

## Appendix F

### Consent to Participate in Biologic Sample Collection Discussion Groups

#### **Title of Study**

Biologic Sample Collection Discussion Groups

#### **Researchers**

National Center on Birth Defects and Developmental Disabilities,  
National Center for Chronic Disease Prevention and Health Promotion,  
National Center for Environmental Health, and  
Office of Genomics and Disease Prevention of the  
Centers for Disease Control and Prevention

#### **Purpose**

The Centers for Disease Control and Prevention (CDC) is doing a study to learn more about what women think about collecting genetic material on themselves and their children. Westat is helping CDC gather groups of women who received a cheek cell sample kit for the National Birth Defects Prevention Study. We are asking you to join the group because we are interested in your ideas about the kit and the collection process.

#### **Procedures**

If you agree to join the study, we will assign you to a group of about three to twelve women who also participated in the National Birth Defects Prevention Study and received a cheek cell sample kit.

We will ask what your group thought about the cheek cell sample kit and the collection process. We will also ask how you made your decision about completing the kit. Your group will talk for about 2½ hours. We will audiotape the group discussions to make sure we heard clearly all that is said by the group. When the study is finished, we will erase all tapes. Only first names of participants will be disclosed during introductions. Responses to questions will be attributed to the group and not connected with the names of participants. Transcripts and summaries of the discussion groups will be made but will not contain any information that could identify any individual.

#### **Risks**

Talking about your experience with the cheek cell sample kit might be difficult for some people. If at any point during the group discussion you feel uncomfortable answering any question, you may refuse to comment, or you may stop at any time.

#### **Benefits**

There is no personal benefit to you for taking part in this study. The major benefit is that these discussions may result in better ways to collect genetic samples. This information will be helpful for all studies that collect genetic material.

#### **Confidentiality**

All information that we gather in this study will be kept private. This is assured under Section 301(d) of the Public Health 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. Records may be reviewed by officials checking on the quality of the research. 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. We will keep records of what you say, but we will not keep your names. We will not name any person who was in the group in any articles or reports. When we finish the study, we will destroy the tapes.

**Costs/Compensation**

If you agree to participate in the group discussion, you will receive a \$50 money order to cover childcare costs. You will receive an additional \$50 in cash at the facility after the discussion is finished to thank you for your time and effort. We will also provide \$20 to cover transportation to and from the discussion facility, or we will provide taxi service at no cost to you.

**Right to Refuse or Withdraw**

Participation in the group discussion is voluntary. If you do not want to be in this group, it will not affect your personal life in any way. You may refuse to answer any of the questions asked in your group. You may stop being in the group at any time.

**Contacts**

If you have any questions about this study, please call the Principal Investigator, Dr. Margaret Honein, at 404-498-4315. If you have any questions about your rights as a subject in this study, please call the Office of the Deputy Associate Director for Science for CDC at 1-800-584-8814. Please leave your phone number, a brief message, and refer to protocol #2087. Someone will call you back as soon as possible.

I have read this consent form or had its contents explained to me. All of my questions have been answered.

**SIGNATURE**

Name: \_\_\_\_\_

Date: \_\_\_\_\_

Please keep this form for your records.