OMB#	<b># 091</b>	0-0796
Exp.	07/33	1/2021

Uniqu	e ID:	

#### **SCREENER**

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** 

Rationale/Justification	Table 1: Justification for Screener Questions			
Assess if there is an individual in the home that lives in the state where the discussion group is taking place (and within 30 minutes of the discussion group locations)  Termination Point for if the individual in the home does not live in the discussion group state  Assess if the adult is between 19-54 years of age  Termination Point if individual is younger than 19 or older than 54 years old  Belationship with tobacco company, market research company, ad agency, media, or health care and past participation in tobacco research  Termination Point for individuals who work for a tobacco company or have friends or family who work for a tobacco company OR for those who have participated in tobacco research in the past 6 months  7-8 Verify lifetime cigarette use and current cigarette use  Termination Point for individuals who have had fewer than 100 lifetime cigarettes  Verify cigarette quit status  Termination Point if individual quit less than 6 months ago or more than 5 years ago  10-  Assess e-cigarette use status  11  Assess hookah use status  Assess smokeless tobacco use status  Assess cigar product use status  Assess cigar product use status  Gender identity		Rationale/Justification		
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21 Race		Gender identity		
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22	Ethnicity			
	Termination Point for eligible individuals who are not willing to			
	comply with 20, 21, and 22			
23	Sexual orientation			
24	Education level			
25	Employment status			
26	Income			
27	Willing to be audio recorded during focus group as part of this study			
28	Willing to participate in the study			
	Termination Point for eligible individuals who are not willing to			
	comply with 27 or 28			

[Note to the interviewer: Text to read will be shown in plain text. Instructions will be shown in *red italics* and should not be read.]

Hi, my name is \_\_\_\_\_ from [FACILITY NAME], a local market research firm! We are working on a research study about tobacco products and would like to include your opinions. I want to assure you that we are not from a tobacco company or a company that sells quit-smoking aids. We just want to find out what people in this area think about tobacco products and nicotine. If you qualify and participate in the discussion group, you will get \$75 as a token of appreciation for your time.

To see if you qualify for the discussion group, we would like you to answer a few questions. The screening survey asks basic questions about yourself and about tobacco. There are no right or wrong answers, and only the researchers will know how you answer these questions, so please be honest. We will try our best to keep your information private. Still, your information could be shared by accident. Your participation is voluntary and you can stop at any time. There is no direct benefit to you for participating in the screening survey.

We will let you know in the next few days if you were selected. If so, you will be asked to attend a 90-minute discussion group nearby.

If you have any questions about the discussion group, you may contact the project staff through Dawnyéa D. Jackson of Rescue at 202-871-6550 ext 251or djackson@rescueagency.com.

- 1. Do you consent to participate in this short screening survey? [Do NOT read answer choices. Select one response.]
  - a. Yes
  - b. No → [Read and end call; Does NOT Qualify] That's okay. Thank you for your time!

## [ASK ALL]

Great! I have a few questions to make sure you are eligible to participate.

- 2. Do you live in [specific state of research]? [Do NOT read answer choices. Select one response.]
  - a. Yes
  - b. No → Skip to disqualify script [Does NOT Qualify]
  - c. Prefer not to say / Refuse to answer → Skip to disqualify script [Does NOT Qualify]
- 3. What town or city specifically? \_\_\_\_\_ [Open-ended. Write response] [Do NOT disqualify based on response, continue through survey. Participants should live within 30 min driving distance from focus group location.]
- 4. How old are you? \_\_\_\_\_ [Do NOT read answer choices. Record response.]
  - a. 18 years or younger → *Skip to disqualify script* [Does NOT Qualify]
  - b. 19 to 24 years
  - c. 25 to 39 years
  - d. 40 to 54 years
  - e. 55 years or older → Skip to disqualify script [Does NOT Qualify]
  - f. Prefer not to say / Refuse to answer → Skip to disqualify script [Does NOT Qualify]
- 5. In the past five years (including now), have you, a member of your immediate family or a close friend worked for any of the following types of businesses? **SELECT ALL THAT APPLY** 
  - a. An advertising or public relations firm
  - b. A marketing or market research firm or department

