

ICR Non-Substantive CHANGE REQUEST MEMO

Birth Defects Study to Evaluate Pregnancy exposureS (BD-STEPS)

OMB NO. 0920-0010

Expiration Date 2/28/2023

Summary:

We propose to make two non-substantive changes to the currently-approved protocol for the Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS).

1. To streamline the process by which women who are eligible are notified of and administered the stillbirth portion of BD-STEPS.
2. To add questions to the BD-STEPS interview to ask women about receipt of a COVID-19 vaccine

Non-substantive change 1:

Briefly summarize changes

We currently administer two interviews to women eligible for the stillbirth portion of BD-STEPS. In the current protocol, women complete the first interview (completed by all BD-STEPS-eligible women) and are then recruited for the second interview (only completed by women eligible for the stillbirth portion of BD-STEPS). Based on feedback from study staff and participants, we would like to streamline the process so that women eligible for the stillbirth portion are initially recruited for both interviews and can more easily and logically complete both interviews in a single phone call, if that is their preference. In order to implement this change, some minor adjustments need to be made to our compensation structure.

Description of change

Currently, initial contact with eligible participants is through a mailed introductory packet that provides information about the first interview and a \$20 gift card thanking them for taking the time to review the materials. Participants who complete the first interview are later mailed a second packet containing a Thank You letter and gift card (\$30) thanking them for completing the first interview. For women eligible for the stillbirth portion, this packet also contains an introductory letter providing information about the second interview and a gift card (\$10) thanking them for reviewing the material about the second interview. Participants who complete the second interview receive a final Thank You letter and gift card (\$10) for participating.

To allow women who are eligible for the stillbirth portion to complete both interviews in a single session, the current Introductory Letters will be revised to inform them about their eligibility and options for completing both interviews. This introductory packet will still include the \$20 gift card. We propose eliminating the introductory packet and incentive for the second interview. We would like to move the \$10 gift card that is currently included for reviewing the recruitment material for the second interview to the thank you packet for completing the second interview. Participants who complete both interviews in the same sitting will be mailed a thank you packet containing a \$30 gift card for completing the first interview and a \$20 gift card for completing the second. If a participant chooses to complete the second interview at a different time than the first interview, they will receive a thank you letter for the first interview that contains the \$30 gift card (as is currently done). These participants will receive an additional \$20 compensation upon completing the second interview. The telephone introduction script and the closing of the computer assisted telephone interview contain minor revisions to allow language offering the participants the option to continue to the second part of the interview or to schedule the second part of the interview for a time convenient for the participant. The telephone introductory script for the second part of the interview

ICR Non-Substantive CHANGE REQUEST MEMO

contains revisions allowing it to serve as the script for calling participants back who chose to schedule the second part of the interview at a later time.

Reason for change

The primary purpose for this change is to allow women eligible for the stillbirth portion of BD-STEPS the option of completing both interviews on a single phone call, if they choose to do so. The current protocol and compensation structure requires that a second introductory letter be sent, and sending such a letter is unnecessary and potentially confusing if the participant has already completed both interviews.

Attachments: (Revised versions reflecting the proposed change request)

List them with their corresponding numbers

- *Att37_IntroLetter for SBnoBD: (Combined Intro Letter to participants whose pregnancies ended in a stillbirth without a birth defect)*
- *Att37A_Intro Letter_for SBw/BD and Controls: Combined Intro Letter to participants whose pregnancies ended in a stillbirth without a BDSTEPS eligible defect with unaffected pregnancies [i.e., controls].*
- *Att44A_Combined ThankYou Letter (sent to participants completing both interviews in the same session)*
- *Att44B_Thank You Reminder Letter for completing the first interview (sent to participants who complete the first interview to thank them for completing the first interview and to remind them of the second interview)*
- *Att44_Thank You letter for completing the second interview at a later time (sent to participants who complete the second interview at a later time. They have already received the \$30 card for completing the first interview)*
- *Att17_BD2_ENG_IntroPhoneScripts_20190318_wSB supplemental intro*
- *Att45_BD2_StillbirthPilot_IntroPhoneScript_English_4.30.2019*
- *Att18_BDSTEPSII_CATI_V8.0_20200312*

Background & Justification:

Brief explanation for the change requested, including the reason (purpose or benefit) for the requested change
These requested changes are in response to study staff and feedback from participants eligible for the stillbirth portion of BD-STEPS expressing the desire to have the option to complete both interviews together. Many participants are emotionally overwhelmed after they experience a stillbirth and some participants have expressed that given the amount of mental and emotional preparation they needed to participate in the first interview, it would be preferable to complete both interviews in the same sitting. As an example, some women choose to have family or friends with them at the time of the interviews, and this support is easier to arrange if both interviews are administered on the same day. These changes will also lessen participant burden because it requires fewer mailings and phone calls for recruitment and reminders for the second interview. In addition, it is likely that participation rates for the second interview will improve as loss to follow-up after the first interview will be reduced.

