

ICR Non-Substantive CHANGE REQUEST MEMO

ICR Title

OMB NO. 0920-0010

Expiration Date 04/30/2026

Summary:

Briefly summarize changes

We propose to modify the Birth Defects Study To Evaluate Pregnancy exposures (BD-STEPS) to include additional study sites, reduce the number of data collection instruments, and make minor modifications to the telephone interview instrument. Item specific burden estimates will remain unchanged, however overall annual burden estimates will be reduced with the removal of one study instrument.

Description of change

Seven Centers for Birth Defects Research and Prevention (CBDRP) historically participated in BD-STEPS: Arkansas (AR), California (CA), Iowa (IA), Massachusetts (MA), North Carolina (NC), New York (NY), and CDC/NCBDDD's Division of Birth Defects and Infant Disorders (DBDID) which serves as the site of record for Georgia (GA). For two Centers, AR and MA, women who experienced a stillbirth were also mailed additional information about the stillbirth-specific portion of the study and asked additional questions by phone.

Beginning with a new round of funding on September 1, 2023, an eighth CBDRP Center, Texas (TX), was added to BD-STEPS. An additional Center, NY, will also conduct stillbirth-specific activities. Along with the implementation of BD-STEPS data collection activities for these two Centers, we are also requesting the following non-substantive changes for all BD-STEPS deliveries from January 1, 2024 onward: (1) removal of the infectious disease consent and (2) minor edits to the telephone administered interview.

Reason for change

The purpose of this non-substantive change request is to update the number of Centers included in BD-STEPS following a competitive Notice of Funding Opportunity. With the proposed changes, there will be an overall reduction in burden per subject.

Attachments:

- Core Computer Assisted Telephone Interview
 - o Attachment C1a: English (tracked changes)
 - o Attachment C1a: English (clean)
 - o Attachment C1b: Spanish (tracked changes)
 - o Attachment C1b: Spanish (clean)

Background & Justification:

Brief explanation for the change requested, including the reason (purpose or benefit) for the requested change

BD-STEPS continues to follow-up on promising findings from the National Birth Defects Prevention Study. BD-STEPS researchers study potential risk factors for birth defects and have expanded to study potential risk factors for stillbirths. BD-STEPS Centers have been funded every 5 years starting in 2013 and a new funding period began on September 1, 2023. Adding Centers will improve the diversity and size of the study population, resulting in more generalized and robust findings.

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The BD-STEPS extension request was approved by OMB on 4/24/2023. For this non-substantive change request, we are updating the participating study sites, making minor edits to one data collection instrument, and removing one data collection instrument.

Effect of Proposed Changes on Current Approved Instruments:

- Show a crosswalk of the changes in table below

A list of current and newly funded* Centers for Birth Defects Research and Prevention (CBDRP) sites is shown below.

1. Arkansas
 - a. Also conducts Stillbirth-Specific Activities
2. California
3. Georgia
4. Iowa
5. Massachusetts
 - a. Also conducts Stillbirth-Specific Activities
6. New York
 - a. Also conducts Stillbirth-Specific Activities*
7. North Carolina
8. Texas*

*New as of 9/1/2023

Please see a crosswalk below of proposed changes to specific data collection instruments.

Form	Current/Question Item	Requested Change
Core Computer Assisted Telephone Interview (Attachment C1)	V620. During this time period, did you take any medications, remedies, or treatments that we haven't already talked about (such as over the counter or prescription medications for constipation (for example, prucalopride)?)	Minor wording change V620. During this time period, did you take any medications, remedies, or treatments that we haven't already talked about? For example, Ozempic or Wegovy, or over the counter or prescription medications for constipation (such as prucalopride)?
	Section HH: Closing [INTERVIEWER ONLY QUESTION]: Is this a MA or AR participant? If [YES AND A STILLBIRTH WITHOUT A BIRTH DEFECT] then skip to HH4]]	No change in text for subjects; change in interviewer instructions to update study sites. Section HH: Closing IF THE MOTHER REPORTED ONE OF THE OCCUPATIONAL CATEGORIES OF INTEREST, ASK HH1. OTHERWISE, BEGIN WITH HH4.
	FOR HH8, INTERVIEWERS WILL NEED TO USE STATE AND INFANT STATUS TO DETERMINE WHICH SCRIPT TO USE: HH8. <u>FOR IA, NY, NC CENTERS AND A LIVEBORN INFANT:</u> That completes the interview, but as you read in the advance packet, you may be asked to	Minor wording change to shorten script to remove information on the infectious disease consent. FOR HH8, INTERVIEWERS WILL NEED TO USE STATE AND INFANT STATUS TO DETERMINE WHICH SCRIPT TO USE:

