

**U.S. Food and Drug Administration
Center for Tobacco Products
The Real Cost Monthly Implementation Assessment
OMB Control No. 0910-NEW
Supporting Statement Part A**

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

This information collection supports the development and implementation of the U.S. Food and Drug Administration’s public education efforts related to tobacco use. CTP’s public education efforts such as “The Real Cost” advances the objectives of the Make America Healthy Again Commission by effectively reducing tobacco use and exposure to harmful chemicals—a leading contributor to chronic diseases—through public education. By preventing tobacco initiation and promoting smoking cessation, CTP addresses a critical factor in the development of chronic diseases while reducing healthcare costs.

“The Real Cost” Monthly Implementation Assessment (MIA) umbrella generic is a mixed methods generic information collection (gen IC) mechanism that will serve as a formative and implementation evaluation of “The Real Cost” campaign. Formative and implementation evaluations provide real-time insights into whether an intervention (in this case, “The Real Cost” campaign) is being delivered as intended. The MIA study will be conducted using virtual discussion groups or interviews as well as web-based surveys that are self-administered on personal computers or web enabled mobile devices to collect rapid data on “The Real Cost” campaign content (quantitative). “The Real Cost” campaign has evolved over time and while message delivery used to be done only through TV advertisements, the campaign now delivers campaign messages through a variety of formats, such as digital ads, partnerships with social media influencers, and custom content within existing video games or TV shows. For simplicity, we use the term “stimuli” to refer to all campaign content, including content that is in development as well as content that is currently in market.

FDA launched “The Real Cost” in February 2014, seeking to reduce tobacco use among at-risk teens ages 12–17 in the United States who are open to using tobacco products, or who have already experimented with tobacco products. Complementary evaluation studies, including the “Evaluation of FDA’s Public Education Campaign on Teen Tobacco (ExPECTT),” were implemented to measure awareness of “The Real Cost” paid media campaign among teens ages 12–17 in the United States, and to understand how awareness is related to change in key outcomes.

There is a need to assess the receptivity of proposed ads in order to inform the development of future campaign messaging. These data will help inform any changes necessary to messages in development to improve receptivity. Additionally, although outcome evaluation studies of “The Real Cost” have and continue to assess the impact of awareness on outcomes, no studies have sought to assess the implementation of “The Real Cost.” As FDA continues to increase the presence of “The Real Cost” on digital channels (e.g., Hulu, YouTube, Instagram), the need

for an implementation assessment has become clear as these messages are received by the intended audience on digital channels differently compared to how the messages are received on broadcast channels. Before the migration of campaign ads to digital channels, ads from “The Real Cost” were primarily aired on broadcast TV. In the broadcast space, for people to avoid receiving the message, they needed to be proactive (e.g., finding the remote to change the channel or leaving the room). In the digital space, however, people need to be proactive to watch the full message, like stopping scrolling on social media. Assessment of this information is integral to understanding self-reported ad awareness levels, as well as how our audience experiences and processes the ads as they are airing in a digital, real-world setting. Therefore, we propose a study to help us understand teens’ receptivity to messages that are both in market and in development, how teens experience the messages, how they engage with messages, the extent to which teens report being exposed to messages, and how teens process the messages. Data gathered from this assessment will also provide the necessary and timely information to optimize developing and current campaign messages, the digital media buy (i.e., where, how, and when ads are shown), and creative rotations (i.e., which ads are shown).

2. Purpose and Use of the Information

The purpose of the MIA study is to provide a rapid and flexible method for collecting formative and implementation evaluation data on campaign exposure, awareness, attention, and processing, as well as receptivity to both in-market stimuli and stimuli in development, to understand the extent to which “The Real Cost” is being implemented. Specifically, the study will examine how “The Real Cost” is being received by the intended audience and if it is being successfully delivered to the intended audience. To evaluate the implementation of “The Real Cost” campaign, we will evaluate the following key components about “The Real Cost” ads:

- Receptivity to messaging.
- Awareness of “The Real Cost” brand and stimuli.
- Attention to and engagement with “The Real Cost” stimuli.
- Processing of “The Real Cost” stimuli, including:
 - Main message comprehension.
 - Acceptance and/or rejection of the stimuli.
- Perceived effectiveness of “The Real Cost” stimuli.
- Potential unintended consequences of viewing “The Real Cost” stimuli

In addition to the above components, the gen ICs will ask respondents to report on tobacco use, media use, and other psychographic and demographic items. Findings will be used by FDA to optimize campaign messages and creative rotations to better meet its public health education mission.

Quantitative survey data from up to 2,000 unique respondents ages 12-20 years in the United States will be collected every 1-2 months (for a total of 24 waves). Quantitative survey data may be comprised from items found in all MIA study modules with the exception of Module G in Attachments 2a and 2b. For quantitative survey data collections, we will use a rotating module approach to inform campaign development, flighting, and media buy. For example, in one month we may field questions from Section J of the umbrella generic instruments (see

Attachments 2a and 2b), but suppress that section the next time we field survey data collection to ask questions from Section K. This design offers flexibility to assess new stimuli messages,¹ examine their performance over time, and provide the ability to pivot and add new measures as necessary. Collecting survey data every 1-2 months will also allow us to obtain timely information on stimuli awareness, perceived effectiveness, and teen attention and processing of the stimuli.

