|  |
| --- |
| *[Display at bottom of Introduction screen]*Paperwork Reduction Act Statement:  According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number.  The valid OMB control number for this information collection is 0910-0796.  The time required to complete this information collection is estimated to average 3 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.  Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRASTAFF@fda.hhs.gov. |

U.S. Food and Drug Administration
Center for Tobacco Products

[Text within brackets will not show to participants]

[Appendix B:
Recruitment Screener]

Menthol User Audience Research

*In-depth Interview (IDI) Web Screener*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *Note: This screener is to identify (n=24) eligible participants in 1) localities with a menthol ban (n=12) and 2) localities without a menthol ban (n=12). Localities with a menthol ban currently in effect in the United States include* [*Massachusetts*](https://www.mass.gov/guides/2019-tobacco-control-law) *(sales and on-site consumption restricted to licensed smoking bars effective 6/1/20),* [*San Francisco*](https://www.sfdph.org/dph/files/EHSdocs/Tobacco/Flavored_Tobacco_FAQ.pdf) *(sales ban enforced 1/1/2019), and* [*Minneapolis/St. Paul*](http://clearwaymn.org/wp-content/uploads/2019/02/Menthol-Case-Studies-Minneapolis-St.-Paul-Duluth-FINAL-2.pdf) *(sales restricted to select tobacco products shops and liquor stores 8/1/2018 and 11/1/2018). Participants must meet the core eligibility criteria in Table 1.* Table 1. Core Participant Eligibility Criteria

|  |  |
| --- | --- |
| **Category** | **Criteria** |
| Inclusion Criteria (Localities with a menthol ban) | * Established cigarette smokers (more than 100 lifetime cigarettes) who frequently (20-30 days per month) or occasionally (1-19 days per month) smoked menthol cigarettes (brand preference menthol or both) prior to ban implementation.
* Live in locality with a menthol ban (Massachusetts, San Francisco, Minneapolis/St. Paul)
* Speak English
* Aged 21 or older
* Reside in United States
 |
| Inclusion Criteria (Localities without a menthol ban) | * Established tobacco users (more than 100 cigarettes in lifetime) who frequently (20-30 days per month) or occasionally (1-19 days per month) smoke menthol cigarettes (brand preference menthol or both)
* Lives in a locality without a menthol ban (anywhere except Massachusetts, San Francisco, Minneapolis/St. Paul)
* Speak English
* Aged 21 or older
* Reside in United States
 |
| Exclusion Criteria | * Participated in a focus group or interview in the past 6 months
* Currently employed by the federal government or a tobacco company
 |

*To ensure our sample reflects the population of people who use menthol cigarettes, participants will be recruited based on the priority enrollment characteristics in Table 2.*Table 2. Priority Enrollment Characteristics

|  |  |
| --- | --- |
| **Category** | **Characteristic to prioritize when recruiting** |
| Race | * Black / African American
 |
| Ethnicity | * Hispanic
 |
| Quit status [Ban]Quit Intention [No Ban] | * Former cigarette smoker
* Plan to quit in 6 months or sooner
 |
| Gender Identity | * Female
* Transgender / Non-binary
 |
| Age | * Young adults aged 21 - 30
 |
| Sexual Orientation  | * Bisexual
* Gay or lesbian
* Pansexual or omnisexual
* Queer
* Asexual
 |
| Socioeconomic Status | * Not enough money to get by
* Just enough money to get by
 |
| Geography | * Four U.S. Census regions
 |
| Urbanicity/Rurality | * Urban
* Rural
* Suburban
 |

 |

**INTRODUCTION**

Thank you for your interest in this study sponsored by the U.S. Food and Drug Administration (FDA). Please answer the following questions to see if you are eligible to participate in an online interview about menthol cigarette use.

The interview will be led by a researcher through an online video platform. If you’re eligible for the interview, you can participate from home using a computer, tablet, or smartphone. The discussion will last an average of 90 minutes, and you will receive a $75 token of appreciation for participating.

To determine your eligibility for this study, we need to ask you a few questions. These questions should take no more than 3 minutes.

**[WILLING]** Are you willing to answer a few questions to see if you are qualified to participate in the study?

1. Yes
2. No

[IF WILLING = 1, CONTINUE]

[IF WILLING = 2, TERMINATE AND DISPLAY: “Thank you for your time.”]