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- c. A marketing or market research consultant
- d. Any kind of media company like a TV station or radio station or newspaper
- e. The federal government or a federal government agency
- f. A manufacturer or representative of tobacco

[IF response is YES to f. A manufacturer or representative of tobacco → *Skip to disqualify script - Does NOT Qualify*]

- 6. Have you ever received money or gift cards from a company for sharing your opinions about tobacco in a discussion group, interview, or survey?
  - a. Yes, within the past six months → *Skip to disqualify script [Does NOT Qualify]*
  - b. Yes, more than six months ago
  - c. No, never
  - d. Prefer not to say/ Refuse to answer → *Skip to disqualify script* [Does NOT Qualify]
- 7. Have you smoked at least 100 cigarettes in your ENTIRE LIFE? [Do NOT read answer choices. Record response.]
  - a. Yes
  - b. No → Skip to disqualify script [Does NOT Qualify]
  - c. Prefer not to say/ Refuse to answer → *Skip to disqualify script* [Does NOT Qualify]
- 8. On how many of the PAST 30 DAYS did you smoke a cigarette?

  \_\_\_\_\_[Open-ended. Write response]

  [IF response is 0 → Skip to QUESTION 9]

  [IF response is 1-30 → Skip to QUESTION 10]
- 9. When is the last time that you had a cigarette? \_\_\_\_\_[Open-ended. Write response]

[IF response is less than 6 months  $\rightarrow$  Skip to disqualify script - Does NOT Qualify]

[IF response is 6 months to 5 years & IF Q4 = c or d  $\rightarrow$  Skip to QUESTION 10]

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[IF response is 6 months to 5 years & IF Q4 = b  $\rightarrow$  Skip to disqualify script - Does NOT Qualify] [IF response is more than 5 years ago  $\rightarrow$  Skip to disqualify script - Does NOT Qualify]

[IF QUESTION 4 = b, c, or d AND QUESTION 8 = 1-30  $\rightarrow$  QUALIFY FOR CURRENT SMOKER]

[IF QUESTION 4 = c or d AND QUESTION  $8 = 0 \rightarrow QUALIFY$  FOR FORMER SMOKER]

**FOR CURRENT SMOKERS:** Some people that smoke cigarettes also use other tobacco products. I'm curious about your past or current use of other types of tobacco products.

**FOR FORMER SMOKERS:** Some people that have stopped smoking cigarettes, use nicotine replacement therapies or other tobacco products, so I'm curious about your past or current use of other types of products that contain nicotine.

# [E-Cigarettes]

- 10. Have you EVER used an e-cigarette such as Fin, NJOY, JUUL, Blu, e-Go, Suorin, or Vuse, even one time? [Do NOT read answer choices. Record response.]
  - a. Yes
  - b. No [SKIP TO QUESTION 12]
  - c. Prefer not to say / Refuse to answer

11.On how many of the PAST 30 DAYS did you u	ise an e-cigarette such as
Fin, NJOY, JUUL, Blu, e-Go, Suorin, or Vuse? _	[Open-
ended. Write response]	

# [Hookah]

- 12. Have you EVER smoked tobacco from a hookah or waterpipe even one time? [Do NOT read answer choices. Record response.]
  - a. Yes

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<ul><li>b. No [SKIP TO QUESTION 14]</li><li>c. Prefer not to say / Refuse to answer</li></ul>
13. On how many of the PAST 30 DAYS did you smoke tobacco from a hookah or waterpipe?[Open-ended. Write response]
[Smokeless]
<ul> <li>14. Have you EVER used smokeless tobacco products like chewing tobacco, snuff, dip or snus even one time? [Do NOT read answer choices. Record response.] <ul> <li>a. Yes</li> <li>b. No [SKIP TO QUESTION 16]</li> <li>c. Prefer not to say / Refuse to answer</li> </ul> </li> </ul>
15. On how many of the PAST 30 DAYS did you use smokeless tobacco products like chewing tobacco, snuff, dip or snus?  [Open-ended. Write response]
[Cigar Products]
16. Have you EVER smoked a regular cigar, cigarillo, or little cigar such as Black and Milds, Swisher Sweets, Dutch Masters, White Owl, or Phillies Blunts even one time? This does not include using the paper to smoke marijuana. [Do NOT read answer choices. Record response.] a. Yes b. No → [FORMER SMOKER SKIP TO QUESTION 18] [CURRENT SMOKER SKIP TO QUESTION 20]
c. Prefer not to say / Refuse to answer
17.On how many of the PAST 30 DAYS did you smoke a regular cigar, cigarillo, or little cigar such as Black and Milds, Swisher Sweets, Dutch Masters, White Owl, or Phillies Blunts?[Open-ended.