In addition, mixed methods data from up to 400 participants ages 12-20 years in the United States will be collected two to three times a year (up to 8 mixed methods data collections total). Mixed methods data will be collected using items in Module G in combination with other MIA study modules in Attachments 2a and 2b.

We will use online panels to recruit respondents for the study. To be eligible, respondents must be between the ages of 12-20 years and have not participated in the MIA quantitative data collection within the past 2 months (e.g., respondents who have participated in a quantitative data collection in January will be allowed to take it again in April of the same year). Participants will only be eligible to participate in an MIA mixed methods data collection if they have not already participated within the past year.

Instrument testing will be used to aid in item clarity (e.g., address typos and decrease confusing wording) and skip pattern testing. Based on this testing, some items may be updated non-substantively for clarity. Based on skip pattern testing and instrument length, some items may be excluded.

Under this generic clearance, individual gen ICs for waves/months will be submitted to OMB along with a memo describing the wave/month, modules, and stimuli (supporting documentation) associated with that wave/month. Instruments associated with the MIA generic collection will be approved as part of the umbrella collection criteria. Modifications to the MIA generic collection instruments will require OMB review and approval. Individual gen ICs will be reviewed by the IRB of record, senior leadership from the Center for Tobacco Products, and PRA specialists prior to submission to OMB. As the variety of modules from month to month is not significant, gen ICs will be automatically approved within 10 days of submission.

3. Use of Information Technology and Burden Reduction

Data collection for the quantitative surveys will be web-based. Respondents can take the survey on a personal computer, smartphone, or tablet at a time and location of their choosing. This type of data collection allows the respondent to be candid with their responses. It also increases accuracy of the data because respondents tend to provide more honest responses with this method, as compared to other types of data collection methods, especially when it is clear the answers will remain private. In addition, using a web-based survey will allow for more respondents to respond in a cost-effective and timely manner compared to in-person data collection. The self-administered, web-based survey permits greater expediency with respect to

¹ Stimuli are comprised from content from FDA's The Real Cost campaign (<https://therealcost.betobaccofree.hhs.gov/vapes>; <https://www.youtube.com/user/KnowTheRealCost>; <https://www.instagram.com/therealcost/>)

data processing and analysis (e.g., several back-end processing steps, including coding and data entry are automatic instead of manually processed) because data are transmitted electronically, rather than by mail. These efficiencies save time due to the speed of data transmission, as well as receipt in a format suitable for analysis.

The mixed methods data will be collected electronically using online collaboration tools to reduce burden by allowing participants to participate in a location that is convenient to them and without the need for added travel/commuting. Virtual interview and focus group participants will access an online platform such as Zoom, Teams, GoToWebinar, and other applications, which allow users to meet online and can be accessed using a computer, tablet, or mobile device. Webinar platforms include several security protection features including, but not limited to, the ability to lock a meeting so no one else can join, restrict screen-sharing to the host only, enable a waiting room to restrict access to only those who should join, and remove a participant, if needed.

4. Efforts to Identify Duplication and Use of Similar Information

This information collection does not duplicate previous efforts. FDA’s “The Real Cost” campaign includes specific messages delivered through a variety of media sources. There are no existing data sources that contain measures on awareness and receptivity to these campaign messages. In designing the proposed data collection activities, we took several steps to ensure that this effort does not duplicate ongoing efforts and that no existing data sets would address the proposed study questions. We carefully reviewed existing data sets to determine whether any of them are sufficiently similar or could be modified to address FDA’s need for implementation data on the campaign. Data sources we examined for this purpose include ongoing national surveillance systems such as the National Youth Tobacco Survey (NYTS), the Youth Risk Behavior Surveillance System (YRBSS), the National Health Interview Survey (NHIS), and the Population Assessment of Tobacco and Health (PATH). We also reviewed data collected to evaluate other national tobacco-focused media campaigns such as CDC’s “Tips From Former Smokers” campaign. We concluded that these data sources do not include the measures or frequency of data collection needed to assess the implementation of the campaign and how the campaign’s intended audience attends, receives, and processes campaign messages.

Further, this study is a complement to “The Real Cost” Campaign Outcomes Evaluation Study: Cohort 3 (Outcomes Study; OMB Control No: 0910-0915), reducing the burden on respondents in the Outcomes Study to respond to longer surveys in an attempt to answer all questions pertaining to “The Real Cost” stimuli and campaign.

This formative and implementation evaluation differs from the longitudinal outcome evaluation (“The Real Cost” Campaign Outcomes Evaluation Study: Cohort 3 (Outcomes Study; OMB Control No: 0910-0915) in the following ways:

1. It is designed to rapidly gain an understanding of how teens pay attention to and process campaign messaging, rather than how exposure to messaging affects campaign outcomes.

