

Non-substantive Change Request
OMB # 0920-0573
National HIV Surveillance System (NHSS)
April 28, 2025

Summary of Request: CDC is requesting a change request to revise questions in the National HIV Surveillance System (NHSS) OMB No. 0920-0573 to align with E.O. 14168 *Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*.

Description of Changes Requested: This request includes both minor (de minimis) updates to terms, deletions, and updates to sex questions collected on the Adult HIV Confidential Case Report Form (ACRF), the Pediatric HIV Confidential Case Report Form (PCRF), and Standards Evaluation Report (SER). Please check the boxes below if your request includes:

- X Revision of an existing question(s)
- X Deletion of an existing question(s)

Changes to both the ACRF and PCRF

Specific changes that will be applied to both the ACRF and PCRF are described in table 1A. Revised forms with changes tracked and changes accepted for the ACRF are included as Attachment 3a and the PCRF as Attachment 3b. Updated technical guidance for completing the ACRF and PCRF are provided in Attachments 4a and 4b respectively. Updates to corresponding data elements are included in Attachment 3c. Attachment file are provided with changes tracked and changes accepted. For both the ACRF and PCRF, collection of sex assigned at birth has been renamed to “Sex” and the response option of “unknown” was updated to “unknown/undetermined.” The “unknown” response has been historically collected and is used to indicate sex could not be found in secondary data sources such as laboratory reports and medical records. It is important to keep the unknown category as an option to maintain data quality over time and because it is used by the reporting software used by health departments to exclude case information from being reported to CDC (e.g., case reports marked as unknown are not sent to CDC). The response label was revised to: “unknown/undetermined” to better align with recommended terminology when CDC is the secondary data collector. The collection of gender identity, along with all response options was removed from both forms.

Changes to the PCRF only

Table 1 B details additional changes needed for the PCRF only. These changes include minor changes in formatting and minor (de minimis) updates to terms of currently approved questions to align with E.O.14168 and agency guidance. In most instances, the proposed change uses terms that have been used on previously approved versions of the form. The changes to the PCRF primarily involve replacing “birthing person” with “biological mother” in applicable fields and replacing “breastfeeding/chestfeeding” with “breastfeeding.” These terms are only found on the PCRF and are not found on the ACRF. The terms “biological mother” and “breastfeeding” have been used on prior approved versions of the PCRF.

Changes to the Standards Evaluation Report (SER)

A minor (de minimis) change in wording is being requested for the Standards Evaluation Report (SER) to align with E.O.14168. Specific changes are noted on the form provided Attachment 3d (provided in tracked changes and changes accepted) and outlined in Table 2.

All proposed form changes will be implemented for data collection upon approval and reporting software updated as soon as possible.

Description of Changes in Burden: We estimate that these changes will not impact burden and will not result in any changes in approved burden hours for these forms or the overall burden hours of the ICR.

Table 1A. Description of Changes to both the Adult HIV Confidential Case Report Form (ACRF) and Pediatric HIV Confidential Case Report Form (PCRF)

Form	Type of Change	Section, Variable	Requested Change	Reason for Change
ACRF and PCRF	Revision (De Minimis)	Section IV (ACRF & PCRF): Patient Demographics, Variable: Sex at Birth	Revised label from "Sex at Birth" to "Sex"	Change consistent with OMB guidance on implementing Section 3(e) of Executive Order 14168.
ACRF and PCRF	Revision	Section IV (ACRF & PCRF): Patient Demographics, Variable: Sex at Birth, Response Option "Unknown"	Revised the response option label "Unknown" to "Unknown/Undetermined."	Unknown category has been historically collected and is important to maintain to indicate sex could not be found in secondary data sources such as laboratory reports and medical records. Response label was revised to: "unknown/undetermined" to better align with recommended terminology when CDC is the secondary data collector.
ACRF and PCRF	Deletion	Section IV (ACRF & PCRF): Patient Demographics, Variable: Gender Identity	Variable has been deleted	Change consistent with OMB guidance on implementing Section 3(e) of Executive Order 14168.
ACRF and PCRF	Deletion	Section IV (ACRF & PCRF): Patient Demographics, Variable: Gender Identity	Variable "Date Identified" , associated with the gender identity collected, deleted.	Variable no longer needed since associated with gender identity variable being deleted.
ACRF	Deletion	Section IV	Variable "Specify" ,	Variable no longer needed since

and PCRF		(ACRF & PCRF): Patient Demographics, Variable: Gender Identity	associated with the gender identity collected, deleted.	associated with gender identity variable being deleted.
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Table 1.B Description of Changes to the PCRF Only