[NOTE: PLEASE USE THE FOLLOWING TERMINATION LANGUAGE IMMEDIATELY AFTER ANY RESPONSE THAT LEADS TO THE OPTION TERMINATE: “Thank you answering these questions. Unfortunately, you are not eligible to participate in this interview. Thank you for your time.”]

[ASK ALL]

**[AGE]** What is your age?

 \_\_\_ years [NUMERIC, WHOLE NUMBERS ONLY. ALLOW 1-99]

[TERMINATE IF AGE < 21]

[ASK ALL]

**[ZIP\_1]** What is your current 5-digit zip code?

 \_ \_ \_ \_ \_ [NUMERIC, VALIDATE 5-DIGIT ZIP CODE FORMAT]

[PROGRAMMER: CREATE **AREA\_1** VARIABLE FROM ZIP\_1 WITH THE FOLLOWING CATEGORIES:

1. MASSACHUSETTS
2. SAN FRANCISCO
3. MINNEAPOLIS/ST. PAUL
4. ANY OTHER AREA

[ASK IF AREA\_1 = MASSACHUSETTS OR SAN FRANCISCO OR MINNEAPOLIS/ST. PAUL]

**[ZIP\_2]** What was your 5-digit zip code at the beginning of [IF AREA\_1 = MASSACHUSETTS: “2020” OR IF AREA\_1 = SAN FRANCISCO: “2019” OR IF AREA\_1 = MINNEAPOLIS/ST. PAUL: “2018”]?

1. Same as current
2. Other, specify: \_ \_ \_ \_ \_ [NUMERIC, VALIDATE 5-DIGIT ZIP CODE FORMAT]
3. Don’t know [TERMINATE]

[PROGRAMMER: CREATE **AREA\_2** VARIABLE FROM ZIP\_2 WITH THE FOLLOWING CATEGORIES:

1. MASSACHUSETTS
2. SAN FRANCISCO
3. MINNEAPOLIS/ST. PAUL
4. ANY OTHER AREA

[TERMINATE IF AREA\_1 ≠ AREA\_2]

[ASK ALL]

Have you ever worked for…? [MULTIPLE SELECT]

**[WRK\_TOB]** A tobacco company [TERMINATE]

**[WRK\_FED]** The U.S. federal government (not including as a member of the military) [TERMINATE]

**[WRK\_NON]** None of the above

[ASK ALL]

**[FG]** When was the last time you participated in an interview or a focus group for a research study?

1. Within the last 6 months [TERMINATE]
2. 7 months to less than 2 years ago
3. 2 years to less than 3 years ago
4. 3 years ago or more
5. Never
6. Don't know [TERMINATE]

[ASK ALL]

**[AUDIO]** Are you okay with being audio recorded during the interview?

1. Yes
2. No [TERMINATE]

[ASK ALL]

**[SMK\_100]** Have you smoked at least 100 cigarettes in your entire life?

1. Yes
2. No [TERMINATE]

[ASK IF AREA\_2 = MASSACHUSETTS OR SAN FRANCISCO OR MINNEAPOLIS/ST. PAUL]

**[SMK\_30DB]** In the year before [IF AREA\_2 = MASSACHUSETTS: “June 2020” OR IF AREA\_2 = SAN FRANCISCO: “January 2019” OR IF AREA\_2 = MINNEAPOLIS/ST. PAUL: “August 2018”], about how many days per month did you smoke? *(Your best guess is fine)*

1. 1-19
2. 20+
3. 0 [TERMINATE]

[ASK IF AREA\_2 = MASSACHUSETTS OR SAN FRANCISCO OR MINNEAPOLIS/ST. PAUL AND (SMK\_30DB = 1 OR 2)]

**[MENTH\_B]** In the year before [IF AREA\_2 = MASSACHUSETTS: “June 2020” OR IF AREA\_2 = SAN FRANCISCO: “January 2019” OR IF AREA\_2 = MINNEAPOLIS/ST. PAUL: “August 2018”], was your usual cigarette brand menthol or non-menthol?