2. The study is designed with the ability to assess receptivity to messages in development among a sample of the intended audience prior to dissemination. Examining receptivity during the developmental stage allows FDA to ensure future efforts can potentially improve awareness, attention, processing, and receptivity.
3. Having a separate, monthly implementation evaluation offers additional benefits:
 - a. It can potentially provide a deeper understanding of factors driving campaign awareness rates. By frequently examining stimuli awareness, attention, receptivity, and processing for each message, closer to the time each stimulus is airing, we can better understand how changes in the stimuli launch schedule and media buy relate to change in ad awareness.
 - b. The ability to assess innovative messaging strategies that may be disseminated for a limited time (e.g., campaign content integrated into existing TV shows popular among teens; campaign content disseminated during events popular among teens); the longitudinal outcome studies have been limited to examining awareness of more traditional video ads that are on air for an extended time.

5. Impact on Small Businesses or Other Small Entities

No impact on small businesses or other small entities is anticipated. Respondents in this study will be members of the general public who agreed to participate in the mixed method studies, not business entities.

6. Consequence of Collecting the Information Less Frequently

Without the information collection requested for this assessment, it would be difficult to determine if the development or implementation of FDA's media campaign needs to be adjusted to better reach the intended audience. Failure to collect these data could reduce effective use of FDA's program resources to benefit teens in the United States. Respondents in this assessment are surveyed on approximately a 1-2 month basis. While there are no legal obstacles to reducing burden, lack of information needed to evaluate the development and implementation of FDA's teen tobacco education campaign may impede the federal government's efforts to improve public health. Careful consideration has been given to how frequently the campaign's intended audience should be surveyed for campaign implementation assessment purposes. We believe the repeated cross-sectional design will provide sufficient data to understand how teens attend to, receive, and process "The Real Cost" campaign messaging.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The message testing activities fully comply with the guidelines in 5 CFR 1320.5

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register on April 27, 2023 (88 FR 25660). FDA received no PRA-related comments.

The following individuals inside the agency have been consulted on the design of the study, instrument development, or intra-agency coordination of information collection efforts:

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FDA collaborates with other federal government agencies that sponsor or endorse public education efforts, such as the CDC's Office on Smoking and Health (CDC/OSH) and the National Institutes of Health National Cancer Institute (NIH/NCI). These affiliations serve as information channels, help prevent redundancy, and promote the use of consistent measures of effectiveness. Coordination activities include:

- Review of proposed messages for stimuli;
- Review of questionnaires for testing purposes;
- Sharing data; and
- Standardizing survey tools where at all possible.

The following individuals outside the agency have been consulted on study development. Additionally, input has been solicited and received from FDA on the design of this study, including participation by FDA in meetings with OMB.

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9. Explanation of Any Payment or Gift to Respondents

At each wave of quantitative data collection, KnowledgePanel members ages 18 to 20 who complete the MIA survey will receive nonmonetary panel points valued between \$1.00 and \$2.00 credited to their KnowledgePanel account to thank them for their time. For parents recruited from the KnowledgePanel for the online MIA survey, KnowledgePanel will provide nonmonetary panel points to parents of teens who complete each survey (Table 1). An individual respondent could take the survey up to 8 times during the study period making the total highest possible incentive amount for all waves valued in points between \$8 to \$16. We estimate that the survey will take approximately 25 minutes to complete. The teen respondent's parent or guardian does not receive panel points for completing the screener. The proposed token of appreciation allows us to treat respondents justly and with respect by acknowledging competing demands for their time and the effort they spend participating (Gelinis et al., 2018).

Regarding mixed method data collections (comprised of both discussion group and survey participation), we estimate studies to be no more than 90 minutes per participant. Participants ages 18-20 years will be offered the following tokens of appreciation \$50-\$75 (45-60 minutes) and \$100 (90 minutes). For youth participants ages 12-17, the following token of appreciation values will be offered: \$30-\$50 (45-60 minutes) and \$60 (90 minutes). Industry data often compensate participants in discussion groups and interviews at approximately \$1.92 per minute, equating to \$57.60 for a 30-minute session, \$86.40 for a 45-minute session, \$115.20 for a 60-minute session, and \$172.80 for a 90-minute session (Boyd, 2019). Though offering youth participants 50% less falls below industry standards, these token of appreciation values will enhance youth participation and improve response rates without introducing bias or being non-coercive (Singer and Kulka, 2002) Additionally, research shows that token of appreciation values are effective, perceived as fair incentives, and best practices to justify youth compensation payments values of \$50 for sessions under an hour and \$60 for sessions that last 90 minutes (Singer and Couper, 2008) FDA mixed methods data collections may recruit youth considered at risk for tobacco product use (e.g., youth who are susceptible to tobacco product use), which poses challenges for recruitment due to lower representation of youth groups in research panels.

