

National Birth Defects Prevention Study – Atlanta

Introductory Telephone Script and Informed Consent

Mother of Living Case Child or Living Control Child

Hello, may I speak with <First and Last Name of Mother>? My name is <Interviewer> and I am calling for the <Atlanta> National Birth Defects Prevention Study. Recently we mailed a letter to you asking you to participate in the research study. Did you receive this letter?

[IF SUBJECT ASKS WHERE YOU ARE CALLING FROM OR WHO BATTELLE IS, STATE: “I am calling for the <Centers for Disease Control> from Battelle in Durham, NC. Battelle is a public health research organization.”]

IF NO: We are enrolling families in <Atlanta>, hoping to discover clues about what causes birth defects. To do this, we are interviewing mothers of healthy infants as well as mothers whose babies had birth defects. You were selected from women who recently had babies. The study involves a telephone interview about your health, diet, and lifestyle. We are interested in having you participate in the study, but first need to send you a letter describing the study. May I get your current address to send you the letter?

NO [SKIP TO UNDECIDED SUBJECT SCRIPTS]

YES [RECORD ADDRESS.] Thank you. Your participation will help us understand more about the causes of birth defects and their prevention.

IF YES: RESPOND TO SUBJECT’S QUESTIONS; ASK IF SHE HAS QUESTIONS.

READ INFORMED CONSENT TELEPHONE SCRIPT:

This is an interview study to discover clues about what causes birth defects. Interviews are being conducted as part of the National Birth Defects Prevention Study.

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

- Your pregnancies,
- Your health, including prescription and non-prescription drugs you may have taken,
- Your diet,
- Your family background,
- Your work and hobbies,
- Your lifestyle, and
- Your baby’s father.

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

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

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

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

ANSWER QUESTIONS:

We are interviewing mothers of healthy infants as well as mothers whose babies had birth defects. Some children were selected through a surveillance (tracking) program called the <Metropolitan Atlanta Congenital Defects Program> that has been run by the <Centers for Disease Control> for the past <30> years. (State laws give us permission to review medical records when birth defects are present. This is how we identified most mothers in the study.) Mothers whose babies don't have birth defects were selected randomly from women who gave birth in the same year.

Thousands of women are taking part in this national study. Three hundred mothers of infants diagnosed with birth defects and one hundred mothers of healthy infants will be interviewed each year for a total of five years in <Atlanta>. Nationwide, 16,000 women will be surveyed. Interviews are being conducted in Atlanta and seven states.

Confidentiality and Certificate of Confidentiality: [REFER TO HUMAN SUBJECTS FACT SHEET.] All information that we gather in this study will be kept private. 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 participating sites when and if it has been approved by research review committees. However, the shared data will not contain any information that could identify you or any other individual. This information will be used only for the study of birth defects. If you would like a copy of the Certificate of Confidentiality for this study, you may call Ms. Carolyn Sullivan or Ms. Tineka Yowe-Conley at **404-498-4315**, and a copy will be sent to you.

Voluntary Participation in Interview and Cheek Cell Kit: The study has two parts – the (1) telephone interview and (2) optional cheek cell kit. Participation in all parts of this study is voluntary. You can do the interview but decide not to do the cheek cell kit. 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 or cheek cell samples destroyed or removed from the study (by calling Ms. Tineka Yowe-Conley at 1-404-498-4315).

Incentive for Interview: We enclosed a \$20.00 money order with your letter to thank you for your time (for the interview).

Voluntary Cheek Cell Kit (Buccal Cells): The Cheek Cell Kit is entirely voluntary (optional). It will help us understand the genetics of birth defects. After the interview, we will mail a kit to you with small, soft brushes to collect cell samples from the inside of the mouth for yourself, your child, and your child's father. (The brush is similar to a tiny toothbrush.) We will enclose \$20.00 per family in the kit to provide for any inconvenience. You can decide whether to take part in this part of the study after you receive the kit. The kit will include directions and all necessary materials to collect the samples. (Cheek cell samples will be stored without your names.) We will also send an additional \$20 money order after you return the cheek cell samples to compensate you for the time required to complete the entire study.

