through September 2023</p> <p><input type="checkbox"/> No</p> <ul style="list-style-type: none"> <li>• In 2023, 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</li> </ul>	
SER Form Page 4. Section B. Laboratory	Added a new question: Describe how your program has expanded or plans to expand electronic data exchange capacity for laboratory data as well as other sources of data (e.g. electronic medical records).	To capture information on an outcome noted in NOFO PS24-0047.
SER Form Page 4-5. Section C. Pediatric/Perinatal	Language of the questions was updated. Example: In <Year-1>, did you link <del>case reports for persons</del> <del>women</del> with diagnosed HIV infection <del>reported to the surveillance system</del> <del>whose assigned sex at birth is not male to the state/local/territory</del> birth certificate data <del>file from the vital records office</del> for all <Year-2> births to identify all perinatally exposed infants with a residence of birth in your jurisdiction?	To align with new terminology standards in the Division of HIV Prevention (DHP).
SER Form Page 5. Section D. Geocoding and Data Linkage	Replaced original question with 2 questions to add clarity and improve flow. In addition, a follow up question on why standards were not met was added. The follow up question will only appear in REDCap if a standard was not met. New questions: In <Year-1>, how frequently did your program geocode addresses in eHARS to the census tract level and ensure the census tract is populated in eHARS?  In <Year-1>, did your program submit linked American Community Survey (ACS) data within 30 days of the availability of the ACS data? <i>(will only appear if the jurisdiction does not send census tracts to CDC)</i>	To capture the new/modified process standards. The follow up question is being moved from the EOYR so that all information on performance is captured in the SER form.
SER Form Page 6. Section E. Cluster Detection	The questions were modified slightly to capture frequency of activity instead of a yes/no response. In addition, a follow up question on why standards were not met was added. The follow up question will only appear in REDCap if a standard was not met. Example: In <Year-1>, <del>how frequently</del> did your program analyze molecular data <del>by</del> using CDC-recommended approaches <del>at least monthly</del> to identify HIV <del>transmission</del> clusters and outbreaks?	To better capture how close the health department is to meeting the standard. The follow up question is being moved from the EOYR so that all information on performance is captured in the SER form.
SER Form Page 6. Section F. Monthly eHARS Data Transfer to CDC	A new section F was added to capture information on the standard that assesses transmission of eHARS data to CDC. <b>The response for the number of on-time monthly transmissions will be populated by CDC.</b> Health departments will respond to the follow up question if they had fewer than 12 on-time transmissions.	To capture information on the data transmission process standard. The follow up question is being moved from the EOYR so that all information on performance is captured in the SER form.

SER Form Page 6. Section G. HIV Surveillance Policies and Procedures	A new section G was added to capture information on the standard that assesses availability of up-to-date policies and procedures for HIV surveillance. Health departments will populate the year they last completed a review and if a review was not done in the previous year, they will respond to the follow up question.	To capture information on the policy and procedure process standard. The follow up question is being moved from the EOYR so that all information on performance is captured in the SER form.
SER Form Page 6. Section H. Data Quality Outcome Standard	The outcome standard on data quality was moved to a new section (H). The health department will upload the SAS output generated from the CDC-provided SAS program. Health departments who do not meet the standard will respond to the follow up question.	To separate it from the outcome standards that will be calculated at CDC. The follow up question is being moved from the EOYR so that all information on performance is captured in the SER form.
SER Form Page 6-12. Section I. Outcome Standards Calculated at CDC	The previous 'Section F. Submission of Required Outcome Standards with SAS Tables' has been changed to 'Section I. Outcome Standards Calculated at CDC'. The previous table of standards was deleted and replaced with a separate table for each category of standards. <b>These variables will all be populated by CDC.</b> Health departments will only have to provide information on why a standard was not met and plans for improving performance for those standards that were not met.	To better structure the section which now only includes outcome standards that will be calculated at CDC. The follow up question is being moved from the EOYR so that all information on performance is captured in the SER form.
SER Form Page 12-13. Section J. Cluster Detection and Response Outcome Standards	The former Section I. Cluster Response Performance Measures was replaced with Section J. Cluster Detection and Response Outcome Standards. The new outcome standards will be mostly pre-populated by CDC. Only questions 1b and 1c will need to be entered by the health department. Health departments will only respond to the follow up questions on why a standard was not met and plans for improving performance for those standards that were not met.	To capture the new outcome standards for cluster detection and response activities. The follow up question is being moved from the EOYR so that all information on performance is captured in the SER form.
Page 13, Section K. Data and Dissemination	The language of the first three questions in this section was updated to reflect the updated language in the outcome standards. Three additional yes/no questions were added on health equity analyses, cluster activities, and syndemics. A follow up question was added, but only health departments who do not meet a standard will need to respond to this question. We are also requesting the URLs to their reports for all met standards. New questions: Did your program publish and disseminate analyses on health equity per CDC guidance in <Year-1>? Did your program share summary information about clusters and CDR activities (for example, in an annual report or public dashboard) in <Year-1>? In <Year-1>, did your program's reports incorporate analyses that describe relevant syndemics?	To align with the new/modified outcome standards. The follow up question is being moved from the EOYR so that all information on performance is captured in the SER form.
Page 13, Section K. Data and Dissemination	Added a new question: Describe how your program has increased availability and accessibility of data displays such as data dashboards.	To capture information on an outcome noted in NOFO PS24-0047.
SER Form Page 13-15, Section L. Security and Confidentiality	The answer options were expanded to include N/A for some of the questions. A few of the questions were reworded so that a "Yes" is the desired response for all questions. One new question on enhancements to security was added. A	To clarify the intent of the questions and to provide more contextual information when there are gaps in performance.

	<p>follow up question was added that will only be responded to when any of the questions have a “No” response. The ORP certification form will no longer be uploaded in the SER, because it will be included in the Annual Progress Report.</p> <p>New question: Did your program make enhancements or updates to security and confidentiality policies and procedures, as needed? (If none were needed, select N/A)</p>	
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