Ipsos, the contractor responsible for collecting and storing quantitative data on behalf of FDA, has experience conducting recruitment campaigns specifically with youth. Clients include MADD,

CDC Foundation, AAA, Harvard University, Tufts University as well as many others. In total, thousands of interviews have been conducted with this audience. Ipsos also has experience building custom panels with youth including the Truth Longitudinal Cohort which is a custom online panel of 10,000 youth ages 15 to 21. Their observations indicate that tokens of appreciation, such as panel points, minimize non-response bias, help to complete data collection goals in a timely manner, reduce overall burden, and reduce costs. Other studies have used similar token amounts to the proposed amount for this study (e.g., Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications, OMB Control Number 0910-0810; Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communication, OMB Control Number 0910-0796).

Although most of the published research on this topic is based on mail, telephone, or in-person surveys, there are now several studies on the effects of tokens of appreciation within the context of a web-based survey. For example, a 2006 meta-analysis of 32 studies indicates that such tokens increase the odds that potential respondents will begin a web survey, and a second meta-analysis of 26 studies shows that they increase the odds of completing a web survey once respondents have begun it (Görizt et al., 2006).

Table 1. Token of Appreciation Schedule

Activity	Respondent	Points or Monetary Equivalent	Total Possible Monetary Equivalent or Incentive Across 3 Year Study Period
Online Survey	All panel members aged 18-20 years at each wave of data collection	1000 to 2000 points/\$1 to \$2	\$8 to \$16
Online Survey	All panel members who are parents of respondents under age 18 years at each wave of data collection	1000 to 2000 points/\$1 to \$2	\$8 to \$16
Mixed Methods (Online Survey + Virtual Discussion Group or Interview)	All respondents aged 18-20 years at each mixed method study	n/a	\$50 to \$100
Mixed Methods (Online Survey + Virtual Discussion Group or Interview)	All respondents under age 18 years at each mixed method study	n/a	\$30 to \$60

10. Assurance of Confidentiality Provided to Respondents

Privacy Analysis & Design

In developing this study, CTP consulted FDA's Privacy Office to identify potential risks to the privacy of respondents and other individuals whose information may be handled by or on behalf of FDA in the performance of this study. FDA designed the study to minimize privacy risks in keeping with the Fair Information Practice Principles (FIPPs) and applying controls selected from the National Institute of Standards and Technology (NIST), Special Publication 800-53, *Security and Privacy Controls for Federal Information Systems and Organizations*. CTP also identified privacy compliance requirements and coordinated with FDA's Privacy Office to ensure responsible offices in CTP satisfy all in accordance with law and policy. A privacy threshold analysis was approved by HHS on February 22, 2023.

PII Collection

The external contractor analyzing the data on behalf of the FDA is RTI International (RTI). The external sub-contractor collecting and storing the quantitative data on behalf of the FDA is Ipsos. The Ipsos KnowledgePanel, an established national online panel of adults, is solely maintained by Ipsos. Data from the voluntary respondents (parents participating in the Ipsos KnowledgePanel who have children participating in the MIA; panel members ages 18-20 participating in the MIA) will be processed by Ipsos to de-identify it before being shared with either RTI or FDA. KnowledgePanel is maintained solely by Ipsos in the Ipsos Amazon Web Services (AWS) platform and accessed solely by employees of Ipsos who are designated as requiring access based on their role and duties. Ipsos does not allow external third-party access to the KnowledgePanel. Data will be transmitted by standard SSH File Transfer Protocol (SFTP) or Liquid Files that limit the number of people who receive the information and the time-period it is accessible.

The MIA quantitative data collection will recruit respondents from the Ipsos KnowledgePanel, an established national online panel of adults. All KnowledgePanel respondents are adults, 18 years and older. As the respondents are already part of Ipsos's internal KnowledgePanel, having given consent for Ipsos to contact them, and the method they wish to be contacted, no additional PII is required to facilitate study recruitment. The respondents have already consented and approved Ipsos to possess and maintain the information they voluntarily submit.

Data collection under the MIA umbrella generic will consist of an online survey (administered every 1-2 months; total of 24 waves of survey data) and mixed methods studies (administered 2-3 times a year; total of 8 mixed methods data collections). Ipsos will send out a request through KnowledgePanel to parents of individuals ages 12-20 asking them to complete a brief screener to determine study eligibility for their child. Ipsos will also screen KnowledgePanel respondents who are 18-20 years or older into the MIA data collections. Ipsos will not collect any personally identifiable information (PII) from adults on behalf of the MIA. Ipsos already has the following PII for adult KnowledgePanel respondents: first and last names, mailing address, email addresses, phone numbers, and date of birth. Ipsos will not share this PII with RTI or FDA. Date of birth (DOB) will be collected in the youth surveys in order to

differentiate between youths in the same household by facilitating the addition of a respondent ID across surveys. The respondent ID will be added by Ipsos. Because Ipsos fields the data collections and sends RTI de-identified datasets, neither RTI nor FDA will receive any DOB data. Ipsos will not collect any other PII from the child of the adult KnowledgePanel respondent.

