

APPENDIX C1

SCREENER

TITLE OF INFORMATION COLLECTION: Creative Concept Testing Designed to Prevent Youth ENDS, Cigarette and Other Tobacco Product Use

Overview:

Recruitment will be conducted by telephone online, or in-person by trained recruiters. Individuals from a diverse range of racial/ethnic groups and socioeconomic backgrounds are eligible to participate.

Recruitment will continue until a representative sample of the required number of participants for each group is obtained. An existing panel participant database, which generates call lists of individuals who have voluntarily signed up to participate in research, will be used to identify individuals interested in research participation. In instances where a sufficient sample is not recruited via panel, in-person recruitment strategies will be used (see protocol for more information).

The research team has demonstrated capability in recruiting individuals from diverse demographic backgrounds. Time necessary to complete this survey is an average of five minutes per response for PARENTS and an average of five minutes per response for YOUTH.

Before recruiting commences, all recruiters will attend training to ensure the screening procedures are administered consistently.

Table 1. Justification for Screener Questions

Item(s)	Rationale/Justification
	Questions for Parent
1-4	Assess if there is a youth in the home between ages of 12 and17 (and will not turn 18 by the time the study takes place) and if legal guardian gives permission for the youth to participate in the study
	Termination Point for if there is not a youth in the home within the appropriate age ranges
5	Assess if youth will be comfortable discussing the project in English
	Termination Point if discomfort with English language
6	Income level of household
7-8	Verify race/ethnicity
9	Relationship with tobacco company, market research company, ad agency, media, or health care
	Termination Point for individuals who work for a tobacco company or have friends or family who work for a tobacco company
10	Ask if legal guardian gives permission for the youth to participate in the study
	Termination Point if parent/guardian does not wish their child to participate
	Questions for Youth
11	Ask if youth has engaged in a discussion group, survey, or interview about tobacco in the last 6 months
	Termination Point for youth who have engaged in a discussion group, survey, or interview about tobacco within the last 6 months
12a-c 13a-c 14a-b 15a-c	Verify [tobacco use] use status. Identify youth who are at risk and experimenters. Exclude youth who are closed to using [tobacco product] as well as established [tobacco product] users.
	Termination Point for youth who do not meet criteria in 12b-c, 13a-c, and 14b
16	Youth willing to be audio recorded during interview as part of this study
17	Youth willing to participate in the study
	Termination Point for eligible youth who are not willing to comply with 16 or 17

18	Collect name, phone number, email address, and home address (for scheduling purposes only; this information will be deleted on a weekly basis)
19	Unique identification number created at this point.

INTRODUCTION:

Hello, my name is _____, and I am calling on behalf of , a professional marketing research company. We are currently inviting people to participate in a focus group. We're hoping there may be someone in your household who may qualify. Please be assured that this research does not involve sales of any kind, we are just interested in your opinions. The focus group will be held on _____ and will last approximately **95 minutes**. Those who participate will receive a \$25 prepaid debit card as a thank you for their time. A parent or guardian of a participant will also receive a \$25 prepaid debit card as a thank you for their time. May I please ask you a few questions to see if someone in your household qualifies for this study?

SECTION 1: READ TO PARENT

1. Do you have any children currently living in the household?
 1. Yes
 2. No **TERMINATE**
2. Please tell me the gender, age, and grade level of the children living in the home.

CHILD 1: (GENDER) _____ (AGE) _____ (GRADE) _____
CHILD 2: (GENDER) _____ (AGE) _____ (GRADE) _____
CHILD 3: (GENDER) _____ (AGE) _____ (GRADE) _____
CHILD 4: (GENDER) _____ (AGE) _____ (GRADE) _____
- 2a. If child is 17. Will your child turn 18 by X date: TERMINATE if child will turn 18 before the focus group will take place.

