

Moderator Guide (90 Min)

TITLE OF INFORMATION COLLECTION: Nicotine Education Project: Qualitative Study to Gain Insights from Adult Current and Former Smokers to Educate the General Public about Changing Nicotine Standards

Reviewer Note: Moderator instructions are in brackets. The Moderator Guide consists of questions that researchers anticipate are relevant to ask. However, this does not mean that every question listed will definitely be asked. As per standard protocol for focus group research, researchers will allow the conversation to unfold naturally. Certain questions listed may no longer be asked because they may not be relevant to a particular discussion.

Activity	Equipment	Instruments
Check-In Survey	<i>Paper Survey, Pen/Pencil</i>	<i>Check-In Survey</i>
Study Introduction	<i>Audio Recorder, Moderator Guide</i>	
General Discussion	<i>Audio Recorder, Moderator Guide</i>	<i>Question prompts for discussion</i>
TOTAL TIME		

1. CHECK-IN SURVEY

In the folder you were given, there is a survey called the Check-In Survey that you can start filling out now. Please do not write your name anywhere on the survey. Let me know if you have any questions. Otherwise, just let one of us know when you're done.

[After each participant completes the Check-In Survey, Moderator/Assistant should circulate and instruct participants to insert the completed survey upside down in the bottom of their Participant Folder].

[At this time a full group introduction will be provided.]

2. SURVEY INTRODUCTION

Welcome and thank you for participating in tonight's discussion. My name is _____.

Tonight, I am interested in hearing your opinions about tobacco products. You have been asked to participate in tonight's discussion because you use or have used one or more of the tobacco products that we are going to discuss tonight. When I say tobacco products I am referring to things like cigarettes, cigars or cigarillos, hookah, smokeless products like chew, dip or snus,

and e-cigarettes or vapes. I am not referring to cannabis or marijuana, or the mixing of tobacco with them.

Before we begin, I want 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 kept private to the extent allowable by law. Your name and contact information, which only the study staff knows, will not be given to anyone else, and no one will contact you after this discussion is over.
- Tonight's discussion will be audio-recorded. The recordings will help me write the final report and will be kept in a secure location and then destroyed at the end of the study. No names will be mentioned in the final report created from these discussion groups.
- Behind me is a one-way mirror. Behind that are some of my colleagues. We are also video streaming our group for those who couldn't be here in person. They're watching to make sure that I ask you all of the questions I have for you today.
- Most importantly, there are no right or wrong answers. I want to know your opinions, so don't hold back on giving me your honest opinions.
- Please turn off your cell phones.
- Do you have any questions before we begin?

3. DISCUSSION

[Theme 1: Tobacco Norms]

First, we are going to talk about some of your first memories of smoking and your thoughts on smoking.

1. Thinking back to when you first started smoking, did it seem...
 - a. Rebellious? Grown up? Cool? Other?
 - b. How is this the same or different than your current perceptions of smoking?
2. Why do you think people continue to smoke?

[Theme 2: Knowledge and Product Perceptions]

Now we're going to talk about what we already know about tobacco products, and our opinions about how harmful or not harmful they are.

[Nicotine Knowledge]

1. What is tobacco?
2. What is nicotine?
 - a. What, if any, differences are there between tobacco and nicotine?
3. How does nicotine compare to the other ingredients/chemicals in cigarettes?
4. What, if anything, does nicotine do to someone's body (cancer, addiction, other health issues, etc.)?
 - a. Does it affect everyone the same way?
 - b. Does it affect some people differently?
5. What words would you use to describe cigarettes?
6. What is in a cigarette?

[Addiction]

1. What is addiction?
2. What causes addiction to cigarettes?
3. What keeps people smoking?
4. How much of a role does/did you think nicotine play/played in your addiction?
5. Are there any other ingredients in cigarettes that you think drive addiction?