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participate in other parts of the study. To thank you for your time, we will send you a \$30 gift card. Along with the gift card, we may mail you two consent forms. One of the forms asks for your permission to request leftover newborn bloodspots that were already collected shortly after your baby's birth by your state's newborn screening program. This part of the study will help us to understand the role genetic and other biologic factors have in causing birth defects. The other form asks for your permission to request your infectious disease information that was already reported by your physician to your state's health department. This information will be used to study how infectious diseases may play a role in why some babies have birth defects. If you choose to return the consent forms, we will send you a \$10 gift card for each consent form returned as a token of appreciation for your continued interest in our study.

AR and MA:

LIVE BIRTHS WITH BIRTH DEFECTS:

That completes the interview, but as you read in the advance packet, you may be asked to participate in other parts of the study. To thank you for your time, we will send you a \$30 gift card. Along with the gift card, we may mail you two consent forms. One of the forms asks for your permission to request leftover newborn bloodspots that were already collected shortly after your baby's birth by your state's newborn screening program. This part of the study will help us to understand the role genetic and other biologic factors have in causing birth defects. The other form asks for your permission to request your infectious disease information that was already reported by your physician to your state's health department. This information will be

HH8. FOR IA, NC, and TX CENTERS AND A LIVEBORN INFANT: That completes the interview, but as you read in the advance packet, you may be asked to participate in other parts of the study. To thank you for your time, we will send you a \$30 gift card. Along with the gift card, we may mail you a consent form. This form asks for your permission to request leftover newborn bloodspots that were already collected shortly after your baby's birth by your state's newborn screening program. This part of the study will help us to understand the role genetic and other biologic factors have in causing birth defects. If you choose to return the consent form, we will send you a \$10 gift card as a token of appreciation for your continued interest in our study.

AR, MA, or NY:

LIVE BIRTHS WITH BIRTH DEFECTS:

That completes the interview, but as you read in the advance packet, you may be asked to participate in other parts of the study. To thank you for your time, we will send you a \$30 gift card. Along with the gift card, we may mail you a consent form. This form asks for your permission to request leftover newborn bloodspots that were already collected shortly after your baby's birth by your state's newborn screening program. This part of the study will help us to understand the role genetic and other biologic factors have in causing birth defects. If you choose to return the consent form, we will send you a \$10 gift card as a token of appreciation for your continued interest in our study.

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used to study how infectious diseases may play a role in why some babies have birth defects. If you choose to return the consent forms, we will send you a \$10 gift card for each consent form returned as a token of appreciation for your continued interest in our study.

CONTROLS:

That completes the first part of the interview. To thank you for your time completing this part of the interview, we will send you a \$30 gift card. Along with the gift card, we may mail you two consent forms. One of the forms asks for your permission to request leftover newborn bloodspots that were already collected shortly after your baby's birth by your state's newborn screening program. This part of the study will help us to understand the role genetic and other biologic factors have in causing birth defects. The other form asks for your permission to request your infectious disease information that was already reported by your physician to your state's health department. This information will be used to study how infectious diseases may play a role in why some babies have birth defects. If you choose to return the consent forms, we will send you a \$10 gift card for each consent form returned as a token of appreciation for your continued interest in our study.

STILLBIRTHS WITH A BIRTH DEFECT:

That completes the first part of the interview. To thank you for your time completing this part of the interview, we will send you a \$30 gift card. Along with the gift card, we may mail you a consent form that asks for your permission to request your infectious disease information that was already reported by your physician to your state's health department. This

CONTROLS:

That completes the first part of the interview. To thank you for your time completing this part of the interview, we will send you a \$30 gift card. Along with the gift card, we may mail you a consent form. This form asks for your permission to request leftover newborn bloodspots that were already collected shortly after your baby's birth by your state's newborn screening program. This part of the study will help us to understand the role genetic and other biologic factors have in causing birth defects. If you choose to return the consent form, we will send you a \$10 gift card as a token of appreciation for your continued interest in our study.

STILLBIRTHS WITH OR WITHOUT A BIRTH DEFECT:

That completes the first part of the interview. To thank you for your time completing this part of the interview, we will send you a \$30 gift card.

