

Table of Contents

General Introductory Scripts.....	3
Mother of Living Case/Living Control Child.....	3
Mother of Stillborn or Deceased Child, or Therapeutic Abortion (TAB).....	7
Mother: Affected Pregnancy with Unknown Outcome.....	13
Revised Short Telephone Script: Interview Already Scheduled.....	18
Arkansas and North Carolina Introductory Scripts.....	19
AR & NC Mother of Living Case/Control Child.....	19
AR & NC Mother of Stillborn or Deceased Child, or Therapeutic Abortion (TAB).....	24
AR & NC Mother: Affected Pregnancy with Unknown Causes.....	30
AR & NC Revised Short Telephone Script: Interview Already Scheduled.....	36
AR & NC Parent/Guardian of Minor Script and Informed Consent.....	37
Iowa Introductory Scripts.....	41
IA Mother of Living Case/Control Child.....	41
IA Mother of Stillborn or Deceased Child, or Therapeutic Abortion (TAB).....	44
IA Mother: Affected Pregnancy with Unknown Causes.....	47
IA Revised Short Telephone Script: Interview Already Scheduled.....	50
California Introductory Scripts.....	51
CA - Mother of Living Case/Control Child.....	51
CA - Mother of Stillborn or Deceased Child, or Therapeutic Abortion (TAB).....	56
CA - Mother: Affected Pregnancy with Unknown Causes.....	60
CA - Revised Short Telephone Script: Interview Already Scheduled.....	65
Massachusetts Introductory Scripts.....	66
MA Mother of Living Case/Living Control Child.....	66

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).

MA Women of Stillborn or Deceased Child, or Therapeutic Abortion (TAB).....71
MA Women: Pregnancy with Unknown Outcome.....76
MA Revised Short Telephone Script: Interview Already Scheduled.....81

General Introductory Scripts

Mother of Living Case/Living Control Child

[INTRO1] 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.>> 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 <Interview Contractor>; we conduct all the interviews for the study.”]

[LTR_S] Recently, we mailed you some information about the study, called the Birth Defects Study To Evaluate Pregnancy exposureS, or BD-STEPS. This information was mailed to you in a large envelope that contained a blue folder with BD-STEPS printed on it. Did you receive the information?

IF NO (DID NOT RECEIVE INTRO PACKET):

[NOLET_LIVE] 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 about your health, medications, and lifestyle. We would like you to participate in the study, but first we need to give you more information about the study. May I get your current address to send you the information?

NO [SKIP TO PROBES]

YES [RECORD ADDRESS.] Thank you. We will mail the study information to you shortly. We can call you back in <time period> to answer questions about the study and see if we can schedule an interview after you have received the information packet. Or I can tell you more about the study now if you like. Would you like to hear more about the study now?

IF NO [DID NOT RECEIVE INTRO PACKET AND WOULD NOT LIKE TO HEAR MORE ABOUT STUDY]. Thank you for your time today. We look forward to talking to you after you have received the packet of information. Would you like to set up a time for us to call you back after you’ve had a chance to receive and review the packet?

YES (WISH TO SET CALL BACK):

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

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

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

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

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

RECORD RESPONSE AND ADDRESS IN TRACKING

1. Email: [provide field in which to type email address; prefill with email address in Symphony, if one exists]

2. Text: [provide field in which to type mobile phone number; prefill with number from current RL but allow edits]

NO (DO NOT WISH TO SET CALL BACK):

Thank you for your time today. We will call you back in <time period>.

IF YES (RECEIVED INTRO PACKET) OR YES (WOULD LIKE TO HEAR MORE ABOUT THE STUDY NOW)

RESPOND TO SUBJECT’S QUESTIONS, THEN CONTINUE READING SCRIPT.

[STUDY_ 2012] 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.

ONLY FOR INTERVIEWS WHEN MOM’S AGE IS UNKNOWN:

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

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

IF UNDER 15 [THANK_AGE] “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.”

[INFORM] The interview takes about 55 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.

[FOR THOSE WHO DID NOT RECEIVE INTRO PACKET BUT ANSWERED ‘YES’ TO WISH TO HEAR MORE ABOUT THE STUDY] Now, I’d like to read you some of the information that is part of the packet that you will be receiving in the mail soon. It will take less than two minutes to read. 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.

All information that we gather in this study will be kept confidential. This is because the study 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 but we will never use any names or addresses in reports or publications. 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?

[FOR ALL WHO RECEIVED MAILING]

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

ANSWER QUESTIONS

[Q_NAME] *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 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>.

[Q_CONFID] *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 or addresses in reports or publications.

[Q_PART] *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>).

[Q_INCENTIVE] *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).

[Q_INFO] *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.

[INFORM2] 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: AR, GA, MA, NC, NY] 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.

[INFORM3] 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.

[START.] Do you wish to continue/be interviewed?

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

PROBES:

General:

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.

Not willing to provide address:

Could we send the packet to the address of a relative or friend?

Do you have any questions about the study I might be able to address?

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?

YES (WISH TO BE INTERVIEWED NOW):

[TWER] 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. (Will it be O.K. for my supervisor to listen? [or for us to record the interview]?)

YES (OK TO LISTEN IN): → [T_CHKDOB.] 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.

Thank you for agreeing to participate in BD-STEPS.

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

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

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

RECORD RESPONSE AND ADDRESS IN TRACKING

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

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.

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

[INTRO1] 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. 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 INTERVIEWER CONTRACTOR IS, STATE: “I am with <Interview Contractor>; we conduct all the interviews for the study.”]

[LTR_S] Recently, we mailed you some information about the study, called the Birth Defects Study To Evaluate Pregnancy exposures, or BD-STEPS. This information was mailed to you in a large envelope that contained a blue folder with BD-STEPS printed on it. Did you receive the information?

NO (DID NOT RECEIVE INTRO PACKET):

[NOLET_DECEASE] We are inviting women to take part in this study to discover clues about what causes birth defects. To do this, we are interviewing women whose pregnancies were affected by a birth defect as well as women whose pregnancies were not affected by birth defects. You were selected from women who recently had a pregnancy affected by a birth defect. <DECEASED OR SB ONLY: 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 about your health, medications and lifestyle. We would like you to participate in the study, but we first need to give you more information about the study. May I get your current address to send you the information?

NO [SKIP TO PROBES]

YES [RECORD ADDRESS.] Thank you. We will mail the study information to you shortly. We can call you back in <time period> to answer questions about the study and see if we can schedule an interview after you have received the information packet. Or I can tell you more about the study now if you like. Would you like to hear more about the study now?

IF NO [DID NOT RECEIVE INTRO PACKET AND WOULD NOT LIKE TO HEAR MORE ABOUT STUDY]. Thank you for your time today. We look forward to talking to you after you have received the packet of information. Would you like to set up a time for us to call you back after you've had a chance to receive and review the packet?

YES (WISH TO SET CALL BACK):

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

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

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

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

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

RECORD RESPONSE AND ADDRESS IN TRACKING

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

NO (DO NOT WISH TO SET CALL BACK):

Thank you for your time today. We will call you back in <time period>.

YES (RECEIVED INTRO PACKET) OR YES (WOULD LIKE TO HEAR MORE ABOUT THE STUDY NOW):

RESPOND TO SUBJECT'S QUESTIONS, THEN CONTINUE READING SCRIPT.

[STUDY_ 2012] 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.

IF RESPONDENT RECEIVED INITIAL PACKET: <DECEASED OR SB ONLY: 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 in the future.

ONLY FOR INTERVIEWS WHEN MOM'S AGE IS UNKNOWN:

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

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

IF UNDER 15 [THANK_AGE] “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.”

[INFORM] The interview takes about 55 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.

[FOR THOSE WHO DID NOT RECEIVE INTRO PACKET BUT ANSWERED ‘YES’ TO WISH TO HEAR MORE ABOUT THE STUDY] Now, I’d like to read you some of the information that is part of the packet that you will be receiving in the mail soon. It will take less than two minutes to read. 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.