# [NRT]

Write response]

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<i>answ</i> a. b.	Have you used EVER used any nicotine replacement therapy as the patch, gum, lozenges, inhaler, or nasal spray? [Do NOT reader choices. Record response.]  Yes No [SKIP TO QUESTION 20] Prefer not to say / Refuse to answer
a. b. c. d.	On how many of the PAST 30 DAYS have you used the following ine replacement therapy products? [Open-ended. Write response]  Nicotine patch  Nicotine gum  Nicotine lozenges/tablets  Nicotine inhaler  Nicotine nasal spray
Thanks for questions a [Demogra	-
a. b. c.	What is your current gender? [Read answer choices. Select one onse.] Male Female Other, please specify: Prefer not to say / Refuse to answer → Skip to disqualify script [Does NOT Qualify]
a. b. c. d. e.	What is your race? Choose all that apply. [Read answer choices. select multiple responses among answer choices a-e.]  American Indian and Alaska Native Asian Black / African American Native Hawaiian and Other Pacific Islander White / Caucasian Prefer not to say / Refuse to answer → Skip to disqualify script [Does NOT Qualify]

22. What is your ethnicity? [Do not read answer choices. Select one response.]

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- a. Hispanic or Latino
- b. Not Hispanic or Latino
- c. Prefer not to say / Refuse to answer → Skip to disqualify script [Does NOT Qualify]
- 23. Are you interested in taking part in the discussion group? It will be held at \_\_\_\_\_ (INSERT FACILITY LOCATION)

  a. Yes
  - b. No → Skip to disqualify script [Does NOT Qualify]
- 24. Just so you know, we'd like to audio record the discussion group. Would you be willing to be audio recorded during the discussion group? This is just to help the discussion group leader have a record for their analysis.
  - a. Yes
  - b. No → Skip to disqualify script [Does NOT Qualify]

[IF QUESTION 4 = b, c, or d AND QUESTION 8 = 1-30  $\rightarrow$  QUALIFY FOR CURRENT SMOKER]

[IF QUESTION 4 = c or d AND QUESTIONS 11, 13, 15, 17, or 19 = 1-30  $\rightarrow$  QUALIFY FOR FORMER SMOKER, USE NICOTINE]

[F QUESTION 4 = c or d AND QUESTIONS 11, 13, 15, 17, and 19 = 0 OR QUESTIONS 10, 12, 14, 16, and 18 = NO  $\rightarrow$  QUALIFY FOR FORMER SMOKER, QUIT ALL FORMS OF NICOTINE]

**[Qualify Script - Meets criteria]** - Great, thank you for answering all of our questions. Congrats! You have qualified for one of the discussion groups. We will call you within 48 hours to let you know if you're invited to participate in the discussion group and provide details. If you attend, you'll receive \$75 for your participation! → *Proceed with documenting participant contact information to determine potential focus group scheduling.*Notes for scheduling:

- Recruit 12 participants per focus group for 8 to show.
- All participants must be able to read and write in English.
- Q4: All participants must be 19-54 years old.

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- Q5: All participants must have smoked at least 100 cigarettes in their lifetime.

[Disqualify Script - Does not meet criteria] - Those are all the questions I have for you today. Unfortunately, you don't qualify to participate in our discussion groups this time. Thanks for your time and have a great day!

Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average eight minutes per response to complete the screener (the time estimated to listen and complete). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to <a href="mailto:PRAStaff@fda.hhs.gov">PRAStaff@fda.hhs.gov</a>