Supporting Statement A

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Supporting Statement A

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JUSTIFICATION SUMMARY

Goal of the project: The primary purpose and use of information collected under MTTCA is to inform the development and pretesting of materials for the Centers for Disease Control and Prevention's (CDC) ongoing national tobacco education campaign (NTEC). The MTTCA clearance is also used to develop other health messages that are not specifically associated with the NTEC (e.g., emerging tobacco products communication initiative, Surgeon General's Reports, etc.). There is also a need to continue to test prevention and cessation messages related to combustible tobacco products (e.g., cigarettes, cigar/little cigars, and cigarillos) and non-combustible products (e.g., electronic cigarettes or e-cigarettes, heated tobacco products).

Intended use of the resulting data: CDC will continue to use the MTTCA clearance to develop and test messages and materials for NTEC, as well as CDC's ongoing programmatic initiatives including, but not limited to, reports from the Office of the Surgeon General and other communication efforts and materials.

Methods to be used to collect: A variety of qualitative and quantitative information collection strategies are supported through this mechanism, including in-depth interviews; in-person and online focus groups; and online surveys.

The subpopulation to be studied: The study population will be adults who smoke and adults who do not smoke aged 18 years and older. The existing clearance also includes youth aged 13-17 years.

How data will be analyzed: Quantitative data will be analyzed using aggregate measures such as percentages and means. The qualitative data will be analyzed using thematic analysis. Focus group responses will be completely transcribed and read thoroughly, and codes will be created manually to identify themes and patterns of response.

A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

This package is a three-year revision request, with changes, to the 0920-0910 Message Testing for Tobacco Communication Activities (MTTCA) clearance. Since 2012, OMB approval of a generic clearance of MTTCA has been continuously maintained, with minor adjustments as ad testing has evolved to keep pace with

product types, audience segmentation, and/or dissemination channels. CDC is authorized to conduct information collection supporting these activities under the Public Health Service Act (41USC 241) Section 301 (see Attachment 1). This documentation established a unified information collection framework for the development of tobacco-related health messages, including messages related to the NTEC.

Since 2012, CDC has successfully planned, implemented, and evaluated the NTEC, which includes health messages for the intended audience (adults who smoke, aged 18 years and older) and messages tailored to specific audience segments (e.g., adults who smoke menthol cigarettes). The existing clearance also includes youth ages 13-17 years old. The campaign is delivered through a variety of media channels and formats, including television ads, radio ads, digital ads, out-of-home, and print materials. To keep the intended audience engaged and ensure continued effectiveness of the campaign, new ads must be developed. For this reason, CDC is submitting this renewal request to continue to test messages and materials for NTEC, the emerging tobacco products communication initiative which is a campaign to encourage educators to speak with middle and high school students about the risks of e-cigarette use and empower them to avoid or quit e-cigarettes, reports from the Office of the Surgeon General, and other communication efforts.

Significant improvements have been made in reducing the smoking prevalence in the United States since the first Surgeon General’s Report came out more than 50 years ago, yet cigarette smoking is still the leading cause of preventable disease and death in the United States, accounting for more than 480,000 deaths every year, or one of every five deaths (HHS, 2014). In addition, more than 16 million Americans live with a smoking-related disease (HHS, 2014). In 2020, the prevalence of cigarette smoking among adults was 12.5%, with higher rates of tobacco use among people with household incomes below $35,000 and with people without a college diploma (Cornelius et al., 2022). In 2018, the Surgeon General released an advisory on the e-cigarette epidemic among youth stressing the importance of protecting youth from nicotine addiction. In 2022, e-cigarettes were the most commonly used tobacco product among high school (14.1%; 2.14 million) and middle school (3.3%; 380,000) students (Park-Lee et al., 2022).

A coordinated series of health message testing activities will be required to support future development of effective, audience-specific and channel-specific messages for NTEC, the emerging tobacco products communication initiative, reports from the Surgeon General, and other communication efforts. Attachment 3 provides an overview of projected program needs during the time period of

January 31, 2024 through January 31, 2027, including estimated burden to respondents.

A2. Purpose and Use of the information Collection

The primary purpose and use of information collection under MTTCA will be to inform the development and pretesting of materials for CDC's ongoing NTEC. Since approval of the extension to MTTCA in January 2021, this mechanism has been used to support rough-cut testing of television, radio, and print ads for NTEC.

