

Table of contents:

Introductory Script and Informed Consent (Mother of Living Case/Control Child).....	pg 2
Introductory Script and Informed Consent (Mother of Stillborn or Deceased Child or TAB).....	pg 6
Introductory Script and Informed Consent (Mother: Affected Pregnancy with Unk Outcome)....	pg 10
Revised Short Telephone Script: Interview Already Scheduled.....	pg 14
CONTINUED Minor Script.....	pg 15
Parent/Guardian of Minor Script and Informed Consent.....	pg 15

Public reporting burden of this collection of information is estimated to average 10 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).

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.>>

IA INTERVIEWS SKIP TO YES, RECEIVED INFORMATION

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 RTI International; we conduct all the interviews for the study.”]

IF NO (DID NOT RECEIVE INFORMATION):

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 birth defects. 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 (RECEIVED INFORMATION) [IA SCRIPT RESUMES HERE],
RESPOND TO SUBJECT’S QUESTIONS, THEN CONTINUE READING 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 an interview for the National Birth Defects Prevention Study?

NO/DK/RF [CONTINUE READING SCRIPT]

YES I can’t complete the interview today if you participated in the National Birth Defects Prevention Study. But, sometimes the names of studies sound familiar. Would you like us to check our records to see if you participated in the previous study and call you back later?

YES We will call you back as soon as our record check is complete and will give you a chance to hear more about the study and decide then if you would like to participate. Is there a chance your name has changed or you might have completed an interview under a different name? If so, please let me know this name or these names. **[RECORD NAME(S)]** Thank you again for the time you’ve spent speaking with me today.

NO Thank you again for the time you’ve spent speaking with me today. If you change your mind or if you have any questions, please call 1-888-743-7324. Thank you. Goodbye.”

**INTERVIEWS WHEN MOM'S AGE IS UNKNOWN
OR KNOWN UNDER 18 (AR and NC 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 AND NC), CONTINUE TO REGULAR SCRIPT;

IF 15 YEARS OR OLDER (CA, GA, IA, NY, MA), CONTINUE TO REGULAR SCRIPT

IF UNDER 15 “We appreciate your consideration of participation in BD-STEPS. However, our study procedures prevent us from including you in this study since you are under 15. Thank you again for the time you’ve spent speaking with me today.”

NC ONLY

(SKIP ABOVE SCRIPT IF KNOWN UNDER 18):

We are interested in having you participate in the study. Because [**IF KNOWN UNDER 18:** “Our records show...”] you are younger than 18, we are required to ask, do you live with a parent or guardian?

**NO (DOES NOT LIVE WITH PARENT OR GUARDIAN), THEN
CONTINUE TO REGULAR SCRIPT;**

YES (DOES LIVE WITH PARENT OR GUARDIAN), THEN CONTINUE

IF 15-17 YEARS (AR) OR 15-17 AND LIVING WITH PARENT (NC)

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

YES (WILLING TO SHARE WITH PARENT), see CONTINUED Minor Script (pg 15)

NO (NOT WILLING TO SHARE WITH PARENT), “Thank you for taking the time to talk to me about this study today. If you change your mind or if you have any questions, please call 1-888-743-7324. Thank you. Goodbye.”

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 sheet with the letter we sent you. Do you have any more questions?

ANSWER QUESTIONS

How did you get my name: We are interviewing mothers of babies who had birth defects as well as mothers of babies without birth defects. 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: The study will give you different opportunities to participate, but all participants will begin with a telephone interview. <<After the telephone interview, we will ask for your consent to request leftover newborn blood spots that were collected shortly after the birth of your baby.>> We might also ask for your consent to review some of your medical records or for you to complete some additional questions online. 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 <<share biologic specimens 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 biologic 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).

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 share your information with other researchers involved in this study, which may include health information

about you and your baby and personal information such as where you live. < [FOR CENTERS ELECTING TO INCLUDE CO-SIBLING CONTROLS] If you are the mother of twins, triplets or other multiples, we will also include some limited medical information such as sex, date of birth, gestational age, birth weight and medical diagnoses on all babies from your pregnancy in our study. > 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 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>> OR <<insert local IRB contact>>. 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? [or for us to record the interview]?)

YES (OK TO LISTEN IN): VERIFY NAME AND/OR BIRTHDATE OF CHILD. PROCEED WITH INTERVIEW.

NO (NOT OK TO LISTEN): SET UP "NO MONITORING SIGNAL OR SIGN" FOR SUPERVISOR. THEN VERIFY NAME AND/OR BIRTHDATE OF CHILD. PROCEED WITH INTERVIEW.

Do you wish to continue/be interviewed?

