Form Approved
OMB No. 0920-0573
Expiration Date: XX/XX/XXXX

National HIV Surveillance System (NHSS)

Attachment 3e.

Standards Evaluation Report Form

Public reporting burden of this collection of information is estimated to average 8 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30329; ATTN: PRA (0920-0573).

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20XX* Standards Evaluation Report (SER)

PART 1. Process and Outcome Standards for Case Surveillance

Process Standards for Case Surveillance

A. Death Ascertainment

☐ We are a separately funded city AND all death ascertainment is done at the state level. (*Skip to section B: Routine Interstate Duplicate Review (RIDR)).*

☐ We are a state, territory, or separately funded city and perform our own death ascertainment. (*Respond to the questions below by completing the tables*).

1. Date of Death. In 20XX*, did your surveillance program perform record linkage of HIV case reports with the following data sources to identify all deaths occurring in 20XX*?

NOTE: You are required to link and load into eHARS vital statistics records **AND** the SSDMF				
Death File	**Linked Deaths Through what Date (Mo/Yr)?*** (e.g., March 2015, December 2014, etc.)		**All Results Loaded in eHARS?**	**Results Loaded Manually or Imported?**
☐ Vital statistics	Choose an item.	Choose an item.	☐Yes ☐No	☐ Manually ☐ Imported
AND				
☐ SSDMF	Choose an item.	Choose an item.	☐Yes ☐No	☐ Manually ☐ Imported

*Enter the end date of the most recent file you linked. For example: In 2015, if you linked a vital statistics file that included death records from January 2013 to July 2014, you would respond July 2014.

2. Cause of Death. In 20XX*, did your surveillance program perform record linkage of HIV case reports with the following data sources?

NOTE: At a minimum, you are required to link and load into eHARS the NDI-Plus (if not prohibited) or, if NDI is prohibited, you are required to link and load a final vital statistics file.					
Death File	**Linked Deaths Through what Date (Mo/Yr)?*** (e.g., July 2012 or if prohibited by law indicate "**Prohibited**")			**All Results Loaded in eHARS?**	**Results Loaded Manually or Imported?**
☐ NDI-Plus	Choose an item.	Choose an item.	☐ Prohibited	☐Yes ☐No	☐ Manually ☐ Imported
☐ Vital statistics - final	Choose an item.	Choose an item.		☐Yes ☐No	☐ Manually ☐ Imported

*Enter the end date of the most recent file you linked. For example: In 2015, if you linked a vital statistics file that included death records from January 2013 to July 2014, you would respond July 2014.

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3. HIV cases not reported to eHARS. **In 20XX*, did your surveillance program search all vital records for deaths mentioning HIV-infection and for which there was no previously reported case in eHARS?** ☐ Yes ☐ No

☐ No death record linkage was performed in 20XX*. (*Respond to the items directly below*).

If you did not meet all three standards in 1, 2, and 3 above, please discuss: a. Why you did not meet the minimum standards for death record linkage in 20XX*. b. Your plan to ensure your program meets this standard in 20XX*.

B. Routine Interstate Duplicate Review (RIDR)

☐ We are a separately funded city and all RIDR resolution is done at the state level. (*Skip to section C: Laboratory*).

☐ We are a state, territory, or separately funded city, and perform our own RIDR resolution. *(Please complete the table below for the **January 20XX* and August 20XX*** rounds).*

Please confirm that you have attached the RIDR progress table to your SER submission. NOTE: please submit ONLY the progress table. Do NOT send the entire Excel file as it contains personally identifying information in the tabs. ☐ Yes ☐ No
(*Respond to items below*).

Percent of RIDR pairs resolved by December 31, 20XX* for RIDR list received January and August 20XX*: *(Based on CDC-supplied RIDR completion report)*	%	If ≥ 95%, *skip to section C: Laboratory*.
		If <95%, respond to the questions directly below.
If <95% of the pairs on your RIDR list received in January and August 20XX* were not resolved by December 31, 20XX*, please discuss: a. Why you did not completely resolve the RIDR pairs on the January and August 20XX* lists. b. Your plan to complete both lists and ensure your program meets this standard in 20XX*.		

