

Participant ID: \_\_\_\_\_

**RTI/FDA Focus Groups - Youth**  
**Screening Questionnaire**  
*Qualitative Study on Acute Nicotine Toxicity Warnings for E-Liquids*

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**Parent Introduction:**

Hello, this is \_\_\_\_\_ from [FACILITY NAME], a local market research firm. May I please speak to Mr. Ms. \_\_\_\_\_?

(Hello, Mr./Ms. \_\_\_\_\_ this is \_\_\_\_\_ from [FACILITY NAME], a local market research firm. We are working with RTI International, a nonprofit research organization, and the Food and Drug Administration (FDA) on a research study about tobacco products. I want to assure you that we are not from a tobacco company or a company that sells quit-smoking aids. We are recruiting for an upcoming group discussion in which participants will be asked to discuss their knowledge and beliefs related to e-cigarettes. We believe it is particularly important to talk with teens about this issue. Can we speak to \_\_\_\_\_ **[teen's name]** to see if he/she is able to participate in the study? If he/she is able to participate, we will need you to sign a permission form prior to his/her participation in the study. If your child qualifies for the study, I will ask to speak to you again at the end of the call so that I can give you more information. Before I ask to speak with \_\_\_\_\_ **[teen's name]**, I'd like you to ask [him/her] to go sit somewhere that's quiet and private, where no one else can hear [his/her] answers.

IF PARENT QUESTIONS THE NEED FOR PRIVACY, SAY:

We have a rule that everyone who participates in our research is assured privacy to the extent possible, including children.

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**Adolescent Introduction:**

Hello \_\_\_\_\_, my name is \_\_\_\_\_. I'm with [FACILITY NAME]. We're working with RTI International, a nonprofit research organization, and the Food and Drug Administration (FDA) on a research study about tobacco products, and we're interested in talking to teens about e-cigarettes.

We are holding a focus group discussion on [DATE] with approximately 11 other teens like you. The discussion group starts at [TIME] and will last no longer than 60 minutes, as part of the discussion group you will also be asked to fill out a worksheet. For study purposes, the group

discussion will be audio recorded, and other staff will also observe the discussion in person or via video-streaming. In appreciation for your participation, you will be reimbursed for your time, effort, and travel expenses. Participation in the group is completely voluntary, and your responses will be kept private to the extent allowable by law and nothing you say will be shared with your parent or guardian. Would it be OK if I ask you a few questions now in order to see if you are eligible to be in one of the groups? Your answers to these questions will also be kept private to the extent allowable by law.

[YES] Continue. Great! Please find a comfortable place where it is quiet and you can talk by yourself and where you are the only person who can hear my questions and nobody else can hear your answers. Have you found a good place? (Do you want to take a minute to find a place where you can talk by yourself?)

[NO] **THANK AND END CALL**

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Q1. Before I start, how old will you be on [DAY], [DATE]

If  $\leq 12$  → **Thank and end call**

If  $\geq 13$  and  $\leq 16$  → **Continue with Youth Screener**

If = 17 but will be 18 by date of focus group discussion → **Thank and end call**

If = 17 and will still be 17 by date of focus group discussion → **Continue with Youth Screener**

If  $\geq 18$  → **Administer Adult Screener**

[YES] **Thank and end call.**

[NO] **Continue**

Q2. On a scale of 1-5, how comfortable are you understanding and speaking English? 1 is very uncomfortable, 3 is somewhat comfortable, and 5 is very comfortable. \_\_\_\_\_

**[TERMINATE if 3 or lower]**

Q3. On a scale of 1-5, how comfortable are you talking in a group of people your age? 1 is very uncomfortable, 3 is somewhat comfortable, and 5 is very comfortable. \_\_\_\_\_

**[TERMINATE if 3 or lower]**

The next questions are about electronic nicotine products, such as e-cigarettes, e-hookahs, vape pens, mods, vapes, and hookah pens. These products are battery-powered, use liquid nicotine or e-liquid rather than tobacco leaves, and produce vapor instead of smoke. Some common brands include Fin, Juul, NJOY, Blu, e-Go and Vuse.