Effect of Proposed Changes on Current Approved Instruments:

- *Show a crosswalk of the changes in table below*

| Form | Current/Question Item | Requested Change |
|------------------|---|---|
| Att37 and Att37A | These letters currently introduce participants to the first interview | These letters have been revised to introduce participants to both |

ICR Non-Substantive CHANGE REQUEST MEMO

| | | |
|----------------------------|--|--|
| | only | interviews and inform them of the option to complete both interviews on a single call or schedule the second interview at the participant's convenience. |
| Att44B | This letter currently thanks the participant for completing the first interview (with a \$30 gift card) and contains a \$10 gift card for their time reviewing information on the second interview. | This letter has been revised to thank participants for completing the first interview (with a \$30 gift card) and to remind them to complete the second interview. The \$10 gift card will not be included and has been added to the existing \$10 gift card (to make a total of \$20) thanking them for completing both interviews. |
| ATT44A | | New letter that will accompany the \$30 and \$20 gift cards for completing both interviews. The \$20 gift card is an increase and reflects the addition of the \$10 card currently provided with the introduction letter to the second interview. |
| Att44 | This letter is currently sent to thank participants for completing the second interview and contains a \$10 gift card | This letter now serves as a thank you for completing the second interview at a later date and will contain the proposed \$20 gift card |
| Att17 | This is the telephone script used when calling participants to ask if they would like to participate in the first interview | This script was revised to introduce participants to a 2-part interview and now contains language informing participants of the option to take both parts of the interview together or scheduling the second part of the interview at a later time convenient for them. |
| Att45 | This telephone introductory script is currently used when calling participants who have completed the first interview to introduce them to the second interview and ask if they would like to participate. | This script has been revised to serve as the script when calling participants who have completed the first part of the interview but chose to schedule the second part for a later date. |
| Att18 BD-STEPSII_CATI_V8.0 | This is the CATI (computer assisted telephone interview) that currently serves as the first interview. | Minor revisions to the closing script to reflect the revisions described in this request. |

ICR Non-Substantive CHANGE REQUEST MEMO

Note: All changes are being made to both the English and Spanish versions of these documents.

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*
This proposed change would not impact the potential sample of respondents as presented in our last approved OMB package [Statement B].

Non-substantive change 2:

Briefly summarize changes

We propose to add COVID-19 to a list of vaccines that we asked women about receiving just before or during early pregnancy.

Description of change

The computer-assisted telephone interview (CATI) asks participants if they received any of 9 specific vaccines in the month before through the third month of pregnancy. This non-substantive change adds one vaccine to that list so that participants will now be asked about receipt of 10 specific vaccines. Subjects will be asked whether they received COVID-19 vaccinations. If the participant reports that they received a COVID-19 vaccination during this exposure period they will be asked whether they know the type of vaccine they received (e.g., Pfizer, Moderna); and the dates of each dose. This change is being made to both the English and Spanish version of the BD-STEPS CATI.

Reason for change

This change is being made so that we can capture information on receipt of COVID-19 vaccination during pregnancy in our study population of women who were pregnant during the SARS-CoV-2 pandemic.

Attachments: (Revised versions reflecting the proposed change request)

List them with their corresponding numbers

- Att18_BDSTEPS_CATI_V8.0

Background & Justification:

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

Two vaccines against COVID-19 were approved in the United States in December 2020. Although pregnant women were not included in the randomized controlled trials that determined the efficacy of the vaccine, they are not contraindicated during pregnancy. Therefore, it is important to understand any potential impacts of the vaccine for women who receive it during pregnancy. BD-STEPS provides a unique opportunity to capture this important information. The changes to the questionnaire were reviewed and approved by the Vaccine Task Force of CDC's Coronavirus Disease-2019 (COVID-19) Emergency Response.

Effect of Proposed Changes on Current Approved Instruments:

| Form | Current/Question Item | Requested Change |
|---------------------------|--|--|
| Att18 BDSTEPSII_CATI_V8.0 | V156: [If they report receipt of any vaccines in the month before through the third month of pregnancy] Which vaccines did you get? PROBE: READ LIST IF NECESSARY | V156: [If they report receipt of any vaccines in the month before through the third month of pregnancy] Which vaccines did you get? PROBE: READ LIST IF NECESSARY |

ICR Non-Substantive CHANGE REQUEST MEMO

| | | |
|--|--|--|
| | <ul style="list-style-type: none"> - Chickenpox Vaccine - Flu Vaccine - Hepatitis A Vaccine - Hepatitis B Vaccine - HPV Vaccine (Human Papillomavirus) - Measles, Mumps, Rubella Vaccine) - Meningococcal Vaccine - Pneumococcal Vaccine, Polyvalent - Shingles Vaccine <p>V157: When did you get [NAME OF VACCINE]?</p> <p>a. MM/DD/YYYY or</p> <p>b. MONTH OF PREGNANCY(B1, P1, P2, P3) or</p> <p>c. HOW LONG AGO (with units for days, weeks, months, years)</p> <p>d. DK</p> <p>e. RF</p> | <ul style="list-style-type: none"> - COVID-19 - Chickenpox Vaccine - Flu Vaccine - Hepatitis A Vaccine - Hepatitis B Vaccine - HPV Vaccine (Human Papillomavirus) - Measles, Mumps, Rubella Vaccine) - Meningococcal Vaccine - Pneumococcal Vaccine, Polyvalent - Shingles Vaccine <p>V156a: [Only for those who report getting the COVID-19 vaccine]: Do you know what type of COVID-19 vaccine you received? What was it?</p> <p>V157: When did you get [NAME OF VACCINE]?</p> <p>a. MM/DD/YYYY or</p> <p>b. MONTH OF PREGNANCY(B1, P1, P2, P3) or</p> <p>c. HOW LONG AGO (with units for days, weeks, months, years)</p> <p>d. DK</p> <p>e. RF</p> <p>V157a: [Only for those who report getting the COVID-19 vaccine]: When did you get your second dose of vaccine for COVID-19?</p> <p>a. Did not receive 2nd dose or</p> <p>b. MM/DD/YYYY or</p> <p>c. MONTH OF PREGNANCY(B1, P1, P2, P3) or</p> <p>d. HOW LONG AGO (with units for days, weeks, months, years)</p> <p>d. DK</p> <p>e. RF</p> |
|--|--|--|

Note: All changes are being made to both the English and Spanish versions of these documents.

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*
This proposed change would not impact the burden as presented in our last approved OMB package [Statement B].