1. Menthol
2. Non-menthol [TERMINATE]
3. Both
4. No usual brand [TERMINATE]

[ASK ALL]

**[SMK\_30D]** During the past 30 days, on how many days did you smoke cigarettes?

 \_\_\_\_ [NUMERIC, WHOLE NUMBERS ONLY. ALLOW 0-30]

[ASK IF SMK\_30D = 1-30]

**[MENTH\_NB]** Is your current usual cigarette brand menthol or non-menthol?

1. Menthol
2. Non-menthol
3. Both
4. No usual brand

[TERMINATE IF AREA\_1 = ANY OTHER AREA AND MENTH\_NB = 2 OR 4]

[GENERATE VARIABLE **SAMPLE** WITH THE FOLLOWING VALUES:

* IF (AREA\_2 = MASSACHUSETTS OR SAN FRANCISCO OR MINNEAPOLIS/ST. PAUL) AND (MENTH\_B = 1 OR 3), DESIGNATE AS SAMPLE GROUP 1 (BAN)
* IF AREA\_1 = ANY OTHER AREA AND SMK\_30D = 1-30 AND (MENTH\_NB = 1 OR 3), DESIGNATE AS SAMPLE GROUP 2 (NO BAN)]

[IF CRITERIA IS NOT MET FOR SAMPLE GROUP 1 (BAN) OR 2 (NO BAN), TERMINATE]

[ASK IF SMK\_30D = 1-30]

**[QUIT]** Do you plan to quit smoking cigarettes for good...

1. In the next 7 days
2. In the next 30 days
3. In the next 3 months
4. In the next 6 months
5. In the next year
6. More than one year from now
7. I do not plan to quit smoking cigarettes for good
8. Not sure/uncertain

[ASK ALL]

**[EDUC]** What is the highest level of education you have completed?

1. Less than high school diploma
2. High school graduate or GED
3. Some college
4. Technical or associates degree (2-year)
5. 4-year degree
6. Graduate or professional degree

[ASK ALL]

**[RACE]** Which of these best describes your racial and/or ethnic background? You may select more than one.

1. American Indian or Alaska Native
2. Asian
3. Black or African American  ​
4. Hispanic, Latin(a/o), Latinx
5. Pacific Islander or Native Hawaiian
6. White
7. Prefer not to answer [EXCLUSIVE]

[ASK ALL]

**[INC]** Considering your own income and the income from any other people who help you, how much money do you have?

1. Not enough money to get by
2. Just enough money to get by
3. Enough to only worry about money for fun or extras
4. Never have to worry about money
5. Prefer not to answer

[ASK ALL]

**[EMPLOY]** Are you currently…? Please select the option that best describes you.

1. Employed for wages
2. Self-employed
3. Out of work for 1 year or more
4. Out of work for less than 1 year
5. A homemaker
6. A student
7. Retired
8. Unable to work

[ASK ALL]

**[URBAN]** Would you consider the area that you live in to be urban, rural, or suburban?

1. Urban
2. Rural
3. Suburban

[ASK ALL]

**[SEXOR]** Which of the following best represents how you think of yourself? Select all that apply.

1. Straight or heterosexual
2. Bisexual
3. Gay or lesbian
4. Pansexual
5. Queer
6. Asexual
7. I am not sure yet
8. Something else
9. Prefer not to answer [EXCLUSIVE]

[ASK ALL]

**[GENDID]** What is your gender identity? Select all that apply.

1. Woman
2. Man
3. Transgender woman
4. Transgender man
5. Non-binary or gender non-conforming
6. Another gender identity
7. Prefer not to answer [EXCLUSIVE]

[ASK ALL]

**[MARITAL]** What is your marital status?

1. Married
2. Widowed
3. Divorced
4. Separated
5. Never married

[ASK ALL]

Over the last 2 weeks, how often have you been bothered by the following problems?

**[NERVE]** Feeling nervous, anxious, or on edge

1. Not at all
2. Several days
3. More than half the days
4. Nearly every day

**[WORRY]** Not being able to stop or control worrying

1. Not at all
2. Several days
3. More than half the days
4. Nearly every day

**[INTEREST]** Having little interest or pleasure in doing things

1. Not at all
2. Several days
3. More than half the days
4. Nearly every day

**[DOWN]** Feeling down, depressed or hopeless

1. Not at all
2. Several days
3. More than half the days
4. Nearly every day

**CLOSING SCRIPTS**

DECLINED TO BEGIN SCREENER: “Thank you for your time.”

COMPLETED SCREENER: “You have completed the online screener. One of our recruiters will be in touch if you qualify for this study. Thank you for your time. If you have any questions, you can contact us at [VENDOR PHONE NUMBER] or [VENDOR EMAIL].”