

**BD-STEPS
Introductory Telephone Script
and Informed Consent**

**Mother of Living Case Child or
Living Control Child**

Hello, may I speak with <First and Last Name of Mother>? My name is <Interviewer> and I am calling about a health study being conducted by <state grantee> and funded by the Centers for Disease Control and Prevention. Recently, we mailed you some information about the study. Did you receive the information?

[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 NO: We are inviting mothers to take part in this study to discover clues about what causes birth defects. To do this, we are interviewing mothers whose babies had birth defects as well as mothers of babies without these conditions. You were selected from women who recently had a baby in <state>. The study involves a telephone interview in which we ask about your health, medications, and lifestyle. We would like you to participate in the study, but first we need to send you the information about the study. May I get your current address to send you the information?

NO [SKIP TO UNDECIDED SUBJECT SCRIPTS]

YES [RECORD ADDRESS.] Thank you. Your participation will help us understand more about the causes of birth defects and their prevention. We will call you back in <time period> to answer questions about the study and see if we can schedule an interview.

**IF YES,
RESPOND TO SUBJECT’S QUESTIONS.**

READ INFORMED CONSENT TELEPHONE SCRIPT:

This is a study to discover clues about what causes birth defects. The study is called the Birth Defects Study To Evaluate Pregnancy exposureS or BD-STEPS, and for it we are interviewing women about their recent pregnancies.

BD-STEPS is a continuation of a previous study called the National Birth Defects Prevention Study. If you have been pregnant before 2012 it is possible that you have participated in this earlier study that included an hour long phone interview and cheek cell collection. Did you complete the interview for the National Birth Defects Prevention Study?

IF YES: Thank you again for your participation in the National Birth Defects Prevention Study. We appreciate your willingness to participate in BD-STEPS. However, our study procedures prevent us from including you in this second study. Thank you again for the time you’ve spent speaking with me today.

If NO/DK/RF Proceed with interview

The interview takes about 45 minutes (*but we can do it in short sections*). It covers a broad range of questions about:

- Your pregnancies
- Your health
- The prescription and non-prescription medicines you may have taken
- Your family background
- Your work
- Your lifestyle, and
- A few questions about your baby’s father

Some of the questions ask about sensitive issues such as sexually transmitted diseases and induced abortions.

Some women interviewed find it emotionally difficult to discuss their pregnancies. There is no other likely risk.

Taking part in the study will not benefit you or your family directly; however, the findings may help others in the future to prevent birth defects.

We enclosed a question and answer document with the letter we sent you. Do you have any more questions?

ANSWER QUESTIONS.

We are interviewing mothers of babies who had birth defects as well as mothers of babies without these conditions. Some babies were selected through the <state> surveillance program which tracks babies born with birth defects. State laws give us permission to review medical records when birth defects are present. This is how we identified most mothers in the study. We selected mothers whose babies don't have birth defects randomly from women who gave birth in the same year. Thousands of women are taking part in this study. Around 200 mothers of babies diagnosed with a birth defect and 75 mothers of babies without birth defects will be interviewed each year in <insert State>. We plan to conduct the study for at least three years in <insert state>.

Confidentiality and Certificate of Confidentiality: [REFER TO HUMAN SUBJECTS FACT SHEET.]

We will keep any identifying information that you provide during your interview confidential. This is assured by a Certificate of Confidentiality that 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 were subjects in the research during any time the certificate was in effect. However, you should understand that the investigators are not prevented from reporting information obtained from you to authorities in order to prevent serious harm to yourself or others. Records may be reviewed by officials checking on the quality of the research. 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. If you would like a copy of the Certificate of Confidentiality for this study, you may call <insert local study contact and contact number>, and a copy will be sent to you.

Voluntary Participation in Interview, Saliva (Spit) Collection and Other Parts: The study has two parts where we will ask for your active participation: (1) the telephone interview and (2) the saliva (spit) collection. In addition, we might also ask for your consent to review some of your medical records. <<**We will also ask for your consent to request a leftover newborn blood spot that was collected shortly after the birth of your baby**>>. Participation in all parts of this study is voluntary, meaning that it is your choice to take part or not. For instance, you can do the interview but decide not to collect saliva or not allow your medical records to be shared. You are free to withdraw from any or all parts of this study at any time. At any time in the future, you may have your interview responses or saliva samples removed from the study (by calling <insert local study contact and contact number>).