To date, NTEC has had a significant impact on cessation behaviors among U.S. adults who smoke because of the continued use of graphic and hard-hitting ads (Davis et al., 2017). During 2012-2018, the campaign was associated with approximately one million sustained quits among U.S. adults who smoke, and more than 16.4 million quit attempts (Murphy-Hoeferet al., 2020). NTEC has also been associated with increased knowledge of tobacco-related health risks (Huang et al., 2015) and lower odds of relapse (Davis et al., 2022). Furthermore, a cost-effectiveness study has shown that for every $3,800 spent on the Tips campaign between 2012 and 2018, an early death was prevented (Shrestha et al., 2021). More information about the impact of the campaign can be found at the website cdc.gov/tips under the heading *Tips* Impact and Results.

The data collected utilizing the "Emerging Tobacco Products Communication Initiative Pre-testing of Ads" information collection has been used to select a new creative concept to refresh messaging and creative assets for the campaign's focus population (U.S. middle and high school educators, including teachers, counselors, administrators, and gym teachers/coaches) about ways to prevent vaping among students. The creative concept testing results refined the new creative approach, including the tone, types of images that resonate with the focus population, and key messages and information that educators find helpful. The results guided the development of new creative assets, including the scripts, location, and casting for live-action videos, and the updated campaign branding and style (campaign name, colors, fonts, etc.).

The data collected utilizing the rough cut information collection will be used to inform CDC whether rough-cut ads communicate credibly with the intended audience. Rough-cut testing is crucial to ensuring that the ad informs the intended audience of the health consequences caused by smoking cigarettes and motivates them to take action (e.g., quit smoking cigarettes or talk to a loved one about the dangers of smoking cigarettes). Additionally, rough-cut testing is a way to measure any unanticipated confusion, ambiguity, or lack of understanding of the ad's message. Lastly, rough cut testing informs development of new ads for future campaigns.

The MTTCA generic clearance is founded on a strategic and systematic approach to the design and testing of high-quality health messages, campaigns, and programs, and employs accepted methods of health message development, including input from public health partners and pre-testing with intended audiences. (Figure 1) (National Cancer Institute, 2002). Figure 1 depicts the steps of planning, developing, implementing, and evaluating health communication programs in a systematic way.

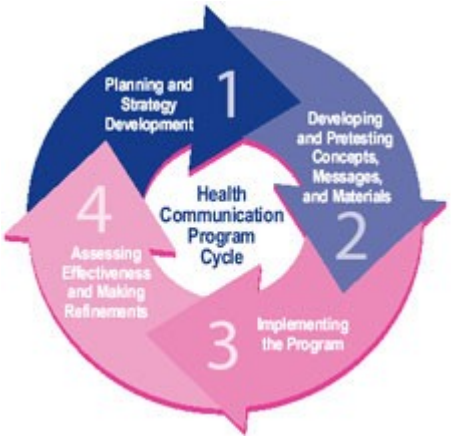

Figure 1. Health Communication Program Cycle

This approach is outlined below:

1) **Planning and Strategy Development.** This step can occur via formal needs assessments with partners and intended users (i.e., the intended audience) and a review of published literature and epidemiological data related to a specific health problem. A needs assessment can be accomplished by conducting surveys, for example, to determine pressing health needs or concerns of the intended audience. Next, CDC must understand an intended audience's current behaviors, beliefs, attitudes, and knowledge about tobacco-related issues to effectively design health messages, programs, and campaigns. This information can be gained with focus groups, interviews, and/or surveys. These will guide selection and application of behavioral theories to a program's strategies and messages and audience segmentation (Fishbein & Yzer, 2003; Noar, 2006; Thackeray & Neiger, 2000).

2) **Developing and Pretesting Concepts, Messages, and Materials.** In this second step, CDC designs draft messages that must be tested with members of the intended audience. Audience feedback, in the form of interviews, focus groups or surveys, is incorporated into subsequent revisions. Audience testing informs the final development of messages, materials or advertisements and is

essential for ensuring that federal dollars are expended appropriately on health messages that are effective.

3) **Implementing the Program/Campaign.** CDC implements the campaign and conducts process evaluation to ascertain to what extent the campaign was implemented as planned and under what conditions. This information helps campaign developers identify areas for improvement.

4) **Assessing Effectiveness and Making Refinements.** CDC must conduct outcome evaluation of the campaign to assess the degree to which the campaign was effective. This process also captures lessons learned for improving subsequent iterations of the program and for similar future efforts. Information collection for campaign assessment and evaluation activities has been approved in a separate but related information collection request (OMB No. 0920-1083, exp. 03/31/2023, Extended Evaluation of the National Tobacco Prevention and Control Public Education Campaign).