C. Laboratory

1. In 20XX*, did your surveillance program identify the number of laboratories (in state and out of state laboratories) that conducted HIV-related testing for providers and facilities in your jurisdiction?

☐ Yes
- Number of laboratories? Click here to enter text.
  - Please describe how your program obtained this number. Click here to enter text.

☐ No
- What is the number of HIV-testing laboratories that reported at least one HIV test result to your program during 20XX*?
  - Number of laboratories: Click here to enter text.

2. Are you aware of any laboratories that conducted HIV-related testing for providers and facilities within your jurisdiction that did not report any results to your program?

☐ Yes
- Approximately what percentage of your jurisdiction's patients are missing laboratory results because of this? Click here to enter text.

☐ No

3. Of the laboratories that reported to your program during 20XX*, are you aware of any laboratories that did not submit all positive/reactive HIV detection test results, all CD4 results (<200 and ≥200), or all viral load results (detectable and undetectable)? For example, Laboratory XYZ usually sends 500 viral load results (both detectable and undetectable) each month. However, during August, undetectable viral load results were not received from Laboratory XYZ.

☐Yes

- 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 20XX* 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.
- After the error was identified, did the laboratory or laboratories report the missing test results during 20XX*? ☐ Yes ☐ No (If no, skip to question 4)
- If the laboratory reported the missing test results, were the test results entered into eHARS before the December 20XX* data transfer? ☐ Yes ☐ No

☐ No

- In 20XX*, 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

4. Did any other issues arise that prevented your program from receiving all CD4 and viral load results performed in 20XX*? For example, Laboratory XYZ was transmitting CD4 results via ELR but the laboratory reports parsed from the HL7 ELR reader/translator were not sent to the HIV Program.

☐ Yes

- Estimate the percentage of test results that were missing among all CD4 and viral load results performed in 20XX*. Click here to enter text.
- Were the issues resolved? ☐ Yes ☐ No (If no, skip to question 5)
- If the issues were resolved, were the results entered into eHARS before the December 20XX* data transfer? ☐ Yes ☐ No

☐ No

5. By December 20XX*, did your surveillance program transfer to CDC via eHARS all CD4 (< 200 and ≥ 200) and viral load (detectable and undetectable) test results from laboratory reports received from 20XX*-20XX*?

Year reports were received	CD4 results				Viral load results			
	Yes	No	If "no", what % of results received have been transferred to CDC?	Describe type of CD4 results received (e.g., All values, <500, <200)	Yes	No	If "no", what % of results received have been transferred to CDC?	Describe type of viral load results received (e.g., Any result, detectable)
20XX*	☐	☐	%	Click here to enter text.	☐	☐	%	Click here to enter text.
20XX*	☐	☐	%	Click here to enter text.	☐	☐	%	Click here to enter text.
20XX*	☐	☐	%	Click here to enter text.	☐	☐	%	Click here to enter text.

At minimum, reports received from January 20XX through September 20XX*

Outcome Standards for Case Surveillance

NOTE: *All areas **MUST** run the CDC-supplied SAS program against the December 20XX* frozen eHARS SAS datasets to evaluate and report on your program's outcome standards.* ***In addition, all SAS table output MUST be attached to your SER submission.***

6. Submission of Required SAS Outcome Standard Tables

Please confirm that you have attached the following five SAS outcome tables to your SER submission. I have attached:

Case ascertainment tables:	☐ Yes	☐ No
Intrastate case duplication rate tables:	☐ Yes	☐ No
Risk factor ascertainment tables:	☐ Yes	☐ No
Completeness of CD4 and VL tables:	☐ Yes	☐ No
Data quality for case surveillance tables:	☐ Yes	☐ No