[Product Perceptions]

Group Activity: Now we are going to work on a group activity. On the board at the front of the room we have a spectrum. On the left end of the spectrum we have “no harm” and on the right end of the spectrum we have “a lot of harm”. We are going to work together to plot where each nicotine product fits on this spectrum. I have pictures of each product that we can stick up and move around based on our conversation. As we talk about where to place each nicotine product on the spectrum please share your thoughts on the harm or lack thereof. We will plot the following:

- a. Cigarettes
- b. E-cigarettes or vapes (tobacco based, like JUUL, Suorin, Fin, NJOY, Blu, e-Go, or Vuse, NOT ones used for marijuana)
- c. Smokeless tobacco (snuff, dip or snus)
- d. Cigars, cigarillos, or little cigars (Black and Milds, Swisher Sweets, Dutch Masters, White Owl, or Phillies Blunts)
- e. Hookah or waterpipe
- f. IQOS (I-Quit-Ordinary-Smoking). IQOS is a tobacco heating system. IQOS heats specially designed heated tobacco units up to 350°C, without combustion, fire, ash, or smoke. This generates a flavorful nicotine-containing vapor, releasing the true taste of heated tobacco, similar to vaping
- g. NRT

[Moderator works with group to plot each of the products]

[Moderator asks the following about each nicotine product during the activity: Have you heard of (insert nicotine product)?]

1. What makes certain tobacco products have different levels of harm?
2. Are there other risks associated with using tobacco products?
 - a. Social?
 - b. Financial?
 - c. Mental Health?
3. Are there benefits to using some of these tobacco products? What are they?

[Theme 3: Perceptions around Quitting]

Now we’re going to talk more about quitting.

1. Does smoking cigarettes seem easier or harder to ‘quit’ than other products?
2. What are the advantages, or good things that might happen if you [quit completely, use NRT to quit, switch completely to IQOS/E-cigarettes]?
3. What are the disadvantages, or good things that might happen if you [quit completely, use NRT to quit, switch completely to IQOS/E-cigarettes]?
4. Who would support you [quitting completely, using NRT to quit, switching completely to IQOS/E-cigarettes]?
5. Who would be against you [quitting completely, using NRT to quit, switching completely to IQOS/E-cigarettes]?

6. What things would make it easy for you to [quit completely, use NRT to quit, switch completely to IQOS/E-cigarettes]?
7. “Using a scale of 1 to 10 (1 being “there’s no way” and 10 being “definitely will do”), how likely are you to try quitting cigarettes in the next 6 months?”
 - a. Reflecting on your response, can you share the number you chose and why?

[Theme 4: Initial Thoughts about Very Low Nicotine Cigarettes]

Now we’re going to switch gears a bit and talk about the FDA and a potential new change to tobacco products. FDA is considering a standard that would lower nicotine levels in combustible tobacco products like cigarettes, cigars, cigarillos, and little cigars.

1. The first thing I’d like to ask you is what do you think a low nicotine cigarette is? Has anyone ever heard of lower-nicotine cigarettes? If so, what have you heard?

[Theme 5: Nicotine Perceptions After Informational Statement]

Now I’d like to share with you a little bit of information about nicotine and get your thoughts about it.

STATEMENT BOARD 1: Nicotine is a highly addictive drug found in the tobacco plant. Most tobacco products, including cigarettes, cigars, pipe tobacco, hookah, dip, and e-cigarettes, contain nicotine. Different tobacco products have different health risks, but using any tobacco product that contains nicotine can lead to addiction. This is because nicotine changes your brain to make you want more of it. Some products, like cigarettes, are designed to deliver nicotine to your brain as fast as possible to keep you smoking once you start, even if you want to stop. Most people know that cigarettes are addictive, but many people do not understand the role of nicotine in cigarette addiction, disease and death. Nicotine is what keeps people smoking, but it is not what makes cigarettes so deadly. Every time you light a cigarette, you create and inhale more than 7,000 chemicals. It is this toxic mix of chemicals that causes serious disease and death in smokers and people exposed to their smoke.

