

BD-STEPS – Stillbirth Pilot Supplement

Introductory Telephone Script and Informed Consent

Mother of Stillborn Baby With or Without Birth Defects and Livebirths

The text in the double brackets is for the mothers of Stillborn babies.

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Telephone Script: Interview attempted after core maternal interview

That completes the first part of the interview, but you have the option to continue now with the second part of the interview, or you can schedule for another time. Would you like to continue now to the second part of the interview?

YES

WANTS TO SCHEDULE APPOINTMENT

WANTS TO COMPLETE INTERVIEW AT ANOTHER TIME, UNSPECIFIED

REFUSES TO PARTICIPATE IN ANY FURTHER INTERVIEWS

IF WANTS TO CONTINUE INTERVIEW NOW: Okay, as a reminder, the interview you just completed for BD-STEPS focused on the early parts of your pregnancy. This second part of the interview will focus on the later part of your pregnancy. This interview only takes about 20 to 30 minutes to complete. (PROBE, IF NEEDED: We can do it in short sections if you prefer.) Please bear with me one moment while I set up the next part of the interview.

INTERVIEWER: ALERT SUPERVISOR TO TRANSFER CORE MATERNAL CDC CATI DATA TO STILLBIRTH CDC CATI. THEN LAUNCH STILLBIRTH CDC CATI.

IF WANTS TO SCHEDULE APPOINTMENT:

RECORD DATE AND TIME (INCLUDE TIME ZONE) OF APPOINTMENT.

VERIFY PHONE NUMBER: I need to verify your telephone number where you can be reached for the call.

CONFIRM: We have scheduled your appointment on <DAY, DATE> at <TIME>. Would you please call us at our toll-free number 1-888-743-7324 if you need to change your appointment?

[APP_REMIND] Would you like us to provide a reminder before your appointment?

IF YES, [REMIND_TYPE] Would you like an email or a text reminder?

RECORD RESPONSE AND ADDRESS IN TRACKING

1. Email: [provide field in which to type email address; prefill with email address in Symphony, if one exists]
2. Text: [provide field in which to type mobile phone number; prefill with number from current RL but allow edits]

IF DOESN'T WANT TO CONTINUE AND DOESN'T WANT TO SCHEDULE: OK, we will call you in a few days to schedule the second part of the interview. Please call us at our toll-free number 1-888-743-7324 if you would like to schedule a time that is convenient for you.

IF REFUSES TO CONTINUE WITH STILLBIRTH SUPPLEMENTAL INTERVIEW: Thank you again for your time and efforts. Your contribution to this important study will help us greatly in our efforts to better understand the causes of birth defects.

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Telephone Script: Callback to complete stillbirth interview after core maternal interview completed

Hello, may I speak with <First and Last Name of Mother>? My name is <Interviewer> and I am calling on behalf of the <Arkansas Center for Birth Defects Research and Prevention at Arkansas Children's Hospital or Massachusetts Department of Public Health >.

IF INTERVIEW IS SCHEDULED:

Thank you for completing the first part of your interview for the Birth Defects Study To Evaluate Pregnancy exposureS, BD-STEPS. I am calling to conduct the second part of the interview we scheduled for this time. I KNOW THAT I MAY BE CALLING ON YOUR CELL PHONE RIGHT NOW. If you are currently driving, we will call you back at another time.

[IF SUBJECT ASKS WHERE YOU ARE CALLING FROM OR WHO INTERVIEW

CONTRACTOR IS, STATE: "I am with Abt Associates; we conduct all the interviews for the study."]

Is this still a convenient time to conduct the interview?

NO (NOT A CONVENIENT TIME):

When would be a more convenient time for me to call you to conduct the telephone interview?

RECORD DATE AND TIME (INCLUDE TIME ZONE) OF NEW APPOINTMENT.

VERIFY PHONE NUMBER: I need to verify your telephone number where you can be reached for the interview.

CONFIRM: We will call you on <DAY, DATE> at <TIME> on <PHONE NUMBER>. Would you please call us at our toll-free number <1-888-743-7324> if you need to change your appointment?

[APP_REMIND] Would you like us to provide a reminder before your interview appointment?

IF YES, [REMIND_TYPE] Would you like an email or a text reminder?

RECORD RESPONSE AND ADDRESS IN TRACKING

1. Email: [provide field in which to type email address; prefill with email address in Symphony, if one exists]
2. Text: [provide field in which to type mobile phone number; prefill with number from current RL but allow edits]

Thank you. We look forward to talking with you later.