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

PROBES:

Is there anything else you would like to ask?

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.

YES (WISH TO BE INTERVIEWED LATER):

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?

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 agreeing to participate in BD-STEPS.

NO (DOES NOT WISH TO BE INTERVIEWED):

-[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. 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.

IA INTERVIEWS SKIP TO YES, RECEIVED INFORMATION

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 RTI International; we conduct all the interviews for the study."]

NO (DID NOT RECEIVE INFORMATION):

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.

**YES (RECEIVED INFORMATION) [IA SCRIPT RESUMES HERE]:
RESPOND TO SUBJECT'S QUESTIONS, THEN CONTINUE READING 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 an interview for the National Birth Defects Prevention Study?

NO/DK/RF [CONTINUE READING SCRIPT]

YES I can't complete the interview today if you participated in the National Birth Defects Prevention Study. But, sometimes the names of studies sound familiar. Would you like us to check our records to see if you participated in the previous study and call you back later?

YES We will call you back as soon as our record check is complete and will give you a chance to hear more about the study and decide then if you would like to participate. Is there a chance your name has changed or you might have completed an interview under a different name? If so, please let me know this name or these names. **[RECORD NAME(S)]** Thank you again for the time you've spent speaking with me today.

NO Thank you again for the time you've spent speaking with me today. If you change your mind or if you have any questions, please call 1-888-743-7324. Thank you. Goodbye."

**INTERVIEWS WHEN MOM'S AGE IS UNKNOWN
OR KNOWN UNDER 18 (AR and NC 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 and NC) CONTINUE TO REGULAR SCRIPT;

IF 15 YEARS OR OLDER (CA, GA, IA, NY, MA) CONTINUE TO REGULAR SCRIPT

IF UNDER 15 “We appreciate your consideration of participation in BD-STEPS. However, our study procedures prevent us from including you in this study since you are under 15. Thank you again for the time you’ve spent speaking with me today.”

NC ONLY

(SKIP ABOVE SCRIPT IF KNOWN UNDER 18):

We are interested in having you participate in the study. Because [**IF KNOWN UNDER 18**: “Our records show...”] you are younger than 18, we are required to ask, do you live with a parent or guardian?

**NO (DOES NOT LIVE WITH PARENT OR GUARDIAN), THEN
CONTINUE TO REGULAR SCRIPT;**

**YES (DOES LIVE WITH PARENT OR GUARDIAN), THEN
CONTINUE**

IF 15-17 YEARS (AR), OR 15-17 AND LIVING WITH PARENT (NC)

We are required to ask for your parent or guardian’s permission for you to participate in the study. In order for them to make that decision, they would need to see the letter and brochure we sent to you. Are you willing to show these materials 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 me about this study today. If you change your mind or if you have any questions, please call 1-888-743-7324. Thank you. Goodbye.”

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 sheet with the letter we sent you. Do you have any more questions?
ANSWER QUESTIONS.

How did you get my name: We are interviewing women who had a pregnancy affected by a birth defect as well as women whose pregnancies were not 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 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: The study will give you different opportunities to participate, but all participants will begin with a telephone interview. We might also ask for your consent to review some of your medical records or for you to complete some additional questions online. 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 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 biologic 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).

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 share your information with other researchers involved in this study, which may include information about your health and personal information such as where you live. < [FOR CENTERS ELECTING TO INCLUDE CO-SIBLING CONTROLS] If you are the mother of twins, triplets or other multiples, we will also include some limited medical information such as sex, date of birth, gestational age, birth weight and medical

diagnoses on all babies from your pregnancy in our study. >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 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 or for us to record the interview?)

YES (OK TO LISTEN IN): VERIFY NAME AND/OR BIRTHDATE OF CHILD. PROCEED WITH INTERVIEW.

NO (NOT OK TO LISTEN): SET UP "NO MONITORING SIGNAL OR SIGN" FOR SUPERVISOR. THEN VERIFY NAME AND/OR BIRTHDATE OF CHILD. PROCEED WITH INTERVIEW.

Do you wish to continue/be interviewed?

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

PROBES:

Is there anything else you would like to ask?

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.

YES (WISH TO BE INTERVIEWED LATER):

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?

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 agreeing to participate in BD-STEPS.

NO (DOES NOT WISH TO BE INTERVIEWED):

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. 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.

IA INTERVIEWS SKIP TO YES, RECEIVED INFORMATION

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 RTI International; we conduct all the interviews for the study."]

NO (DID NOT RECEIVE INFORMATION):

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

YES (RECEIVED INFORMATION) [IA INTERVIEW RESUMES HERE]:

RESPOND TO SUBJECT'S QUESTIONS, THEN CONTINUE READING 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?

