FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF COLLECTION OF QUALITATIVE DATA ON TOBACCO PRODUCTS AND COMMUNICATIONS (0910-0796)

TITLE OF INFORMATION COLLECTION: Menthol User Audience Research

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

FDA Center for Tobacco Products (CTP) is considering a potential product standard that would prohibit the sale of menthol cigarettes The potential federal menthol ban provides an important opportunity to promote smoking cessation or other less harmful behaviors, particularly among communities of color, low-income populations, young adults, and LGBTQ+ individuals who are disproportionately impacted by menthol cigarette smoking. However, gaps exist in our understanding of segments of adult menthol cigarette users and communication strategies to support menthol cigarette smokers in less harmful behaviors (such as cessation or moving down the harm continuum).

The purpose of this information collection is to examine demographic, sociocultural, psychographic, and behavioral characteristics of adult menthol cigarette users to identify segments that are most likely to adopt less harmful behaviors in response to targeted messaging; and to identify communication strategies to support menthol smokers in less harmful behaviors.

In depth interviews will be conducted and will focus on the following sections:

1. General Psychographics – The purpose of this section is to understand participants' typical behaviors, interest, work, and goals.
2. Tobacco Use History – The purpose of this section is to gain a deep understanding of each participant's personal experience with menthol cigarettes and, if applicable, other tobacco products and experiences with quitting.
3. Tobacco Use Environment and Sociocultural Factors – The purpose of this section is to understand how tobacco interacts with participants' lives, including tobacco/menthol cigarette norms, acceptability, family use, and perceptions of others.
4. Summary/Messaging Territories – The purpose of this section is to understand which harms, motivators, and facilitators to quitting resonate most with participants. This section will inform message framing.

Results from this information collection will provide valuable insights into target audience segmentation and messaging opportunities to inform FDA CTP health communication efforts to support menthol smokers in less harmful behaviors.

2. **Intended use of information:**

The objective of this research is to understand audiences of adults who use menthol cigarettes and how to support menthol cigarette users in less harmful behaviors. The results of this information collection will inform target audience segmentation, messaging opportunities,

and, ultimately, the development of health communication materials. The list below illustrates a range of purposes and uses for the proposed information collection:

- Examine the demographic, sociocultural, psychographic, and behavioral characteristics of adults who use menthol cigarettes to identify segments that are most likely to adopt less harmful behaviors in response to targeted messaging.
- Identify characteristics/segments of adult menthol cigarette users that are more likely to quit or switch to a lower harm product.

Identify messaging opportunities and communication strategies to support menthol cigarette users in less harmful behaviors.

3. **Description of respondents:**

Respondents will consist of a total of 24 participants, approximately 12 adults who currently use menthol cigarettes in localities where menthol cigarettes are available and approximately 12 adults in localities where a menthol ban is in place who used menthol cigarettes when the ban was implemented. To obtain a reasonably diverse sample, we will monitor our sample during recruitment to strive for diversity on race, ethnicity, age, sexual and gender identity, geography, socioeconomic status, and quit intentions. We will prioritize recruitment of Black/African American respondents, Hispanic respondents, female and transgender/non-binary respondents, young adults aged 21-30, participants who identify with a sexual orientation other than heterosexual/straight, participants with lower socioeconomic status (i.e., report having “not enough” or “just enough” money to get by).

4. **Date(s) to be Conducted:**

The study is projected to occur between July 2022 and September 2022

5. **How the Information is being collected:**

RTI (Research Triangle Institute), the research contractor, will manage data collection which will be conducted through 24 virtual in-depth interviews (IDIs) with adults who currently use menthol cigarettes in localities where menthol cigarettes are available and with adults in localities where a menthol ban is in place who used menthol cigarettes when the ban was implemented (Massachusetts, San Francisco, and Minneapolis/St. Paul). The interviews will take approximately 90 minutes to complete per participant.

For the information collection, L&E Research will send email invitations (Appendix A) to the target audiences explaining the study and inviting them to complete a brief screener that they access by clicking a link. Next, participants will complete a screener (Appendix B) to determine eligibility based on the study inclusion criteria.

