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 Sur	veillance Case Report Form	
Type of Change	Itemized Changes / Justification	Impact to Burden
Administrative	Question 9A. Sex: □ Female □ Male Changes: • 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 Form (CRF)	C- 2024 Multi-site Gram-Negative Surveillan	nce Initiative (MuGSI) Case Report
Type of Change	Itemized Changes / Justification	Impact to Burden
Administrative	 Question 7: Sex Changes: Changed question text from "Sex at to "Sex" Changed "Unknown" option to "Mi value" Removed the option for "Transgend" 	issing
	Justification: We have removed the check for "transgender" to be in compliant with th Defending Women Executive Order. Additionally, seeing this data collection for for a secondary data collection, a check box "missing value" has been added for the situ where the medical record, that is being abstracted, does not document male or fem sex. There is no expected burden change b on this change. <u>Additionally, we are submit</u> this form as we are still in the process of collecting data from calendar year 2024. O data collection forms are based on the date	he rm is x of ation ale based itting Dur

	culture, and therefore in order to be compliant		
	with the EO for all years of data		
HAIC.400.1 – HAI	C- 2025 Multi-site Gram-Negative Surveillance Ini	tiative (MuGSI) C	Case Report
Form (CRF)			
Гуре of Change	Itemized Change / Justification	Impact to Burder	1
spe or enunge	itemied Change / Subtrication		-
Administrative	Question 7: Sex	None	
	Changes:		
	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</u>		
	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		
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	ace (HAIC) Case Report – 2022		L
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	 Changed question text for "Sex at birth" to "Sex" 		
	Renamed "unknown" checkbox to "missing value"		
	Removed checkbox for transgender		
	Justification: We have removed the check box for "tr	-	
	compliant with the Defending Women Executive Orde		
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	from calendar year 2022. Our data collection forms a		

	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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Community Interf	ace (HAIC) Case Report – 2022	
Гуре of Change	Itemized Change / Justification	Impact to
- Jpe of endinge		Burden
Administrative		None
	Changes:	
	Changed question text for "Sex at birth" to "Sex"	
	Renamed "unknown" checkbox to "missing value"	
	Removed checkbox 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	
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	ace (HAIC) Case Report – 2023	
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HAIC.400.4 Invasi	ve Staphylococcus aureus Healthcare-Associated Infections Commun	nity Interface
(HAIC) Case Repo		5
Type of Change	Itemized Change / Justification	Impact to Burden
Administrative HAIC.400.4 Invasi (HAIC) Case Repo	Question 7. Sex: □ Yes □ No □ Missing Value Changes: • Changed question text for "Sex at birth" to "Sex" • Renamed "unknown" checkbox to "missing value" • Removed checkbox 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. 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. ve Staphylococcus aureus Healthcare-Associated Infections Communities of the stape of th	
Type of Change	Itemized Change / Justification	Impact to
Administrative	Question 7. Sex: □ Yes □ No □ Missing Value Changes: • Changed question text for "Sex at birth" to "Sex" • Renamed "unknown" checkbox to "missing value" • Removed checkbox 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. Additionally, we are submitting this form as we are still in the process of collecting data	

HAIC.400.7 HAIC	 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. C - CDI Case Report and Treatment Form – 2024 	
Гуре of Change		Impact to Burden
Administrative	 Question 12. Patient Sex: □ Male □ Female □ Missing Value Changes: Changed question text for "Sex at birth" to "Patient Sex" Renamed "unknown" checkbox to "missing value" Removed checkbox 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. 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 	None
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HAIC.400.7 HAIC	historical forms. C - CDI Case Report and Treatment Form – 2025 Itemized Change / Justification	Impact to Burden

HAIC.400.11: HAIC Candidemia Case Report Form - 2024		
Type of Change	Itemized Changes / Justification	Impact to Burden
	Question 15. Sex: □ Female □ Male Changes:	None

	• Removed "Check if Transgender" option 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.	
HAIC.400.11: HAIC C	Candidemia Case Report Form - 2025	
Type of Change	Itemized Change / Justification	Impact to Burden
Administrative	Question 15. Sex: Female Male	None
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	Changes:	
	Changes:Removed "Check if Transgender"	
	• Removed "Check if Transgender"	
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