All information that we gather in this study will be kept confidential. This is because the study 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 but we will never use any names or addresses in reports or publications. 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?

[FOR ALL WHO RECEIVED MAILING]

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

ANSWER QUESTIONS.

[Q_NAME] *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 and/or a stillbirth. Your pregnancy was identified through the <state> surveillance program that tracks pregnancies affected by birth defects and/or stillbirths. 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 pregnancies were not affected by birth defects from women who gave birth in the same year. Thousands of women are taking part in this study. Around 200 women whose pregnancies were affected by birth defects and 75 women whose pregnancies were not affected by birth defects will be interviewed in <State> each year. We plan to conduct the study for at least three years in <State>.

[Q_CONFID] *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 or addresses in reports or publications.

[Q_PART] *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 or by phone. 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>).

[Q_INCENTIVE] *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).

[Q_INFO] *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.

[INFORM2] 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: AR, GA, MA, NC, NY] 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.

[INFORM3] 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.

[START.] Do you wish to continue/be interviewed?

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

PROBES:

General:

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.

Not willing to provide address:

Could we send the packet to the address of a relative or friend?

Do you have any questions about the study I might be able to address?

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?

YES (WISH TO BE INTERVIEWED NOW):

[**TWER**] 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. (Will it be O.K. for my supervisor to listen? [or for us to record the interview]?)

YES (OK TO LISTEN IN): → [T_CHKDOB.] 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.

Thank you for agreeing to participate in BD-STEPS.

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

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

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

RECORD RESPONSE AND ADDRESS IN TRACKING

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

Thank you 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.

Mother: Affected Pregnancy with Unknown Outcome

[INTRO1] 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. 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 INTERVIEWER CONTRACTOR IS, STATE: “I am with <Interview Contractor>; we conduct all the interviews for the study.”]

[LTR_S] Recently, we mailed you some information about the study, called the Birth Defects Study To Evaluate Pregnancy exposureS, or BD-STEPS. This information was mailed to you in a large envelope that contained a blue folder with BD-STEPS printed on it. Did you receive the information?

NO (DID NOT RECEIVE INTRO PACKET):

[NOLET_UNK] 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 give you more information about the study. May I get your current address to send you the information?

NO [SKIP TO PROBES]

YES [RECORD ADDRESS.] Thank you. We will mail the study information to you shortly. We can call you back in [time period] to answer questions about the study and see if we can schedule an interview after you have received the information packet. Or I can tell you more about the study now if you like. Would you like to hear more about the study now?

IF NO [DID NOT RECEIVE INTRO PACKET AND WOULD NOT LIKE TO HEAR MORE ABOUT STUDY]. Thank you for your time today. We look forward to talking to you after you have received the packet of information. Would you like to set up a time for us to call you back after you’ve had a chance to receive and review the packet?

YES (WISH TO SET CALL BACK):

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

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

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

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

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

RECORD RESPONSE AND ADDRESS IN TRACKING

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

RL but allow edits]

NO (DO NOT WISH TO SET CALL BACK):

Thank you for your time today. We will call you back in <time period>.

YES (RECEIVED INTRO PACKET) OR YES (WOULD LIKE TO HEAR MORE ABOUT THE STUDY NOW):

RESPOND TO SUBJECT'S QUESTIONS, THEN CONTINUE READING SCRIPT.

[STUDY_ 2012] 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.

ONLY FOR INTERVIEWS WHEN MOM'S AGE IS UNKNOWN:

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

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

IF UNDER 15 [THANK_AGE] "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."

[INFORM] The interview takes about 55 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.

[FOR THOSE WHO DID NOT RECEIVE INTRO PACKET BUT ANSWERED 'YES' TO WISH TO HEAR MORE ABOUT THE STUDY] Now, I'd like to read you some of the information that is part of the packet that you will be receiving in the mail soon. It will take less than two minutes to read. 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.

All information that we gather in this study will be kept confidential. This is because the study 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 but we will never use any names or addresses in reports or publications. 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?

[FOR ALL WHO RECEIVED MAILING]

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

ANSWER QUESTIONS.

[Q_NAME] *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 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>.

[Q_CONFID] *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 or addresses in reports or publications.

[Q_PART] *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 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>).

[Q_INCENTIVE] *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).

[Q_INFO] *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.

[INFORM2] 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: AR, GA, MA, NC, NY] 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.

[INFORM3] 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.

[START.] Do you wish to continue/be interviewed?

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

PROBES:

General:

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.

Not willing to provide address:

Could we send the packet to the address of a relative or friend?

Do you have any questions about the study I might be able to address?

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?

YES (WISH TO BE INTERVIEWED NOW):

[**TWER**] 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. (Will it be O.K. for my supervisor to listen? [or for us to record the interview]?)

YES (OK TO LISTEN IN): → [**T_CHKDOB.**] 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.

Thank you for agreeing to participate in BD-STEPS.

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

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

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

RECORD RESPONSE AND ADDRESS IN TRACKING

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

Thank you 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.

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.]

[INTRO_CONSENT] 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. 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. 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 <Interview Contractor>; 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 telephone interview?
RECORD DATE AND TIME (INCLUDE TIME ZONE) OF NEW APPOINTMENT.
VERIFY PHONE NUMBER: I need to verify your telephone number where you can be reached for the interview.
CONFIRM: We will call you on <DAY, DATE> at <TIME> on <PHONE NUMBER>. Would you please call us at our toll-free number <1-888-743-7324> if you need to change your appointment?

[APP_REMIND] Would you like us to provide a reminder before your interview appointment?
IF YES, [REMIND_TYPE] Would you like an email or a text reminder?
RECORD RESPONSE AND ADDRESS IN TRACKING

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

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

YES (CONVENIENT TIME NOW):

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

Arkansas and North Carolina Introductory Scripts

AR & NC Mother of Living Case/Control Child

[INTRO1] 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.>> 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 <Interview Contractor>; we conduct all the interviews for the study.”]

[LTR_S] Recently, we mailed you some information about the study, called the Birth Defects Study To Evaluate Pregnancy exposureS, or BD-STEPS. This information was mailed to you in a large envelope that contained a blue folder with BD-STEPS printed on it. Did you receive the information?

IF NO (DID NOT RECEIVE INTRO PACKET):

[NOLET_LIVE] 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 about your health, medications, and lifestyle. We would like you to participate in the study, but first we need to give you more information about the study. May I get your current address to send you the information?

NO [SKIP TO PROBES]

YES [RECORD ADDRESS.] Thank you. We will mail the study information to you shortly. We can call you back in <time period> to answer questions about the study and see if we can schedule an interview after you have received the information packet. Or I can tell you more about the study now if you like. Would you like to hear more about the study now?

IF NO [DID NOT RECEIVE INTRO PACKET AND WOULD NOT LIKE TO HEAR MORE ABOUT STUDY]. Thank you for your time today. We look forward to talking to you after you have received the packet of information. Would you like to set up a time for us to call you back after you’ve had a chance to receive and review the packet?

YES (WISH TO SET CALL BACK):

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

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

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

[APP_REMIND] Would you like us to provide a reminder before your appointment?
IF YES, [REMIND_TYPE] Would you like an email or a text reminder?
RECORD RESPONSE AND ADDRESS IN TRACKING

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

NO (DO NOT WISH TO SET CALL BACK):

Thank you for your time today. We will call you back in <time period>.

IF YES (RECEIVED INTRO PACKET) OR YES (WOULD LIKE TO HEAR MORE ABOUT THE STUDY NOW)

RESPOND TO SUBJECT'S QUESTIONS, THEN CONTINUE READING SCRIPT.

[STUDY_ 2012] 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.

(FOR AR CONTROLS: 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. This is a study to discover clues about what causes birth defects. In addition, we have expanded the study to include research into why stillbirths happen.

