**Form Approved**

**OMB No. 0920-0910**

**Expiration Date 1/31/2015**

**Moderator’s Guide:**

Women’s Perceptions of Tobacco Products

Pregnant Women

1. **WELCOME AND GROUND RULES (5 minutes)**

Welcome and thank you for participating in tonight’s discussion. My name is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Tonight, I am interested in hearing your opinions about various tobacco and nicotine-containing products. You have been asked to participate in tonight’s discussion because you use or used to use tobacco products.

Before we begin, I want to let you know that I work for a not-for-profit research organization, and this research was sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). I do not work for a tobacco company or a company that sells quit-smoking aids. Tonight’s discussion is for research purposes only and is not for any marketing purposes. Also, I would like to go over a few ground rules for our discussion tonight, which will last about 90 minutes.

* Your participation is voluntary and you have the right to not answer any question or withdraw from the study at any time.
* If at any time you are uncomfortable with my questions, you can choose not to answer. Just let me know that you prefer not to answer.
* Everything we discuss today will be maintained in a secure manner. We won’t share anything you say with anyone outside the research team.
* Tonight’s discussion will be audio and video recorded. The recordings will help me write the final report and will be kept in a secure location. In any reports or papers we write, we will not refer to you by name or use any information that can be used to identify you.
* Study team members are viewing our discussion to hear your thoughts and opinions first hand. At the end, I’m going to go into the back and see if they have any last minute questions for you.

**Public reporting burden of this collection of information is estimated to average 90 minutes per response, 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 Information Collection Office; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0910)**

* Most importantly, there are no right or wrong answers. I just want to hear your opinions.
* I’m not a medical doctor or an expert on smoking or tobacco, so I won’t be able to answer any specific medical questions you may have about tobacco or smoking. Please contact your healthcare provider if you have any medical questions related to tonight’s discussion.
* Please silence your cell phones.

Do you have any questions before we begin?

1. **INTRODUCTION (10 minutes)**

[*Purpose: to introduce everyone, get them talking, and make them comfortable*]

FOCUS GROUPS [IF PREGNANT] We brought you here tonight because you all have something in common--you’re all pregnant. Let’s begin by going around the table and hearing a little more about each of you. Tell us your first name and a little bit about your pregnancy—when are you due, do you know if you’re having a boy or girl, [FOR CHILDREN GROUPS] do you have other kids?

*Skip:* [IF PLANNING]We brought you here tonight because you all have something in common--you’re all planning to become pregnant within the next year. Let’s begin by going around the table and hearing a little more about each of you. Tell us your first name and a little bit about yourself—are you planning for your first baby, [FOR CHILD REN GROUPS] or do you already have other children?

Another thing you all have in common is that you currently smoke [or recently quit smoking]. Let’s talk more about this.

*INTERVIEWS – PREGNANT SMOKERS*

I’d like to hear a little more about you. Tell me your first name and a little bit about your pregnancy—when are you due, do you know if you’re having a boy or girl, [FOR CHILDREN GROUPS] do you have other kids? We are talking with you tonight because you are a pregnant smokers and we are also talking with other women like you in this city and other cities to hear their thoughts about tobacco.

ALL

[CURRENT SMOKERS]

1. What do you currently smoke and how often?

*Probe: type of smoked product, brand, number of cigarettes/day*

1. How long have you smoked?
2. A. What do you enjoy or like about smoking? [SOLICIT RESPONSE FROM MAJORITY OF PARTICIPANTS AND LIST ON A FLIPCHART AND REFER TO FOR NEXT QUESTION ] Do you agree or disagree with any of the items listed here?

B. What do you dislike or not enjoy about smoking? [SOLICIT RESPONSE FROM MAJORITY OF PARTICIPANTS AND LIST ON A FLIPCHART AND REFER TO FLIPCHART] Do you agree or disagree with any of the items listed here?

1. Have you tried to quit smoking? When [IF UNCLEAR PREGNANT AT TIME, ASK – were you pregnant then? Why or why not? What was hard about quitting? What was easy?

A5. *SKIP* [IF PLANNING] Has your tobacco use or behavior changed since planning to become pregnant?

[IF PREGNANT] Has your tobacco use or behavior changed since becoming pregnant?

If so, how? What prompted this change?

*Probe: Behaviors can include things like changing brands, cutting back, hiding your smoking from others, etc.*

A6. Have you ever tried any other tobacco products, like chewing tobacco, cigars, or snus?

If yes, describe the product (if smokeless tobacco product). What made you try it?