Q4. Have you ever tried electronic nicotine products (such as e-cigarettes), even just one time?

- Yes **(go to Q5)**
- No **Thank the respondent and terminate.**
- Don't Know **Thank the respondent and terminate.**
- Refused **Thank the respondent and terminate.**

Q5. In the last 60 days, have you used electronic nicotine products (such as e-cigarettes)?

- Yes **(go to Q6)**
- No **Thank the respondent and terminate.**
- Don't Know **Thank the respondent and terminate.**
- Refused **Thank the respondent and terminate.**

Q6. Does the electronic nicotine product you use most often contain nicotine?

- Yes **(go to Q7)**
- No **Thank the respondent and terminate.**
- Don't Know **Hold and check with RTI.**
- Refused **Thank the respondent and terminate.**

Some e-cigarettes can be bought as one-time, disposable products, while others can be bought as re-usable kits with a cartridge or tank system. Some people refill their own e-cigarettes with nicotine fluid, sometimes called “e-liquid” or “e-juice.”

Q7. Does the electronic nicotine product that you used or now use most of the time have a way for you to refill it with e-liquid or e-juice or for you to replace a part such as a cartridge when it runs out of e-liquid or e-juice?

- Yes **(go to Q8)**
- No **Thank the respondent and terminate.**
- Don't Know **Thank the respondent and terminate.**
- Refused **Thank the respondent and terminate.**

Q8. Think about the electronic nicotine product that you use most of the time. What do you do to your electronic nicotine product when it runs out of e-liquid or e-juice?

- You replace a cartridge or cartomizer on your electronic nicotine product  
**Recruit as “Closed ENDS (cartridge) user” and go to Q8.**
- You pour e-liquid or e-juice into the tank of your electronic nicotine product  
**Recruit as “Open ENDS users” and go to Q8.**
- You do both equally as much (replace cartridge or cartomizer and pour e-liquid or

e-juice into the tank of your electronic nicotine product)

**Recruit as either “Closed ENDS (cartridge) users” or as “Open ENDS users” and go to Q8.**

- Don't Know **Thank the respondent and terminate.**  
 Refused **Thank the respondent and terminate.**

Q8. Have you participated in a focus group discussion\* or interview within the past 6 months?

[YES] **Thank and end call.**

[NO] **Continue**

\* If the respondent doesn't know what a “focus group” is or needs clarification, say “a focus group is just another name for a group discussion. It involves a group of individuals who talk about a particular topic such as tobacco use.”

Q9. Are you male or female? (**Recruit equal numbers of males and females**)

- Male [ASSIGN TO MALE GROUP]  
 Female [ASSIGN TO FEMALE GROUP]

Q10. What grade are you in?

- 7<sup>th</sup> grade  
 8<sup>th</sup> grade  
 9<sup>th</sup> grade  
 10<sup>th</sup> grade  
 11<sup>th</sup> grade  
 12<sup>th</sup> grade  
 No longer attending school  
 Other \_\_\_\_\_

Q11. Are you Hispanic, Latino/a, or of Spanish origin?

- No, not of Hispanic, Latino/a, or Spanish origin -- **Skip to Q13**  
 Yes

Q12. Choose all that apply.

- Mexican, Mexican American, Chicano/a  
 Puerto Rican  
 Cuban  
 Another Hispanic, Latino/a, or Spanish origin

Q13. What is your race or ethnicity? Choose all that apply. (**Read list. Recruit a mix.**)

- White  
 Black or African American

- American Indian or Alaska Native
- Asian Indian
- Chinese
- Filipino
- Japanese
- Korean
- Vietnamese
- Other Asian
- Native Hawaiian
- Guamanian or Chamorro
- Samoan
- Other Pacific Islander

From what you told me it looks like you are eligible to participate in the study. I would like to invite you to participate in a group discussion with about 11 other people your age. The discussion will last no more than 60 minutes, will be audio-taped, and observed by the study group. As I said earlier, your participation and everything you say during the discussion will remain private to the extent allowable by law. You will receive \$25 for participating. Are you interested in participating in this study?