1. First, just tell me your overall thoughts about the text.
2. Is any of this information new to you?
3. Is anything unclear or confusing in the text?
4. In your own words, what is the overall, main message that the text is trying to tell you?
5. How trustworthy do you think this information is?
6. Do you have any other questions about nicotine?

[Theme 6: FDA's Lower Nicotine Standard Perceptions after Informational Statements]

A. Now we're going to switch gears a bit and talk about the FDA and a potential new change to combustible tobacco products. FDA is considering a standard that would lower nicotine levels in combustible tobacco products like cigarettes, cigars, little cigars/cigarillos. Combustible refers to tobacco products that burn to create the smoke that is inhaled, typically cigarettes and cigar products. [Scenario 1]: Specifically, the FDA is considering reducing nicotine levels in all cigarettes; or [Scenario 2]: The FDA is considering reducing nicotine levels in all cigarettes, cigars, AND little cigars/cigarillos. [Moderator will ask questions specific to the scenario in place at the time of the focus group.]

1. Have you heard of this at all?
2. **Scenario 1:** Has anyone ever heard of lower-nicotine cigarettes? When we say lower-nicotine, we do not mean light cigarettes. If so, what have you heard?
Scenario 2: Has anyone ever heard of lower-nicotine cigarettes, cigars or little cigars/cigarillos? When we say lower-nicotine, we do not mean light cigars or little cigars/cigarillos. If so, what have you heard?
3. Do you believe there is a non-addictive level of nicotine?
4. What are your initial thoughts about this proposed change?
5. Why do you think FDA is considering this new change?
Scenario 1: Why do you think FDA is attempting to lower the level of nicotine in cigarettes?
Scenario 2: Why do you think FDA is attempting to lower the level of nicotine in cigarettes, cigars, and little cigars/cigarillos?
6. Does this fit within the role of the FDA?
7. What's the role of FDA?
8. What role does FDA take in regulating tobacco products?
 - a. Officially, the FDA's role is to regulate the sale and production of tobacco products, and to educate the public about its consequences. Is that something you have heard before?
9. How much of a role do you think they take in regulating tobacco products?
 - a. Involved too much?
 - b. Involved too little?
 - c. Involved at just right the amount?
10. Do you see the change to combustible tobacco products as a good or bad thing? Why?
 - a. What good can come from it?
 - b. What bad can come from it?
11. How do you think other people will react?
 - a. Who will react that way? Why?
12. Do you think this would change how parents will speak to kids about smoking?
13. Are there certain smokers where this wouldn't help or make things worse?

B. *Now we'd like to give you a little more information about Very Low Nicotine Cigarettes:*

STATEMENT BOARD 2: Currently, a cigarette has between 10- 14 mgs of nicotine; in contrast a low nicotine content cigarette could have between 0.2 and 0.7mg nicotine. Due to the low amount of nicotine in the cigarette, you cannot get more nicotine from the cigarette by taking a deeper or harder puff.

1. Does this additional information change how you feel about this change to combustible tobacco products?
2. Are there disadvantages to having a low nicotine cigarette?
3. How do you think smoking a low nicotine cigarette would be different from smoking a regular cigarette?
4. What would having a low nicotine cigarette mean for you? Would you do anything differently (e.g., smoke more cigarettes, stop smoking, use a different tobacco product)?

C. Now, let me give you a bit more information about this change and why FDA is considering lowering nicotine in cigarettes.

STATEMENT BOARD 3: The new product standard would lower the amount of nicotine in cigarettes to minimally addictive or non-addictive levels, which will help prevent future generations from becoming addicted to cigarettes. This product standard may also help addicted smokers to quit smoking cigarettes or switch to a potentially less harmful tobacco product.

1. Does this additional information change how you feel about this possible change to combustible tobacco products?
2. Does it change how you feel toward FDA?
3. How do you think lowering the amount of nicotine to a non-addictive level would affect you, if at all?
4. Will this change effectively help people quit? Why or why not?
5. Do you think it would change how people try to quit?
6. Do you think it will change when people attempt to quit smoking?
 - a. Will they hold off on quitting until the change to combustible tobacco products takes place?
 - b. Will it have no impact?
7. Who do you think this will impact the most? Impact the least?

