

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.

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 >. Thank you for your previous participation in the Birth Defects Study To Evaluate Pregnancy exposureS called BD-STEPS. We are contacting previous participants to request additional information. Recently, we mailed you some information. If you did not receive the information, please let us know if you would like it resent. 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.”]

IF RESEND REQUESTED [VERIFY AND RECORD ADDRESS AND THEN, CONTINUE READING SCRIPT]. Note: If no address available (i.e., homeless), ask, “Could we send the packet to the address of a relative or friend?”

FOR THOSE WHO DID NOT RECEIVE INTRO PACKET, ASK: “Would you like for me to read the Rights of Research Subjects Fact Sheet to you? This information was also included in the original packet of information you received for BD-STEPS.”

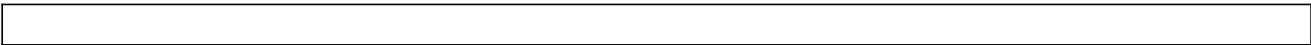
IF YES: As a participant in the study, you should know that you have a right to all of the following things:

- Be informed of the nature and purpose of the study.
- Be given an explanation of the procedures to be followed in the study.
- Be given a description of any discomforts and risks reasonably to be expected from the study procedures.
- Be given an explanation of any benefits you can reasonably expect from participation.
- Be informed of medical treatment, if any, available to you during and after the study if complications should arise.
- Be given an opportunity to ask any questions concerning the study or procedures involved.
- Be informed that you may withdraw from the study at any time without penalty.
- Be given the opportunity to decide to participate or not without the use of any force or undue influence on your decision.

After hearing this information, do you have any questions?

IF NO: [CONTINUE READING SCRIPT].

Public reporting burden of this collection of information is estimated to average 5 minutes, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0010).



In BD-STEPS, our purpose is to learn more about birth defects. In this follow-up interview, we want to learn more about why some pregnancies end in a stillbirth and some do not. <<**FOR STILLBIRTH:** We are very sorry for your loss.>> We understand that it may be uncomfortable for some women to talk about their pregnancy experience. Except for this discomfort, there are 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 your pregnancy outcome.>> Taking part in the interview will not benefit you or your family directly; however, your 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.

While the interview you completed for BD-STEPS focused on the early parts of your pregnancy, this interview will mainly focus on the later part of your pregnancy. This interview only takes about 25 minutes to complete (**if mother expresses concern about the length of the interview, say “We can do it in short sections if needed”**). Thousands of women are taking part in this study during a three year period. Over 600 women will be interviewed each year in <**Arkansas or Massachusetts**>.

You can choose not to participate. This decision will not affect the care or services you or your family receive. If you choose to participate, it would be helpful if you complete all the questions. However, you can choose not to answer any question, and you are free to stop the interview at any time.

All information that we gather will be kept confidential. This is because the study (i.e., BD-STEPS) has been given a Certificate of Confidentiality by the Centers for Disease Control and Prevention. This means that anything you tell us will not have to be given out to anyone, even if a court orders us to do so, unless you say it’s okay. We may share information about you with other researchers involved in our study, but we will never use any names in reports or publications. Information will only be used for the purpose of research, and will only be shared after appropriate approvals are obtained by the study’s Data Sharing Committee and human research protection committees at the researchers’ institution. You should also understand that study investigators are not prevented from reporting information obtained from you to authorities in order to prevent serious harm to yourself or others.

After hearing this information, do you have any questions?

IF YES: REFER TO QUESTIONS/ANSWERS.

IF NO: If you have any concerns about the study or how it is conducted, you may 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 participant, 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.

**INTERVIEWS WHEN MOM’S AGE IS UNKNOWN
OR KNOWN UNDER 18 (AR only)**

FOR ALL UNKNOWN AGE:

Before we get started, I need to ask your age. How old are you?

IF 18 YEARS OR OLDER (AR), CONTINUE TO REGULAR SCRIPT;

IF 15 YEARS OR OLDER (MA), CONTINUE TO REGULAR SCRIPT

IF 15-17 YEARS (AR Only),

We are required to ask for your parent or guardian’s permission for you to participate. In order for them to make that decision, they would need to see the information we sent to you. Are you willing to show the information to your parent or guardian and discuss your participation with them?

YES (WILLING TO SHARE WITH PARENT), see PARENT SCRIPT

NO (NOT WILLING TO SHARE WITH PARENT), “Thank you for taking the time to talk to

If you agree 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 PARTICIPANT'S NAME AND TODAY'S DATE.

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

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]**

YES (WISH TO BE INTERVIEWED 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 were selected from women who previously completed 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: We enclosed a **\$10 gift card** as a token of appreciation for your time and interest (for the interview). If you choose to complete the interview, we will send you an additional \$10 gift card to thank you for your time. <**Note: This is in addition to the \$30 enclosed incentive for the “general” 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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Revised Short Telephone Script: Interview Already Scheduled

[SHORT VERSION OF SCRIPT FOR WOMEN WHO ALREADY CONSENTED AT THE TIME THE INTERVIEW WAS SCHEDULED – FULL CONSENT SCRIPT WAS PREVIOUSLY READ TO SUBJECT. THE INTERVIEW BEGINS WITH THIS REMINDER.]

Hello, may I speak with <First and Last Name of Mother>? My name is <Interviewer> and I am calling from the <Arkansas Center for Birth Defects Research and Prevention at Arkansas Children’s Hospital OR Massachusetts Department of Public Health> to conduct the interview we scheduled for this time.

NO (NOT A CONVENIENT TIME): When would be a more convenient time for me to call you to conduct the interview?

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

VERIFY AND RECORD 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?

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>

Thank you. We look forward to talking with you at that time.

YES (CONVENIENT TIME NOW): [START THE INTERVIEW; RECORD DATE OF VERBAL CONSENT]

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

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 NOT PREVIOUSLY ASKED:

If you agree 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 PARTICIPANT’S NAME AND TODAY’S DATE.

NO (NOT OK TO LISTEN): SET UP “NO MONITORING SIGNAL OR SIGN” FOR SUPERVISOR. THEN VERIFY AND RECORD PARTICIPANT’S NAME AND TODAY’S DATE. PROCEED WITH INTERVIEW.

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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.