For the mixed methods data collection, the webinar or discussion board platform collects information that a participant gives them to access the platform (e.g., name, email address and/or phone number, etc.). Webinar or discussion board platforms also collect additional data once the platform is accessed such as IP address, MAC address, and device type. FDA staff and contractors will not have access to any data that participants provide to use the webinar platform or any data that the webinar platform collects while the platform is in use. Furthermore, FDA staff and contractors will not have the ability to link data obtained from the webinar platform to any participant. For data quality management, PII in the form of audio recordings (biometric identifiers) or screen recordings may be used as a means of quality control and/or data assurance. Permission (active consent) for this type of PII is obtained from all respondents. Respondents must agree to have study activities audio recorded. Audio files are used to produce a transcript for the purpose of developing a report and then destroyed. Audio recordings, including any transcripts made from the audio recordings, will not be linked to any other PII or transmitted to FDA.

The MIA will also collect the following non-PII data, including information relating to a respondent's: (1) race/ethnicity; (2) acculturation; (3) sex; (4) sexual orientation; (5) perceived financial situation; (6) tobacco use; (7) media campaign awareness; (8) awareness of other media campaigns; (9) attention and processing of the media campaign stimuli; (10) receptivity and comprehension of the media campaign stimuli; (11) beliefs and knowledge; (12) psychographic information (attitudes, interests, personality, values, opinions), and (13) media use.

Data gathered through the adult KnowledgePanel member will be de-identified prior to transmission to RTI for data analysis. Delivered data includes only survey data, non-PII demographics, survey weights, audio files, and transcripts of audio recordings

As the relationship with Ipsos KnowledgePanel respondents is wholly between Ipsos and the individual respondents, at no time will either RTI or FDA have access to any of the quantitative respondent information, including PII. Only Ipsos employees are permitted access to respondent information. Neither FDA nor RTI will have access to data files containing PII for survey data (e.g., respondent name, email address, date of birth, and phone numbers).

RTI study staff will be provided with de-identified data and will store it on a secure RTI share drive. The data will remain on RTI's secure shared drive and the Federal Information Processing Standards (FIPS)-low server and will be stored on the study share drive and the FIPS-low server for three years after the project has ended. RTI will also securely share de-identified datasets with relevant FDA staff through a restricted SharePoint site. Only staff who are granted access to the SharePoint site by the RTI SharePoint manager will have access to the data files. FDA will store these data on a secure drive. Only the necessary RTI and FDA study

staff will have access to de-identified data. Only RTI and FDA project staff directly involved in analysis will have access to the de-identified data. No respondent identifiers will be contained in data delivery and reports to FDA and results will only be presented in aggregate form.

Ipsos and KnowledgePanel operations are governed and certified under ISO (International Organization for Standardization, information security standard) 27001, the European Union General Data Protection Regulation (GDPR) when appropriate and complies with all applicable US Federal regulations. Terms of the contract issued by the FDA also specify data security and privacy standards and requirements and are binding on RTI and Ipsos.

We are not collecting any Protected Health Information, defined as “Personally identifiable information that relates to a person’s health, medical treatment or payment, and which was obtained from a “covered entity” (health care provider, health plan, or healthcare clearinghouse), as defined by HIPAA (Health Insurance Portability and Accountability Act) regulations.”

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 that 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 respondents in the consent form of the protections that the Certificate provides.

Privacy Act Applicability

The information collection is not subject to the Privacy Act of 1974 as the FDA will not have access to any personally identifiable information. Hence, no Privacy Act Statement is required to be displayed on the form, website, mobile application or other point at which individuals submit their information.

Data Minimization

The PII collected for this study is limited to the minimum necessary to achieve the authorized purpose and produce a valid study. The PII is necessary to determine household eligibility.

Likewise, any potentially sensitive information gathered from respondents in association with their PII is limited to that which is essential for the study, such as tobacco use. Items such as psychographic information are collected to measure correlates of tobacco use among the intended audience.

FDA has minimized the risk of unnecessary access, disclosure, use or proliferation of PII about respondents. FDA and other parties involved in the study maintain study records containing PII

only as long as required (until 3 years after the project has ended). Access to PII is restricted by role to personnel who must access this information. Sensitive records are kept in a secure location until destruction occurs. Ipsos and RTI have in place standard operating procedures ensure the security and privacy of recorded information during all phases of the destruction process, including pickup and transport of records to the destruction site. All PII, including electronic PII, will be destroyed as stipulated in the PIA.

For the quantitative data collection, non-identifiable or de-identified data (i.e., responses to the study, but without any PII) will be sent by Ipsos to RTI and then securely transferred to FDA. No PII will be sent to or be accessible by RTI or FDA at any time.

For the mixed methods data collection, RTI will share the non-identifiable or deidentified data with FDA using a secure transfer method.

