

Non-substantive Change Request
OMB Control Number 0920-0010
[NCBDDDD] Birth Defects Study to Evaluate Pregnancy exposureS (BD-STEPS)
Date Submitted: 3/27/2025

Summary of request: CDC/NCBDDDD is requesting a change request to:

1. Revise one question in one questionnaire to align with EO 14168 *Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*.
2. Make a minor edit to skip pattern logic.

Description of Changes Requested:

This request updates the response options for one question on infant sex used in the Birth Defects Study to Evaluate Pregnancy exposureS (BD-STEPS)/form C1 to be in accordance with EO 14168. We are also requesting one minor modification to the skip pattern logic in the same form.

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 (if applicable):

There is no change in Burden Hours associated with the modifications made to comply with EO 14168 or with the modification to the skip pattern.

Our previous burden estimates were calculated under the extreme situation based on 100% complete participation but given expectations of ~ 60% participation we anticipate no change to burden.

Table A: Description of Changes to Burden

Form	Approved Burden (Responses)	Approved Burden (Hours)	Description of Changes to Burden
Core Computer Assisted Telephone Interview (Attachment C1)	3,030	2,778	No change
Linkage to Reportable Infectious Disease Consent (Attachments D2 and D3)	0	0	No change
Residual Newborn Bloodspot Consent (Attachments E2-E5)	1,850	463	No change
Online Occupational Questionnaire (Attachment F1)	830	277	No change
Supplemental Computer Assisted Telephone Interview (Attachment	640	267	No change

G1)			
Authorization Form for Stillbirth COVID-19 Sub-Study (Attachment G6)	157	40	No change
Total	6,507	3,825	No change

Table B: Description of Changes to Forms

Form	Type of Change	Question/Item	Requested Change
Core Computer Assisted Telephone Interview (Attachment C1)	Minor wording change	B3. In addition to the baby we have already discussed, what was the sex of the [B1=2: other; B1 >2: [1 st , 2 nd , etc.] additional] baby? [RECORD FOR EACH ADDITIONAL BABY] a. Girl b. Boy c. Indeterminate d. DK e. RF	B3. In addition to the baby we have already discussed, what was the sex of the [B1=2: other; B1 >2: [1 st , 2 nd , etc.] additional] baby? [RECORD FOR EACH ADDITIONAL BABY] a. Female b. Male c. Undetermined d. Missing
	No change in text for subjects; change in interviewer instructions to update study sites.	HH8. <u>FOR IA, NC, and TX CENTERS AND A LIVEBORN INFANT</u> : That completes the interview, but...	HH8. <u>FOR IA and NC CENTERS AND A LIVEBORN INFANT</u> : That completes the interview, but...
		<u>FOR CENTERS THAT ARE NOT COLLECTING BLOODSPOTS (STATE: CA, GA) OR FOR A NON-LIVEBORN INFANT EXCEPT AR, MA, AND NY STILLBIRTHS</u> : That completes the interview...	<u>FOR CENTERS THAT ARE NOT COLLECTING BLOODSPOTS (STATE: CA, GA, TX) OR FOR A NON-LIVEBORN INFANT EXCEPT AR, MA, AND NY STILLBIRTHS</u> : That completes the interview...