IF NO CHILDREN BETWEEN 12 AND 17 IN HOUSEHOLD – THANK AND TERMINATE

**RESPONDENTS MUST BE BETWEEN THE AGES OF 12 AND 17
GROUPS TO BE SEPARATED BY AGE & SELF-REPORTED TOBACCO USE**

3. Are you the parent or legal guardian of the children living in the household?
 1. Yes **GO TO SECTION 2**
 2. No
4. Can I speak to the parent or legal guardian of the children?
 1. Yes
 2. No **IF NOT HOME, FIND OUT WHEN THEY WILL BE HOME AND CALL BACK.**

READ TO PARENT: Thanks for the information. Your children may be eligible to participate in our focus groups. The focus group is a research study to understand what youth think about different kinds of message to stop and reduce youth e-cigarette use. As I mentioned before, the focus group will be held on _____ and will last approximately **95 minutes**. Those who participate will receive a \$25 gift card as a thank you for their time and their parent or guardian will also receive a \$25 gift card.

THERE WOULD BE NO ATTEMPT TO SELL YOU OR YOUR CHILD ANYTHING AS ALL OF THE INFORMATION GATHERED IN THE FOCUS GROUP WILL BE USED FOR RESEARCH PURPOSES ONLY AND KEPT PRIVATE TO THE EXTENT ALLOWABLE BY LAW.

Let me ask you a few more questions please.

SECTION 2:

READ TO PARENT AND ASK THEM TO ANSWER THE FOLLOWING QUESTIONS ON BEHALF OF THEIR CHILD

5. Will your child be comfortable discussing this project in English?

Yes **CONTINUE**
No **TERMINATE**

6. We are hoping to speak to people from households who represent various income levels. Which best describes your total annual household income?

Less than \$30,000	<input type="checkbox"/>	CONTINUE
\$30,000 - \$54,999	<input type="checkbox"/>	CONTINUE
\$55,000 - \$74,999	<input type="checkbox"/>	CONTINUE
\$75,000 - \$99,999	<input type="checkbox"/>	CONTINUE
\$100,000 or more	<input type="checkbox"/>	CONTINUE
Don't Know/Prefer Not to Answer	<input type="checkbox"/>	CONTINUE

We are hoping to speak to people from households that represent various races and/or ethnicities.

7. Would you consider your child Hispanic or Latino?

Yes **CONTINUE**
No **CONTINUE**

8. What race or races best describes your child? (You can choose one answer or more than one answer)

American Indian or Alaska Native	<input type="checkbox"/>	1 CONTINUE
Asian	<input type="checkbox"/>	2 CONTINUE
Black or African American	<input type="checkbox"/>	3 CONTINUE
Native Hawaiian or Other Pacific Islander	<input type="checkbox"/>	4 CONTINUE
White	<input type="checkbox"/>	5 CONTINUE

9. Do you, your child, or any member of your immediate family or a close friend work for...? (Select all that apply)

- A. A market research company
- B. A tobacco company (manufacturer or importer of tobacco products) **TERMINATE**
- C. An advertising agency or public relations firm
- D. The media (TV/radio/newspapers/magazines)
- E. A health care professional (doctor, nurse, pharmacist, dietitian, etc.)
- F. None of these

10. If your son/daughter qualifies, do you give permission for him/her to take part in the focus group?

1. Yes
2. No **TERMINATE**

TO PARENT/GUARDIAN:

I would now like to speak with your son/daughter to ask him/her a few questions about teens' opinions on smoking. May I please speak with him/her now? **IF NOT HOME, FIND OUT WHEN THEY WILL BE HOME AND CALL BACK.**

TO YOUTH:

ONCE RESPONDENT IS ON THE PHONE READ:

Hello, my name is _____, and I am calling on behalf of YPulse, a professional marketing research company. I just spoke with your mom/dad/guardian and she/he said it would be okay if I ask you a few questions to see if you qualify to take part in a focus group, which is a gathering of other kids your age to talk and share opinions on important topics. We're hoping that you may qualify. Please be assured that this research does not involve sales of any kind, we are just interested in your opinions. The focus group will be held on _____ and will last approximately **95 minutes**. Those who participate will receive a \$25 Visa prepaid debit card as a thank you for their time. May I please ask you a few questions?

11. 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 **TERMINATE**
- B. Yes, more than six months ago
- C. No
- D. I'm not sure

TOBACCO EXPERIMENTER QUESTIONS:

Switching gears now, I'd like to ask you a few questions about vaping, or using an e-cigarette; sometimes these products are also called vapes, vape pens, hookah pens, personal vaporizers and mods, e-cigars, pipes, or e-hookahs. I will be calling the products e-cigarettes from now on. I will also use the term "vaping" to describe using these products. Please know that when I ask about "vaping" I am referring to using vapes or vaping only, not smoking traditional cigarettes or any other substance.