- [YES] Continue
- [NO] **Thank and end call**

Because you are under age 18, we will need a parent or guardian's permission for you to be in the focus group. Will you be able to have a parent or a guardian sign a form giving you permission to attend?

- [YES] Continue
- [NO] **Thank and end call**

I'm glad that you will be able to join us! The focus group discussion will take place on **[Day], [Date], at [Time.] at [site location].**

Will you be available to participate at this time?

- [YES] Continue
- [NO] **Thank and end call**

You will need to bring the permission form I will send you with your parent or guardian's signature when you come to the focus group. If you don't have this permission form, you won't be able to participate. I would also like to send you a confirmation letter and directions to the place where we will hold the focus group or group discussion. In order to do so, please verify your mailing address and phone number where you can be reached. We are asking for your contact information only for the purpose of sending you a reminder letter and giving you a call to remind you of the discussion group. We will destroy all contact information when we are finished with the focus group.

We are only inviting a few people, so it is very important that you let us know as soon as possible if for some reason you are unable to attend. Please call **[recruiter]** at **[telephone number]** if this should happen. We look forward to seeing you on **[date]** at **[time]**. If you normally wear corrective lenses, contacts, or glasses to read please remember to have them with you during the focus group.

**Parent Information for Adolescents Scheduled to Participate:**

Now, I would like to give your parent/guardian this information that I just gave you about the focus group or group discussion. I will not share your responses to the questions I asked you.

**Instructions to the Parent/Guardian**

Your child is eligible to participate in the focus group or group discussion and has been scheduled to participate on [DAY], [DATE] at [TIME]. Because your child is under 18, we must get written permission from you in order for him/her to participate. We will be sending you a permission form to review and sign if you consent to your child's participation. If you will be accompanying your child to his/her session, please bring this completed for with you. If you are unable to accompany your child, he/she must bring the signed permission form with him/her in order to participate. Your child will be given \$25 for his/her participation. If you accompany your child, you will receive \$15.

**Paperwork Reduction Act Statement:** The public reporting burden for this information collection has been estimated to average 6 minutes per response to complete the Screener (the time estimated to read and review). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

Participant ID: \_\_\_\_\_



**\*\*NOTE\*\* THIS PAGE MUST BE STORED SEPARATELY FROM THE SCREENER AND FOCUS GROUP DATA. PLEASE DESTROY UPON COMPLETION OF FOCUS GROUP.**

NAME: \_\_\_\_\_

ADDRESS: \_\_\_\_\_

CITY: \_\_\_\_\_

ZIP CODE: \_\_\_\_\_

E-MAIL \_\_\_\_\_

What is the best time to reach you? What is the best telephone number to reach you at that time?

BEST TIME TO BE REACHED: \_\_\_\_\_

BEST PHONE NUMBER: \_\_\_\_\_

Is there another time and number we can try if we miss you?

ALTERNATE TIME: \_\_\_\_\_

ALTERNATE PHONE NUMBER: \_\_\_\_\_

Thank you. That's all the questions I have today. Please try to arrive at least 15 minutes before the starting time. If you have any questions or find that you are unable to attend, please call [facility's phone number] as soon as possible. Thank you again for your time. We look forward to seeing you at [TIME] on [DATE].

**OMB No. 0910-0796**  
**Exp. 06/30/18**

***Read if necessary:***

*contact Jennifer Alexander of RTI at 1 800 334 8571, extension 28219. If you have concerns about how participants are being treated in the study, you may contact RTI's Office of Research Protection toll-free at 1-866-214-2043.*