MTTCA provides a unified clearance framework for a variety of tobacco-related communication activities primarily related to steps 1-3 described above, which may occur on an as-needed basis, or in the context of a planned series utilizing a variety of methodologies. In the initial generic clearance period, we outlined the following purposes and uses of information to be collected. We plan to continue using the MTTCA clearance in these ways:

- Provide critical knowledge about specific intended audiences for tobacco communication activities conducted by CDC.
- Understand individuals' attitudes, knowledge and beliefs around combustible tobacco use, non-combustible use and quitting behaviors and how this may influence perception of messages.
- Develop and refine message concepts and pretest draft materials for clarity, salience, appeal, and persuasiveness to intended audiences.
- Ensure quality of health information and prevent ineffective and wasteful message dissemination by CDC to the public.
- Allow for the collection of health and other employment-specific information from individuals who apply to be spokespersons for the campaign.

CDC will request OMB approval for each data collection activity through submission of a specific Information Collection Request (ICR) that describes its purpose, use, methodology, and impact on affected respondents. Given that every data collection instrument will be based upon specific data collection needs for different stages of health communication planning and implementation, it is not possible to develop one instrument for use in all instances. Attachments 3a-3n provide illustrative examples of previously OMB approved instruments, such as

moderator’s guides and surveys, that could be used for a variety of information collections. Future instruments are not expected to have any extensive revisions from those used previously under this clearance. The proposed changes to the MTTCA are to extend the duration of the generic clearance, increase the number of responses and burden hours, and remove the upper age limit, previously 54 years of age, to include all adults aged 18 years and older.

A3. Use of Improved Information Technology and Burden Reduction

Whenever possible and appropriate, information collections submitted for approval under this generic clearance will use electronic data collection methods such as web-based surveys to collect and process data in order to reduce respondent burden and to make data processing and reporting maximally efficient. We anticipate that 99.5% of responses will be electronic; focus groups conducted in-person would be the exception. Further, electronic data collection methods will be employed to minimize COVID-19 and/or other exposure risks as appropriate for the public health situation at the time of data collection. If interviews and focus groups are conducted in-person during periods of high COVID-19 and/or other exposure risk, additional precautions will be put into place to ensure staff, contractors, and participants are protected from COVID-19 and/or other exposure. Mitigation strategies could include a) enacting social distancing protocols (i.e., six feet of space between persons to eliminate close contact), b) requiring appropriate personal protective equipment (PPE) use by all parties (e.g., N95 or three-layer cotton masks), c) symptom screening prior to data collection, and d) disinfection of surfaces between sessions/interviews. The precautions may be revised to add or remove strategies as needed. Precautions may vary from site to site based on conditions on the ground and the timing of when activities are conducted. Project-specific plans will be described in each ICR as applicable. In-depth interviews, focus groups, and surveys will be conducted with electronic and/or over-the-phone data collection methods when possible. The results will not be available to the public on the Internet because they are collected to inform the development and pretesting of materials for CDC’s ongoing NTEC and the emerging tobacco products communication initiative.

As computer technology has continued to improve and become more widespread, opportunities to pretest messages on the internet using either web-based surveys, online focus groups, or online hybrid qualitative/quantitative methodologies have increased. Further, in all message, concept, material, and ad testing, the number of questions will be held to the absolute minimum required for the intended use of the data. The following are examples of the types of technology that may be used to reduce burden and that have been used successfully by CDC in the past to collect information; evolving technologies may also be employed.

In-Depth Interviews: In-depth interviews consist of one-on-one interviews with members of intended audiences or other key stakeholders. These interviews will be conducted by telephone or online whenever possible to reduce burden and maximize convenience for participants.

Focus Groups: Focus groups are ideal for testing creative concepts and for eliciting feedback on visual stimuli. Focus groups will be conducted online whenever possible to reduce burden and maximize convenience for participants.

Online Surveys and Bulletin Boards: Online systems are ideal because of the ease of presenting visual stimuli (e.g., the concepts or advertisements) to respondents and recording their feedback. Online methods for interviews, focus groups, bulletin boards and surveys can also minimize burden because they can be completed in the respondent's home or workplace, at the respondent's convenience and do not require the presence of an interviewer. They are less burdensome than mailed questionnaires in that they eliminate the need to handle and return paper copies (Stempel III & Stewart, 2000).

A web-enabled panel approach uses online technology to collect data from households that participate in an ongoing panel. The panels are very large (more than 1.7 million people in the U.S.), allowing quick selection from the overall pool and the rapid identification of several potential respondents from extremely small subgroups of the population. Web panels provide a highly efficient, low cost, and low burden method of data collection for formative message testing. Online surveys can be of short or medium length as required to meet project needs. Short surveys are appropriate for testing near completed ads and medium length surveys may be required for other project activities.