INTERVIEWS WHEN MOM'S AGE IS UNKNOWN OR KNOWN UNDER 18 (AR and NC only)

FOR ALL UNKNOWN AGE:

[T_CHK] 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 UNDER 15 [THANK_AGE] “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):

[T_CK1] 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)

[T_CHK2] 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)

[INTRO7P] Thank you very much.

[CALL_IN] 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.

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.”

[INFORM] (FOR ALL SUBJECTS EXCEPT AR CONTROLS: The interview takes about 55 minutes (*but we can do it in short sections*)). It covers a broad range of questions about:

(FOR AR CONTROLS: There are two parts to the interview. After you complete the first part of the interview, you can complete the second part of the interview on the same call or you can schedule it for a later date. The first part of the interview takes about 55 minutes and the second part of the interview takes about 20 to 30 minutes. We can also do the interview in short sections. At the end of this interview, you can decide to continue to the second part of the interview or schedule it for a later time. The interview 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.

FOR AR CONTROLS: 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 **and stillbirths**.

[FOR THOSE WHO DID NOT RECEIVE INTRO PACKET BUT ANSWERED ‘YES’ TO WISH TO HEAR MORE ABOUT THE STUDY] Now, I’d like to read you some of the information that is part of the packet that you will be receiving in the mail soon. It will take less than two minutes to read. 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.

All information that we gather in this study will be kept confidential. This is because the study 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 but we will never use any names or addresses in reports or publications. 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?

[FOR ALL WHO RECEIVED MAILING]

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

ANSWER QUESTIONS

[Q_NAME] *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 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>.

[Q_CONFID] *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 or addresses in reports or publications.

[Q_PART] *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>).

[Q_INCENTIVE] *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).

[Q_INFO] *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.

[INFORM2] 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: AR, GA, MA, NC, NY] 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.

[INFORM3] 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.

[START.] Do you wish to continue/be interviewed?

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

PROBES:

General:

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.

Not willing to provide address:

Could we send the packet to the address of a relative or friend?

Do you have any questions about the study I might be able to address?

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?

YES (WISH TO BE INTERVIEWED NOW):

[**TWER**] 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. (Will it be O.K. for my supervisor to listen? [or for us to record the interview]?)

YES (OK TO LISTEN IN): → [**T_CHKDOB.**] 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.

Thank you for agreeing to participate in BD-STEPS.

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?

[**APP_REMIND**] [**DO NOT SHOW FOR CA or IA**] Would you like us to provide a reminder before your interview appointment?

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

RECORD RESPONSE AND ADDRESS IN TRACKING

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

Thank you for agreeing to participate in BD-STEPS.

NO (DOES NOT WISH TO BE INTERVIEWED):

IF NO:

-[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.]

AR & NC Mother of Stillborn or Deceased Child, or Therapeutic Abortion (TAB)

[INTRO1] 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. 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 INTERVIEWER CONTRACTOR IS, STATE: “I am with <Interview Contractor>; we conduct all the interviews for the study.”]

[LTR_S] Recently, we mailed you some information about the study, called the Birth Defects Study To Evaluate Pregnancy exposureS, or BD-STEPS. This information was mailed to you in a large envelope Did you receive the information?

NO (DID NOT RECEIVE INTRO PACKET):

[NOLET_DECEASE] We are inviting women to take part in this study to discover clues about what causes birth defects and/or stillbirths. You were selected from women who recently had a pregnancy affected by a birth defect and/or a stillbirth. Your pregnancy was identified through the <state> surveillance program that tracks pregnancies affected by birth defects and/or a stillbirth>. <DECEASED OR SB ONLY: 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 stillbirths in the future. The study involves a telephone interview about your health, medications and lifestyle. We would like you to participate in the study, but we first need give you more the information about the study. May I get your current address to send you the information?

NO [SKIP TO PROBES]

YES [RECORD ADDRESS.] Thank you. - We will mail the study information to you shortly. We can call you back in <time period> to answer questions about the study and see if we can schedule an interview after you have received the information packet. Or I can tell you more about the study now if you like. Would you like to hear more about the study now?

IF NO [DID NOT RECEIVE INTRO PACKET AND WOULD NOT LIKE TO HEAR MORE ABOUT STUDY]. Thank you for your time today. We look forward to talking to you after you have received the packet of information. Would you like to set up a time for us to call you back after you’ve had a chance to receive and review the packet?

YES (WISH TO SET CALL BACK):

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

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

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

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

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

RECORD RESPONSE AND ADDRESS IN TRACKING

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

NO (DO NOT WISH TO SET CALL BACK):

Thank you for your time today. We will call you back in <time period>.

YES (RECEIVED INTRO PACKET) OR YES (WOULD LIKE TO HEAR MORE ABOUT THE STUDY NOW):

RESPOND TO SUBJECT'S QUESTIONS, THEN CONTINUE READING SCRIPT.

[STUDY_ 2012] (FOR ALL SUBJECTS EXCEPT AR STILLBIRTHS: 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. IF RESPONDENT RECEIVED INITIAL PACKET: <DECEASED OR SB ONLY: 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.

(FOR AR STILLBIRTHS: 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. This is a study to discover clues about what causes birth defects. In addition, we have expanded the study to include research into why stillbirths happen. 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 stillbirths in the future.

INTERVIEWS WHEN MOM'S AGE IS UNKNOWN OR KNOWN UNDER 18 (AR and NC only)

FOR ALL UNKNOWN AGE:

[T_CHK] 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 UNDER 15 [THANK_AGE] "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):

[T_CHK1] 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)

[T_CHK2] 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)

[INTRO7P] Thank you very much.

[CALL_IN] 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.

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.”

[INFORM] (FOR ALL SUBJECTS EXCEPT AR STILLBIRTHS: The interview takes about 55 minutes (*but we can do it in short sections*). It covers a broad range of questions about:

(FOR AR STILLBIRTHS: There are two parts to the interview. After you complete the first part of the interview, you can complete the second part of the interview on the same call or you can schedule it for a later date. The first part of the interview takes about 55 minutes and the second part of the interview takes about 20 to 30 minutes. We can also do the interview in short sections. At the end of this interview, you can decide to continue to the second part of the interview or schedule it for a later time. The interview 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 [FOR AR STILLBIRTHS]: “and stillbirths.”

[FOR THOSE WHO DID NOT RECEIVE INTRO PACKET BUT ANSWERED ‘YES’ TO WISH TO HEAR MORE ABOUT THE STUDY] Now, I'd like to read you some of the information that is part of the packet that you will be receiving in the mail soon. It will take less than two minutes to read. 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.

All information that we gather in this study will be kept confidential. This is because the study 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 but we will never use any names or addresses in reports or publications. 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?

[FOR ALL WHO RECEIVED MAILING]

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

ANSWER QUESTIONS.

[Q_NAME] *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 and/or a stillbirth. Your pregnancy was identified through the <state> surveillance program that tracks pregnancies affected by birth defects and/or stillbirths. State laws give us permission to review medical records when birth defects are present. (FOR AR STILLBIRTHS: The loss of babies through stillbirth are also reported to the <<State>>

Department of Public Health.) This is how we identified most women in the study. We selected women whose pregnancies were not affected by birth defects from women who gave birth in the same year. Thousands of women are taking part in this study. Around 200 women whose pregnancies were affected by and 75 women whose pregnancies were not affected by birth defects will be interviewed in <State> each year. We plan to conduct the study for at least three years in <State>.

[Q_CONFID] *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 or addresses in reports or publications.

[Q_PART] *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>).

[Q_INCENTIVE] *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).

[Q_INFO] *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.

[INFORM2] 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: AR, GA, MA, NC, NY] 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.

[INFORM3] 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.

[START.] Do you wish to continue/be interviewed?

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

PROBES:

General:

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.

Not willing to provide address:

Could we send the packet to the address of a relative or friend?

Do you have any questions about the study I might be able to address?

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?

YES (WISH TO BE INTERVIEWED NOW):

[TWER] 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. (Will it be O.K. for my supervisor to listen? [or for us to record the interview]?)