Incentive for Interview: We enclosed a **\$20 gift card with your letter** as a token of appreciation for your time and interest (for the interview).

Voluntary Saliva Collection: The saliva (spit) collection is entirely voluntary (optional). This part of the study will help us understand how genetic or inherited factors play a role in birth defects. After the interview, we will mail you a kit with saliva collection containers for you, your baby, and your baby's father. To collect saliva from your baby's mouth, the kit will include small sponges and a collection container. To collect saliva from you and the baby's father, the kit will include a tube with an attached funnel. We will **enclose a \$20 gift card in the kit** as a token of appreciation for your time and interest. You can decide whether to do this part of the study after you receive the kit. The kit will include easy-to-follow directions (saliva samples will be stored without your names). We will also send an additional **(third) \$20 gift card**

after you return the saliva samples as a token of appreciation for the time and interest needed to complete the entire study.

For More Information: If you'd like more information about the study, please contact <insert local study contact and contact number>. 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.

You can choose not to participate. The decision not to participate will not affect the care or services you or your family receives.

You can choose not to answer any specific questions. You are free to stop the interview at any time.

We will keep any identifying information that you provide during your interview confidential. The information you provide may be shared with other birth defects researchers, but we will never use any names in reports or publications.

If you have any concerns about the study or how it is conducted, you may contact <insert local study contact and contact number>. 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.

My supervisor may listen in from time to time to make sure I'm doing the best job I can. She may also record the interview as part of her supervision. (If you agree to be interviewed, will it be O.K. for my supervisor to listen?)

Do you wish to continue/be interviewed?

OR: When would be a convenient time to conduct the telephone interview?

PROBES:

- We can start now and see how far we get.
- We can do the interview in short sections such as 10 or 15-minute sessions, if that would be more convenient.
- I can set an appointment with you to call back at a convenient time.

IF YES:

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 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?

Thank you for agreeing to participate in BD-STEPS.

IF NO: We would like to know for what reason or reasons you have decided not to participate.

[RECORD REASONS. REFER TO UNDECIDED SUBJECT SCRIPTS.]

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

**BD-STEPS
Introductory Telephone Script
and Informed Consent**

**Mother of Stillborn or Deceased Child, or
Therapeutic Abortion (TAB)**

Hello, may I speak with <First and Last Name of Mother>? My name is <Interviewer> and I am calling about a health study being conducted by <state grantee> and funded by the Centers for Disease Control and Prevention. Recently, we mailed you some information about the study. Did you receive the information?

[IF SUBJECT ASKS WHERE YOU ARE CALLING FROM OR WHO INTERVIEWER CONTRACTOR IS, STATE: "I am with Abt Associates; we conduct all the interviews for the study."]

IF NO: We are inviting families to take part in this study to discover clues about what causes birth defects. You were selected from women who recently had a pregnancy affected by a birth defect. Your pregnancy was identified through the <state> surveillance program that tracks pregnancies affected by birth defects. We are sorry about your loss and extend our deepest sympathy to you. We understand that it may be difficult for you to think and talk about your experience. However, we are interested in factors that may help prevent birth defects and pregnancy problems in the future. The study involves a telephone interview in which we ask about your health, medications and lifestyle. We would like you to participate in the study, but we first need to send you the information about the study. May I get your current address to send you the information?

NO [SKIP TO UNDECIDED SUBJECT SCRIPTS]

YES [RECORD ADDRESS.] Thank you. Your participation will help us understand more about the causes of birth defects and their prevention. We will call you back in [time period] to answer questions about the study and see if we can schedule an interview.

IF YES: RESPOND TO SUBJECT'S QUESTIONS.

READ INFORMED CONSENT TELEPHONE SCRIPT:

This is a study to discover clues about what causes birth defects. The study is called the Birth Defects Study To Evaluate Pregnancy exposureS or BD-STEPS, and for it we are interviewing women about their recent pregnancies.