For online bulletin boards, respondents can respond to a pre-loaded discussion guide at their own convenience while a trained, live moderator monitors responses throughout the duration of the bulletin board.

Web-based surveys are an especially convenient option for eliciting feedback on visual stimuli. With web-based surveys, respondents view an ad, complete an online survey and then submit the data electronically and securely over the Internet. Online methods for bulletin boards and surveys are described in more detail in Part B. Relative to less technically advanced methods, these data collection approaches have the advantages of speed, cost, access and reduced burden.

All personally identifiable information (PII) – participant names and telephone numbers, for example – will be stored separately from survey data and will not be shared with CDC. These data are used only to generate a sample, allowing participants to respond anonymously. The PII for contact information is stored with the companies that manage sample and CDC never receives it. Any PII collected will be destroyed at the end of data collection and will only be used for initial contact. Given this is not a longitudinal study, no PII is required for maintenance or re-contact after an interview has taken place. Although demographic information (e.g., age, gender, race/ethnicity, household income, educational attainment, etc.) may be collected, no direct personal identifiers (e.g., date of birth, full name, phone number, social security number, etc.) will be maintained. Data will be stored on password protected computers only accessible to study personnel.

A4. Efforts to Identify Duplication and Use of Similar Information

To prepare for data collection, CDC reviewed existing published literature, and unpublished qualitative pretesting reports (e.g., the findings from previous formative testing) when they were available. CDC also consults with outside experts to identify information that could facilitate message development. Health messages developed by CDC are unique in their mix of intended audience, health behavior, concept, and execution. Therefore, there are no similar data available.

To help prevent redundancy, CDC collaborates with other federal government agencies that sponsor or endorse health communication projects, such as the U.S. Food and Drug Administration's Center for Tobacco Products (FDA CTP). FDA CTP is investing in a number of public education campaigns aimed at youth and young adults (i.e., *The Real Cost*, *Fresh Empire*, and *This Free Life*) to educate them about the dangers of regulated tobacco products. In addition, FDA CTP also makes available to state partners materials from its *Every Try Counts* campaign, an adult-focused campaign that uses encouraging messages to get people to quit smoking, however they are no longer doing paid placements for this campaign.

CDC and FDA CTP are coordinating and collaborating closely on tobacco information collections and material development to avoid duplication of efforts and to support respective campaign messaging. Regularly scheduled conference calls are held to review plans and share research findings of mutual interest. These collaborations serve as information channels, help prevent redundancy, and promote use of consistent measures of effectiveness. Coordination activities include the review of data collection instruments and other support materials for testing purposes. Relevant communications will be documented in each ICR submitted to OMB for approval under MTTCA. CDC will share with FDA CTP all

future findings from the formative work that will be submitted to OMB under this revised package to ensure that future duplication of efforts is preempted.

A5. Impact on Small Businesses or Other Small Entities

ICRs will not involve small businesses or other small entities.

A6. Consequences of Collecting the Information Less Frequently

This package supports the essential steps of conducting needs assessments, assessing intended audience awareness, attitudes, knowledge, beliefs, and behaviors; and testing messages on dimensions such as clarity, salience, appeal, and persuasiveness (i.e., the ability to influence behavioral intention). Skipping these steps has a high potential cost. A program designed without a clear understanding of the issue or message from the intended audience's perspective can be minimally effective, at best. Untested messages can waste communication resources and opportunities because the messages may be perceived as unclear or irrelevant. Untested messages can also have unintended consequences, such as jeopardizing the credibility of federal health agencies.

A7. Special Circumstances Relating to the Guidelines of 5 CRF 1320.5

There are no special circumstances that require data collection to be conducted in a manner inconsistent with 5 CFR 1320.5 (d) (2). The information collection fully complies with the guidelines in 5 CFR 1320.5.

A8. Comments in Response to the FRN and Efforts to Consult Outside the Agency

Part A: PUBLIC NOTICE

A 60-day Federal Register Notice was published in the *Federal Register* on January 23, 2023, vol. 88 No. 14, pp. 3992-3994 (see Attachment 2).

CDC did not receive public comments related to this notice.

NTEC has been funded primarily with funds from the Affordable Care Act/Public Health Fund
designated for smoking education since 2010. CDC consulted with FDA CTP on this revision request to 0920-0910 as part of our ongoing coordination and collaboration on data information collections.