For More Information: If you'd like more information about the study, please contact Ms. Tineka Yowe-Conley at 1-404-498-4315. 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. There will be no bad effects from this decision; it will not affect the care or services you or your family receive.

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

All your answers are confidential. Your identity will remain private. The information you provide may be shared with other birth defects researchers, but without any information that could identify you.

If you have any concerns about the study or how it is conducted, you may contact < Ms. Tineka Yowe-Conley > at <404-498-4315>. If you have questions about your rights as a subject in this research study, please call the Office of the Deputy Associate Director for Science for CDC at 1-800-584-8814, leave a message including your name, phone number, and refer to protocol #2087, and someone will call you back as soon as possible.

My supervisor may listen in from time to time to make sure I'm doing the best job I can. (If you do agree to be interviewed, will it be O.K. for my supervisor to listen?)

Do you wish to continue/be interviewed?

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

PROBES:

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

IF YES:

RECORD DATE AND TIME (INCLUDE TIME ZONE).

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 <1-877-719-2027> if you need to change your appointment.

Thank you for agreeing to participate in the National Birth Defects Prevention Study.

National Birth Defects Prevention Study

**Atlanta
Introductory Telephone Script
and Informed Consent**

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

Hello, may I speak with <First and Last Name of Mother>? My name is <Interviewer> and I am calling for the Atlanta National Birth Defects Prevention Study. Recently we mailed a letter to you asking you to participate in the research study. Did you receive this letter?

[IF SUBJECT ASKS WHERE YOU ARE CALLING FROM OR WHO BATTELLE IS, STATE: “I am calling for the <Centers for Disease Control> from Battelle in Durham, NC. Battelle is a public health research organization.”]

IF NO: We are enrolling families in <Atlanta>, hoping 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 a surveillance (tracking) program called the <Metropolitan Atlanta Congenital Defects Program> that has been run by the <Centers for Disease Control> for the past <30> years. We are sorry about your loss and extend our 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. (The study involves a telephone interview about your health, diet, and lifestyle.) We are interested in having you participate in the study, but first need to send you a letter describing the study. May I get your current address to send you the letter?

NO	[SKIP TO UNDECIDED SUBJECT SCRIPTS]
YES	[RECORD ADDRESS.] Thank you. Your participation will help us understand more about the causes of birth defects and their prevention.

IF YES: RESPOND TO SUBJECT’S QUESTIONS; ASK IF SHE HAS QUESTIONS.

READ INFORMED CONSENT TELEPHONE SCRIPT:

This is an interview study to discover clues about what causes birth defects. Interviews are being conducted as part of the National Birth Defects Prevention Study.

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

- Your pregnancies,
- Your health, including prescription and non-prescription drugs you may have taken,
- Your diet,
- Your family background,
- Your work and hobbies,
- Your lifestyle, and
- Your baby’s father.

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

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

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

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

ANSWER QUESTIONS.

We are interviewing mothers of healthy infants 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 a surveillance (tracking) program called the <Metropolitan Atlanta Congenital Defects Program> that has been run by the <Centers for Disease Control> for the past <30> years. (State laws give us permission to review medical records when birth defects are present. This is how we identified most women in the study.) Women whose babies don't have birth defects were selected randomly from women who gave birth in the same year.

Thousands of women are taking part in this national study. Three hundred mothers of infants diagnosed with birth defects and one hundred mothers of healthy infants will be interviewed each year for a total of five years in <Atlanta>. Nationwide, 16,000 women will be surveyed. Interviews are being conducted in Atlanta and seven states.