Form	Type of Change	Section, Variable	Requested Change	Reason for Change
PCRF	Revision (De Minimis)	Section VII (PCRF): Patient History, Variable: Birthing Person's HIV Infection Status	Update language from "birthing person" to "biological mother"	Changed at program's discretion to align with E.O. and agency guidance. Proposed wording from previously approved form versions.
PCRF	Revision (De Minimis)	Section VII (PCRF): Patient History, Variable: Date of birthing person's first positive test result to confirm infection	Update language from "birthing person" to "biological mother"	Changed at program's discretion to align with E.O. and agency guidance. Proposed wording from previously approved form versions.
PCRF	Revision (De Minimis)	Section VII (PCRF): Patient History, Variable: Child breastfed/chestfed by birthing person	Update language from "breastfed/chestfed" to "breastfed" and "birthing person" to "biological mother"	Changed at program's discretion to align with E.O. and agency guidance. Proposed wording from previously approved form versions.
PCRF	Revision (De Minimis)	Section VII (PCRF): Patient History, Variable: Child received pre-masticated/pre-chewed food from birthing person	Update language from "birthing person" to "biological mother"	Changed at program's discretion to align with E.O. and agency guidance. Proposed wording from previously approved form versions.
PCRF	Revision (De Minimis)	Section VII (PCRF): Patient History, Section Title: After 1977 and before the earliest known diagnosis of HIV infection, the birthing person had:	Update language from "birthing person" to "biological mother"	Changed at program's discretion to align with E.O. and agency guidance. Proposed wording from previously approved form versions.
PCRF	Revision (De Minimis)	Section VII (PCRF): Patient History, Section Title: Birthing person	Update language from "birthing person" to	Changed at program's discretion to align with E.O. and agency guidance.

		had	“biological mother”	Proposed wording from previously approved form versions.
PCRF	Revision (De Minimis)	Section VII (PCRF): Patient History, Variable: Been breastfed/chestfed by non-birthing person	Update language from “breastfed/chestfed” to “breastfed” and “non-birthing person” to “woman (not biological mother)”	Changed at program’s discretion to align with E.O. and agency guidance. Proposed wording from previously approved form versions.
PCRF	Revision (De Minimis)	Section VII (PCRF): Patient History, Variable: Received pre-masticated/pre-chewed food from non-birthing person	Update language from “non-birthing person” to “a person (not biological mother)”	Changed at program’s discretion. The pre-masticated/pre-chewed food could be provided by a person of either sex. Proposed wording from previously approved form versions.
PCRF	Revision (De Minimis)	Section X (PCRF): Birth History, Variable Response: Birthing person or physician’s preference	Update language from “birthing person” to “biological mother”	Changed at program’s discretion to align with E.O. and agency guidance. Proposed wording from previously approved form versions.
PCRF	Revision (De Minimis)	Section XI (PCRF): Birthing Person History Section title	Update section title from “Birthing Person History....” To “Biological Mother History.....”	Changed at program’s discretion to align with E.O. and agency guidance. Proposed wording from previously approved form versions.
PCRF	Revision (De Minimis)	Section XI (PCRF): Birthing Person History, Variable: Birthing Person Date of Birth	Update language from “birthing person” to “biological mother”	Changed at program’s discretion to align with E.O. and agency guidance. Proposed wording from previously approved form versions.
PCRF	Revision (De Minimis)	Section XI (PCRF): Birthing Person History, Variable: Birthing Person Last Name Soundex	Update language from “birthing person” to “biological mother”	Changed at program’s discretion to align with E.O. and agency guidance. Proposed wording from previously approved form versions.
PCRF	Revision (De Minimis)	Section XI (PCRF): Birthing Person History, Variable: Birthing Person Country of Birth	Update language from “birthing person” to “biological mother”	Changed at program’s discretion to align with E.O. and agency guidance. Proposed wording from

				previously approved form versions.
PCRF	Revision	Section XI (PCRF): Birthing Person History, Variable: Birthing Person State ID Number	Update language from “birthing person” to “biological mother”	Changed at program’s discretion to align with E.O.14168. Proposed wording from previously approved form versions.
PCRF	Revision	Section XI (PCRF): Birthing Person History, Variable: Birthing Person City/County ID Number	Update language from “birthing person” to “biological mother”	Changed at program’s discretion to align with E.O. and agency guidance. Proposed wording from previously approved form versions.
PCRF	Revision	Section XI (PCRF): Birthing Person History, Variable: Other Birthing Person ID	Update language from “birthing person” to “biological mother”	Changed at program’s discretion to align with E.O. and agency guidance. Proposed wording from previously approved form versions.
PCRF	Revision	Section XI (PCRF): Birthing Person History, Variable: Has the birthing person ever been pregnant before this pregnancy?	Update language from “birthing person” to “biological mother”	Changed at program’s discretion to align with E.O. and agency guidance. Proposed wording from previously approved form versions.
	Revision	Section XI (PCRF): Birthing Person History, Variable: Was a test result (with a specimen collection date within the 6 weeks on or before delivery) documented in the birthing person’s labor and delivery records?	Update language from “birthing person” to “biological mother”. Removed the word “a” and “the”. Added punctuation of “?” to end of the variable question.	Modified to reduce the space the question occupied on the form and added punctuation to complete the sentence. Changed at program’s discretion to align with E.O. and agency guidance. Proposed wording from previously approved form versions.
PCRF	Revision	Section XI (PCRF): Birthing Person History, Variable: Did birthing person receive any antiretrovirals (ARVs) prior to this pregnancy?	Update language from “birthing person” to “biological mother”	Changed at program’s discretion to align with E.O. and agency guidance. Proposed wording from previously approved form versions.
PCRF	Revision	Section XI (PCRF): Birthing Person History, Variable: Did birthing person receive any	Update language from “birthing person” to “biological mother”	Changed at program’s discretion to align with E.O. and agency guidance. Proposed wording from