Potential participants who are interested in participating and appear to qualify will be contacted by phone using the confirmation script (Appendix C) to complete the screening process. After a participant is determined to be eligible, has confirmed interest in participating in the study, and scheduled a time for the interview, L&E Research will send them recruitment communications (Appendix D) outlining the overall purpose of the research, confirming the date and time for the interview, and providing instructions for

joining the interview. During the recruitment process, L&E Research will provide the research contractor RTI with access to a secure portal that provides real-time information about participant recruiting and interview scheduling. The portal will include first and last names, email addresses, scheduled interview times, and responses to screener questions for recruits as interviews are scheduled. This information can be viewed in the portal and may also be downloaded as an Excel file. RTI will provide periodic updates about scheduled interviews to FDA, but will never include personally identifiable information (i.e., last name, phone number, or email). One day prior to the scheduled interview, L&E Research will send a reminder email and phone call to participants about their interview, and participants who do not log in for their interview will receive a follow-up call from L&E Research.

Interviewers from RTI will conduct the individual in-depth interviews with participants online using Zoom Webinar, an online video-conferencing platform. During each interview, the moderator will first share a link (via Zoom chat) to the informed consent (Appendix F). Participants will provide consent by checking a box ("Yes" or "No") in the online form, rather than providing a signature. The RTI interviewer will be available via the live Zoom video meeting to answer any questions for the participant. Then, the moderator will cover some "housekeeping" items (e.g., audio recording, minimizing distractions, privacy), and give the participant an opportunity to ask questions.

After consenting, participants will be instructed to advance to the next screen which will be a short online questionnaire (Appendix E). Then, the moderator will lead the participant through the discussion using a semi-structured interview guide (Appendix G). Throughout the interview, a notetaker will document the conversation, and we will audio record the sessions for later analysis. Zoom Webinar allows for observers to join the session without being visible to participants. Observers from RTI and FDA will be allowed to observe silently and will be muted once they log into the session, and thus only the RTI interviewer and notetaker will be able to interact with the participant.

The interview guide will examine the demographic, sociocultural, psychographic, and behavioral characteristics of adults who use menthol cigarettes to identify segments that are most likely to adopt less harmful behaviors in response to targeted messaging. Each interview will last on average 90 minutes.

6. **Confidentiality of Respondents:**

OMB Control Number 0910-0796 is covered under a Privacy Impact Assessment that has been approved by the Department of Health and Human Services (PIA Unique Identifier: P-9008729-198376).

Concern for privacy and protection of respondents' rights will play a central role in the study implementation; storage and handling of data; and data analysis and reporting. This study has been reviewed and approved by the Institutional Review Board (IRB) of RTI International, the research organization contracted to manage data collection. The IRB's primary concern is protecting respondents' rights, one of which is maintaining the privacy of respondent information to the fullest extent of the law.

L&E Research, the vendor recruiting for the interviews, maintain databases of potential participant information as part of their normal operations. In this study, specific PII

(participant first name, last name, and email addresses) will be shared with RTI to facilitate scheduling of the interviews. RTI will assign a unique alphanumeric ID number to each participant. RTI will not share any PII with FDA.

Data from completed screeners, questionnaires, and interviews will be compiled into an analytic data set by RTI International. That data set will use alphanumeric ID numbers for each participant and will not include PII. RTI International will share the analytic data set with FDA. All information that can identify individual respondents will be maintained in a form that is separate from the data provided to FDA. All data will be kept in a secured fashion that will not permit unauthorized access. Confidentiality of the information submitted is protected from disclosure under the Freedom of Information Act under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20). These methods will be approved by FDA's Institutional Review Board and will be implemented as described.

For the interviews, participant first names will be visible on the screen when livestreaming and audio-taping participants. Transcripts sent to the FDA will not contain participants' first or last names.

All participants will be assured that the information will be used only for research purposes and will be kept private to the extent allowable by law. The study instructions and informed consent will include information explaining to respondents that their information will be kept confidential. Participants will be assured that their answers to screener, questionnaire, and interview questions will not be shared with anyone outside the research team and that their names will not be reported with responses provided. Participants will be told that the information obtained from all of the interviews will be combined into a summary report so that
details of individual questionnaires cannot be linked to a specific participant.

To ensure compliance with all applicable information security laws, statutes, and agency directives, RTI has implemented the IT security guidelines and principles published by the National Institute of Standards and Technology (NIST). RTI's network meets all NIST confidentiality, integrity, and availability security standards for both low and moderate risk. RTI's security practices include the use of a virtual private network (VPN) and SSL and IPsec for encryption of data in transit when required based on project needs. RTI will store data for up to 10 years before deletion.

This study is funded by the FDA, a Department of Health and Human Services supported agency, and is covered by a Certificate of Confidentiality (CoC). Section 2012 of the 21st Century Cures Act includes significant amendments, to the previous statutory authority for such protections, to enhance privacy protections for individuals who are the subjects of federally funded research, under subsection 301(d) of the Public Health Service Act (42 U.S.C. 241). Specifically, the amended authority requires the FDA to issue a CoC to investigators or institutions engaged in research funded by the Federal government to protect the privacy of individuals who are subjects of this research. We will notify participants in the consent form of the protections that the Certificate provides.