Notice and Transparency

All respondents are provided notice regarding the collection and use of the information they provide. The purpose of the studies and intended use of the information collected under this umbrella generic will be described on the first page of the gen IC screeners. Parents will be told that the information collected will determine their household's eligibility for the study. When required by the external IRB, parents will provide their permission for their child to participate in the study. Respondents under the age of 18 years must first read an electronic informed assent form and provide their acceptance before they can participate.. Respondents who are 18-20 years of age (19-20 in AL or NE) must read an electronic informed consent form and provide their consent. All study materials and website pages clearly state that the study is being sponsored by the FDA.

Individual Participation and Control

Participation in studies under the MIA umbrella generic is entirely voluntary. Respondents may choose to not join the studies and are free to withdraw at any time without incurring any negative consequences. For the quantitative data collection, all parent permission, respondent assent (for respondents under age 18) and consent (for respondents ages 18-20) forms, affirmative assent or consent is obtained electronically by clicking "next" below the electronic assent/consent text on their personal mobile device, tablet, or laptop.

For the mixed methods data collection, parent permission, respondent assent (for respondents under age 18) and consent (for respondents ages 18-20) forms, affirmative assent or consent will either be collected electronically or verbally, depending on the mode of data collection.

Third-Party Accountability

Ipsos is held accountable for complying with privacy and security procedures (including reporting data breaches) by its sub-contract with RTI and their contract with FDA, which requires that Ipsos complies with 45 CFR part 46 and with the contractor's current Federal-wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP),

Department of Health and Human Services. RTI agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subject's protections in accordance with 45 CFR part 46 and the Assurance of Compliance. RTI also has an established protocol in place for privacy breaches that includes Ipsos notifying RTI and the RTI Project Director notifying RTI's IRB and CTP, who, in turn, notifies FDA's IRB. In addition, RTI has an Incident Response and Breach Notification Plan in place that activates first responders when an incident occurs, and as required by law, a breach notification policy with respect to protected health information. RTI subcontractors are accountable via contract terms for all data that it handles, uses, shares, and maintains as part of this survey.

Data Security

Ipsos' and RTI's data security procedures for the FIPS moderate network, which is the network on which the data containing PII from the evaluation will be stored, have respectively been reviewed by a FedRAMP certified Third Party Organization and both deemed acceptable. This organization issued an Authorization to Operate (ATO) to each company for the FIPS moderate networks. PII will remain on the FIPS-moderate networks following the end of data collection and for 3 years after the project has ended.

Advarra's Institutional Review Board (IRB) has reviewed and approved the study protocol and permission, consent, and assent forms (Attachments 4, 5, and 6) for the MIA. These forms include language for parental permission and respondent assent (for respondents under age 18) or consent (for respondents ages 18 to 20). The IRB's primary concern is protecting respondents' rights, one of which is maintaining the privacy of respondent information to the fullest extent allowable by law.

Concern for privacy and protection of respondents' rights plays a central part in the implementation of the MIA and will receive the utmost emphasis. All consenting documents include an explanation of the Certificate of Confidentiality (CoC). This text explains that the CoC provides legal protection for respondent information, and outlines contexts in which respondent information may or may not be shared. The text specifically notes that the CoC does not affect federal, state or local reporting requirements such as reporting of child abuse, communicable diseases, and threats to harm self or others. The text also explains that PII will not be disclosed. When required by the external IRB, parental permission is obtained from the parent or guardian for those who are ages 12 to 17 (12 to 18 in AL and NE in accordance with state laws); subsequently, assent is requested. Respondents who are 18-20 (19-20 in AL and NE) provide their own consent. Signed consent and assent are waived in this study. Security for respondents who participate in studies under this generic umbrella is assured in a number of ways: (1) when required by the external IRB, parental permission is collected for all eligible respondents ages 12 to 17 prior to study participation; (2) respondents for the quantitative surveys log onto the study's secure server hosted by Ipsos using a unique identifier and password; (3) respondents are provided with information about the privacy of their data ; (4) respondents are asked to provide their assent or consent to participate and (5) respondents have the option to decline to respond to any question in the surveys or mixed methods studies

for any reason. All study staff who handle or analyze data are required to adhere to standard data security policies.

Implementation of data security systems and processes occur as part of the data collection.

Data security provisions involve the following:

- All data collection activities are conducted in full compliance with FDA regulations to maintain the privacy of data obtained from respondents and to protect the rights and welfare of human research subjects as contained in their regulations. Respondents receive information about privacy protections as part of the informed consent process.
- All survey data entered via the study's web-based survey is encrypted, as the responses will be on a website with an SSL certificate applied. Data are passed through a firewall and then collected and stored on a protected network share. Only authorized project staff members have access to the data on the secure network share.
- Respondents access the online surveys with a unique link sent to them and complete the survey on a secure server online.

All respondents are assured that the information they provide is maintained in a secure manner and will be used only for the purpose of this research. Respondents are assured that their answers will not be shared with family members and that their names will not be reported with responses provided. Respondents are told that the information obtained from the data collections will be combined into summary reports so that details of individual responses cannot be linked to a specific respondent.

Respondents participate on a voluntary basis. The voluntary nature of the information collection is described in the assent/consent forms (Attachments 4, 5, and 6).