YES (OK TO LISTEN IN): → **[T_CHKDOB.]** 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.

Thank you for agreeing to participate in BD-STEPS.

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

[APP_REMIND] Would you like us to provide a reminder before your interview appointment?
IF YES, [REMINDTYPE] Would you like an email or a text reminder?
RECORD RESPONSE AND ADDRESS IN TRACKING

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

Thank you 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 taking the time to talk to me about the study.

AR & NC Mother: Affected Pregnancy with Unknown Outcome

[INTRO1] 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. 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 INTERVIEWER CONTRACTOR IS, STATE: "I am with <Interview Contractor>; we conduct all the interviews for the study."]

[LTR_S] Recently, we mailed you some information about the study, called the Birth Defects Study To Evaluate Pregnancy exposureS, or BD-STEPS. This information was mailed to you in a large envelope that contained a blue folder with BD-STEPS printed on it. Did you receive the information?

NO (DID NOT RECEIVE INTRO PACKET):

[NOLET_UNK] 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 give you more information about the study. May I get your current address to send you the information?

NO [SKIP TO PROBES]

YES [RECORD ADDRESS.] Thank you. - We will mail the study information to you shortly. We can call you back in [time period] to answer questions about the study and see if we can schedule an

interview after you have received the information packet. Or I can tell you more about the study now if you like. Would you like to hear more about the study now?

IF NO [DID NOT RECEIVE INTRO PACKET AND WOULD NOT LIKE TO HEAR MORE ABOUT STUDY]. Thank you for your time today. We look forward to talking to you after you have received the packet of information. Would you like to set up a time for us to call you back after you've had a chance to receive and review the packet?

YES (WISH TO SET CALL BACK):

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

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

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

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

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

RECORD RESPONSE AND ADDRESS IN TRACKING

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

NO (DO NOT WISH TO SET CALL BACK):

Thank you for your time today. We will call you back in <time period>.

YES (RECEIVED INTRO PACKET) OR YES (WOULD LIKE TO HEAR MORE ABOUT THE STUDY NOW)

RESPOND TO SUBJECT'S QUESTIONS, THEN CONTINUE READING SCRIPT.

[STUDY_ 2012] 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.

INTERVIEWS WHEN MOM'S AGE IS UNKNOWN OR KNOWN UNDER 18 (AR and NC only)

FOR ALL UNKNOWN AGE:

[T_CHK] 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 UNDER 15 [THANK_AGE] "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):

[T_CHK1] 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)

[T_CHK2] 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)

[INTRO7P] Thank you very much.

[CALL_IN] 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.

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.”

[INFORM] The interview takes about 55 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.

[FOR THOSE WHO DID NOT RECEIVE INTRO PACKET BUT ANSWERED 'YES' TO WISH TO HEAR MORE ABOUT THE STUDY] Now, I'd like to read you some of the information that is part of the packet that you will be receiving in the mail soon. It will take less than two minutes to read. 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.

All information that we gather in this study will be kept confidential. This is because the study 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 but we will never use any names or addresses in reports or publications. 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?

[FOR ALL WHO RECEIVED MAILING]

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

ANSWER QUESTIONS.

[Q_NAME] *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 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>.

[Q_CONFID] *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 or addresses in reports or publications.

[Q_PART] *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 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>).

[Q_INCENTIVE] *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).

[Q_INFO] *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.

[INFORM2] 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: AR, GA, MA, NC, NY] 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.

[INFORM3] 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.

[START.] Do you wish to continue/be interviewed?

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

PROBES:

General:

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.

Not willing to provide address:

Could we send the packet to the address of a relative or friend?

Do you have any questions about the study I might be able to address?

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?

YES (WISH TO BE INTERVIEWED NOW):

[TWER] 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. (Will it be O.K. for my supervisor to listen? [or for us to record the interview]?)

YES (OK TO LISTEN IN): → **[T_CHKDOB.]** 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.

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

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

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

RECORD RESPONSE AND ADDRESS IN TRACKING

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

Thank you 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 taking the time to talk to me about the study.

AR & NC 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.]

[INTRO_CONSENT] 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. 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. 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 <Interview Contractor>; 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 telephone interview?

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

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

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

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

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

RECORD RESPONSE AND ADDRESS IN TRACKING

1. Email: [provide field in which to type email address; prefill with email address in Symphony, if one exists]

2. Text: [provide field in which to type mobile phone number; prefill with number from current RL but allow edits]

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

YES (CONVENIENT TIME NOW):

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

All your answers are confidential.

You can choose not to answer any specific questions.

You are free to stop the interview at any time

(FOR AR STILLBIRTHS AND CONTROLS: There are two parts to the interview. After you complete the first part of the interview, you can choose to continue to the second part of the interview or schedule it for a later 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.

AR & NC Parent/Guardian of Minor Script and Informed Consent

[INTRO_PROMPT] 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. 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.

[FOR LIVING CASE/CONTROL CHILD]:

[P_LIVE]

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)]:

[P_DEC]

We are inviting women to take part in this study to discover clues about what causes birth defects and/or stillbirths. To do this, we are enrolling women in <state> hoping to discover clues about what causes birth defects and/or stillbirths. <Your daughter OR MOIB NAME> was selected from women who recently had a pregnancy affected by a birth defect and/or a stillbirth. Her pregnancy was identified through the <state> surveillance program that tracks pregnancies affected by birth defects and/or stillbirths. <DECEASED OR SB ONLY: 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 stillbirths in the future.

[FOR AFFECTED PREGNANCY WITH UNKNOWN OUTCOME]:

[P_UNK]

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 <Interview Contractor>; we conduct all the interviews for the study."]

[P_CONSENT1] 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 REVIEWED INFORMATION):

Would you like to hear more about the study now?

NO (DID NOT RECEIVE INTRO PACKET AND DO NOT WISH TO HEAR MORE ABOUT THE STUDY NOW):

Thank you for your time today.

[Set Call Back] When would be a good time to call you back? Day _____ Time _____

YES (REVIEWED INFORMATION)

OR

YES (DID NOT REVIEW INFORMATION BUT WOULD LIKE TO HEAR MORE ABOUT THE STUDY):

[P_CONSENT2] Do you have any questions now about the study after what you have heard so far <<or what <your daughter OR MOIB NAME> received in the mail>> ?

YES (HAVE QUESTIONS):

RESPOND TO PARENT/GUARDIAN'S QUESTIONS.

NO DO NOT HAVE ANY QUESTIONS NOW)

CONTINUE:

The interview takes about 55 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

[P_CONSENT3] 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.

[P_CONSENT4] 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.

[P_CONSENT5] 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.

[FOR THOSE WHO DID NOT REVIEW MATERIALS BUT ANSWERED 'YES' TO WISH TO HEAR MORE ABOUT THE STUDY] Now, I'd like to read you some of the information that is part of the packet that was

mailed to <Your daughter OR MOIB NAME> . It will take less than two minutes to read. As a participant in the study, you should know that

<Your daughter OR MOIB NAME> has 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 <Your daughter OR MOIB NAME> can reasonably expect from participation.
- Be informed of medical treatment, if any, available to <Your daughter OR MOIB NAME> 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 <Your daughter OR MOIB NAME> 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 <Your daughter OR MOIB NAME>'s decision.

All information that we gather in this study will be kept confidential. This is because the study has been given a Certificate of Confidentiality by the Centers for Disease Control and Prevention. This means that anything <Your daughter OR MOIB NAME> tells 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 <Your daughter OR MOIB NAME> with other researchers but we will never use any names or addresses in reports or publications. You should also understand that study investigators are not prevented from reporting information obtained from <Your daughter OR MOIB NAME> to authorities in order to prevent serious harm to <Your daughter OR MOIB NAME> or others.

After hearing this information, do you have any questions?

[ANSWER QUESTIONS]

[P_CONSENT6] 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):

[PARENTDATA] 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.

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.

[NO_PCONSENT] 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.