Measure	Standard	Result	
Completeness of Case Ascertainment	Did your surveillance program ascertain at least (≥) 85% of the expected number of persons newly diagnosed with HIV infection in 20XX* by the end of December 20XX*?	%	
Intrastate Duplicate Review	Were there less than or equal to (≤) 1% duplicate case reports among all (cumulative) cases reported to your surveillance program through December 31, 20XX* by the end of December 20XX*?	%	
Risk Factor Ascertainment	Did at least (≥) 70% of HIV cases newly reported to your surveillance program in 20XX* have sufficient risk factor information to be classified into a known HIV transmission category by the end of December 20XX*?	%	
Completeness of Initial CD4	Did at least (≥) 60% of adults and adolescents newly diagnosed with HIV infection in 20XX* have a CD4 count or percent based on a specimen collected within three months following their initial diagnosis, reported by the end of December 20XX*?	%	
Completeness of Initial Viral Load	Did at least (≥) 60% of adults and adolescents newly diagnosed with HIV infection in 20XX* have a viral load based on a specimen collected within three months following their initial diagnosis reported by the end of December 20XX*?	%	
Data Quality	In 20XX*, did 97% of case records pass all selected data edits? That is, did 97% of case records contain no errors?	%	
		Yes	**No**
Data Reporting and Dissemination	In 20XX*, did you develop and disseminate a comprehensive revision of your integrated HIV Epidemiologic Profile?	☐	☐
	In 20XX*, did you develop and disseminate updates to the HIV Epidemiologic Profile in the form of updates to core epidemiologic tables and figures, fact sheets, supplemental reports, slide sets, or other publications (but not a comprehensive revision)?	☐	☐
	In 20XX*, did you develop and disseminate an annual HIV surveillance report?	☐	☐
Security and Confidentiality	Has your program submitted a document (signed by the ORP) certifying that in 20XX* your program was in full compliance with the *Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action (2011)*?	☐	☐
	In 20XX*, did all persons with access to any HIV surveillance data (including all IT personnel with access to eHARS or other HIV surveillance databases) complete an annual security and confidentiality training and sign a confidentiality statement?	☐	☐
	Did your program conduct the required annual review of your written security and confidentiality policies and procedures to assess whether changes in legislation, technology, or priorities, personnel, or other situations require changes in policies and procedures?	☐	☐
	While under FOA PS13-1302 has your program completed (or participated in the completion of) an initial assessment across relevant programs to identify policy and environmental needs for implementing the *Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action (2011)*?	☐	☐

PART 2. Process and Outcome Standards for HIV Incidence Surveillance (HIS)

(Only for Areas Conducting HIS)

Please indicate if you used HIS funds only, case surveillance funds only, or both HIS and case surveillance funds to conduct HIS activities for 20XX*.

☐ HIS funds only ☐ Case funds only ☐ Both HIS and case funds

NOTE: *All areas **MUST** use the CDC-supplied SAS program against the December 20XX* frozen SAS datasets to evaluate and report your program's testing treatment history (TTH) and serologic testing algorithm for recent HIV seroconversion (STARHS) result completeness.* ***Please confirm that you have attached****:*

Incidence Completeness Report: ☐ Yes ☐ No. (*Respond to items below*).
Incidence Data Quality Report: ☐ Yes ☐ No. (*Respond to items below*).

Measure	Standard	Result
Completeness of Testing and Treatment History (TTH)	For cases diagnosed in 20XX*, did at least (≥) 85% have testing and treatment history (TTH) data entered in eHARS by the end of December 20XX* (see line 10 of the Incidence Completeness Report)?	%
Completeness of STARHS Result	For cases diagnosed in 20XX* (excluding AIDS cases diagnosed within 6 months), did at least (≥) 60% have a valid STARHS result from a specimen that was collected within 3 months of HIV diagnosis entered by the end of December 20XX* (see line 14 of the Incidence Completeness Report)?	%
Data Quality	In 20XX*, did 97% of case records pass all selected data edits related to HIS data (see line 3 of the Incidence Data Quality Report)?	%

OPTIONAL ACTIVITIES

PART 3. Molecular HIV Surveillance (MHS)

(Only for Areas Conducting MHS)

Please indicate if you used MHS funds only, case surveillance funds only, or both MHS and case surveillance funds to conduct MHS activities for 20XX*.

