

Non-substantive Change Request
OMB Control Number 0920-0978
Emerging Infections Programs (EIP)
Expiration Date:09/30/2027
Date Submitted: 04/23/2025

Summary of request: CDC/NCEZID is requesting a change request to revise questions to align with EO 14168 *Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*.

Description of Changes Requested: This request updates sex to be in accordance with EO 14168 for the following 13 approved EIP ICR/Forms. (The remainder of approved EIP forms are all in compliance with EO14168.):

- FN.200.9 Hemolytic Uremic Syndrome (HUS) Surveillance
- HAIC.400.1 HAIC MuGSI Case Report Form - 2024
- HAIC.400.1 HAIC MuGSI Case Report Form - 2025
- HAIC.400.4 Invasive Methicillin-Resistant *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report – 2022
- HAIC.400.4 Invasive Methicillin-Sensitive *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report – 2022
- HAIC.400.4 Invasive Methicillin-Resistant *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report – 2023
- HAIC.400.4 Invasive Methicillin-Sensitive *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report – 2023
- HAIC.400.4 Invasive *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report – 2024
- HAIC.400.4 Invasive *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report – 2025
- HAIC.400.7 HAIC - CDI Case Report and Treatment Form – 2024
- HAIC.400.7 HAIC - CDI Case Report and Treatment Form – 2025
- HAIC.400.11: HAIC Candidemia Case Report Form - 2024
- HAIC.400.11: HAIC Candidemia Case Report Form - 2025

Note: FN.200.1-200.8 FoodNet Variable List – Updates to one of the sex question values for the FoodNet Active Surveillance data collection instrument is being delayed due to the technical effort involved and is awaiting further guidance before revising the data dictionary. The change will be updated as soon as the technical issue has been resolved.

FoodNet Active Surveillance conducts secondary data collection. Data collected by participating state and local surveillance are transmitted to FoodNet monthly in excel format. The states transfer their local data into our ‘sex’ column using M or F, and coding any missing information as U, interpreted as unknown. The U variable is mapped to missing when received at CDC and shared with any group requesting FoodNet data as a missing value.

Please check the boxes below if your request includes:

X Revision of an existing question(s)

Deletion of an existing question(s)

Description of Changes to Burden:

There is no change in Burden Hours associated with the modifications made to comply with EO 14168

Explanation for Program Changes or Adjustments

FN.200.9 - HUS Surveillance Case Report Form		
Type of Change	Itemized Changes / Justification	Impact to Burden
Administrative	Question 9A. Sex: <input type="checkbox"/> Female <input type="checkbox"/> Male Changes: <ul style="list-style-type: none">Removed “Unknown” option Justification: The value of “Unknown” was removed from the CRF to comply with the “Defending Women” Executive Order.	No impact to burden.
HAIC.400.1 – HAIC- 2024 Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form (CRF)		
Type of Change	Itemized Changes / Justification	Impact to Burden
Administrative	Question 7: Sex Changes: <ul style="list-style-type: none">Changed question text from “Sex at birth” to “Sex”Changed “Unknown” option to “Missing value”Removed the option for “Transgender” Justification: We have removed the check box for “transgender” to be in compliant with the Defending Women Executive Order. Additionally, seeing this data collection form is for a secondary data collection, a check box of “missing value” has been added for the situation where the medical record, that is being abstracted, does not document male or female sex. There is no expected burden change based on this change. <u>Additionally, we are submitting this form as we are still in the process of collecting data from calendar year 2024. Our data collection forms are based on the date of</u>	None

culture, and therefore in order to be compliant with the EO for all years of data

HAIC.400.1 – HAIC- 2025 Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form (CRF)

Type of Change	Itemized Change / Justification	Impact to Burden
Administrative	<p>Question 7: Sex</p> <p>Changes:</p> <ul style="list-style-type: none"> • Changed question text from “Sex at birth” to “Sex” • Changed “Unknown” option to “Missing value” • Removed the option for “Transgender” <p>Justification: We have removed the check box for “transgender” to be in compliant with the Defending Women Executive Order. Additionally, seeing this data collection form is for a secondary data collection, a check box of “missing value” has been added for the situation where the medical record, that is being abstracted, does not document male or female sex. There is no expected burden change based on this change. <u>Additionally, we are submitting this form as we are still in the process of collecting data from calendar year 2025. Our data collection forms are based on the date of culture, and therefore in order to be compliant with the EO for all years of data</u></p>	None