Iowa Introductory Scripts

IA Mother of Living Case/Control Child

[INTRO1] 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.>> 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 **<Interview Contractor>**; we conduct all the interviews for the study."]

[INFORM] The interview takes about 55 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.

[QUESTIONS.]

[IA SCRIPT SHOULD READ AS FOLLOWS:]

Do you have any questions?

ANSWER QUESTIONS

[Q_NAME] *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 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>.

[Q_CONFID] *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 or addresses in reports or publications..

[Q_PART] *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>).

[Q_INCENTIVE] *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).

[Q_INFO] *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.

[INFORM2] 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. 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.

[INFORM3] 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.

[START.] Do you wish to continue/be interviewed?

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

PROBES:

General:

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 NOW):

[TWER] 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. (Will it be O.K. for my supervisor to listen? [or for us to record the interview]?)

YES (OK TO LISTEN IN): → **[T_CHKDOB.]** 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.

Thank you for agreeing to participate in BD-STEPS.

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

[APP_REMIND] Would you like us to provide a reminder before your interview appointment?
IF YES, [REMIND_TYPE] Would you like an email or a text reminder?
RECORD RESPONSE AND ADDRESS IN TRACKING

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

Thank you for agreeing to participate in BD-STEPS.

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

[INTRO1] 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. 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 INTERVIEWER CONTRACTOR IS, STATE: "I am with <Interview Contractor>; we conduct all the interviews for the study."]

[INFORM] The interview takes about 55 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. <DECEASED OR SB ONLY: 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.

[QUESTIONS.]

[IA SCRIPT SHOULD READ AS FOLLOWS:]

Do you have any questions?

ANSWER QUESTIONS.

[Q_NAME] *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 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>.

[Q_CONFID] *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 or addresses in reports or publications.

[Q_PART] *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>).

[Q_INCENTIVE] *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).

[Q_INFO] *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.

[INFORM2] 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. 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.

[INFORM3] 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.

[START.] Do you wish to continue/be interviewed?

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

PROBES:

General:

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 NOW):

[TWER] 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. (Will it be O.K. for my supervisor to listen? [or for us to record the interview]?)

YES (OK TO LISTEN IN): → **[T_CHKDOB.]** 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.

Thank you for agreeing to participate in BD-STEPS.

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?

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

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

RECORD RESPONSE AND ADDRESS IN TRACKING

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

Thank you 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 taking the time to talk to me about the study.

IA Mother: Affected Pregnancy with Unknown Causes

[INTRO1] 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. 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 INTERVIEWER CONTRACTOR IS, STATE: “I am with <Interview Contractor>; we conduct all the interviews for the study.”]

[INFORM] The interview takes about 55 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.

[QUESTIONS.]

[IA SCRIPT SHOULD READ AS FOLLOWS:]

Do you have any questions?

ANSWER QUESTIONS.

[Q_NAME] *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 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>.

[Q_CONFID] *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 or addresses in reports or publications.

[Q_PART] *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 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>).

[Q_INCENTIVE] *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).

[Q_INFO] *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.

[INFORM2] 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. 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.

[INFORM3] 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.

[START.] Do you wish to continue/be interviewed?

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

PROBES:

General:

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 NOW):

[TWER] 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. (Will it be O.K. for my supervisor to listen? [or for us to record the interview]?)

YES (OK TO LISTEN IN): → **[T_CHKDOB.]** 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.

Thank you for agreeing to participate in BD-STEPS.

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

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

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

RECORD RESPONSE AND ADDRESS IN TRACKING

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

Thank you 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 taking the time to talk to me about the study.

IA 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.]

[INTRO_CONSENT] 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. 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. 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 <Interview Contractor>; 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 telephone interview?

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

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

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

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

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

RECORD RESPONSE AND ADDRESS IN TRACKING

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

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

YES (CONVENIENT TIME NOW):

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

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.

California Introductory Scripts

CA - Mother of Living Case/Control Child

[INTRO1] 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.>> 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 <Interview Contractor>; we conduct all the interviews for the study."]

[LTR_S] Recently, we mailed you some information about the study, called the Birth Defects Study To Evaluate Pregnancy exposureS, or BD-STEPS. This information was mailed to you in a large envelope that contained a blue folder with BD-STEPS printed on it.. Did you receive the information?

IF NO (DID NOT RECEIVE INTRO PACKET):

[NOLET_LIVE] 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 about your health, medications, and lifestyle. We would like you to participate in the study, but first we need give you more the information about the study. May I get your current address to send you the information?

NO [SKIP TO PROBES]

YES [RECORD ADDRESS.] Thank you. We will mail the study information to you. We can call you back in <time period> to answer questions about the study and see if we can schedule an interview after you have received the information packet. Or I can tell you more about the study now if you like. Would you like to hear more about the study now?

IF NO [DID NOT RECEIVE INTRO PACKET AND WOULD NOT LIKE TO HEAR MORE ABOUT STUDY]. Thank you for your time today. We look forward to talking to you after you have received the packet of information. Would you like to set up a time for us to call you back after you've had a chance to receive and review the packet?

YES (WISH TO SET CALL BACK):

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

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

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

NO (DO NOT WISH TO SET CALL BACK):

Thank you for your time today. We will call you back in <time period>.

IF YES (RECEIVED INTRO PACKET) OR YES (WOULD LIKE TO HEAR MORE ABOUT THE STUDY NOW):

RESPOND TO SUBJECT'S QUESTIONS, THEN CONTINUE READING SCRIPT.

[STUDY_ 2012] 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.

ONLY FOR INTERVIEWS WHEN MOM'S AGE IS UNKNOWN:

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

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

IF UNDER 15 [THANK_AGE] "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."

[INFORM] The interview takes about 55 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.

[FOR THOSE WHO DID NOT RECEIVE INTRO PACKET BUT ANSWERED ‘YES’ TO WISH TO HEAR MORE ABOUT THE STUDY] Now, I’d like to read you some of the information that is part of the packet that you will be receiving in the mail soon. It will take less than two minutes to read. 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.

All information that we gather in this study will be kept confidential. This is because the study 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 but we will never use any names or addresses in reports or publications. 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?

[FOR ALL WHO RECEIVED MAILING]

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

ANSWER QUESTIONS

[Q_NAME] *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 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>.

[Q_CONFID] *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 or addresses in reports or publications..

[Q_PART] *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 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>).

[Q_INCENTIVE] *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).

[Q_INFO] *For More Information:* If you'd like more information about the study, please contact < Dr. Gary Shaw at 650-721-5746>. If you have questions about your rights as a subject in this research study, please contact the Committee for the Protection of Human Subjects, California Health and Human Services Agency at 1-916-326-3660 or cphs-mail@oshpd.ca.gov and refer to protocol #13-10-1398, 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.

[INFORM2] 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. 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.

[INFORM3] If you have any concerns about the study or how it is conducted, you may contact < Dr. Gary Shaw at 650-721-5746>. If you have questions about your rights as a subject in this research study, please contact the Committee for the Protection of Human Subjects, California Health and Human Services Agency at 1-916-326-3660 or cphs-mail@oshpd.ca.gov and refer to protocol #13-10-1398, and someone will call you back as soon as possible.

[START.] Do you wish to continue/be interviewed?

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

PROBES:

General:

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.

Not willing to provide address:

Could we send the packet to the address of a relative or friend?

Do you have any questions about the study I might be able to address?

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?

YES (WISH TO BE INTERVIEWED NOW):

[TWER] 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. (Will it be O.K. for my supervisor to listen? [or for us to record the interview]?)

YES (OK TO LISTEN IN): → [T_CHKDOB.] 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.

Thank you for agreeing to participate in BD-STEPS.

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?

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 taking the time to talk to me about the study.

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

[INTRO1] 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. 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 INTERVIEWER CONTRACTOR IS, STATE: “I am with <Interview Contractor>; we conduct all the interviews for the study.”]