☐ MHS funds only ☐ Case funds only ☐ Both MHS and case funds

Process Measures for MHS Surveillance

In 20XX*, did your program identify all laboratories that conduct HIV genotypic resistance testing for providers and facilities in your jurisdictions?

☐ Yes

- Number of laboratories? Click here to enter text.
- Please describe how your program obtained this number. Click here to enter text.

☐ No

- What is the number of laboratories that reported at least one HIV nucleotide sequence to your program during 20XX*? Click here to enter text.

In 20XX*, did your program identify any laboratories that conduct HIV genotypic resistance testing for providers and facilities within your jurisdiction that did not report all HIV nucleotide sequences to your program?

☐ Yes

- Approximately what percentage of HIV nucleotide sequences in a given year is typically reported by this laboratory or laboratories? Click here to enter text.
- Approximately what percentage of the HIV nucleotide sequences expected from this laboratory or laboratories in 20XX* was not received? Click here to enter text.

☐ No

Process		Result	
		Yes	Yes
In 20XX*, did your program validate HIV nucleotide sequence data received from laboratories?		☐	☐
In 20XX*, did your program transfer to CDC via eHARS all HIV nucleotide sequence data received from laboratories in 20XX*-20XX?*			
Year of diagnosis	20XX*	☐	☐
	20XX*	☐	☐
	20XX*	☐	☐
In 20XX*, did your program establish or improve processes to collect ARV use history data for all persons newly diagnosed with HIV infection?		☐	☐

For 20XX, at a minimum, sequences received from January 20XX* through September 20XX*.

Outcome Standards for MHS Surveillance

HIV nucleotide sequence data completeness and antiretroviral (ARV) use history data completeness should be assessed using molecular HIV surveillance data entered through December 31, 20XX* and the SAS program provided by CDC.

Please confirm that you have attached the MHS SAS outcome table to your SER submission.

☐ Yes ☐ No

Measure	Standard	Result
Completeness of Initial HIV Nucleotide Sequence	For cases diagnosed in 20XX*, did at least (≥) 50% of newly diagnosed persons have an initial HIV nucleotide sequence (i.e., obtained from a specimen collected for HIV genotype [resistance] testing within 3 calendar months following HIV diagnosis) in eHARS by the end of December, 20XX*?	%
Completeness of ARV Use History	For cases diagnosed in 20XX*, did at least (≥) 85% of newly diagnosed persons with an initial HIV nucleotide sequence have ARV use data in eHARS by the end of December 20XX*?	%

PART 4. Perinatal HIV Exposure Surveillance

(Only for Areas that Conducted PHERS)

Please indicate if you used case surveillance funds to conduct Perinatal HIV Exposure Surveillance for 20XX*. ☐ Yes ☐ No

Process	Result	
	Yes	**No**
In 20XX*, did your program conduct active and passive surveillance on perinatal HIV exposure, including medical record review for opportunistic infections, adverse outcomes of ARV exposure, and linkage to birth registries?	☐	☐
In 20XX*, did your program conduct active and passive surveillance on HIV-infected women?	☐	☐

PART 5. Geocoding and Data Linkage (GDL)

(Only for Areas that Conducted GDL Activities)

Please indicate if you used case surveillance funds to conduct Geocoding and Data Linkage activities for 20XX*.
☐ Yes ☐ No

Process	Result	
	Yes	**No**
Did your program collect HIV surveillance information according to routine surveillance procedures, including local street address, city, and state of residence at diagnosis, for each newly diagnosed HIV case?	☐	☐
Did your program have a Memorandum of Agreement (MOA) for the 5-year funding period in place?	☐	☐
Did your program apply geocoding standards provided by CDC, including cleaning and standardizing the data and the collection of variables derived from the geocoding process?	☐	☐
Did your program geocode, to the census tract level, residence at HIV disease diagnosis information for cases diagnosed in 20XX* per CDC guidance?	☐	☐
Did your program report data to CDC?	☐	☐

NOTE TO OMB REVIEWERS: Year indicators of "XX" will be updated annually to reflect the new measurement period.