

Moderator's Guide - Biologics Non-Participants

I. Introduction

Welcome. We appreciate the time and effort you are making to be here. Today, we will be talking about how you made the decision to participate in the National Birth Defects Prevention Study which involved an in-depth interview and the collection of cheek cells. We will also be discussing different ways to collect genetic samples. The reason we asked you to be part of the group discussions is so that we can hear your opinions and ideas. Please don't hesitate to speak up. There are no wrong answers. Your ideas are very important to us. Everything that you tell us today will be kept confidential. Please remember to use only your first name during our discussion today. We are using an audiotape to record this session for accuracy. We will transcribe the audiotapes and combine your responses. Only your first name will be used and it will not be connected with any answers or comments you provide today. A summary report of the discussion will be made and will be shared with study investigators. The report will not contain any information that could identify any individual. Thanks so much for being here and agreeing to participate.

II. Opening Question:

First, I'd like to start by asking each of you to take a minute to tell the rest of the group a little about yourself. Tell us your first name and anything you would like to share about yourself with the group.

Participants introduce themselves.

Thank you.

Objectives: To determine general feelings participants have about genetic testing. Since all participants completed the first portion of the study (the interview), we want to determine whether participants had decided if they would complete biologics before agreeing to complete the interview or whether their decision regarding biologics participation was a direct result of their interview experience.

We would like to start talking generally about why you might or might not decide to participate in a study that collects genetic information. From your perspective, what are the reasons you would decide to share genetic information? (Probe: benefits to self, family, society) From your perspective, what are the reasons you would not decide to share genetic information? What are some reasons that you

would refuse to share genetic information? (Probe: barriers, risks, mistrust, harm, etc)

One thing you know about everyone here is that you all have participated in a study that is trying to figure out what causes birth defects. When you were invited to participate in the study, you were told that it included two parts: (1) a telephone interview and (2) a cheek cell sample kit. You were also told that you could participate in any part of the study and were not required to participate in parts that you did not wish to do. If you can, remember when you first were invited to participate in the study and were still thinking about participating. The introductory kit that was sent to you before the interview is available and will be passed around.

1. What were some of your initial reactions to being asked to participate in the study?
2. What were some of your reactions to the materials sent to you that described the study? (Probe: were they clear, confusing, compelling,...)
3. What were the main reasons you decided to participate in the study?
4. Because this study gives participants money as a thank you for the time involved, what role did compensation have in your decision to participate? Any role?
5. When you agreed to participate in the study, did you think to yourself that you would participate in all or just one part of the study?

Each of you agreed to participate in the study. All of you completed the interview. After completing the interview a cheek cell sample kit was mailed to you so that genetic information could be collected and used in the study. We did not receive cheek cell brushes from anyone in this group and we'd like to understand why.

III. Decision-making factors

Objectives: To determine what changes can be made to the cheek cell sample kit or to the incentive amount to help increase biologic participation. To determine if receiving the kit from an institution other than the government would increase biologics participation.

Try to remember when you were deciding to participate in the cheek cell collection part of the study...

1. How did you feel about being asked to collect a cheek cell sample?
2. How did the information in the cheek cell sample kit affect your decision to collect or not collect a cheek cell sample?
3. How did you feel about the compensation offered for providing genetic information? Probe: was it a factor at all, was it too low, too high,

- enough? Did the money you received in your kit affect your decision to not collect cheek cells? Was the \$20 you were to receive after returning your kit the wrong amount?
4. What role did the number of brushes included for each family member have in affecting your decision not to collect cheek cells? Would your decision have been different if more brushes were included for each family member?
 5. Did you consult with family, friends, or other trustworthy sources of information to help make a decision about providing cheek cells for this study?
 6. Did the credibility of the researchers and their institutions affect your decision in any way? Who would be most credible/reputable/trustworthy to you?
 7. Who in your household made the final decision to not collect cheek cell samples?
 8. How long did it take you to decide to not complete the kit? Probe: Did you talk to someone or look for more information about genetic samples first?

Each of you should have received a cheek cell sample kit. SHOW KIT – take it, open it up, describe each part (letter, money order, consent forms, collection instructions, colored envelopes, brushes, mailer, folder with quotes) and ask, Does this look familiar to you?