YES (CONVENIENT TIME NOW):

[START2] Thank you for agreeing to participate. I want to remind you that:

This part of the interview will mainly focus on the later part of your pregnancy. It should take about

20 to 30 minutes. (We can complete it in short sections if you would like.)
All your answers are confidential.
You can choose not to answer any specific questions.
You are free to stop the interview at any time

If you have time now, we would like to go ahead and start the interview. **[IF PARTICIPANT HAS QUESTIONS, REFER TO QUESTIONS/ANSWERS]**

IF YES: Thank you for agreeing to participate. **[START THE INTERVIEW; RECORD DATE OF VERBAL CONSENT]**

IF APPOINTMENT WAS NOT SCHEDULED:

Thank you for completing the first part of your interview for the Birth Defects Study To Evaluate Pregnancy exposureS, BD-STEPS. At the end of that interview, you asked to schedule the second part of the interview at a later time. I am calling to see if we could find a time suitable for you to take the second part. It takes about 20 to 30 minutes. Or you could take the interview now if that suits you. Would you like to take the interview now?

IF YES: Thank you for agreeing to participate. **[START THE INTERVIEW; RECORD DATE OF VERBAL CONSENT]**

IF NO (BUT WISH TO SCHEDULE THE INTERVIEW FOR LATER): When would be a better time to call you back?

RECORD DATE AND TIME (INCLUDE TIME ZONE) OF APPOINTMENT.

VERIFY PHONE NUMBER, RECORD IF DIFFERENT THAN THE NUMBER ON FILE: I need to verify your telephone number where you can be reached for the interview.

CONFIRM: We have scheduled your appointment on <DAY, DATE> at <TIME>. Would you please call us at our toll-free number 1-888-743-7324 if you need to change your appointment?

Would you like us to provide a reminder before your interview appointment?

IF YES, Would you like an email, text or voicemail reminder? <**RECORD RESPONSE AND ADDRESS IN TRACKING**>

Thank you for taking the time to talk to me about this study today. I look forward to speaking with you again on **[Repeat date and time]**. Goodbye.

NO (DOES NOT WISH TO BE INTERVIEWED):

PROBES:

Do you have any questions about the study I might be able to address (**SEE QUESTIONS/ANSWERS**)?

Is there anything else you would like to ask (**SEE QUESTIONS/ANSWERS**)?

We can start now and see how far we get.

We can do the interview in short sections such as 5-10 minute sessions, if that would be more convenient.

I can set an appointment with you and call back at a convenient time.

Would you like to set up an appointment for me to call back at a more convenient time?

Would you like me to explain a little more about the study?

It is fine if you prefer not to tell us, but may we ask you why you have decided not to participate?

If NO: Thank you for taking the time to talk to me about the study.

If YES: What is your reason or reasons for not participating [RECORD REASONS.]

Thank you for your time in talking with me about this study. Goodbye.

QUESTIONS/ANSWERS

How did you get my name: You are one of the women who previously completed the first part of the BD-STEPS interview.

Confidentiality and/or Certificate of Confidentiality: The Certificate of Confidentiality protects your legal rights under the Public Health Service Act (*under section 301[d] of the Public Service Act 42 U.S.C. 241[d]*). The Certificate of Confidentiality prevents study staff from being forced under a court order or other legal action to identify you or anyone else in this study. This protection lasts forever (even after death) for any persons who participated in the research during any time the certificate was in effect. Records may be reviewed by officials checking on the quality of the research. As previously noted, information about you may be shared with other researchers when and if it has been approved by research review committees. We will never use any names in reports or publications.

Voluntary Participation: Participation is voluntary, meaning that you have the choice to take part or not. You are free to withdraw at any time. At any time in the future, you may have your interview responses removed from the study by calling <**Dr. Wendy Nembhard at 501-364-5001 (Arkansas) or toll-free at 1-877-662-4567 OR Rebecca Lovering at 617-624-5529 or toll-free at 1-888-302-2101 (Massachusetts)**>.

Incentive for Interview: If you choose to complete this part of the interview, we will send you an additional \$20 gift card to thank you for your time. <**Note: This is in addition to the incentive for the completion of the “first part of the” BD-STEPS CATI.**>

For More Information: If you’d like more information about the study, please contact <**Dr. Wendy Nembhard at 501-364-5001 (Arkansas) or toll-free at 1-877-662-4567 OR Rebecca Lovering at 617-624-5529 or toll-free at 1-888-302-2101 (Massachusetts)**>. If you have questions about your rights as a subject in this research study, please call the Office of the Deputy Associate Director for Science for CDC at **1-800-584-8814**. Leave a message including your name, phone number, and refer to Protocol #2087, and someone will call you back as soon as possible.

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CONTINUED Minor Script (AR ONLY)**

IF YES (WILLING TO SHARE WITH PARENT):

Thank you very much. What is your parent or guardian's name? Is that Mr. or Ms. or Mrs. or Dr.? _____

RELATIONSHIP: mother___, father___, stepmother___, stepfather___, guardian___, OTHER, SPECIFY _____

Is your <PARENT/GUARDIAN> available at this time?

IF NOT: When is a good time to speak to <her /him>? Day _____ Time _____ **(RECORD TIME ZONE)**

Is there another phone number at which we could reach <her/him>? _____

Also, <s/he> can call us at our toll free number, **1-877-662-4567 (AR participants only)** if she has any questions. I will call your <PARENT/GUARDIAN> at the time and number you suggested. Thank you very much for your time and I look forward to speaking with you again.

