**OMB# 0910-0674**

**Exp. 03/31/2016**

**Quantitative Study of Youth Reactions to Rough-Cut Advertising Designed to Prevent Smokeless Tobacco Use Among Rural Youth**

**OVERVIEW**

Survey participants will be recruited during lunch, in the hallways between classes, or at another time designated by the appropriate local administrator. There will be 2-4 recruiters per school on campus to administer the electronic or paper screeners and the youth assent form via paper or tablet, and provide instructions and materials for parental consent.

Before recruiting commences, all recruiters will attend training to ensure the screening procedures are administered consistently. All recruiters will wear a lanyard nametag with the For Marsh Group and Michael Cohen Group logos.

Rationale/Justification for Screener Items:

|  |  |
| --- | --- |
| **Item(s)** | **Rationale/Justification** |
| 1 | Initial agreement to participate in the research study |
| ***Termination Point for students who do not wish to participate.*** | |
| 2 | Verify age. Ensure all participants are between the ages of 12-17. |
| 3 | Verify gender. Ensure all participants are male. |
| 4a-b | Verify race/ethnicity. Ensure all participants self-identify as White (non-Hispanic). |
| ***Termination Point for students who do not meet criteria in 2, 3, and 4a-b.*** | |
| 5  6 | Distractor questions. |
| 7  8  9a-d | Verify smokeless tobacco status. Identify students who are at-risk or experimenters. Exclude students who (a) are closed to using smokeless tobacco (b) have used smokeless tobacco more than 100 times in their entire lifetime or |
| ***Termination Point for students who do not meet criteria in 7,8, and 9a-d.*** | |
| 10-11 | Student name and 1st period class (obtained for scheduling purposes only) |
| 12-13 | Student agreement to either return a signed Parent/Guardian consent form to study staff the next day (q12) or deliver a Parent/Guardian notification that day (q13). |
| ***Termination Point for eligible students who are not willing to comply with 12 (or 13).*** | |

**Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 5 minutes per response to complete the screener (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 PRAStaff@fda.hhs.gov**

**RECRUITER SCRIPT**

Hi! I’m [NAME]. I work for a research company (Michael Cohen Group – point to logo on nametag) and we are at your school this week conducting surveys. Surveys are a type of research used to gather opinions on a specific topic. If you are interested, qualify and participate, you will receive $20. The surveys will take place during either the regular school day or before or after school. They will last about 20 minutes. We will show you some advertisements for a public health campaign, and all you have to do is tell us what you think. There are no wrong answers – we just want your opinion.

If you are interested, all you have to do now is answer a few questions on my tablet [clipboard] to see if you are eligible to participate. If you don’t want to participate, or if we determine that you are not eligible to participate, there are no consequences to you and it will have no effect on your grades or how you teachers or staff at your school think of you. It’s completely your choice and we are prohibited from sharing any information you provide to us during the screening process or in the surveys with your parent(s)/guardian(s), teachers, or anyone else outside of the research team.

Do you want to complete the screener to see if you are eligible to participate? [If yes, continue. If no, thank and move on.]

***Note-*** *The screener will be programmed as an electronic survey that students will complete via tablet during the recruitment period. In some cases we may employ paper screeners should the need arise.*

**Please answer the following questions.**

1. We will be conducting surveys at your school on <<**DATE/TIME/LOCATION**>>.

Would you be interested in participating in our survey?

Yes **CONTINUE to Q2**

No thanks **TERMINATE**

|  |  |
| --- | --- |
| TERMINATION  CRITERIA | Terminate if Q1= “No thanks” |
| TERMINATION  LANGUAGE [shown on separate screen] | Thank you for your time. Please return this [clipboard/tablet] back to the study staff. |

2. How old are you?

Under 12

12

13

14

15

16

17

18 or Over

3. What is your gender?

Male

Female

4a. Are you Hispanic or Latino?

Yes

No

4b. Which of the following best describes your race? (Mark all that apply)

American Indian or Alaska Native

Asian

Black or African American

Native Hawaiian or Pacific Islander

White

|  |  |
| --- | --- |
| TERMINATION CRITERIA | Terminate if Q4b ≠ “White”  **[Programmer: white + any other race/ethnicity should continue to Q5]** |
| TERMINATION LANGUAGE [shown on separate screen] | Thank you for your interest in participating in this study. Unfortunately, based on the responses you provided, you do not meet the specifications we are looking for to complete this study. Please return this [clipboard/tablet] back to the study staff. |

5. During the past 7 days, did you drink a can, bottle, or glass of soda or pop, such as Coke, Pepsi, or Sprite? (Do not count diet soda or diet pop.)