7. **Amount and justification for any proposed incentive**

Participants that complete the interview will receive a gift card valued at $75 through L&E Research (the vendor recruiting for the interviews). Participants can apply the token of appreciation to online retailers or request a prepaid visa gift card.

Monetary tokens of appreciation are used not only to express appreciation for participation, but also to offset the time and cost burden that participation places on participants. According to the Bureau of Labor Statistics (BLS) in February 2022, the average hourly wage in the U.S. is $31.58, equivalent to $47.37 for 90 minutes. Additional factors requiring an incentive for this study that is higher than the BLS average hourly rate include:

- Participants are required to join the group from a quiet location where there are no distractions, which may require childcare or special accommodations during that time. The Bureau of Labor Statistics calculated that in May 2020, that the average hourly wage of childcare workers is $12.88, making the average cost of 90 minutes of childcare a minimum of $19.32.
- The interviews will be conducted online, and participants must have a computer and broadband Internet to participate in the interviews.
- In some of the localities where we aim to recruit (i.e., San Francisco, California), the average annual wage and childcare is much higher than the US average.

Additionally, this token of appreciation is warranted as we aim to over-recruit several harder-to-reach populations, including people who are Black/African American, Hispanic, LGBTQ+, and low socioeconomic status (SES) participants. These populations are more likely to be menthol smokers (the target audience for our research), therefore it is essential that we can successfully recruit these populations to meet the goals of this study. The above populations are considered harder-to-reach for several reasons: (1) Historical and ongoing experiences with the health care system have caused mistrust among African Americans (Scharff, 2010). This continues to reduce our ability to recruit African American participants into all types of research studies. (2) Socially disadvantaged groups, such as people who are lower socioeconomic status and sexual and gender minorities, are consistently underrepresented in all types of research studies (Bonevski, 2014). One reason for this may be because people who are lower socioeconomic status may be unable to take time off work for research study participation. Finally, the target audience of this study requires recruiting participants from specific geographic locations with menthol flavored cigarette bans, however, these populations may be harder to reach due to the specificity of their geographical location. The token of appreciation is necessary to ensure adequate representation of these populations (Groth, 2010). The token of appreciation treats participants justly and with respect by recognizing and acknowledging the effort they expend to participate (Gelinas, 2018). When applied in a reasonable manner, tokens of appreciation are not an unjust inducement—they are an approach that acknowledges participants for their participation (Halpern, 2004).

If the token of appreciation is not adequate, participants may agree to participate and then not show up or drop out early. Low participation may result in inadequate data collection, or, in the worst cases, loss of government funds associated with recruitment, vendor fees, and

moderator and observer time (Morgan, 1998). Therefore, a $75 token of appreciation for a 90-minute interview is reasonable to equalize the burden on the population we aim to recruit.

8. **Questions of a Sensitive Nature**

The majority of questions asked will not be of a sensitive nature. There will be no requests for a respondent's Social Security Number (SSN). However, it will be necessary to ask some questions that may be considered to be of a sensitive nature in order to assess specific health behaviors, such as menthol cigarette use. These questions are essential to the objectives of this data collection. Although we do not anticipate any risks from these health questions, some participants may perceive them to be sensitive. Some questions about menthol use may be more sensitive because a subset of the participants will be from localities where menthol cigarette sales are banned. Importantly, these questions do not place participants at risk as they ask about menthol use, not menthol sales. Questions concerning lifestyle (e.g., smoking behavior, menthol use) could be considered sensitive but not highly sensitive.

Collection of detailed demographic information, including race/ethnicity, sexual orientation, and gender identity could be considered sensitive but are necessary in order to better understand disparities in menthol use and implications for messaging strategies to address the needs of different populations. Decades of research has shown significant disparities in tobacco use by race/ethnicity (e.g., Harlow et al., 2019; Odani et al, 2018), gender identity (e.g., Johnson et al, 2019; Delahanty et al, 2019), and sexual orientation (e.g., Johnson et al, 2019; McCabe et al., 2018). Therefore, collecting detailed information on these demographic characteristics will allow us to understand these differences with the goal of reducing these disparities. As multiple studies of youth and young adults have reported approximately 12-15% of the sample identified as gender non-conforming/non-binary (e.g., The Human Rights Campaign 2018 LGBTQ+ Youth Report; The Trevor Project 2020 National Survey on LGBT Youth Mental Health; CTP's evaluation of *This Free Life* campaign), including gender non-conforming/non-binary response options is necessary to identify and assess tobacco use and campaign effectiveness among this population. Gender identity questions with genderqueer/gender non-conforming/non-binary response options as well as sexual orientation questions have been approved by OMB for ExPECTT FU3 and for RESPECT (0910-0808) as well as for ExPECTT 0910-0753.