[LTR_S] Recently, we mailed you some information about the study, called the Birth Defects Study To Evaluate Pregnancy exposureS, or BD-STEPS. This information was mailed to you in a large envelope that contained a blue folder with BD-STEPS printed on it. Did you receive the information?

NO (DID NOT RECEIVE INTRO PACKET):

[NOLET_DECEASE] 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. <DECEASED OR SB ONLY: 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 about your health, medications and lifestyle. We would like you to participate in the study, but we first need to give you more information about the study. May I get your current address to send you the information?

NO [SKIP TO PROBES]

YES [RECORD ADDRESS.] Thank you. We will mail the study information to you shortly. It will be mailed in a folder that will also contain a \$20 gift card as a thank you for your time. We can call you back in <time period> to answer questions about the study and see if we can schedule an interview after you have received the information packet. Or I can tell you more about the study now if you like. Would you like to hear more about the study now?

IF NO [DID NOT RECEIVE INTRO PACKET AND WOULD NOT LIKE TO HEAR MORE ABOUT STUDY]. Thank you for your time today. We look forward to talking to you after you have received the packet of information. Would you like to set up a time for us to call you back after you've had a chance to receive and review the packet?

YES (WISH TO SET CALL BACK):

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

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

CONFIRM: We will call you 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?

NO (DO NOT WISH TO SET CALL BACK):

Thank you for your time today. We will call you back in <time period>.

YES (RECEIVED INTRO PACKET) OR YES (WOULD LIKE TO HEAR MORE ABOUT THE STUDY NOW):

RESPOND TO SUBJECT'S QUESTIONS, THEN CONTINUE READING SCRIPT.

[STUDY_ 2012] 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. IF RESPONDENT RECEIVED INITIAL PACKET: <DECEASED OR SB ONLY: 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.

ONLY FOR INTERVIEWS WHEN MOM'S AGE IS UNKNOWN:

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

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

IF UNDER 15 [THANK_AGE] “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.”

[INFORM] The interview takes about 55 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.

[FOR THOSE WHO DID NOT RECEIVE INTRO PACKET BUT ANSWERED ‘YES’ TO WISH TO HEAR MORE ABOUT THE STUDY] Now, I’d like to read you some of the information that is part of the packet that you will be receiving in the mail soon. It will take less than two minutes to read. 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.

All information that we gather in this study will be kept confidential. This is because the study 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 but we will never use any names or addresses in reports or publications. 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?

[FOR ALL WHO RECEIVED MAILING]

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

ANSWER QUESTIONS.

[Q_NAME] *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 pregnancies were not affected by birth defects 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 women whose pregnancies were not affected by birth defects will be interviewed in <State> each year. We plan to conduct the study for at least three years in <State>.

[Q_CONFID] *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 or addresses in reports or publications.

[Q_PART] *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 removed from the study (by calling <insert local study contact and contact number>).

[Q_INCENTIVE] *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).

[Q_INFO] *For More Information:* If you'd like more information about the study, please contact < Dr. Gary Shaw at 650-721-5746>. If you have questions about your rights as a subject in this research study, please contact the Committee for the Protection of Human Subjects, California Health and Human Services Agency at 1-916-326-3660 or cphs-mail@oshpd.ca.gov and refer to protocol #13-10-1398, 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.

[INFORM2] 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. 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.

[INFORM3] If you have any concerns about the study or how it is conducted, you may contact < Dr. Gary Shaw at 650-721-5746>. If you have questions about your rights as a subject in this research study, please contact the Committee for the Protection of Human Subjects, California Health and Human Services Agency at 1-916-326-3660 or cphs-mail@oshpd.ca.gov and refer to protocol #13-10-1398, and someone will call you back as soon as possible.

[START.] Do you wish to continue/be interviewed?

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

PROBES:

General:

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.

Not willing to provide address:

Could we send the packet to the address of a relative or friend?

Do you have any questions about the study I might be able to address?

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?

YES (WISH TO BE INTERVIEWED NOW):

[TWER] 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. (Will it be O.K. for my supervisor to listen? [or for us to record the interview]?)

YES (OK TO LISTEN IN): → **[T_CHKDOB.]** 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.

Thank you for agreeing to participate in BD-STEPS.

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?

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.

CA - Mother: Affected Pregnancy with Unknown Causes

[INTRO1] 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. 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 INTERVIEWER CONTRACTOR IS, STATE: "I am with <Interview Contractor>; we conduct all the interviews for the study."]

[LTR_S] Recently, we mailed you some information about the study, called the Birth Defects Study To Evaluate Pregnancy exposureS, or BD-STEPS. This information was mailed to you in a large envelope that contained a blue folder with BD-STEPS printed on it. Did you receive the information?

NO (DID NOT RECEIVE INTRO PACKET):

[NOLET_UNK] 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 give you more information about the study. May I get your current address to send you the information?

NO [SKIP TO PROBES]

YES [RECORD ADDRESS.] Thank you. We will mail the study information to you. It will be mailed in a folder that will also contain a \$20 gift card as a thank you for your time. We can call you back in [time period] to answer questions about the study and see if we can schedule an interview after you have received the information packet. Or I can tell you more about the study now if you like. Would you like to hear more about the study now?

IF NO [DID NOT RECEIVE INTRO PACKET AND WOULD NOT LIKE TO HEAR MORE

ABOUT STUDY]. Thank you for your time today. We look forward to talking to you after you have received the packet of information. Would you like to set up a time for us to call you back after you've had a chance to receive and review the packet?

YES (WISH TO SET CALL BACK):

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

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

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

NO (DO NOT WISH TO SET CALL BACK):

Thank you for your time today. We will call you back in <time period>.

YES (RECEIVED INTRO PACKET) OR YES (WOULD LIKE TO HEAR MORE ABOUT THE STUDY NOW):

RESPOND TO SUBJECT'S QUESTIONS, THEN CONTINUE READING SCRIPT.

[STUDY_ 2012] 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.

ONLY FOR INTERVIEWS WHEN MOM'S AGE IS UNKNOWN:

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

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

IF UNDER 15 [THANK_AGE] "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."

[INFORM] The interview takes about 55 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.

[FOR THOSE WHO DID NOT RECEIVE INTRO PACKET BUT ANSWERED ‘YES’ TO WISH TO HEAR MORE ABOUT THE STUDY] Now, I’d like to read you some of the information that is part of the packet that you will be receiving in the mail soon. It will take less than two minutes to read. 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.

All information that we gather in this study will be kept confidential. This is because the study 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 but we will never use any names or addresses in reports or publications. 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?

[FOR ALL WHO RECEIVED MAILING]

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

ANSWER QUESTIONS.

[Q_NAME] *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 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>.

[Q_CONFID] *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 or addresses in reports or publications.

[Q_PART] *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 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>).

[Q_INCENTIVE] *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).

[Q_INFO] *For More Information:* If you'd like more information about the study, please contact < Dr. Gary Shaw at 650-721-5746>. If you have questions about your rights as a subject in this research study, please contact the Committee for the Protection of Human Subjects, California Health and Human Services Agency at 1-916-326-3660 or cphs-mail@oshpd.ca.gov and refer to protocol #13-10-1398, 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.

[INFORM2] 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. 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.

[INFORM3] If you have any concerns about the study or how it is conducted, please contact < Dr. Gary Shaw at 650-721-5746>. If you have questions about your rights as a subject in this research study, please contact the Committee for the Protection of Human Subjects, California Health and Human Services Agency at 1-916-326-3660 or cphs-mail@oshpd.ca.gov and refer to protocol #13-10-1398, and someone will call you back as soon as possible.

[START.] Do you wish to continue/be interviewed?

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

PROBES:

General:

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.

Not willing to provide address:

Could we send the packet to the address of a relative or friend?

Do you have any questions about the study I might be able to address?

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?

YES (WISH TO BE INTERVIEWED NOW):

[**TWER**] 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. (Will it be O.K. for my supervisor to listen? [or for us to record the interview]?)

YES (OK TO LISTEN IN): → [**T_CHKDOB.**] 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.