Confidentiality and Certificate of Confidentiality: [REFER TO HUMAN SUBJECTS FACT SHEET.] All information that we gather in this study will be kept private. 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 participating sites when and if it has been approved by research review committees. However, the shared data will not contain any information that could identify you or any other individual. This information will be used only for the study of birth defects. If you would like a copy of the Certificate of Confidentiality for this study, you may call Ms. Carolyn Sullivan or Ms. Tineka Yowe-Conley at **404-498-4315**, and a copy will be sent to you.

Voluntary Participation in Interview and Cheek Cell Kit: The study has two parts – the (1) telephone interview and (2) optional cheek cell kit. Participation in all parts of this study is voluntary. You can do the interview but decide not to do the cheek cell kit. 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 or cheek cell samples destroyed or removed from the study (by calling Ms. Tineka Yowe-Conley at 1-404-498-4315).

Incentive for Interview: We enclosed a \$20.00 money order to thank you for your time (for the interview).

Voluntary Cheek Cell Kit (Buccal Cells): The Cheek Cell Kit is entirely voluntary (optional). It will help us understand the genetics of birth defects. After the interview, we will mail a kit to you with small, soft brushes to collect cell samples from the inside of your mouth. (The brush is similar to a tiny toothbrush.) We will enclose \$20.00 per family in the kit to provide for any inconvenience. You can decide whether to take part in this part of the study after you receive the kit. The kit will include directions and all necessary materials to collect the samples. (Cheek cell samples will be stored without names.) We will also send an additional \$20 money order after you return the cheek cell samples to compensate you for the time required to complete the entire study.

For More Information: If you'd like more information about the study, please contact Ms. Tineka Yowe-

Conley at 1-404-498-4315. 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. There will be no bad effects from this decision; it will not affect the care or services you or your family receive.

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

All your answers are confidential. Your identity will remain private. The information you provide may be shared with other birth defects researchers, but without any information that could identify you.

If you have any concerns about the study or how it is conducted, you may contact < Ms. Tineka Yowe-Conley > at <1-404-498-4315>. If you have questions about your rights as a subject in this research study, please call the Office of the Deputy Associate Director for Science for CDC at 1-800-584-8814, leave a message including your name, phone number, and refer to protocol #2087, and someone will call you back as soon as possible.

My supervisor may listen in from time to time to make sure I'm doing the best job I can. (If you do agree to be interviewed, will it be O.K. for my supervisor to listen?)

Do you wish to continue/be interviewed?

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

PROBES:

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

IF YES:

RECORD DATE AND TIME (INCLUDE TIME ZONE).

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 <1-877-719-2027> if you need to change your appointment.

Thank you for agreeing to participate in the National Birth Defects Prevention Study.

National Birth Defects Prevention Study

Atlanta

REVISED Telephone Script:

Interview Already Scheduled

[SHORT VERSION OF SCRIPT FOR WOMEN WHO ALREADY CONSENTED AT THE TIME THE INTERVIEW WAS SCHEDULED. THE INTERVIEW BEGINS WITH THIS REMINDER.]

Hello, may I speak with <**First and Last Name of Mother**>? My name is <**Interviewer**> and I am calling for the <**Atlanta**> National Birth Defects Prevention Study. 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 BATTELLE IS, STATE: "I am calling for the <Centers for Disease Control> from Battelle in Durham, NC. Battelle is a public health research organization."]

IF NO: When would be a more convenient time for me to call you to conduct the interview?
RECORD DATE AND TIME (INCLUDE TIME ZONE).

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 <1-877-719-2027> if you need to change your appointment.

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

IF YES:

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

- All your answers are confidential.
- You can choose not to answer any specific questions.
- You are free to stop the interview at any time without losing any benefits.

IF NOT PREVIOUSLY ASKED: My supervisor may listen in from time to time to make sure I'm doing the best job I can. Will it be o.k. for my supervisor to listen?

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

IF NO: SET UP "NO MONITORING SIGNAL OR SIGN" FOR SUPERVISOR.
THEN VERIFY NAME AND/OR BIRTHDATE OF CHILD. PROCEED WITH INTERVIEW.