BD-STEPS is a continuation of a previous study called the National Birth Defects Prevention Study. If you have been pregnant before 2012 it is possible that you have participated in this earlier study that included an hour long phone interview and cheek cell collection. Did you complete the interview for the National Birth Defects Prevention Study?

IF YES: Thank you again for your participation in the National Birth Defects Prevention Study. We appreciate your willingness to participate in BD-STEPS. However, our study procedures prevent us from including you in this second study. Thank you again for the time you've spent speaking with me today.

If NO/DK/RF Proceed with interview

The interview takes about 45 minutes (*but we can do it in short sections*). It covers a broad range of questions about:

- Your pregnancies
- Your health
- The prescription and non-prescription medicines you may have taken
- Your family background
- Your work
- Your lifestyle, and
- A few questions about the baby's father

Some of the questions ask about sensitive issues such as sexually transmitted diseases and induced abortions. Some women interviewed find it emotionally difficult to discuss their pregnancies. There is no other likely risk. Taking part in the study will not benefit you or your family directly; however, the findings may help others in the future to prevent birth defects.

We enclosed a question and answer brochure with the letter we sent you. Do you have any more questions?

ANSWER QUESTIONS.

We are interviewing women who had a pregnancy affected by a birth defect as well as women whose pregnancies were not affected by these conditions. You were selected from women who recently had a pregnancy affected by a birth defect. Your pregnancy was identified through the <state> surveillance program that tracks pregnancies affected by birth defects. State laws give us permission to review medical records when birth defects are present. This is how we identified most women in the study. We selected women whose babies don't have birth defects randomly from women who gave birth in the same year. Thousands of women are taking part in this study. Around 200 mothers of babies diagnosed with birth defects and 75 mothers of babies without birth defects will be interviewed in <State> each year. We plan to conduct the study for at least three years in <State>.

Confidentiality and Certificate of Confidentiality: [REFER TO HUMAN SUBJECTS FACT SHEET.]

We will keep any identifying information that you provide during your interview confidential. This is assured by a Certificate of Confidentiality that 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 were subjects in the research during any time the certificate was in effect. However, you should understand that the investigators are not prevented from reporting information obtained from you to authorities in order to prevent serious harm to yourself or others. Records may be reviewed by officials checking on the quality of the research. 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. If you would like a copy of the Certificate of Confidentiality for this study, you may call <insert local study contact and contact number>, and a copy will be sent to you.

Voluntary Participation in Interview, Saliva (spit) Collection and Other Parts: The study has two parts where we will ask for your active participation: (1) the telephone interview and (2) saliva (spit) collection. In addition, we might also ask for your consent to review some of your medical records. Participation in all parts of this study is voluntary, meaning that you have the choice to take part or not. For instance, you can do the interview but decide not to collect saliva or allow your medical records to be shared. You are free to withdraw from any or all parts of this study at any time. At any time in the future, you may have your interview responses or saliva samples removed from the study (by calling <insert local study contact and contact number>).

Incentive for Interview: We enclosed a **\$20 gift card** as a token of appreciation for your time and interest (for the interview).

Voluntary Saliva Collection: The saliva (spit) collection is entirely voluntary (optional). It will help us understand how genetic (or inherited) factors play a role in birth defects. After the interview, we will mail a kit to you with saliva collection containers for you and your baby's father. We will **enclose a \$20 gift card in the kit** as a token of appreciation for your time and interest. You can decide whether to take part in this part of the study after you receive the kit. The kit will include easy-to-follow directions and all necessary materials to collect the samples (saliva samples will be stored without names). We will also send an additional **(third) \$20 gift card** after you return the saliva samples as a token of appreciation for the time and interest needed to complete the entire study.

For More Information: If you'd like more information about the study, please contact <insert local study contact and contact number>. 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.

You can choose not to participate. This decision will not affect the care or services you or your family receives.

You can choose not to answer any specific questions. You are free to stop the interview at any time.

We will keep any identifying information that you provide during your interview confidential. The information you provide may be shared with other birth defects researchers, but we will never use any names in reports or publications.