[Current smokers]

1. Do you think it will help you quit? How would it impact your smoking behavior?
 - a. Would it prompt you to switch to a different product?
 - b. Continue to smoke and supplement nicotine by using something else?
2. Have you ever tried to quit?
 - a. Did you use Nicotine Replacement Therapy (gum or patches) or quit smoking medications to quit?
 - b. Did you use an E-cigarette or vaping to quit?
 - c. Have you used any other method of quitting?
3. How many of you have friends who also smoke?
4. Can you share a little bit about situations when you are more likely to smoke?
5. How do you think these situations may change with the new standard?
6. How do you think your friends who also smoke might make it EASIER for you to [quit completely, use NRT to quit, use Chantix to quit, switch completely to IQOS/E-cigarettes]?
7. How do you think your friends who also smoke might make it more DIFFICULT for you to [quit completely, use NRT to quit, use Chantix to quit, switch completely to IQOS/E-cigarettes]?

[Former Smokers]

1. Does this possible change to combustible tobacco products make you rethink cigarettes in any way?
2. Does it change how you think about smoking cigarettes?
3. Would it make you want to smoke again?

D. Now we'd like to ask some questions about what you think using a low nicotine cigarette or low nicotine cigar/little cigar/cigarillo might feel like

1. **[Scenario 1:** What do you imagine a lower nicotine cigarette feeling like? Tasting like?
Scenario 2: What do you imagine lower nicotine cigarettes, cigars or little cigars/cigarillos feeling like? Tasting like?
2. **Scenario 1:** What words would you use to describe a lower nicotine cigarette? (i.e. safer, lighter, etc.)
Scenario 2: What words would you use to describe the cigarette, cigars or little cigar/cigarillos if they were lower nicotine? (i.e. safer, lighter, etc.)
3. **Scenario 1:** Do you think it makes cigarettes safer?
Scenario 2: Do you think it makes cigarettes, cigars or little cigars/cigarillos safer?
4. Do you think people will start smoking more of the 'new' cigarettes to get the nicotine they need?
5. Do you think people will start using other tobacco products to get higher levels of nicotine? If yes, what types of tobacco products?

E. Now, let me give you more information about what smoking a low nicotine cigarette might feel like.

Statement Board 4 (Current Smokers Only) Because you cannot get more nicotine from a cigarette with very low nicotine content by puffing harder or longer, you will not have as much nicotine in your body as you typically would after smoking a cigarette. This may make you feel symptoms of nicotine withdrawal.

1. What is your initial reaction to this information?
2. Is this new information for you? Or, was this something that you were able to infer from the other boards you were shown?
3. Would knowing this change what you do once this product change goes into effect?

F. We have one final question we'd like to ask you about very low nicotine cigarettes

Statement Board 5 (Current Smokers Only): What if I told you that people who use low nicotine cigarettes and also use Nicotine Replacement Therapy (NRT) have a better chance of quitting than people who use NRT alone?

1. What is your initial reaction to this information?
2. Is this new information for you?
3. Would knowing this change what you do once this product change goes into effect?

5. CHECK OUT

Thank you for your time today. We appreciate you sharing your thoughts with us. Make sure that you collect all of your belongings and turn in your folder containing all your completed survey from today. On your way out please feel free to pick up one of the pamphlets if you or someone you know is interested in information of quitting or staying quit.

You can walk back to where you signed in to check out and collect your envelope. Thanks again!

[Have each participant check out by turning in their folder; make sure that all necessary documents are in the folder. Participant will initial the Check Out Form indicating that they have received their envelope. For each discussion group, there should only be one Check Out Form for administrative purposes. Upon completion of group, organize all completed documents. The team should have a complete folder for each participant.]