*Probe: Likes and dislikes of other tobacco products*

[RECENT QUITTERS]

1. How long did you smoke, and when did you quit smoking? Was this your first quit attempt?
2. How did you quit? Probe: Use of NRTs (i.e., nicotine gum, patch, Chantix, cold turkey, etc)
3. Why did you quit smoking?
4. What was hard about quitting? What was easy?
5. Have you ever tried any other tobacco products, like chewing tobacco, cigars, or snus? If yes, describe the product (if smokeless tobacco product).What made you try it? Do you still use these products? Why or why not? *Probe: Likes and dislikes of other tobacco products*

 **III. NEW AND EMERGING PRODUCTS (30 minutes)**

[*Purpose: to assess awareness, use, reactions to products and marketing, perceptions, and appeal/interest in product*]

[*Allow perceptions of health risks to come up naturally, but do not probe on them directly in this section. Will discuss perceptions of health risks in Section IV*.]

As you may know, there are many different types of tobacco products. Some you smoke or inhale, some you chew, some you keep tucked in your cheek, and some that dissolve in your mouth. We’re here tonight to talk about some of these products.

MODERATOR - PutS products on the table one at a time [SNUS, DISSOLVABLES, E-CIGARETTES IN ROTATING ORDER]—loose product, packages, and encourage women to pass everything around and look at AND TOUCH THE PRODUCTS. tHEY MAY OPEN THE PACKAGES IF THEY WISH. Repeat this process and set of questions for each product with its packaging

*[NOTE TO INTERVIEWERS -IF NOT RECTIFIED IN DISCUSSION, CORRECT PARTICIPANT IF WAY OFF ON HOW PRODUCT IS USED. IF IT IS UNCLEAR AS TO WHICH PRODUCT THEY ARE DESCRIBING, SHOW THE POTENTIAL PRODUCT AND ASK, “Does this look different or the same as what you are describing?”]*

1. Has anyone ever seen this product before?

*Probe: where did you see this product?*

1. What, if anything, have you heard about this product?

Probe: Where did you hear about this product?

1. How would someone use these products? Why might they use them? What makes you think that?

*Probe: along with cigarettes? Instead of cigarettes? As a quit aid?*

1. How do you think using [INSERT PRODUCT] is similar to or different from smoking cigarettes or other tobacco products?

*Probe: frequency of use, nicotine amount, satisfaction, restrictions on use in public places, reactions from other people*

*Probe: what about during pregnancy?*

1. A. Raise your hand if you have tried this product before?

B. If you have used this product, tell me about it.

*Probe: why did you try it?*

*Probe: what was your experience like using the product?*

1. If you’ve never used [INSERT PRODUCT], would you use this? Why or why not?

Would you this product if you were pregnant?

[IF COST MENTIONED] If it cost more or less than cigarettes, would that affect your decision to try the product?

1. Do you know anyone who has used this product?

*Probe: What did they say about it? Why did they use it? Do you know anyone who used it while pregnant?*

1. Based on what you know about [INSERT PRODUCT], what are your overall impressions and thoughts about this product? Why?
2. [SHOW PACKAGING] What about the packaging? What comes to mind when you see the packaging?

*Probe: Does it appear to be directed to anyone in particular (e.g., who would typically use a product like this)? If so who? Why do you think that?*

*Probe: Did you notice the warning label? What is your reaction to it?*

# IV. RISK PERCEPTION OF NEW AND EMERGING PRODUCTS (15 minutes)

[*Purpose: understand how participants think about the health risks of the products, both in isolation and relative to other tobacco products*]

[*If health effects have come up throughout the discussion, refer back to previous conversations and ask additional questions below as necessary to clarify/expand upon these earlier comments*]

Think about all of the products we’ve discussed today—cigarettes, snus, dissolvables, e-cigarettes.

1. In your opinion, are cigarettes harmful to a smoker’s health? If yes, how are they harmful to a smoker’s health? What is in cigarettes that makes them harmful?
2. In your opinion, is smoking harmful to a pregnant woman who smokes or her baby’s health? If yes, how are they harmful to the health of a pregnant woman or her baby? If not, why do you think so? Do you think smoking cigarettes is harmful to your health?
3. In your own words, what does “less harmful” or “more harmful” mean to you?

*Probe: your health (immediate and long-term), health of baby, health of family/children*

1. Do you think [INSERT PRODUCT] is more or less harmful to your health than smoking cigarettes? *Probe: Why?*

*SKIP* [IF PLANNING]Do you think [INSERT PRODUCT] would be more or less harmful to your health than smoking cigarettes if you were pregnant?