IV. Action taken and the factors that affected the action taken with kit and the collection process

Objectives: To determine at what point the participants decided not to complete the cheek cell sample kit. To determine if participants attempted to collect samples but never returned them. Were they waiting on the father, felt like too much time had passed...?, Should information be added to communicate that samples need to be returned quickly with or without the father sample? To determine what changes could be made to the materials included in the cheek cell sample kit to make the collection easier to understand.

Did you receive a kit? (Poll participants by a raise of hands approach – how many of you received a kit? How many of you received more than one kit?)

Now, remember back to when you received the kit, what was the first thing you did with it?

Did you open the kit? (Poll participants by a raise of hands approach – how many of you opened the kit?)

Did you open it up right away or not? Why or why not? What were some of your reactions when you first opened the kit? (Probe: too many parts, confusing, organized, boring, appealing, clear and simple). What parts of the kit did you read and what parts did you ignore (if any)?

1. For those of you who did not open the kit-
 - i. What were some reasons you decided not to open the kit? What was the main reason you didn't open the kit? (Probe: refusal to participate in this component; family member not supportive of this; conscious choice not to share genetic information)
 - ii. Was there something about the kit that kept you from opening it?
 - iii. Was there something about your participation in the overall study that kept you from opening it? (Probe: interview experience (negative); concerns with information security, etc.)

2. For those of you who did open the kit-
 - i. If you opened the kit, what did you think about the way the kit looked? (Prompt: what did you think about the folder, envelopes, placement of the money order, quotes from other study moms...?)

 - ii. Let's talk about the informed consent document (HOLD UP: "Informed Consent for
 - iii. Cheek Cell Samples") Did you read the consent form when you opened the kit? Can you
 - iv. remember anything about the consent form that affected your decision to send cheek cells
 - v. or not? Did you think the consent form was clear? Was there anything about the consent form that was unclear? What?

 - vi. Let's talk about the instructions in the kit (HOLD UP: How to Collect Cheek Cell Samples).
 - vii. Think back to when you opened the kit. Can you remember anything about the instructions
 - viii. that affected your decision to send cheek cells or not? Did you think that the instructions
 - ix. were clear enough to collect the samples? Was there anything about the instructions that was unclear? What?

 - x. Did you **attempt** to collect cheek cell samples from yourself or your child? Did your child's father attempt to collect cheek cell samples? What was your experience? (describe what happened). Probe: problems with collection, problems understanding and following the instructions, problems locating different parts of the kit, problems getting your child's father to collect samples, took too much time.

 - xi. If you attempted to collect cheek cells, what things did you not like about the collection process? Prompt - brush type, child's reaction (gagging, etc), father's reaction, your reaction

 - xii. If you attempted to collect cheek cells, what kept you from sending them in? Probe: Did you think you did the collection process incorrectly? Did

you just forget to send them in? Were you waiting for all family members to complete the kit? Were you too busy and set the kit aside? Was it too inconvenient?

- xiii. Is there anything more you would like to say about the cheek cell sample kit or the process of collecting cheek cells? What advice do you have that could improve the collection of genetic information for future study participants like yourself? Prompt: Would additional information help with decision-making? Would another type of compensation affect your decision?

V. Exploring other collection methods

Objectives: To determine if there is an alternative to cheek cell collection using cytobrushes (blood, saliva, mouthwash) that mothers would prefer for themselves, their child, or their child's father. To determine the feelings mothers have toward supervised collection methods (those that include a health care provider). To determine if collecting samples from the father is a barrier to participation.

As you may know, there are many ways to collect genetic information, so I'd like to get your thoughts about different ways genetic information could be collected in studies like this.

In front of you are three stacks of cards. Each stack of cards shows different ways that genetic information could be collected from you, your child, and your child's father.

Stack 1: Collecting genetic information from moms

We're going to start this discussion with stack 1 - collecting genetic information from you. I'd like us to walk through each of the cards together so I can describe each method.

The first card should look a bit familiar to you; it's the cheek cell collection method.