The project team will not conduct or report on statistical analysis for demographic groups for which there is insufficient statistical power.

To address any concerns about inadvertent disclosure of sensitive information, participants will be fully informed of the applicable privacy safeguards. The informed consent protocol will notify participants that these topics will be covered in the interview. This study includes a number of procedures and methodological characteristics that will minimize potential negative reactions to these types of questions, including the following:

- Participants will be informed that they need not answer any question in the interview that makes them feel uncomfortable or that they simply do not wish to answer;
- The screener and questionnaire are entirely self-administered and maximize respondent privacy without the need to verbalize responses; and

- Participants will be provided with contact information for the Principal Investigator of this study and for RTI's IRB if they have any questions or concerns about this study or about their rights as study participants.

Finally, as with all information collected, these data will be presented with all identifiers removed.

9. **Description of Statistical Methods**

This research relies on qualitative methods and is not intended to yield results that are statistically projectable. The respondent universe for this study is adults who currently use menthol cigarettes in localities where menthol cigarettes are available and adults in localities where a menthol ban is in place who used menthol cigarettes when the ban was implemented. Study participants will be recruited from a national panel of consumers managed by L&E Research. Adult participants will be invited to participate in the study through an email invitation. Potential participants will be screened (via a screener questionnaire linked from the email invitation) to ensure that they meet the study eligibility criteria, and those qualifying for the study will contacted by L&E Research to schedule an interview. We intend for up to 24 participants to complete the interview. To obtain a final sample of up to 24 participants, we estimate that we will need to screen 7,500 potential respondents. This estimate is based on estimates from the recruitment firm about their "click-through" rates on recruitment emails and previous research conducted within this target audience using similar methodologies.

In addition to these criteria, the screener survey will include questions assessing race, ethnicity, age, sexual and gender identity, geography, and quit intentions. To obtain a reasonably diverse sample, we will monitor our sample during recruitment to strive for diversity on each characteristic.

Collection of detailed demographic information, including race/ethnicity, sexual orientation, and gender identity are necessary in order to ensure our sample includes participants that are disproportionately impacted by menthol cigarette use. Research has shown significant disparities in menthol cigarette use by race/ethnicity and sexual orientation (FDA, 2013; Ganz and Delnevo, 2021). Research on gender identity and menthol cigarette use is limited, however significant disparities in tobacco use by gender identity (Delahanty, 2019) have been documented in literature. In 2020, 81% of African American smokers aged 12 and older used menthol cigarettes in the past month, compared to 34% of White smokers (National Survey on Drug Use and Health, 2020). Additionally, in 2020, 51% of lesbian and gay smokers and 46% of bisexual smokers used menthol cigarettes compared to 39% of heterosexual smokers (Truth Initiative – Menthol: Facts, stats and regulations, 2022). Questions on race/ethnicity, sexual orientation, and gender identity are essential to identify participants and assess psychographic, sociocultural, and behavioral characteristics to inform audience segmentation and the development of health communication materials to support menthol smokers.

The sample drawn here is designed primarily to help CTP identify and characterize their target audiences to inform communication strategies. Specifically, the priority research questions are:

- What are the demographic, sociocultural, psychographic, and behavioral characteristics of adult menthol cigarette users?
- What are the characteristics of adult menthol cigarette users who are more likely to quit or switch to a lower harm product?
- What communication strategies and messaging opportunities to adopt less harmful behaviors, such as cessation or moving down the harm continuum, resonate most with menthol user audience segments?

The recruitment firm, L&E Research, has a proven and demonstrated ability using provide real time information about participant recruiting and interview scheduling to orchestrate and support the sampling plan specifications of this study.

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screener (Email Invitation and Recruitment Screener)	7,500	3	375
Scheduling (Recruitment Communications, Confirmation Script)	24	5	2
Interview (Consent, Questionnaire and Interview)	24	90	36
Total Hours			**413**

REQUESTED APPROVAL DATE: June 30, 2022

NAME OF PRA ANALYST: Rachel Showalter
Rachel.Showalter@fda.hhs.gov

PROGRAM CONTACT: Megan Wall
Megan.Wall@fda.hhs.gov

FDA CENTER: Center for Tobacco Products (CTP)

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