Table A8A. External Consultations

Name	**Title**	**Affiliation**	**Phone**	**Email**
OUTSIDE CONSULTANTS				

Gem Benoza	Supervisory Health Communications	FDA, Office of Health Communication and Education	(650) 260-2141	Maria.Benoza@fda.hhs.gov
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Allison Kulas	Social Scientist	FDA, Office of Health Communication and Education	(301) 837-7453	Alison.Kulas@fda.hhs.gov
Anh Zarndt	Health Scientist	FDA, Office of Health Communication and Education	(240) 402-5875	anh.zarndt@fda.hhs.gov

Table A8B. Consultations within CDC

Name	Title	Affiliation	Phone	Email
Brian Armour	Associate Director for Science	CDC, Office of the Associate Director for Science	(404) 498-3014	Bka9@cdc.gov
Cindy Allen	ISSO/CPIC Coordinator	CDC, Office of the Director	(770) 488-5388	Cdl1@cdc.gov
Diane Beistle	Chief	CDC, Health Communications Branch	(770) 488-5066	Zgv1@cdc.gov
Lauren Boyle-Estheimer	Health Communications Specialist	CDC, Health Communications Branch	(404) 498-2283	Yjw7cdc.gov
Elizabeth Courtney-Long	Health Scientist	CDC, Office of the Associate Director for Science	(404) 498-0264	Gmr9@cdc.gov
Michelle O'Hegarty	Health Communications Specialist	CDC, Campaign Development, Health Communications Branch	(770) 488-5582	Izr0@cdc.gov
Lindsey McCarter	Team Lead	CDC, Campaign Development, Health Communications Branch	(770) 488-4239	Lpq4@cdc.gov
Terri Still-LeMelle	Technical Writer-Editor	CDC, Office of the Director	(404) 639-7407	Cse6@cdc.gov

A9. Explanation of Any Payment or Gift to Respondents

Participation in certain data collections will be requested on a voluntary basis without specific incentives. However, CDC may request OMB approval to offer incentives in some circumstances, when a) information is needed from respondents who are difficult to reach or recruit, or b) information collection is time-sensitive and recruitment must be accelerated. Each request to offer an incentive will be appropriately justified on a case-by-case basis and will describe the type of incentive to be offered (cash, gift card, or reward "points") and the amount. Studies have indicated that a monetary gift can increase response rates in survey research (Church, 1993; Greenbaum, 2000; Haveman, 2010).

A10. Protection of the Privacy and Confidentiality of Information Provided by Respondent

For prior rounds of testing under this clearance, submissions were reviewed by staff in CDC's National Center for Chronic Disease Prevention and Health Promotion, who determined that the Privacy Act does not apply. While the CDC data collection contractors may have access to personally identifiable information (PII), no PII will be shared with CDC or any agencies. Participants will respond anonymously and PII will be used only to generate a sample. All data collected and delivered to CDC from contractors will be in the aggregate only. Further, the information that will be reported to and maintained by CDC is not considered a record as defined by the Privacy Act: it will not include individuals' education, financial transactions, medical history, criminal or employment history, name, or the identifying number, symbol, or other identifier assigned to any individual, such as a finger or voice print or a photograph.

CDC anticipates that participation in all data collection under this generic clearance will be voluntary. Prior to submitting a data collection request to OMB for review and approval, CDC will submit a Privacy Narrative to CDC's Security Officer for review and approval. Each project-specific data collection request submitted to OMB for review and approval will include 1) a description of the applicable privacy safeguards[1], 2) a project-specific Privacy Act determination, and 3) a project-specific IRB approval, if required.

Overview of information collection

Although demographic information (e.g., gender, age, and race) may be gathered for screening or in interviews and focus group-type activities to describe an audience segment, no direct personal identifiers (e.g., full name, date of birth, address, phone number, email address, social security number, photograph,

[1]

biometric information, or any other unique identifier that can be linked to an individual) will be collected or maintained.

Quantitative data collections

Privacy protections for quantitative data collections

Respondents will be informed that their participation in the quantitative data collections is entirely voluntary. Although e-mail addresses are used to invite users to participate in the data collection, these data come from existing third-party panelist databases participants have opted into and are protected in accordance with the panel's privacy policy (Attachment 6). To protect the privacy of respondents who agree to participate, they will be given the opportunity to decline to respond to any questions they don't feel comfortable answering. There will be no penalty associated with declining to answer questions. PII is never elicited during quantitative data collections. Quantitative data collections will not use cookies or other means of collecting information outside those explicitly agreed to during the informed consent process participants complete prior to the data collection.

Confidentiality protections for quantitative data collections

For online surveys, online data collections will conform to federal regulations [the Hawkins-Stafford Amendments of 1988 (P.L. 100-297) and the Computer Security Act of 1987] and will be required to comply with comprehensive, written plans to maintain security. Information will be collected electronically through self-administered survey instruments hosted in secure, online, web-based data collection systems. Data will be separated from any identifying information, including the email address of the respondent. There is no online content being planned that will be directed at children younger than 13 years of age.