[IF PREGNANT] Do you think [INSERT PRODUCT] is more or less harmful to your pregnancy or baby than smoking cigarettes?

1. [IF NOT PREVIOUSLY MENTIONED] Before our meeting tonight, had you ever thought whether a type of tobacco product was more or less harmful than other types of tobacco products?

[NOTE TO INTERVIEWER: ALLOW RESPONDENTS TO SAY NO DIFFERNCE IN RISK/HARM]

* If yes, which products do you consider to be least harmful and why?

*Probe: product characteristics, advertisements, personal experience, word of mouth, warning labels*

* If yes, which products do you consider to be most harmful and why?

*Probe: product characteristics, advertisements, personal experience, word of mouth, warning labels*

* If no, why? [NOTE TO INTERVIEWER – HIGH PRIORITY QUESTION]
* [IF NO DIFFERENCE] Why do you think there is no difference?

# V. NRTs (15 minutes)

*[Purpose: to assess awareness, use, reactions to products and marketing, perceptions, and appeal/interest in product]*

Now we’re going to look at another type of product, nicotine replacement therapy, or NRT, that is available over the counter without a prescription.

*[MODERATOR Puts all of the products on the table at once {gum, patches, Lozenges, AND Mini- lozenges}—loose product and packages,—and encourage women to pass everything around and look at it.]*

1. In your own words, what are nicotine replacement therapy products*?* How do you think someone would use these products? Why might they use them? What makes you think that?

Probe: along with cigarettes? Instead of cigarettes? As a quit aid?

NOTE – PARTICIPANT MAY NAME BRANDS AND PRODUCTS – LIST BOTH IN NOTES

1. Has anyone ever…seen these products before? Thought about trying any of these? Used any of these before? If so, tell me about it.

Probe: where have you seen them, why did you try them, what was your experience like using them

1. What, if anything, have you heard about these products?

Probe: how did you hear about them, who did you hear about them from, in what situation

1. Do you know anyone who has used any of these products?

What did they say about it?

Why did they use them, in what circumstances (e.g., pregnancy or not)

1. [SHOW PACKAGING] What about the packaging? What comes to mind when you see the packaging?

*Probe: Does it appear to be directed to anyone in particular? If so who? Why do you think that?*

*Probe: Did you notice the warning label? What is your reaction to it?*

1. How do NRTs compare to other tobacco products, like snus, dissolvables, and e-cigarettes?

*Probe: frequency of use, nicotine amount, satisfaction, restrictions on use, reactions of others observing use, similar/different health effects, overall health risk, and “your health” versus health of others, related to pregnancy*

1. Do you think NRTs could affect your health? Why?

*SKIP* [IF PLANNING]Do you think NRTs could affect your health if you were pregnant?

*Probe: positive and negative, product characteristics, warning label, conversations with physicians or others, during pregnancy*

1. Would you use any of these NRT products? Why or why not? In what circumstances?

*SKIP* [IF PLANNING]Would you use any of these products if you were pregnant?

[IF COST MENTIONED] If it did cost more or less than cigarettes or another tobacco product would that affect your decision to try the product?

*Probe: differences in appeal of one NRT versus another*

# VI. PRODUCT SELECTION AND BEHAVIORS AROUND TOBACCO (10 minutes)

*[Purpose: to assess any changes in use or interest in type of tobacco product since pregnancy as well as any changes in how products are used]*

E1*. SKIP* [IF PLANNING] Have your thoughts about tobacco and health changed since planning to become pregnant? If so, how? What has caused you to think differently?

[IF PREGNANT] Have your thoughts about tobacco and health changed since becoming pregnant? If so, how? What has caused you to think differently?

E2. Are there any other issues that you feel should have be discussed that we didn’t talk about tonight?

E3. We are almost out of time. I’m going to step out a minute and check with the study team members behind the two-way mirror to see if they have any additional questions or comments before we end tonight’s discussion.

# VII. DEBRIEF/CLOSING (5 minutes)

My study team members and I would like to thank you for coming here today and participating in this discussion. This research was sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). Our discussion will help them understand women’s reactions and thoughts about tobacco products. They want you to know that there is no safe tobacco product, including the products shown here today. They advise anyone using tobacco products of any type to stop. There are many ways to help users quit. If you are interested in learning more about quitting and whether to use NRTs, please talk to a healthcare provider. Also, I have some information from CDC and FDA on how users can quit. Feel free to share these materials with tobacco users you might know.