NO/DK/RF [CONTINUE READING SCRIPT]

YES I can't complete the interview today if you participated in the National Birth Defects Prevention Study. But, sometimes the names of studies sound familiar. Would you like us to check our records to see if you participated in the previous study and call you back later?

YES We will call you back as soon as our record check is complete and will give you a chance to hear more about the study and decide then if you would like to participate. Is there a chance your name has changed or you might have completed an interview under a different name? If so, please let me know this name or these names. [RECORD NAME(S)] Thank you again for the time you've spent speaking with me today.

NO Thank you again for the time you've spent speaking with me today. If you change your mind or if you have any questions, please call 1-888-743-7324. Thank you. Goodbye."

**INTERVIEWS WHEN MOM'S AGE IS UNKNOWN
OR KNOWN UNDER 18 (AR and NC 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 AND NC) CONTINUE TO REGULAR SCRIPT;

IF 15 YEARS OR OLDER (CA, GA, IA, NY, MA) CONTINUE TO REGULAR SCRIPT

IF UNDER 15 “We appreciate your consideration of participation in BD-STEPS. However, our study procedures prevent us from including you in this study since you are under 15. Thank you again for the time you’ve spent speaking with me today.”

NC ONLY

(SKIP ABOVE SCRIPT IF KNOWN UNDER 18):

We are interested in having you participate in the study. Because [**IF KNOWN UNDER 18:** “Our records show...”] you are younger than 18, we are required to ask, do you live with a parent or guardian?

**IF NO (DOES NOT LIVE WITH PARENT OR GUARDIAN), THEN
CONTINUE TO REGULAR SCRIPT;**

IF YES (DOES LIVE WITH PARENT OR GUARDIAN), THEN

IF 15-17 YEARS (AR) OR 15-17 AND LIVING WITH PARENT (NC)

We are required to ask for your parent or guardian’s permission for you to participate in the study. In order for them to make that decision, they would need to see the letter and brochure we sent to you. Are you willing to show these materials 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 me about this study today. If you change your mind or if you have any questions, please call **1-888-743-7324**. Thank you. Goodbye.”

- 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 sheet with the letter we sent you. Do you have any more questions?
ANSWER QUESTIONS.

How did you get my name: 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 and Other Parts: The study will give you different opportunities to participate, but all participants will begin with a telephone interview. We might also ask for your consent to review some of your medical records or for you to complete some additional questions online. 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 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 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).

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 share your information with other researchers involved in this study, which may include information about your health and personal information such as where you live. < [FOR CENTERS ELECTING TO INCLUDE CO-SIBLING CONTROLS] If you are the mother of twins, triplets or other multiples, we will also include some limited medical information such as sex, date of birth, gestational age, birth weight and medical

diagnoses on all babies from your pregnancy in our study. >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 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 or for us to record the interview?)

YES (OK TO LISTEN IN): VERIFY NAME AND/OR BIRTHDATE OF CHILD. PROCEED WITH INTERVIEW.

NO (NOT OK TO LISTEN): SET UP "NO MONITORING SIGNAL OR SIGN" FOR SUPERVISOR. THEN VERIFY NAME AND/OR BIRTHDATE OF CHILD. PROCEED WITH INTERVIEW.

Do you wish to continue/be interviewed?

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

PROBES:

Is there anything else you would like to ask?

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.

YES (WISH TO BE INTERVIEWED LATER):

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?

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 agreeing to participate in BD-STEPS.

NO (DOES NOT WISH TO BE INTERVIEWED):

[(REVISED) 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. 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 RTI International; we conduct all the interviews for the study >

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 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 IN TRACKING

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

YES (CONVENIENT TIME NOW):

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. 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 or for us to record the interview?)

IF YES (OK TO LISTEN IN): VERIFY NAME AND/OR BIRTHDATE OF CHILD. PROCEED WITH INTERVIEW.

IF NO (NOT OK TO LISTEN): SET UP “NO MONITORING SIGNAL OR SIGN” FOR SUPERVISOR. THEN VERIFY NAME AND/OR BIRTHDATE OF CHILD. PROCEED WITH INTERVIEW.

BD-STEPS
CONTINUED Minor Script

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 _____

When is a good time to speak to <her /him>? Day _____ Time _____

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

Also, <s/he> can call us at our toll-free number 1-888-743-7324 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.

BD-STEPS
Parent/Guardian of Minor Script
And Informed Consent

Hello, may I speak with <Mr./Ms./Dr.> _____? 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.