Yes **CONTINUE TO Q6**

No **SKIP to Q7**

**[Programmer: ONLY ASK Q6 IF Q5=“Yes”]**

6. During the past 7 days, how many times did you drink a can, bottle, or glass of soda or pop, such as Coke, Pepsi, or Sprite? Your best guess is fine. (Do not count diet soda or diet pop.)

I did not drink soda or pop during the past 7 days

1 to 3 times during the past 7 days

4 to 6 times during the past 7 days

1 time per day

2 times per day

3 times per day

4 times or more per day

7. Have you ever tried smokeless tobacco (such as snus pouches, moist snuff, dip, spit, or chewing tobacco)?

Yes **CONTINUE TO Q8**

No **SKIP to Q9a**

**[Programmer: ONLY ASK Q9 IF Q8=“Yes”]**

8. How many times have you used chewing tobacco snuff or dip in your entire lifetime?

Would you say…

Less than 20 times

20 times, but less than 50 times

50 times, but less than 100 times

More than 100 times **TERMINATE**

|  |  |
| --- | --- |
| TERMINATION CRITERIA | Terminate if:  Q7=“Yes” ***and*** Q8=“More than 100 times” |
| TERMINATION LANGUAGE [shown on separate screen] | Thank you for your interest in participating in this study. Unfortunately,  based on the responses you provided, you do not meet the specifications we are looking for to complete this study. Please return this [clipboard/tablet] back to the study staff. |

9a. Do you think you will use chewing tobacco, snuff or dip in the future?

Definitely yes Probably yes Probably not Definitely not

9b. Do you think you will use chewing tobacco, snuff or dip in the next year?

Would you say…

Definitely yes Probably yes Probably not Definitely not

9c. If one of your best friends were to offer you chewing tobacco, snuff or dip, would you use it? Would you say…

Definitely yes Probably yes Probably not Definitely not

9d. Have you ever been curious about using smokeless tobacco?

Very curious

Somewhat curious

A little curious

Not at all curious

|  |  |
| --- | --- |
| TERMINATION  CRITERIA | Terminate if:  Q7=“No” ***and*** Q9a/Q9b/Q9c=“Definitely Not” ***and*** Q9d=”Not at all curious” |
| TERMINATION LANGUAGE [shown on separate screen] | Thank you for your interest in participating in this study. Unfortunately,  based on the responses you provided, you do not meet the specifications we are looking for to complete this study. Please return this [clipboard/tablet] back to the study staff. |

Thanks! Based on the responses you provided, you meet the specifications for this study.

10. Please enter your first name and last initial (e.g., James M.):

11. Please enter the last name and topic of your 1st period class on Mondays (e.g. 10th grade Chemistry:

**[Programmer: SHOW ‘NEXT’ BUTTON TO CONTINUE TO YOUTH ASSENT FORM]**

**[Programmer: INSERT PARTICIPANT YOUTH ASSENT FORM HERE]**

**[Programmer: AFTER PARTICIPANT COMPLETES & SUBMITS ASSENT FORM**

**SHOW THE FOLLOWING]**

You are almost set!

**[Programmer: SHOW Q11 IF Q2=“12” *OR* SIGNED PARENT/GUARDIAN CONSENT IS REQUIRED BY SCHOOL]**

12. You must obtain permission from a parent/guardian to participate in this study. Do you agree to take home a “Parent/Guardian Consent Form” today and (if your parent/guardian approves) bring back a signed copy to the research staff tomorrow?

Yes

No **TERMINATE** [see language above]

**[Programmer: SHOW Q12 IF Q2>“12” *AND* SCHOOL HAS AGREED TO PASSIVE PARENT/GUARDIAN CONSENT PROCEDURES]**

13. We are required to notify your parent/guardian about this study before you participate.

Do you agree to deliver a “Parent/Guardian Notification” to your parent/guardian today when you get home from school?

Yes

No **TERMINATE** [see language above]

**[Programmer: SHOW NEW SCREEN]**

Congratulations, you are eligible to participate in this study!

We look forward to hearing your opinions in one of the upcoming surveys. In return for your participation, you will receive a $20 pre-paid gift card.

Remember, to participate you must [**IF Q12=VALID RESPONSE THEN INSERT:** “return a signed parent/guardian consent form to one of the research staff tomorrow”; **IF Q12=VALID REPONSE THEN INSERT:** “deliver the Parent/Guardian Notification to your parent/guardian tonight”].

At this time, please return this [clipboard/tablet] back to the study staff and you will receive a paper copy of the [Parent/Guardian Consent Form/Parent/Guardian Notification] and a reminder card with the scheduled date, time and location of your survey.