Through provision of the privacy policy link noted above (Attachment 6) and applicable consent procedures (see Section A11), respondents will be informed prior to participation that their responses will be treated in a secure manner. All data provided by respondents will be treated in a secure manner and will not be disclosed, unless compelled by law. All electronic file transmissions will be encrypted and password protected.

Best practices for online web-based data collection systems and in-person focus groups submitted under 0920-0910 include the following: Surveys sent electronically from web-based data collection systems will be sent to an email address solely dedicated for the information collection project. When respondents begin a survey, all identifiable links to the existing system of records are severed. CDC will not have direct contact with or access to any PII about participants during

this stage. Online data collection systems have access to the email address of panel subscribers, but no match back is possible with the survey response data. Participants will respond anonymously and PII will be used only to generate a sample. IP addresses will not be stored by the online survey system, and no first- or third-party cookies will be stored during survey completion. No link between the respondent's email and the specific survey is made after the potential respondent clicks on the link to start the survey.
For telephone surveys, although demographic information (e.g., age, gender, race/ethnicity, household income, educational attainment, etc.) may be collected, no direct personal identifiers (e.g., full name, social security number, etc.), including phone numbers, will be maintained after a response has been given. Data will be stored on password protected computers only accessible to study personnel.

Qualitative data collections

Privacy protections for qualitative data collections
Respondents will be informed that their participation in the qualitative data collections is entirely voluntary. Although e-mail addresses or other forms of contact information (e.g., phone numbers) may be used to invite panelists to participate in the data collection, these data come from existing third-party panelist databases participants have opted into and are protected in accordance with the panel's privacy policy (Attachment 6). To protect the privacy of respondents who agree to participate, they will be given the opportunity to decline to respond to any questions they don't feel comfortable answering. There will be no penalty associated with declining to answer questions. Qualitative data collections will use first names only and any PII that emerges during the data collection will be redacted from recordings and transcripts. Recordings will be destroyed in accordance with the record retention schedule detailed in the ICR.

Confidentiality protections for qualitative data collections
During qualitative data collection (i.e., online and in-person focus groups), focus group facilities will recruit respondents using their own respondent panels. The identifiable information about panelists is maintained in proprietary records systems of the focus group facilities and is not released. Neither CDC nor the data collection contractors will have access to participant's PII at any point. Although demographic information (e.g., age) can be confirmed through the use of a pre-focus group questionnaire, no direct personal identifiers (e.g., name, phone number, social security number, etc.) will be collected or maintained as part of a pre-focus group questionnaire or during the focus groups. Last names will not be used during group discussions. Any PII disclosed during focus groups will be redacted from transcripts and recordings. All information that is collected from

pre-focus group questionnaires or during the focus group will be immediately entered into a password-protected database, then all paper copies will be shredded and disposed of the same day. The originals entered into the database will not be shared with CDC until de-identified, with any PII removed. Focus groups will be streamed through an encrypted and password protected streaming service which ensure that only study personnel can access the data. Recordings and transcripts will be stored in a secure environment.

Overview of how information will be shared and for what purpose

Information will be collected and evaluated by CDC personnel and/or CDC's data collection contractors. CDC will collaborate with its data collection contractors on instrument development, analysis, interpretation, and implementation of the results from the data. CDC will not have direct contact with participants nor will CDC have access to any personal identifying information about the panelists. The data collection contractors, in collaboration with CDC, plan to analyze data on measures such as perceived effectiveness, comprehension, and believability of the tested advertisements, as well as demographic characteristics, such as state of residence, and smoking status.

Overview of voluntary participation

Independent of the data collection system, all potential respondents will be advised of the nature of the activity, the length of time it will require, and that participation is voluntary. The appropriate advisements on voluntary participation will also be provided to respondents, generally during the recruitment, consent and/or screening process (Attachment 5 includes an example Informed Consent form). These procedures conform to ethical practices for collecting data from human participants.

Overview of data security

All information will be stored on password-protected databases to which only contractors working on a project have access. All information that is collected from paper pre-focus group questionnaires or during the focus group will be immediately entered into a password-protected database, then all paper copies will be shredded and disposed of the same day.

CDC contractors will keep the data in non-aggregate form for six months after information collection has been completed, and then the respondent-level data will be deleted from the password-protected databases. Contractors will provide CDC with de-identified data, to be used for analyses. Only CDC and contractors involved in data analysis will have access to the data. CDC will handle the de-identified data in accordance with the record control schedule (maintained at least six years, but no longer than ten years). No desktop or laptop computer will contain any PII. CDC will retain and destroy records in accordance with the

applicable CDC Records Control Schedule. Data management procedures have not changed since previous approval.