Card A: Shows a woman using a brush to collect cheek cells in her home

Card B: Shows a health care provider using a brush to collect cheek cells from a woman in her home

Card C: Shows a health care provider watching a woman use a brush to collect cheek cells in her home

Card D: Shows a health care provider using a brush to collect cheek cells from a woman in a clinic

Card E: Shows a health care provider watching a

woman use a brush to collect cheek cells in a clinic

Card F: Shows a woman having blood drawn by a health care provider in her home

Card G: Shows a woman having blood drawn by a health care provider in a clinic

Card H: Shows a woman rinsing with mouthwash and spitting it into a collection cup at home

Card I: Shows a woman spitting her saliva into a collection vial at home

Do you have any questions about the methods shown on the cards? Now, I'd like you to sort the cards according to your preferred method, putting your most preferred method on top and your least preferred method on bottom. Remember, there are no right or wrong answers.

Participants sort cards.

Thanks. Now we will take a tally of how the cards were sorted. Please keep your cards in the order that you placed them so they can be clipped together at the end. You will notice that each card has been assigned a letter. What is the letter of the card that you put on top (the card showing the method of research you most prefer for yourself)?

NOTE TO MODERATOR: Go around the room asking mothers for the letter of the card they placed on top (position 1). On a large sheet of paper, record the mother's responses by putting tally marks next to the letters of the cards the mother's put on top (in position 1). Repeat this exercise for all 9 card positions. Following the tally of all cards, begin the discussion of the research method advantages and disadvantages (below) with the card that was most frequently placed on top (in position 1). Continue the discussion of advantages/disadvantages for the cards most frequently found at position 2,3, etc. Probe to determine if there is anything that may overcome the barriers to the least preferred methods, i.e., higher monetary incentive, different type of incentive, collection location, etc.

From your perspective:

1. What are the advantages/benefits of this particular method? (probe: appeal, do-ability, convenience, non-intrusive)
2. What are the drawbacks/disadvantages of this particular method? (probe: aversions, complexity, inconvenience, intrusive)

NOTE TO MODERATOR: If the preferred methods involve a health care provider, ask

the following questions: what type of health care professional do you see collecting the genetic

samples? What qualities would they need to possess? (Probe for: gender, education, race, age, etc)

When the discussion of the mother's preference is complete, have someone clip the cards together in the same order as the mother's ranked them to record later.

Now, we're going to repeat the process except this time, we want to focus on collecting genetic information **from your child** who was part of the study.

Stack 2: Collecting genetic information from your child

We're going to continue this discussion with stack 2 - collecting genetic information from your child. Again, I'd like us to walk through each of the cards together so I can describe each method.

Card A: Shows a woman using a brush to collect cheek cells from her child at home

Card B: Shows a health care provider using a brush to collect cheek cells from the child at home

Card C: Shows a health care provider watching a parent collect cheek cells from their child at home.

Card D: Shows a health care provider using a brush to collect cheek cells from the child in a clinic

Card E: Shows a health care provider watching a parent collect cheek cells from their child in a clinic

Card F: Shows a child having a health care provider drawing blood using a heel stick or finger prick method in the child's home

Card G: Shows a child having a health care provider drawing blood using a heel stick or finger prick method in a clinic

Card H: Shows a mother giving permission to use the newborn screening blood spot (with picture of blood spot for point of reference)

Do you have any questions about the methods shown on the cards? Now, I'd like you to sort the cards according to the method you prefer to do with your child, putting the most preferred method on top and the least preferred method on bottom. Remember, this time focus on the method as related to collecting genetic information from your child. There are no right or wrong answers.

Participants sort cards.

Thanks. Now we will take a tally of how these cards were sorted. Again, please keep your cards in the order that you placed them so they can be clipped together at the end. What is the letter of the card that you put on top (the card showing the method of research you most prefer for your child)?

NOTE TO MODERATOR: Go around the room asking mothers for the letter of the card they placed on top (position 1). On a large sheet of paper, record the mother's responses by putting tally marks next to the letters of the cards the mother's put on top (in position 1). Repeat this exercise for all 8 card positions. Following the tally of all cards, begin the discussion of the research method advantages and disadvantages (below) with the card that was most frequently placed on top (in position 1). Continue the discussion of advantages/disadvantages for the cards most frequently found at position 2,3, etc. Probe to determine if there is anything that may overcome the barriers to the least preferred methods, i.e., higher monetary incentive, different type of incentive, collection location, etc.

From your perspective:

1. What are the advantages/benefits of this particular method? (probe: appeal, do-ability, convenience, non-intrusive)
2. What are the drawbacks/disadvantages of this particular method? (probe: aversions, complexity, inconvenience, intrusive)

NOTE TO MODERATOR: If the preferred methods involve a health care provider, ask the following questions: what type of health care professional do you see collecting the genetic samples? What qualities would they need to possess? (Probe for: gender, education, race, age, etc)

When the discussion of the mother's preference for her child is complete, have someone clip the cards together in the same order as the mother's ranked them to record later.