HAIC.400.4 Invasive Methicillin-Resistant *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report – 2022

Type of Change	Itemized Changes / Justification	Impact to Burden
Administrative	<p>Question 7. Sex: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing Value</p> <p>Changes:</p> <ul style="list-style-type: none"> • Changed question text for “Sex at birth” to “Sex” • Renamed “unknown” checkbox to “missing value” • Removed checkbox for transgender <p>Justification: We have removed the check box for “transgender” to be in compliant with the Defending Women Executive Order. Additionally, seeing this data collection form is for a secondary data collection, a check box of “missing value” has been added for the situation where the medical record, that is being abstracted, does not document male or female sex. There is no expected burden change based on this change. Additionally, we are submitting this form as we are still in the process of collecting data from calendar year 2022. Our data collection forms are based on the date</p>	None

	of culture, and therefore in order to be compliant with the EO for all years of data under collection, this change is needed on historical forms.	
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HAIC.400.4 Invasive Methicillin-Sensitive *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report – 2022

Type of Change	Itemized Change / Justification	Impact to Burden
Administrative	<p>Question 7. Sex: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing Value</p> <p>Changes:</p> <ul style="list-style-type: none"> • Changed question text for “Sex at birth” to “Sex” • Renamed “unknown” checkbox to “missing value” • Removed checkbox for transgender <p>Justification: We have removed the check box for “transgender” to be in compliant with the Defending Women Executive Order. Additionally, seeing this data collection form is for a secondary data collection, a check box of “missing value” has been added for the situation where the medical record, that is being abstracted, does not document male or female sex. There is no expected burden change based on this change. Additionally, we are submitting this form as we are still in the process of collecting data from calendar year 2022. Our data collection forms are based on the date of culture, and therefore in order to be compliant with the EO for all years of data under collection, this change is needed on historical forms.</p>	None

HAIC.400.4 Invasive Methicillin-Resistant *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report – 2023

Type of Change	Itemized Change / Justification	Impact to Burden
Administrative	<p>Question 7. Sex: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing Value</p> <p>Changes:</p> <ul style="list-style-type: none"> • Changed question text for “Sex at birth” to “Sex” • Renamed “unknown” checkbox to “missing value” • Removed checkbox for transgender <p>Justification: We have removed the check box for “transgender” to be in compliant with the Defending Women Executive Order. Additionally, seeing this data collection form is for a secondary data collection, a check box of “missing value” has been added for the situation where the medical record, that is being abstracted, does not document male or female sex. There is no expected burden change based on this change. Additionally, we are submitting this form as we are still in the process of collecting data from calendar year 2023. Our data collection forms are based on the date of culture, and therefore in order to be compliant with the EO for all years of data under collection, this change is needed on historical forms.</p>	None

HAIC.400.4 Invasive Methicillin-Sensitive *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report – 2023

Type of Change	Itemized Change / Justification	Impact to Burden
Administrative	<p>Question 7. Sex: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing Value</p> <p>Changes:</p>	None

	<ul style="list-style-type: none"> • Changed question text for “Sex at birth” to “Sex” • Renamed “unknown” checkbox to “missing value” • Removed checkbox for transgender <p>Justification: We have removed the check box for “transgender” to be in compliant with the Defending Women Executive Order. Additionally, seeing this data collection form is for a secondary data collection, a check box of “missing value” has been added for the situation where the medical record, that is being abstracted, does not document male or female sex. There is no expected burden change based on this change. Additionally, we are submitting this form as we are still in the process of collecting data from calendar year 2023. Our data collection forms are based on the date of culture, and therefore in order to be compliant with the EO for all years of data under collection, this change is needed on historical forms.</p>	
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HAIC.400.4 Invasive *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report – 2024

Type of Change	Itemized Change / Justification	Impact to Burden
Administrative	<p>Question 7. Sex: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing Value</p> <p>Changes:</p> <ul style="list-style-type: none"> • Changed question text for “Sex at birth” to “Sex” • Renamed “unknown” checkbox to “missing value” • Removed checkbox for transgender <p>Justification: We have removed the check box for “transgender” to be in compliant with the Defending Women Executive Order. Additionally, seeing this data collection form is for a secondary data collection, a check box of “missing value” has been added for the situation where the medical record, that is being abstracted, does not document male or female sex. There is no expected burden change based on this change. Additionally, we are submitting this form as we are still in the process of collecting data from calendar year 2024. Our data collection forms are based on the date of culture, and therefore in order to be compliant with the EO for all years of data under collection, this change is needed on historical forms.</p>	None