If you have any concerns about the study or how it is conducted, you may contact <insert local study contact and contact number>. 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.

My supervisor may listen in from time to time to make sure I'm doing the best job I can. She may also record the interview as part of her supervision. (If you agree to be interviewed, will it be O.K. for my supervisor to listen?)

Do you wish to continue/be interviewed?

OR: When would be a convenient time to conduct the telephone interview?

PROBES:

- We can start now and see how far we get.
- We can do the interview in short sections such as 10 or 15-minute sessions, if that would be more convenient.
- I can set an appointment with you to call back at a convenient time.

IF YES:

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 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?

Thank you for agreeing to participate in BD-STEPS.

IF NO: We would like to know for what reason or reasons you have decided not to participate.

[RECORD REASONS. REFER TO UNDECIDED SUBJECT SCRIPTS.]

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

BD-STEPS
Introductory Telephone Script
and Informed Consent

Mother: Affected Pregnancy
with Unknown Outcome

Hello, may I speak with <First and Last Name of Mother>? My name is <Interviewer> and I am calling about a health study being conducted by <state grantee> and funded by the Centers for Disease Control and Prevention. Recently, we mailed you some information about the study. Did you receive the information?

[IF SUBJECT ASKS WHERE YOU ARE CALLING FROM OR WHO INTERVIEWER CONTRACTOR IS, STATE: "I am with Abt Associates; we conduct all the interviews for the study."]

IF NO: We are inviting families to take part in this study to discover clues about what causes birth defects. You were selected from women who recently had a pregnancy affected by a birth defect. We are interested in factors that may help prevent birth defects and pregnancy problems. The study involves a telephone interview about your health, medications, and lifestyle. We would like you to participate in the study, but first need to send you the information about the study in more detail. May I get your current address to send you the information?

NO [SKIP TO UNDECIDED SUBJECT SCRIPTS]

YES [RECORD ADDRESS.] Thank you. Your participation will help us understand more about the causes of birth defects and their prevention. We will call you back in [time period] to answer questions about the study and see if we can schedule an interview

IF YES: RESPOND TO SUBJECT'S QUESTIONS.

READ INFORMED CONSENT TELEPHONE SCRIPT:

This is a study to discover clues about what causes birth defects. The study is called the Birth Defects Study To Evaluate Pregnancy exposureS or BD-STEPS, and for it we are interviewing women about their recent pregnancies.

BD-STEPS is a continuation of a previous study called the National Birth Defects Prevention Study. If you have been pregnant before 2012 it is possible that you have participated in this earlier study that included an hour long phone interview and cheek cell collection. Did you complete the interview for the National Birth Defects Prevention Study?

IF YES: Thank you again for your participation in the National Birth Defects Prevention Study. We appreciate your willingness to participate in BD-STEPS. However, our study procedures prevent us from including you in this second study. Thank you again for the time you've spent speaking with me today.

If NO/DK/RF Proceed with interview

The interview takes about 45 minutes (*but we can do it in short sections*). It covers a broad range of questions about:

- Your pregnancies
- Your health
- The prescription and non-prescription medicines you may have taken
- Your family background
- Your work
- Your lifestyle
- A few questions about the baby's father

Some of the questions ask about sensitive issues such as sexually transmitted diseases and induced abortions. Some women interviewed find it emotionally difficult to discuss their pregnancies. There is no other likely risk.

Taking part in the study will not benefit you or your family directly; however, the findings may help others in the future to prevent birth defects.

We enclosed a question and answer brochure with the letter we sent you. Do you have any more questions?

ANSWER QUESTIONS.

We are interviewing women with healthy babies as well as women who had a pregnancy affected by a birth defect. You were selected from women who recently had a pregnancy affected by a birth defect. Your pregnancy was identified through the <state> surveillance program that tracks babies with birth defects. (State laws give us permission to review medical records when birth defects are present. This is how we identified most women in the study.) Women whose babies don't have birth defects were selected randomly from women who gave birth in the same year. Thousands of women are taking part in this national study. Around 200 mothers of babies diagnosed with birth defects and 75 mothers of healthy babies will be interviewed <in State> each year. We plan to conduct the study for at least three years in <State>.