A11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

All procedures will be developed in accordance with federal, state, and local guidelines to ensure that the rights and privacy of participants are protected and maintained. When applicable, IRB approval will be obtained (see Attachment 4 for an example of an IRB approval letter). When applicable, respondents will complete an IRB approved informed consent process prior to participating in a data collection. Participants will review IRB-approved information which explains that their participation is voluntary, the expected time commitment for participating, and how their privacy and confidentiality will be protected. An example informed consent document appears in Attachment 5. Depending on the specific data collection protocol for an information collection, respondents may provide consent by clicking a button to indicate consent, signing a consent form, or providing verbal consent. Respondents who do not provide informed consent will be thanked for their time and will not participate in the data collection. Participants will be provided with a phone number and email for the principal investigator and for the IRB, should they have any questions or concerns about the study or their rights as a study participant.

Sensitive Questions

The majority of questions asked will not be of a sensitive nature. There will be no requests for a respondent's Social Security Number. Questions asked during the screening about tobacco use or non-combustible product use and some demographic information (e.g., age) could be considered sensitive, although these items would not generally be considered highly sensitive. It may also be necessary to ask some questions considered to be sensitive in order to assess individuals' attitudes and behaviors about tobacco products or non-combustible products and to test ads about the specific health behavior of combustible product and non-combustible product use. These items are not generally considered highly sensitive either. To avoid fear of disclosure of potentially sensitive information, participants will be informed of the applicable privacy safeguards. Sensitive information will only be requested when necessary to describe sample characteristics (e.g., age). Such questions will include a "prefer not to answer" option. In addition, to avoid negative reactions to potentially sensitive questions, several steps may be taken:

- Respondents will be informed that they do not have to answer any question that makes them feel uncomfortable or that they simply do not wish to answer.
- Where possible, use of touch-screen methodology or other self-directed techniques will provide privacy; not having to verbalize a response may increase comfort.
- When such numbers are available and appropriate, participants will be provided with a phone number and email for the principal investigator and for the IRB, should they have any questions or concerns about the proposed project or their rights as a participant.
- Interviewers will be trained to ask questions in a sensitive manner and to handle any subsequent discussion skillfully. Where appropriate, interviewers and respondents will be matched for gender and other demographic criteria (e.g., age, preferred language use).
- If specific health information is obtained from medical professionals, informed consent will be obtained.

Sensitive information will only be requested when necessary for specific project objectives. OMB race/ethnicity standards will be followed.

A12. Estimates of Annualized Burden Hours and Costs

Information will be collected through methods including, but not limited to:

- Screening to ensure proper selection of participants. The estimated burden is two minutes per response.
- In-depth interviews, including interviews conducted with key informants. Interviews will be conducted in-person, by telephone, or online. The estimated burden is 60 minutes per response.
- In-person/Online focus groups, primarily for creative concept testing and social media concept testing. The estimated burden is 60-90 minutes per response.
- Short surveys conducted online or through bulletin boards, for message platform testing, message validation, rough-cut testing and final revised cut testing. The estimated burden is 13-20 minutes per response.
- Medium-length surveys conducted online for quantitative social media concept testing, and validation of advertisements and Surgeon General Report or other health communication materials. The estimated burden is 25-40 minutes per response.

The distribution of CDC’s needs for information collection through screening, surveys, interviews, and focus groups may change over time. An approximate distribution is described in Table A12A below, which shows the estimated

annualized number of respondents for the requested revision as 148,772 and the estimated annualized burden hours as 20,039. Over the course of the three-year renewal, the data collection methods may differ from the anticipated methods indicated below, but the number of responses/respondents and total burden hours will be itemized in each request submitted to OMB for approval under the MTTCA generic clearance.

Table A12A. Estimated Annualized Burden to Respondents

Type of Respondents	Data Collection Method	Total Burden (in hours)	Average Hourly Wage	Total Cost
General Public and Special Populations	Screening	2,480	$33.03	$81,914
	In-Depth Interviews (In Person, Online)	25	$33.03	$826
	Focus Groups (In Person, Online)	942	$33.03	$31,114
	Surveys (Online, Short)	15,453	$33.03	$510,413
	Surveys (Online, Medium)	1,139	$33.03	$37,621
Total		20,039		$661,888

Because the time required to respond to a survey or interview, and to participate in a focus group, has a monetary value, Table A12B estimates the total annual cost to respondents for all activities and breaks the total figure down by the principal data collection strategies that may occur over a one-year period. To calculate this cost, we used the mean hourly wage of $33.03, which represents the Department of Labor estimated mean for state, local, and private industry earnings (Bureau of Labor Statistics, 2023). The total annualized burden cost is estimated at $661,888 per year.