HAIC.400.4 Invasive *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report – 2025

Type of Change	Itemized Change / Justification	Impact to Burden
Administrative	<p>Question 7. Sex: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Missing Value</p> <p>Changes:</p> <ul style="list-style-type: none"> • Changed question text for “Sex at birth” to “Sex” • Renamed “unknown” checkbox to “missing value” • Removed checkbox for transgender <p>Justification: We have removed the check box for “transgender” to be in compliant with the Defending Women Executive Order. Additionally, seeing this data collection form is for a secondary data collection, a check box of “missing value” has been added for the situation where the medical record, that is being abstracted, does not document male or female sex. There is no expected burden change based on this change. Additionally, we are submitting this form as we are still in the process of collecting data</p>	None

	from calendar year 2025. Our data collection forms are based on the date of culture, and therefore in order to be compliant with the EO for all years of data under collection, this change is needed on historical forms.	
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HAIC.400.7 HAIC - CDI Case Report and Treatment Form – 2024

Type of Change	Itemized Changes / Justification	Impact to Burden
Administrative	<p>Question 12. Patient Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Missing Value</p> <p>Changes:</p> <ul style="list-style-type: none"> • Changed question text for “Sex at birth” to “Patient Sex” • Renamed “unknown” checkbox to “missing value” • Removed checkbox for transgender <p>Justification: We have removed the check box for “transgender” to be in compliant with the Defending Women Executive Order. Additionally, seeing this data collection form is for a secondary data collection, a check box of “missing value” has been added for the situation where the medical record that is being abstracted does not document male or female sex. There is no expected burden change based on this change. Additionally, we are submitting this form as we are still in the process of collecting data from calendar year 2024. Our data collection forms are based on the date of specimen collection for the case, and therefore in order to be compliant with the EO for all years of data under collection, this change is needed on historical forms.</p>	None

HAIC.400.7 HAIC - CDI Case Report and Treatment Form – 2025

Type of Change	Itemized Change / Justification	Impact to Burden
Administrative	<p>Question 12. Patient Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Missing Value</p> <p>Changes:</p> <ul style="list-style-type: none"> • Changed question text for “Sex at birth” to “Patient Sex” • Renamed “unknown” checkbox to “missing value” • Removed checkbox for transgender <p>Justification: We have removed the check box for “transgender” to be in compliant with the Defending Women Executive Order. Additionally, seeing this data collection form is for a secondary data collection, a check box of “missing value” has been added for the situation where the medical record that is being abstracted does not document male or female sex. There is no expected burden change based on this change. Additionally, we are submitted this form as we are still in the process of collecting data from calendar year 2025. Our data collection forms are based on the date of specimen collection for the case, and therefore in order to be compliant with the EO for all years of data under collection, this change is needed on historical forms. The 2025 form will also be used for 2026 data collection.</p>	None

HAIC.400.11: HAIC Candidemia Case Report Form - 2024

Type of Change	Itemized Changes / Justification	Impact to Burden
Administrative	<p>Question 15. Sex: <input type="checkbox"/> Female <input type="checkbox"/> Male</p> <p>Changes:</p>	None

	<ul style="list-style-type: none"> Removed “Check if Transgender” option <p>Justification: We have removed the “Check if Transgender” option to be in compliance with the Defending Women Executive Order. There is no expected burden based on this change. Additionally, we are submitting this form as we are still in the process of collecting data from calendar year 2024. Our data collection forms are based on the date of specimen collection for the case, and therefore in order to be compliant with the EO for all years of data under collection, this change is needed on historical forms.</p>	
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HAIC.400.11: HAIC Candidemia Case Report Form - 2025
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Type of Change	Itemized Change / Justification	Impact to Burden
Administrative	<p>Question 15. Sex: <input type="checkbox"/> Female <input type="checkbox"/> Male</p> <p>Changes:</p> <ul style="list-style-type: none"> Removed “Check if Transgender” option <p>Justification: We have removed the “Check if Transgender” option to be in compliance with the Defending Women Executive Order. There is no expected burden based on this change. Additionally, we are submitting this form as we are still in the process of collecting data from calendar year 2024. Our data collection forms are based on the date of specimen collection for the case, and therefore in order to be compliant with the EO for all years of data under collection, this change is needed on historical forms.</p>	None