11. Justification for Sensitive Questions

Most questions asked will not be of a sensitive nature. However, it will be necessary to ask some questions that may be considered sensitive to assess specific health behaviors such as tobacco product use. These questions are essential to the objectives of this data collection. Although we do not anticipate any risks from these questions, some respondents may perceive them to be sensitive. Additionally, some demographic information, such as race and ethnicity, could also be considered sensitive. Collection of detailed demographic information, including race and ethnicity are necessary to assess tobacco use and possible differences in campaign impact across different populations as decades of research has shown higher prevalence of tobacco use among various racial and ethnic groups (e.g., Harlow et al., 2019; Odani et al, 2018.)

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, respondents will be fully informed of the applicable privacy safeguards. The informed consent protocol will notify respondents that these topics will be covered in the survey. This study includes a number of procedures and methodological characteristics that will minimize potential negative reactions to these types of questions, including the following:

- Respondents will be informed that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer.
- Web surveys are entirely self-administered and maximize respondent privacy without the need to verbalize responses.
- Respondents will be provided with a phone number and email address for the Principal Investigator should they have any questions or concerns about the study.
- Respondents will be provided with the phone number and email address for the Ipsos KnowledgePanel Member Support Center should they have questions or comments about their general participation in the quantitative panel.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

An estimated annual reporting burden for this collection will be approximately 249,771 hours (Table 2). This includes the time burden associated with the recruitment materials, parent screeners, consent and assent, surveys, and focus groups/in depth interviews. Our goal is to obtain a sample size of up to 2,000 unique respondents at each quantitative survey wave, for a total 24 waves of survey data collection. Additionally, we aim to obtain a sample size of up to 400 participants for each mixed methods data collection, collected on a basis of twice a year, for a total of 8 mixed methods data collections.

Survey data collection for the MIA is a repeated cross-sectional design and will consist of surveys for up to 2,000 unique respondents aged 12 to 20 administered every 1-2 months over the data collection period, for a total of 48,000 respondents. Mixed methods data collection under the umbrella generic will occur on a basis of two to three times a year, with each mixed method collection recruiting a sample size of up to 400 participants aged 12 to 20 over the course of the data collection, for a total of 3,200 participants. We will need to screen (3 minutes per response) approximately 2,457,310 panel members who may be the parent of an eligible youth over the entire study period. (97,440 screeners at each of the quantitative survey waves, over 24 waves of data collection; 14,844 screeners at each of the mixed methods collections, over 8 total mixed methods data collection points). We will also directly invite 54,577 young adult panel members (ages 18-20 years) to participate in the survey data collection or mixed methods data collection over the course of 36 months. Since the eligible age for data collection is 12 to 20 years old, we intend to screen parents of eligible respondents ages 12 to 17 and directly invite KnowledgePanel members ages 18 to 20. Parents of the teen respondents determined to be eligible through the screener will provide parent permission (3 minutes per response). We estimate that 1,842,983 of the parents who complete the screener will provide their permission for their teen to participate in the MIA study (approximately 75 percent of the 2,457,310 screened). From those contacted, either through parents or directly, we estimate 29,836 eligible teens will provide their assent (3 minutes per response) to participate in the online survey (25 minutes per response) or mixed methods data collection (60-90 minutes), and estimate 21,364 young adults ages 18 to 20 (19 to 20 in Alabama and Nebraska in accordance with state law) will provide their consent (3 minutes per response). We estimate that approximately 42 percent of the

sample for the monthly surveys and mixed method data collection will be respondents aged 18 to 20 (19 to 20 in Alabama and Nebraska).

Over the course of the study period, the 48,000 survey respondents and 3,200 mixed methods participants will receive an invitation (1 minute) and six reminder emails (1 minutes each, 6 minutes total).

The attachments are provided in both English and Spanish. We will not be recruiting separate English-speaking and Spanish-speaking samples for this study. We are simply providing Spanish-language materials for respondents who prefer to complete them over the English-language versions. Regardless of what language the respondents complete the consent/assent and surveys in, the estimated burden hours are identical. The virtual discussion will be conducted in English only.

Table 2. Estimated Annual Reporting Burden

Respondent/ Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Parent Screener	2,457,310	1	2,457,310	0.05 (3 minutes)	122,866
Parent Permission	1,842,983	1	1,842,983	0.05 (3 minutes)	92,149
Invitations	54,577	1	54,577	0.02 (1 minute)	1,092
Assent (Respondents ages 12-17)	29,836	1	29,836	0.05 (3 minutes)	1,492
Consent (Respondents ages 18-20)	21,364	1	21,364	0.05 (3 minutes)	1,068
Online Survey	48,000	1	48,000	0.42 (25 minutes)	20,160
Mixed Methods (Online Survey + Virtual Discussion Group or Interview)	3,200	1	3,200	1.5 (90 minutes)	4,800
Reminder Emails	51,200	6	307,200	0.02 (1 minute)	6,144
Total					249,771