12a. Have you ever tried a [TOBACCO PRODUCT] even one or two puffs?

Yes **CONTINUE**
No **SKIP TO Q13 FOR E-CIGARETTE SUSCEPTIBILITY/AT-RISK QUESTIONS**

12b. For this question, do not tell me your answer, just tell me the letter that corresponds to each answer I read or say stop when I say your answer. About how many times have you used a [cigarette/e-cigarette/cigar/little cigar/cigarillo/hookah/smokeless tobacco] in your entire life? Your best guess is fine. Please just say a number and do not mention the word e-cigarette.

1	A	CONTINUE TO Q12C
2 to 5	B	
6 to 15	C	
16 to 25	D	
26 to 49	E	
50 to 99	F	
100 or more	G	

12c. For this question, do not tell me your answer, just tell me the letter that corresponds to each answer I read or say stop when I say your answer. During the past 30 days, on how many days did you use a [cigarette/e-cigarette/cigar/little cigar/cigarillo/hookah/smokeless tobacco]?

0 days	A	[QUALIFY FOR TOBACCO EXPERIMENTER/DUAL EXPERIMENTER GROUP]
1 or 2 days	B	
3 to 5 days	C	
6 to 9 days	D	
10 to 16 days	E	
16 to 20 days	F	
21 to 29 days	G	
All 30 days	H	

[Tobacco Product] SUSCEPTIBILITY QUESTIONS:

For all these questions, do not tell me your answer – just tell me the letter that corresponds to each answer I read or say stop when I say your answer.

13a. Do you think you will try a [cigarette/e-cigarette/cigar/little cigar/cigarillo/hookah/smokeless tobacco] soon?

Definitely yes	4
Probably yes	3
Probably not	2
Definitely not	1

13b. Do you think you will try a [cigarette/e-cigarette/cigar/little cigar/cigarillo/hookah/smokeless tobacco] at any time in the next year?

Definitely yes	4
Probably yes	3
Probably not	2
Definitely not	1

13c. If one of your best friends were to offer you a [cigarette/e-cigarette/cigar/little cigar/cigarillo/hookah/smokeless tobacco], would you try it?

Definitely yes	4
Probably yes	3
Probably not	2
Definitely not	1

[IF Q13a and Q13b and Q13c = 1, EXCLUDE FROM SUSCEPTIBLE/AT-RISK TOBACCO GROUP AND TERMINATE]

[ALL ELSE QUALIFY FOR AT-RISK FOR TOBACCO USE GROUP]

INVITATION:

Thank you for your responses! We would like to invite you to participate in this study.

FOCUS GROUP:

The face-to-face focus group is where you will be joined by a group of people your age. The focus group would be taking place at _____ in the evening. The group will last approximately 95 minutes or a little more than 1.5 hours. We are inviting only a small number of individuals to be a part of this research project, so your opinions and participation are very important to us. You will receive a \$25 gift card for your participation. Your parent or guardian will also receive a \$25 gift card.

16. We would like to audio record the focus groups. Would you be willing to be audio recorded during the focus group as part of this study?

1. Yes **CONTINUE**
2. No **TERMINATE**

17. Do you consent to taking part in the focus group at _____ (**INSERT FACILITY LOCATION**)?

1. Yes **CONTINUE**
2. No **TERMINATE**

RECRUITER: PLEASE ENSURE RESPONDENT LIVES WITHIN 45 MINUTES OF THE FACILITY.

We will call you to tell you the date and time of the focus groups. It will be on one of these days in the afternoon or evening: (**INSERT DATES**). Because we are only inviting a limited number of people to take part in this study, it is vital that everyone participates. However, if for any reason you are unable to participate in this study or have any further questions about this study, please call _____.

18. Because we need to call you back with the focus group date and time, please confirm your contact details. [Refer to Screener Contact Sheet]

19. Unique identification number ID: []

Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average five minutes for parents and five minutes for youth (the time estimated to read and complete). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRASstaff@fda.hhs.gov