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Parent/Guardian of Minor Script And Informed Consent (AR ONLY)

Hello, <Mr./Ms./Dr.> _____. My name is <Interviewer> and I am calling from the **Arkansas Center for Birth Defects Research and Prevention at Arkansas Children's Hospital.**

We are inviting women to participate in a follow-up interview to help us understand factors that may increase the risk of a stillbirth. <Your daughter OR PARTICIPANT'S NAME> was chosen from <Arkansas or Massachusetts> women who previously participated in our Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS). Her pregnancy was identified through the **Arkansas** surveillance program that tracks pregnancy outcomes. <FOR STILLBIRTH, "We understand that it may be uncomfortable for her to talk about her experience. Except for this discomfort,> the study has no <other> likely risks. <<FOR STILLBIRTH:While we know the causes of some stillbirths, we do not know what causes most of them. We are not aware of any direct association between the questions asked in this interview and her pregnancy outcome.>> Taking part in the study will not benefit your daughter [or PARTICIPANT'S NAME] or your family directly; however, her participation will teach us more about factors that might raise or lower the risk of having a stillbirth and the findings may help other women in the future. She can choose not to participate. This decision will not affect the care or services your daughter [or PARTICIPANT'S NAME] or your family receive.

This study involves a telephone interview about conditions during your daughter's pregnancy, her illnesses, and medications taken during her 2nd and 3rd trimester. Since she is not yet 18, we are required to ask if you will allow her to participate in the study.

Recently, we mailed a packet to <your daughter OR SUBJECT'S NAME> asking her to participate in the research study. Do you have any questions about the study?

YES <RESPOND TO PARENT/GUARDIAN'S QUESTIONS>

NO (WOULD NOT LIKE MORE INFORMATION):

CONTINUE:

The interview takes about 25 minutes (*but we can do it in short sections*).

<Your daughter OR PARTICIPANT'S NAME> can choose not to answer any specific questions. <Your

daughter OR PARTICIPANT'S NAME> is free to stop the interview at any time.

We will share information only with our team of researchers involved in this study, which may include health information about <**your daughter OR PARTICIPANT'S NAME**>. However, the information will only be used for the purpose of research, and it will be kept confidential. It will only be shared after appropriate approvals are obtained by the study's Data Sharing Committee and human research protection committees. We will never use any names or addresses in reports or publications.

If you or <**your daughter OR PARTICIPANT'S NAME**> have any concerns about the study or how it is conducted, you may contact **Dr. Wendy Nembhard at 501-364-5001 (Arkansas participants only) or toll-free at 1-877-662-4567**. If you have questions about your rights as a subject in this research study, please call the Office of the Deputy Associate Director for Science for CDC at **1-800-584-8814**. Leave a message including your name, phone number, and refer to Protocol #2087, and someone will call you back as soon as possible.

If your daughter [or **PARTICIPANT'S NAME**] agrees to be interviewed, will it be O.K. for my supervisor to listen or for us to record the interview for quality control purposes?

YES (OK TO LISTEN IN): VERIFY AND RECORD PARENT/GUARDIAN'S NAME AND TODAY'S DATE.

NO (NOT OK TO LISTEN): SET UP "NO MONITORING SIGNAL OR SIGN" FOR SUPERVISOR. THEN VERIFY AND RECORD PARENT/GUARDIAN'S NAME AND TODAY'S DATE. PROCEED WITH INTERVIEW.

Do you give permission for <**your daughter OR PARTICIPANT'S NAME**> to participate in the interview?

NO (DOES NOT GIVE PERMISSION):

Thank you very much for your time. We would like to know for what reason or reasons you prefer that <**your daughter OR PARTICIPANT'S NAME**> not participate. **[RECORD REASONS]** Thank you for your time in talking with me about this study. Goodbye.

YES (GIVES PERMISSION):

Thank you. We appreciate your help in gathering information for this important study. We must confirm your first and last name to indicate your consent in our records

[RECORD] First Name: _____ Middle name/initial if provided: _____ Last Name: _____

What is your relationship to < **PARTICIPANT'S NAME**>? Mother, Father, Stepmother, Stepfather, Guardian, or OTHER, SPECIFY? **[RECORD RESPONSE]**

We will call <**PARTICIPANT'S NAME**> to set up a convenient time to conduct the telephone interview, or if she is available now, we can explain the study to her, or begin the interview.

IF NOT AVAILABLE: Time convenient for <**your daughter OR PARTICIPANT'S NAME**>:
Day _____ Time _____ **RECORD DATE AND TIME (INCLUDE TIME ZONE).**

VERIFY PHONE #: I need to verify the telephone number where (**PARTICIPANT'S NAME**) can be reached for the interview.

CONFIRM: She can call us at our toll-free number **1-888-743-7324** if she has any questions.

Thank you for allowing <**PARTICIPANT'S NAME**> to participate in this important public health study.