		antiretrovirals (ARVs) during this pregnancy?		previously approved form versions.
PCRF	Revision	Section XI (PCRF): Birthing Person History, Variable Response: Birthing person known to be HIV-negative during pregnancy	Update language from “birthing person” to “biological mother”	Changed at program’s discretion to align with E.O. and agency guidance. Proposed wording from previously approved form versions.
PCRF	Revision	Section XI (PCRF): Birthing Person History, Variable Response: HIV serostatus of birthing person unknown	Update language from “birthing person” to “biological mother”	Changed at program’s discretion to align with E.O. and agency guidance. Proposed wording from previously approved form versions.
PCRF	Revision	Section XI (PCRF): Birthing Person History, Variable: Did birthing person receive any antiretrovirals (ARVs) during labor/delivery?	Update language from “birthing person” to “biological mother”	Changed at program’s discretion to align with E.O. and agency guidance. Proposed wording from previously approved form versions.
PCRF	Revision	Section XI (PCRF): Birthing Person History, Variable Response: HIV serostatus of birthing person unknown	Update language from “birthing person” to “biological mother”	Changed at program’s discretion to align with E.O. and agency guidance. Proposed wording from previously approved form versions.
PCRF	Revision	Section XI (PCRF): Birthing Person History, Variable Response: Birthing person tested HIV negative during pregnancy	Update language from “birthing person” to “biological mother”	Changed at program’s discretion to align with E.O. and agency guidance. . Proposed wording from previously approved form versions.
PCRF	Revision	Section XI (PCRF): Birthing Person History, Variable: Was the birthing person screened for any of the following conditions during pregnancy?	Update language from “birthing person” to “biological mother”	Changed at program’s discretion to align with E.O. and agency guidance. . Proposed wording from previously approved form versions.
PCRF	Revision	Section XI (PCRF): Birthing Person History, Variable: Were any of the following conditions diagnosed for the birthing person during this pregnancy.....	Update language from “birthing person” to “biological mother”	Changed at program’s discretion to align with E.O. and agency guidance. Proposed wording from previously approved form versions.
PCRF	Revision	Section XI (PCRF):	Update language	Changed at program’s

		<p>Birth Person History, Variable: Were substances used by the birthing person during this pregnancy?</p>	<p>from “birthing person” to “biological mother”</p>	<p>discretion to align with E.O. and agency guidance. Proposed wording from previously approved form versions.</p>
PCRF	Revision	<p>Section XI (PCRF): Birth Person History, Variable: Was a toxicology screen done on the birthing person ...</p>	<p>Update language from “birthing person” to “biological mother”</p>	<p>Changed at program’s discretion to align with E.O. and agency guidance. Proposed wording from previously approved form versions.</p>

Table 2. Description of Changes to the Standards Evaluation Report (SER) (Note. Page numbers are based on Track Changes version in the ‘All Markup’ view)

Form	Type of Change	Section, Question	Requested Change	Reason for Change
SER	Revision	SER Page 3. Section C. Pediatric/Perinatal	<p>Update language of Q1A as follows: 1A. In <Year-1>, 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 <Year-2> births to identify all perinatally exposed infants with a residence of birth in your jurisdiction?</p>	<p>Changed to align with E.O. and agency guidance.</p>
SER	Deletion	SER Page 9, Section K. Question 4.	<p>Deleted Question 4. Did your program publish and disseminate analyses on health equity per CDC guidance in <Year-1></p>	<p>Changed to align with E.O. and agency guidance.</p>

Attachments

SSA_NHSS_tracked
SSA_NHSS_clean

SSB_NHSS_tracked
SSB_NHSS_clean

Att_3a Adult Case Report Form_tracked (ACRF)
Att_3a Adult Case Report Form_clean (ACRF)

Att_3b Pediatric Case Report Form_tracked (PCRF)
Att_3b Pediatric Case Report Form_clean (PCRF)

Att_3c NHSS_dataelements_trackedv2
Att_3c NHSS_dataelements_cleanv2

Att_3d SER PS24-0047_tracked
Att_3d SER PS24-0047_clean

Att_4a Technical Guidance_ACRF_tracked
Att_4a Technical Guidance_ACRF_clean

Att_4b Technical Guidance_PCRF_tracked
Att_4b Technical Guidance_PCRF_clean