Confidentiality and Certificate of Confidentiality: [REFER TO HUMAN SUBJECTS FACT SHEET.]

We will keep any identifying information that you provide during your interview confidential. This is assured by a Certificate of Confidentiality that 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 were subjects in the research during any time the certificate was in effect. However, you should understand that the investigators are not prevented from reporting information obtained from you to authorities in order to prevent serious harm to yourself or others. Records may be reviewed by officials checking on the quality of the research. 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.. If you would like a copy of the Certificate of Confidentiality for this study, you may call <insert local study contact and contact number>, and a copy will be sent to you.

Voluntary Participation in Interview, Saliva (spit) Collection and Other Parts: The study has two parts where we will ask for your active participation: (1) the telephone interview and (2) saliva (spit) collection. In addition, we might also ask for your consent to review some of your medical records. Participation in all parts of this study is voluntary, meaning that it is your choice to take part or not. For instance, you can do the interview but decide not to complete the saliva collection kit or allow your medical records to be shared. You are free to withdraw from any or all parts of this study at any time. At any time in the future, you may have your interview responses or saliva samples removed from the study (by calling <insert local study contact and contact number>).

Incentive for Interview: We enclosed a **\$20 gift card** as a token of appreciation for your time and interest (for the interview).

Voluntary Saliva (spit) Collection Kit: The saliva (spit) collection is entirely voluntary (optional). It will help us understand how genetic or inherited factors play a role in the occurrence of birth defects. After the interview, we will mail a kit to you with saliva collection containers. We will **enclose a \$20 gift card in the kit** as a token of appreciation for your time and interest. You can decide whether to do this part of the study after you receive the kit. The kit will include easy-to-follow directions and all the materials you need to collect the samples (saliva samples will be stored without names). We will also send an additional **(third) \$20 gift card** after you return the saliva samples as a token of appreciation for the time and interest needed to complete the entire study.

For More Information: If you'd like more information about the study, please contact <insert local study contact and contact number>. 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.

You can choose not to participate. This decision will not affect the care or services you or your family receives.

You can choose not to answer any specific questions. You are free to stop the interview at any time.

In addition, we might also ask for your consent to review some of your medical records. The information you provide may be shared with other birth defects researchers, but we will never use any names in reports or publications.

If you have any concerns about the study or how it is conducted, you may contact <insert local study contact and contact number>. 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.

My supervisor may listen in from time to time to make sure I'm doing the best job I can. She may also record the interview as part of her supervision. (If you agree to be interviewed, will it be O.K. for my supervisor to listen?)

Do you wish to continue/be interviewed?

OR: When would be a convenient time to conduct the telephone interview?

PROBES:

- We can start now and see how far we get.
- We can do the interview in short sections such as 10 or 15-minute sessions, if that would be more convenient.
- I can set an appointment with you to call back at a convenient time.

IF YES:

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 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?

Thank you for agreeing to participate in BD-STEPS.

IF NO: We would like to know for what reason or reasons you have decided not to participate.

[RECORD REASONS. REFER TO UNDECIDED SUBJECT SCRIPTS.]

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

BD-STEPS

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 for the <**State**> Birth Defects Study To Evaluate Pregnancy exposureS or BD-STEPS. Recently, you scheduled an interview for this time. Is this still a convenient time to conduct the interview?

[IF SUBJECT ASKS WHERE YOU ARE CALLING FROM OR WHO Interviewer contractor IS, STATE:

“I am with Abt Associates; we conduct all the interviews for the study >

IF NO: 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 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?

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

IF YES:

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: My supervisor may listen in from time to time to make sure I'm doing the best job I can. Will it be o.k. for my supervisor to listen?

IF YES: VERIFY NAME AND/OR BIRTHDATE OF CHILD. PROCEED WITH INTERVIEW.

IF NO: SET UP “NO MONITORING SIGNAL OR SIGN” FOR SUPERVISOR.

THEN VERIFY NAME AND/OR BIRTHDATE OF CHILD. PROCEED WITH INTERVIEW.