Table A12B. Estimated Annualized Burden Costs

Respondents	Data Collection Method	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
General Public and Special	Screening	74,386	1	2/60	2,480
	In-Depth Interviews (In	25	1	1	25

Populations	Person, Online)				
	Focus Groups (In Person, Online)	628	1	1.5	942
	Surveys (Online, Short)	71,000	1	20/60 13/60	15,453
	Surveys (Online, Medium)	2,733	1	25/60	1,139
Total		148,772			20,039

A13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

No respondent capital and maintenance costs are anticipated.

A14. Annualized Cost to the Federal Government

Approximately 20% of one full-time equivalent (FTE) staff and 5% of one senior manager FTE will be required to oversee this generic clearance and associated information collection requests. Additional responsibilities will include internal coordination of a specific Information Collection Requests and maintaining proper accounting of burden hours. The total average annualized cost to the government for CDC oversight is $36,217 (Table A14). The majority of data collections will be conducted by contractors on CDC's behalf. The costs of each information collection activity will be itemized in the project-specific request submitted for approval under this generic clearance.

Table A14. Estimated Annualized Cost to the Federal Government

Government Personnel	Time Commitment	Average Annual Salary	Total
GS-13	20%	$ 135,209	$27,042
GS-15	5%	$ 183,500	$9,175
Total			$36,217

A15. Explanation for Program Changes or Adjustments

This package is a three-year renewal request, with changes, to the 0920-0910 MTTCA clearance. The changes that are being proposed are as follows:

- Increase the number of estimated annualized responses (from 77,522 previously approved to 148,772) and increase the estimated annualized burden hours (from 10,458 previously approved to 20,039) starting on the current expiration date of January 31, 2024 to account for planned future activities such as message platform testing, rough-cut testing, and to accommodate some unanticipated activities. Our experience has shown that some needs develop later in the generic clearance period and we need flexibility to accommodate these requests. The principal sources of increases are in the areas of screening and recruitment and short surveys. An itemized summary of estimated changes is provided in Table A15 below.
- Remove the upper age limit, previously 54 years of age, to include all adults aged 18 years or older.

Table A15. Proposed Burden Changes

	Previous Approval		Proposed Changes for Current Revision			
Data Collection Method	No. Respondents	No. Burden Hours	No. Respondents	No. Burden Hours	Change in Respondents	Increase in Burden Hours
Screening and Recruitment	36,267	1,208	74,386	2,480	38,119	1,272
In-depth Interviews	67	67	25	25	-42	-42
Focus Groups (In Person, Online)	288	432	628	942	340	510
Surveys (Online, Short)	36,667	6,112	71,000	15,453	34,333	9,341
Surveys (Online, Medium)	2,733	1,139	2,733	1,139	0	0
Surveys (In-Depth Telephone and Online)	1,500	1,500	0	0	-1,500	-1,500
Total	77,522*	10,458*	148,772	20,039	71,250	9,581

*Note: The numbers in the table above are annualized.

A16. Plans for Tabulation and Publication and Project Time Schedule

Results of the information collections conducted under this generic clearance will be used primarily to inform programmatic efforts, specifically the NTEC, emerging tobacco products communication initiative, reports from the Office of the Surgeon General, and other communication efforts. Information collections may include message platform testing, creative concept testing (i.e., focus groups), and rough-cut testing (i.e., online surveys) related to the development of messages and materials for the NTEC or the emerging tobacco products communication initiative. Quantitative data will be analyzed using conventional tabulation techniques. Qualitative data will be analyzed using thematic analysis. The data will be read thoroughly and initial codes will be created manually, identifying themes and patterns of responses.

Publication and Dissemination Plans
The information collected under this generic clearance will be used primarily for NTEC, reports from the Office of the Surgeon General, and to inform programmatic efforts. Results that may be of interest to the public may be disseminated through presentations at professional meetings.

Project Time Schedule
Table A16 is an example of a project time schedule for an information collection request for rough-cut testing.

Table A16. Estimated Time Schedule for Project Activities

Activity	Timeline
Email invitations sent to respondents for quantitative testing	1-30 days after OMB approval
Online data collection	1-30 days after OMB approval
Complete field work	30-45 days after OMB approval
Validation	45-55 days after OMB approval
Data analysis	55-65 days after OMB approval
Report writing	65-150 days after OMB approval

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

An exemption to this requirement is not being requested. The expiration date of OMB approval will be displayed on all information collection instruments.

A18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.

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