Thank you for agreeing to participate in BD-STEPS.

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 will call you 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.

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 taking the time to talk to me about the study.

CA - 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.]

[**INTRO_CONSENT**] 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. 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. 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 <Interview Contractor>; 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 telephone interview?
RECORD DATE AND TIME (INCLUDE TIME ZONE) OF NEW APPOINTMENT.
VERIFY PHONE NUMBER: I need to verify your telephone number where you can be reached for the interview.
CONFIRM: We will call you on <DAY, DATE> at <TIME> on <PHONE NUMBER>. Would you please call us at our toll-free number <1-888-743-7324> if you need to change your appointment?

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

YES (CONVENIENT TIME NOW):

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

Massachusetts Introductory Scripts

MA Mother of Living Case/Living Control Child

[INTRO1] 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.>> 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 <Interview Contractor>; we conduct all the interviews for the study.”]

[LTR_S] Recently, we mailed you some information about the study, called the Birth Defects Study To Evaluate Pregnancy exposureS, or BD-STEPS. This information was mailed to you in a large envelope that contained a blue folder with BD-STEPS printed on it. Did you receive the information?

IF NO (DID NOT RECEIVE INTRO PACKET):

[NOLET_LIVE] We are inviting women to take part in this study to discover clues about what causes birth defects. To do this, we are interviewing women whose pregnancies were affected by a birth defect as well as women whose pregnancies were not affected by birth defects. You were selected from women who were recently pregnant in <state>. The study involves a telephone interview about your health, medications, and lifestyle. We would like you to participate in the study, but first we need to give you more information about the study. May I get your current address to send you the information?

NO [SKIP TO PROBES]

YES [RECORD ADDRESS.] Thank you. We will mail the study information to you shortly. We can call you back in <time period> to answer questions about the study and see if we can schedule an interview after you have received the information packet. Or I can tell you more about the study now if you like. Would you like to hear more about the study now?

IF NO [DID NOT RECEIVE INTRO PACKET AND WOULD NOT LIKE TO HEAR MORE ABOUT STUDY]. Thank you for your time today. We look forward to talking to you after you have received the packet of information. Would you like to set up a time for us to call you back after you've had a chance to receive and review the packet?

YES (WISH TO SET CALL BACK):

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

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

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

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

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

RECORD RESPONSE AND ADDRESS IN TRACKING

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

NO (DO NOT WISH TO SET CALL BACK):

Thank you for your time today. We will call you back in <time period>.

IF YES (RECEIVED INTRO PACKET) OR YES (WOULD LIKE TO HEAR MORE ABOUT THE STUDY NOW)

RESPOND TO SUBJECT'S QUESTIONS, THEN CONTINUE READING SCRIPT.

[STUDY_ 2012] (FOR ALL SUBJECTS EXCEPT MA CONTROLS): 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.

(FOR MA CONTROLS: 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. This is a study to discover clues about what causes birth defects. In addition, we have expanded the study to include research into why stillbirths happen.

ONLY FOR INTERVIEWS WHEN MOM'S AGE IS UNKNOWN:

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

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

IF UNDER 15 [THANK_AGE] “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.”

[INFORM] (FOR ALL SUBJECTS EXCEPT MA CONTROLS: The interview takes about 55 minutes (*but we can do it in short sections*). It covers a broad range of questions about:

(FOR MA CONTROLS: There are two parts to the interview. After you complete the first part of the interview, you can complete the second part of the interview on the same call or you can schedule it for a later date. The first part of the interview takes about 55 minutes and the second part of the interview takes about 20 to 30 minutes. We can also do the interview in short sections. At the end of this interview, you can decide to continue to the second part of the interview or schedule it for a later time. The interview 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.

[FOR MA LIVING BDSTEPS CASES]: 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.

[FOR MA CONTROLS]: 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 **and stillbirths.**

[FOR THOSE WHO DID NOT RECEIVE INTRO PACKET BUT ANSWERED ‘YES’ TO WISH TO HEAR MORE ABOUT THE STUDY] Now, I’d like to read you some of the information that is part of the packet that you will be receiving in the mail soon. It will take less than two minutes to read. 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.

All information that we gather in this study will be kept confidential. This is because the study 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 but we will never use any names or addresses in reports or publications. 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?

[FOR ALL WHO RECEIVED MAILING]

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

ANSWER QUESTIONS

[Q_NAME] *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. The <state> surveillance program 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 pregnancies were not affected by birth defects from women who were pregnant in the same year in <state>. Thousands of women are taking part in this study. Around 200 women of pregnancies diagnosed with a birth defect and [for MA and AR: 300] 75 women of pregnancies 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>.

[Q_CONFID] *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 or addresses in reports or publications.

[Q_PART] *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>).

[Q_INCENTIVE] *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).

[Q_INFO] *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.

[INFORM2] 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: AR, GA, MA, NC, NY] 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.

[INFORM3] 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.

[START.] Do you wish to continue/be interviewed?

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

PROBES:

General:

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.

Not willing to provide address:

Could we send the packet to the address of a relative or friend?

Do you have any questions about the study I might be able to address?

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?

YES (WISH TO BE INTERVIEWED NOW):

[TWER] 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. (Will it be O.K. for my supervisor to listen? [or for us to record the interview]?)

YES (OK TO LISTEN IN): → [T_CHKDOB.] 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.

Thank you for agreeing to participate in BD-STEPS.

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

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

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

RECORD RESPONSE AND ADDRESS IN TRACKING

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

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 taking the time to talk to me about the study.

MA Women of Stillborn or Deceased Child, or Therapeutic Abortion (TAB)

[INTRO1] 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. 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 INTERVIEWER CONTRACTOR IS, STATE: “I am with <Interview Contractor>; we conduct all the interviews for the study.”]

<< **MA OPL DO NOT READ**>>[LTR_S] Recently, we mailed you some information about the study, called the Birth Defects Study To Evaluate Pregnancy exposureS, or BD-STEPS. This information was mailed to you in a large envelope that contained a blue folder. Did you receive the information?

NO (DID NOT RECEIVE INTRO PACKET):

[NOLET_DECEASE] We are inviting women to take part in this study to discover clues about what causes birth defects and/or stillbirths. To do this, we are interviewing women whose pregnancies were affected by a birth defect and/or a stillbirth as well as women whose pregnancies were not affected by birth defects and/or a stillbirth. You were selected from women who were recently pregnant in <state>. <DECEASED OR SB ONLY: 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 stillbirths in the future. The study involves a telephone interview about your health, medications and lifestyle. We would like you to participate in the study, but we first need to give you more information about the study. May I get your current address to send you the information?

NO [SKIP TO PROBES]

YES [RECORD ADDRESS.] Thank you. We will mail the study information to you shortly. We can call you back in <time period> to answer questions about the study and see if we can schedule an interview after you have received the information packet. Or I can tell you more about the study now if you like. Would you like to hear more about the study now?

IF NO [DID NOT RECEIVE INTRO PACKET AND WOULD NOT LIKE TO HEAR MORE ABOUT STUDY]. Thank you for your time today. We look forward to talking to you after you have received the packet of information. Would you like to set up a time for us to call you back after you’ve had a chance to receive and review the packet?

YES (WISH TO SET CALL BACK):

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

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

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

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

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

RECORD RESPONSE AND ADDRESS IN TRACKING

3. Email: [provide field in which to type email address; prefill with email address in Symphony, if one exists]
4. Text: [provide field in which to type mobile phone number; prefill with number from current

RL but allow edits]

NO (DO NOT WISH TO SET CALL BACK):

Thank you for your time today. We will call you back in <time period>.

YES (RECEIVED INTRO PACKET) OR YES (WOULD LIKE TO HEAR MORE ABOUT THE STUDY NOW):

RESPOND TO SUBJECT'S QUESTIONS, THEN CONTINUE READING SCRIPT.