Now, we're going to repeat this process except this time, we want to focus on collecting genetic information **from the father of your child.**

Stack 3: Collecting genetic information from fathers

We're going to continue this discussion with stack 3 - collecting genetic information from the father of your child. This task will be a bit different than the others because you have more control of you and your child's participation and may have less control of the father's participation. Even so, we'd like to get your thoughts about these methods as related to the dad's participation. Because the cards are familiar to you, we'll quickly walk through each of the cards together.

- Card A: Shows a man using a brush to collect cheek cells in his home
- Card B: Shows a health care provider using a brush to collect cheek cells from a man in his home
- Card C: Shows a health care provider watching a man use a brush to collect cheek cells in his home
- Card D: Shows a health care provider using a brush to collect cheek cells from a man in a clinic
- Card E: Shows a health care provider watching a man use a brush to collect cheek cells in a clinic
- Card F: Shows a man having blood drawn by a health care provider in his home
- Card G: Shows a man having blood drawn by a health care provider in a clinic
- Card H: Shows a man rinsing with mouthwash and spitting it into a collection cup at home
- Card I: Shows a man spitting his saliva into a collection vial at home

Do you have any questions about the methods shown on the cards? Now, I'd like you to sort the cards according to the method you think your child's father would prefer, putting the most preferred method on top and the least preferred method on bottom. Remember, this time focus on the method as related to collecting genetic information from your child's father. There are no right or wrong answers.

Participants sort cards.

Thanks. Now we will take a tally of how these cards were sorted. Again, please keep your cards in the order that you placed them so they can be clipped together at the end. What is the letter of the card that you put on top (the card showing the method of research you think your child's father would most prefer)?

NOTE TO MODERATOR: Go around the room asking mothers for the letter of the card they placed on top (position 1). On a large sheet of paper, record the mother's responses by putting tally marks next to the letters of the cards the mother's put on top (in position 1). Repeat this exercise for all 9 card positions. Following the tally of all cards, begin the discussion of the research method advantages and disadvantages (below) with the card that was most frequently placed on top (in position 1). This time focus the discussion only on the cards placed most frequently on the top and bottom of the stack since the mother is likely only aware of methods the child's father would most prefer and methods the child's father would least prefer. Probe to determine if there is anything that may overcome the barriers to the least preferred methods, i.e., higher monetary incentive, different type of incentive, collection location, etc.

From your perspective:

1. What are the advantages/benefits of this particular method? (probe: appeal, do-ability, convenience, non-intrusive)

2. What are the drawbacks/disadvantages of this particular method? (probe: aversions, complexity, inconvenient, intrusive)

NOTE TO MODERATOR: If the preferred methods involve a health care provider, ask the following questions: what type of health care professional do you see collecting the genetic samples? What qualities would they need to possess? (Probe for: gender, education, race, age, etc)

When the discussion of the preferences for the father of the child is complete, have someone clip the cards together in the same order as the mother's ranked them to record later.

If preferred methods for mother and father differ from preferred method for the child, ask mothers how they would feel about collecting cells using two different methods: one method for themselves and the child's father; a second method for the child.

VI. Closing

Well, that brings us to the end of all my questions. I need to step out for a few minutes to make sure we have everything ready for you.

Moderator checks with observers for up to two additional questions to pose, time permitting.

Upon return, moderator will pose questions from observers, if any.

Thank you for your time and your ideas. The National Birth Defects Study team is extremely grateful for your participation in the study and for the time you've taken today to help us improve it. Before we all leave,

Is there anything else you would like to share with us today? Are there any questions you would like to ask us?

On the table there are business cards with the study team's phone number on them. If you think of something later that you would like to add to what was discussed today OR if you have a question that you'd like to ask us, please feel free to contact us. Your name will not be connected with any answers or comments you have given today or may give in the future. There is also information about support groups for families having children with birth defects available on the table for you to take home. Thanks again and we hope that we may feel free to contact you again, if, as we progress in our work, any new questions arise.

FORM APPROVED: OMB# ####-####
OMB EXPIRATION DATE: mm/dd/yyyy