FOR CENTERS THAT ARE NOT

COLLECTING BLOODSPOTS (STATE: CA, GA) OR FOR A NON-LIVEBORN INFANT EXCEPT AR, MA, AND NY STILLBIRTHS: That completes the interview, but as you read in the advance packet, you may be asked to participate in other parts of the study. So that we may contact you in the future we would like to confirm your address. To thank you for your time, we will send you a \$30 gift card.

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	<p>information will be used to study how infectious diseases may play a role in why some babies have birth defects. If you choose to sign and send back the consent form, we will send you a \$10 gift card as a token of appreciation for your continued interest in our study.</p> <p>STILLBIRTHS WITHOUT A BIRTH DEFECT:</p> <p>That completes the first part of the interview. To thank you for your time completing this part of the interview, we will send you a \$30 gift card.</p> <p><u>FOR CENTERS THAT ARE NOT COLLECTING BLOODSPOTS (STATE: CA, GA) OR FOR A NON-LIVEBORN INFANT EXCEPT AR AND MA STILLBIRTHS</u> : That completes the interview, but as you read in the advance packet, you may be asked to participate in other parts of the study. So that we may contact you in the future we would like to confirm your address. To thank you for your time, we will send you a \$30 gift card. Along with the gift card, we may mail you a consent form. The consent form asks for your permission to request your infectious disease information that was already reported by your physician to your state’s health department. This information will be used to study how infectious diseases may play a role in why some babies have birth defects. If you choose to sign and send back the consent form, we will send you a \$10 gift card as a token of appreciation for your continued interest in our study.</p>	
	<p>HH10. FOR EVERYONE: In the introductory letter we sent you, there was a \$20 gift card included as a token of appreciation for your interest. As I just mentioned, you will be sent a \$30 gift card to thank you for your time to complete the interview We cannot promise you will get a gift card from your chosen store, but could you tell me which one of the following stores you would prefer?</p>	<p>Question removed.</p>

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	<p>[READ LIST]</p> <p align="center">i. Amazon ii. Target iii. Wal-Mart iv. CVS</p>	
	<p>FINAL REMARK [ALL SUBJECTS EXCEPT AR and MA STILLBIRTHS WITH AND WITHOUT DEFECTS AND CONTROLS] [AR AND MA STILLBIRTHS WITH AND WITHOUT DEFECTS AND CONTROLS: Open/Refer to BD-STEPS – Stillbirth Pilot Supplement, Introductory Telephone Script and Informed Consent (Att45)]</p>	<p>No change in text for subjects; change in interviewer instructions to update study sites.</p> <p>FINAL REMARK [ALL SUBJECTS EXCEPT AR, MA, and NY STILLBIRTHS WITH AND WITHOUT DEFECTS AND CONTROLS] [AR, MA, AND NY STILLBIRTHS WITH AND WITHOUT DEFECTS AND CONTROLS: Open/Refer to BD-STEPS – Stillbirth Pilot Supplement, Introductory Telephone Script and Informed Consent (Att45)]</p>
<p>Linkage to Reportable Infectious Disease Consent (Attachments D2 and D3)</p>	<p>See forms D2 and D3</p>	<p>Forms removed.</p>

Effect on Burden Estimate:

Discuss and include a table comparing to previously approved burden

- *Include a burden table and identify changes, or, if the burden isn't changing, state there is no change*

With the exception of the linkage to reportable infectious disease consent (Attachments D2 and D3), this proposed change would not impact the burden as presented in our last approved OMB package. Our previous burden estimates were calculated under the extreme situation based on 100% complete participation. Given expectations of ~ 60% participation and the proposed reduction in the text in the core computer telephone interview, we do not anticipate a change in burden to the remaining instruments even with the addition of one BD-STEPS site and one site added to stillbirth activities. Removal of the linkage to reportable infectious disease consent would reduce the total burden hours from 4,473 to 3,825.

Form	Approved Burden	Requested Burden
Core Computer Assisted Telephone Interview (Attachment C1)	2,778	No change in burden

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Linkage to Reportable Infectious Disease Consent (Attachments D2 and D3)	648	Remove
Residual Newborn Bloodspot Consent (Attachments E2-E5)	463	No change
Online Occupational Questionnaire (Attachment F1)	277	No change
Supplemental Computer Assisted Telephone Interview (Attachment G1)	267	No change
Authorization Form for Stillbirth COVID-19 Sub-Study (Attachment G6)	40	No change
Total		
	3,825	Reduction in burden