[FOR LIVING CASE/CONTROL CHILD]:

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 birth defects. [**Your daughter OR MOIB NAME**] was selected from women who recently had a baby in <state>.

[FOR STILLBORN OR DECEASED CHILD OR THERAPEUTIC ABORTION (TAB)]:

We are inviting women to take part in this study to discover clues about what causes birth defects. To do this, we are enrolling women in <state> hoping to discover clues about what causes birth defects. <**Your daughter OR MOIB NAME**> was selected from women who recently had a pregnancy affected by a birth defect. Her pregnancy was identified through the <state> surveillance program that tracks pregnancies affected by birth defects. We are sorry about her loss and extend our deepest sympathy to your family. We understand that it may be difficult for her to think and talk about her experience. However, we are interested in factors that may help prevent birth defects and pregnancy problems in the future.

[FOR AFFECTED PREGNANCY WITH UNKNOWN OUTCOME]:

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 birth defects. <**Your daughter OR MOIB NAME**> was 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.

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

The study involves a telephone interview about <**your daughter OR MOIB NAME**>'s health, diet, and lifestyle. Since she is not yet 18, we are required to ask if you will allow her to participate in the study. We want to include young women in our study because birth defects sometimes occur among their pregnancies, as well as those of older women.

Recently we mailed a packet to <**your daughter OR MOIB NAME**> asking her to participate in the research study. Have you had a chance to look at the letter and information we sent to her?

NO (HAVE NOT RECEIVED INFORMATION):

When would be a good time to call you back? Day _____ Time _____

YES (HAVE RECEIVED INFORMATION): Would you like some more information about the study?

YES (WOULD LIKE MORE INFORMATION):

RESPOND TO PARENT/GUARDIAN'S QUESTIONS; ASK IF PARENT/GUARDIAN HAS QUESTIONS.

NO (WOULD NOT LIKE MORE INFORMATION):

CONTINUE:

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

- <Your daughter OR MOIB NAME>'s pregnancies
- <Your daughter OR MOIB NAME>'s health
- The prescription and non-prescription medicines <your daughter OR MOIB NAME> may have taken
- <Your daughter OR MOIB NAME>'s family background
- <Your daughter OR MOIB NAME>'s work
- <Your daughter OR MOIB NAME>'s lifestyle, and
- A few questions about <Your daughter OR MOIB NAME>'s 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 <your daughter OR MOIB NAME> or your family directly; however, the findings may help others in the future to prevent birth defects.

<Your daughter OR MOIB NAME> can choose not to participate. The decision not to participate will not affect the care or services <your daughter OR MOIB NAME> or your family receives.

<Your daughter OR MOIB NAME> can choose not to answer any specific questions. <Your daughter OR MOIB NAME> is free to stop the interview at any time.

We will share your information with other researchers involved in this study, which may include health information about <your daughter OR MOIB NAME>...

<ONLY FOR LIVING CASE/CONTROL: and <your daughter OR MOIB NAME>'s baby...>

...and personal information such as where she lives. 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 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>> OR <<insert local IRB contact>>. 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 <your daughter OR MOIB NAME> does agree to be interviewed, will it be

O.K. for my supervisor to listen [or for us to record the interview]?

YES (OK TO LISTEN IN): VERIFY NAME AND/OR BIRTHDATE OF CHILD. PROCEED WITH INTERVIEW.

NO (NOT OK TO LISTEN): SET UP “NO MONITORING SIGNAL OR SIGN” FOR SUPERVISOR. THEN VERIFY NAME AND/OR BIRTHDATE OF CHILD. PROCEED WITH INTERVIEW.

Do you give permission for [**your daughter OR MOIB NAME**> to participate in the interview?

NO (DOES NOT GIVE PERMISSION):

Thank you very much for your time. GO TO **IF NO** BELOW.

YES (GIVES PERMISSION):

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

First Name: _____ Middle name/initial if provided: ____ Last Name: _____

What is your relationship to MOIB? Mother, Father, Stepmother, Stepfather, Guardian, or OTHER, SPECIFY?

We will call (MOIB 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 she wants to participate.

Time convenient for <**your daughter OR MOIB NAME**>:

Day _____ Time _____

RECORD DATE AND TIME (INCLUDE TIME ZONE).

VERIFY PHONE #: I need to verify the telephone number where (MOIB 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 your cooperation/help in the Birth Defects Study To Evaluate Pregnancy exposureS or BD-STEPS. This is an important study to determine the causes of birth defects. It’s important to include young women because birth defects among the pregnancies of young women as well as older women need to be studied.

IF NO: We would like to know for what reason or reasons you prefer that <**your daughter OR MOIB NAME**> not participate.

[RECORD REASONS]

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