[MA_OPL DO NOT READ] [STUDY_ 2012] 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. IF RESPONDENT RECEIVED INITIAL PACKET: <DECEASED OR SB ONLY: 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.

(FOR MA STILLBIRTHS: 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. This is a study to discover clues about what causes birth defects. In addition, we have expanded the study to include research into why stillbirths happen. 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 stillbirths in the future.

ONLY FOR INTERVIEWS WHEN MOM'S AGE IS UNKNOWN:

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

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

IF UNDER 15 [THANK_AGE] “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.”

[INFORM] The interview takes about 55 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 and stillbirths.

<<MA OPL, DO NOT READ>>[FOR THOSE WHO DID NOT RECEIVE INTRO PACKET BUT ANSWERED 'YES' TO WISH TO HEAR MORE ABOUT THE STUDY] Now, I'd like to read you some of the information that is part of the packet that you will be receiving in the mail soon. It will take less than two minutes to read. 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.

All information that we gather in this study will be kept confidential. This is because the study 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 but we will never use any names or addresses in reports or publications. 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?

[FOR ALL WHO RECEIVED MAILING – incl MA OPLs]

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

ANSWER QUESTIONS.

[Q_MA_OPL] [IF MOIB NEEDS MORE INFORMATION ABOUT WHY YOU ARE CALLING]:

The Massachusetts Department of Public Health mailed you some information about this study. It was mailed in a large orange manila envelope with a blue folder in it. You might have also been contacted by phone by a study nurse. You had mailed back a signed consent form that gave us permission to contact you about this study. Today we are calling you to conduct the interview for this study.]

[Q_NAME] *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. The <state> surveillance program tracks pregnancies affected by birth defects. State laws give us permission to review medical records when birth defects are present. (FOR MA STILLBIRTHS: The loss of babies through stillbirth are also reported to the <<State>> Department of Public Health.) This is how we identified most women in the study. We selected women whose pregnancies were not affected by birth defects from women who were pregnant in the same year in Massachusetts. Thousands of women are taking part in this study. Around 200 women whose pregnancies were affected by birth defects and [for MA and AR: 300] 75 women whose pregnancies were not affected by birth defects will be interviewed in <State> each year. We plan to conduct the study for at least three years in <State>.

[Q_CONFID] *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 or addresses in reports or publications.

[Q_PART] *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 or by phone. 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 removed from the study (by calling **<insert local study contact and contact number>**).

[Q_INCENTIVE] *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).

[Q_INFO] *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.

[INFORM2] 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: AR, GA, MA, NC, NY]** 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.

[INFORM3] 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.

[START.] Do you wish to continue/be interviewed?

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

PROBES:

General:

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.

Not willing to provide address:

Could we send the packet to the address of a relative or friend?

Do you have any questions about the study I might be able to address?

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?

YES (WISH TO BE INTERVIEWED NOW):

[TWER] 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. (Will it be O.K. for my supervisor to listen? [or for us to record the interview]?)

YES (OK TO LISTEN IN): → **[T_CHKDOB.]** 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.

Thank you for agreeing to participate in BD-STEPS.

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?

[APP_REMIND] Would you like us to provide a reminder before your interview appointment?
IF YES, [REMINDTYPE] Would you like an email or a text reminder?
RECORD RESPONSE AND ADDRESS IN TRACKING

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

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 taking the time to talk to me about the study.

MA Women: Pregnancy with Unknown Outcome

[INTRO1] 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. 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 INTERVIEWER CONTRACTOR IS, STATE: "I am with <Interview Contractor>; we conduct all the interviews for the study."]

[LTR_S] Recently, we mailed you some information about the study, called the Birth Defects Study To Evaluate Pregnancy exposures, or BD-STEPS. This information was mailed to you in a large envelope that contained a blue folder with BD-STEPS printed on it. Did you receive the information?

NO (DID NOT RECEIVE INTRO PACKET):

[NOLET_UNK] We are inviting women to take part in this study to discover clues about what causes birth defects. To do this, we are interviewing women whose pregnancies were affected by a birth defect as well as women whose pregnancies were not affected by birth defects. You were selected from women who were recently pregnant in <state>. 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 give you more information about the study. May I get your current address to send you the information?

NO [SKIP TO PROBES]

YES [RECORD ADDRESS.] Thank you. We will mail the study information to you shortly. We can call you back in [time period] to answer questions about the study and see if we can schedule an interview after you have received the information packet. Or I can tell you more about the study now if you like. Would you like to hear more about the study now?

IF NO [DID NOT RECEIVE INTRO PACKET AND WOULD NOT LIKE TO HEAR MORE ABOUT STUDY]. Thank you for your time today. We look forward to talking to you after you have received the packet of information. Would you like to set up a time for us to call you back after you've had a chance to receive and review the packet?

YES (WISH TO SET CALL BACK):

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

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

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

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

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

RECORD RESPONSE AND ADDRESS IN TRACKING

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

NO (DO NOT WISH TO SET CALL BACK):

Thank you for your time today. We will call you back in <time period>.

YES (RECEIVED INTRO PACKET) OR YES (WOULD LIKE TO HEAR MORE ABOUT THE STUDY NOW):

RESPOND TO SUBJECT'S QUESTIONS, THEN CONTINUE READING SCRIPT.

[STUDY_ 2012] 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.

ONLY FOR INTERVIEWS WHEN MOM'S AGE IS UNKNOWN:

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

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

IF UNDER 15 [THANK_AGE] "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."

[INFORM] The interview takes about 55 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. 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.

[FOR THOSE WHO DID NOT RECEIVE INTRO PACKET BUT ANSWERED 'YES' TO WISH TO HEAR MORE ABOUT THE STUDY] Now, I'd like to read you some of the information that is part of the packet that you will be receiving in the mail soon. It will take less than two minutes to read. 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.

All information that we gather in this study will be kept confidential. This is because the study 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 but we will never use any names or addresses in reports or publications. 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?

[FOR ALL WHO RECEIVED MAILING]

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

ANSWER QUESTIONS.

[Q_NAME] *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. The <state>

surveillance program 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 pregnancies were not affected by birth defects from women who were pregnant in the same year. Thousands of women are taking part in this study. Around 200 women of pregnancies affected by birth defects and 300 women whose pregnancies were not affected by birth defects will be interviewed <in State> each year. We plan to conduct the study for at least three years in <State>.

[Q_CONFID] *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 or addresses in reports or publications.

[Q_PART] *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 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>).

[Q_INCENTIVE] *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).

[Q_INFO] *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.

[INFORM2] 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: AR, GA, MA, NC, NY] 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.

[INFORM3] 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.

[START.] Do you wish to continue/be interviewed?

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

PROBES:

General:

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.

Not willing to provide address:

Could we send the packet to the address of a relative or friend?

Do you have any questions about the study I might be able to address?

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?

YES (WISH TO BE INTERVIEWED NOW):

[TWER] 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. (Will it be O.K. for my supervisor to listen? [or for us to record the interview]?)

YES (OK TO LISTEN IN): → **[T_CHKDOB.]** 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.

Thank you for agreeing to participate in BD-STEPS.

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

[APP_REMIND] [Would you like us to provide a reminder before your interview appointment?
IF YES, [REMIND_TYPE] Would you like an email or a text reminder?
RECORD RESPONSE AND ADDRESS IN TRACKING

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

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 taking the time to talk to me about the study.

MA 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.]

[INTRO_CONSENT] 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 <Interview Contractor>; 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 telephone interview?

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

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

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

[APP_REMIND] Would you like us to provide a reminder before your interview appointment?
IF YES, [REMIND_TYPE] Would you like an email or a text reminder?
RECORD RESPONSE AND ADDRESS IN TRACKING

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

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

YES (CONVENIENT TIME NOW):

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

All your answers are confidential.

You can choose not to answer any specific questions.

You are free to stop the interview at any time

(FOR MA STILLBIRTHS AND CONTROLS: There are two parts to the interview. After you complete the first part of the interview, you can choose to continue to the second part of the interview or schedule it for a later 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.