12b. Annualized Cost Burden Estimate

Respondents participate on a purely voluntary basis and, therefore, are subject to no direct costs other than time to participate. To calculate the estimated annual cost, the mean hourly wage of \$7.25 was used for youth (ages 12-17) and \$28.05 was used for adults (ages 18-20). The youth costs represent the minimum wage, and the adult costs represent the mean hourly wage for all other Life, Physical, and Social Science occupation earnings from the U.S. Department of Labor Bureau of Labor Statistics (May 2023 data). There are no direct costs to respondents associated with participation in this information collection. Ipsos has conducted many tobacco-related panel surveys of similar length. We have examined diagnostic data from each of these prior surveys and estimate that data collection for this study will take, on average, 3 minutes per respondent for screening, 3 minutes per respondent for assenting/consenting, approximately 25 minutes per respondent for the online surveys, and approximately 90 minutes for the mixed methods data collection. Thus, assuming an average hourly wage of \$7.25 and \$28.05 (youth and adult, respectively) and doubling the rates to account for benefits and overhead, yielding an hourly wage rate of \$14.50 for youth and \$56.10 for adults, the estimated one-time cost to respondents is estimated to be \$13,347,843. The estimated value of respondents' time for participating in the information collection is summarized below.

Table 3. Annualized Cost Burden

Activity	Annual Burden Hours	Hourly Wage Rate	Total Cost ¹
Parent Screener	122,866	\$56.10	\$6,892,783
Parent Permission	92,149	\$56.10	\$5,169,559
Invitation Emails (Respondents ages 18-20)	1,092	\$56.10	\$61,261
Assent (Respondents ages 12-17)	1,492	\$14.50	\$21,634
Consent (Respondents ages 18-20)	1,068	\$56.10	\$59,915
Online Survey - Youth	11,693	\$14.50	\$16,549
Online Survey – Young Adult	8,467	\$56.10	\$474,999
Mixed Methods Collection (Online Survey + Virtual Discussion Group or Interview) - Youth	2,784	\$14.50	\$40,368
Mixed Methods Collection (Online Survey + Virtual Discussion Group or Interview) – Young Adult	2,016	\$56.10	\$113,098
Reminder Emails	6,144	\$56.10	\$344,678
Total			\$13,347,843

¹ Cost were rounded up to the next dollar.

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital, start-up, operating, or maintenance costs associated with this data collection.

14. Annualized Cost to the Federal Government

This information collection is funded through a contract with RTI. The estimated costs attributable to this data collection are \$2,283,692 per year. There are additional contract-funded activities occurring before and after this data collection that include project planning and data analysis. Other activities outside this data collection include coordination with FDA, instrument development, reporting, Advarra IRB, project management and progress reporting. This information collection will occur for three years after OMB approval.

Table 4. Annualized Cost to the Federal Government

Government Personnel	Time Commitment	Average Annual Salary	Total ¹
GS-12	5%	\$106,759	\$5,338
GS-13	20%	\$126,949	\$25,390
GS-13	20%	\$126,949	\$25,390
GS-14	10%	\$150,016	\$15,002
		Total Annual Salary Costs	\$71,120
		Annual Contract Cost	\$2,212,572
		Total Annual Cost	\$2,283,692

¹ Costs were rounded up to the next dollar.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Reporting and Project Time Schedule

Data from the MIA will be used to provide a rapid and flexible method for collecting information on campaign exposure, awareness, receptivity, attention, and processing of “The Real Cost” stimuli to understand the extent to which the campaign is being successfully delivered to the intended audience. Findings will be used to optimize campaign messages and creative rotations.

Estimates will take the form of descriptive data on survey items such as self-reported ad awareness and recall that assess basic exposure, as well as frequency of campaign exposure. Data gathered from discussion groups are qualitative and are not intended to yield results that are statistically projectable. The reporting and dissemination mechanism will consist of three primary components after each survey wave: (1) summary statistics produced from analytic data files on individual stimulus awareness, attention, processing, and receptivity, (2) data analyses summarized in a report format (e.g., PowerPoint presentations, data dashboards, etc.), and/or (3) report writing for various audiences, which could include briefings, written reports,

and/or peer-reviewed journal articles that document study findings. The key events after each round of data collection are listed below.

Approximate Project Schedule

Project Activity	Date
Surveys	July 2025 to July 2028 (Approximate)
Preparation of analytic data files	Approximately 6 weeks after completion of each wave of data collection
Data Analysis	Approximately 12 weeks after completion of each wave data collection
Report Writing	Approximately 16 weeks after completion of each wave of data collection
Mixed Methods Data Collection	July 2025, December 2025, April 2026, July 2026, December 2026, April 2027, December 2027, April 2028 (Approximate)
Transcription of audio files	Approximately 6 weeks after each quarterly data collection
Data Analysis	Approximately 12 weeks after each quarterly data collection
Report Writing	Approximately 16 weeks after each quarterly data collection

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

All data collection instruments will display the OMB approved expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

These information collection activities involve no exception to the Certification for Paperwork Reduction Act Submissions.

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