

**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 (FDA, us or we) public education campaigns related to tobacco use. To reduce the public health burden of tobacco use in the United States and educate the public—especially young people—about the dangers of tobacco use, the FDA Center for Tobacco Products (CTP) is developing and implementing multiple public education campaigns.

“The Real Cost” Monthly Implementation Assessment (MIA) is a repeated cross-sectional survey that will be conducted using 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. “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 smoking cigarettes and/or using electronic nicotine delivery systems (ENDS) products, or who have already experimented with cigarettes and/or ENDS 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 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 received by the intended audience and successfully delivered to the intended audience. We will evaluate the following key components about "The Real Cost" ads:

- Receptivity to messaging.
- Awareness of "The Real Cost" 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 survey 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.

Data from up to 2,000 unique respondents ages 12-20 years in the United States will be collected each month. We will use the Ipsos KnowledgePanel to recruit respondents for the study. To be eligible, respondents must be between the ages of 12-20 years and have not taken the MIA survey within the past 2 months (e.g., respondents who take the survey in January will be allowed to take it again in April).

We will use a rotating module approach from month to month to ensure the survey does not exceed 25 minutes on average while collecting the information we need to inform campaign development, flighting, and media buy. For example, in one month we may field questions from Section J of the surveys (see Attachments 2a and 2b), but suppress that section the following month to allow survey space to ask questions from Section H. This design offers flexibility to assess new stimuli messages, examine their performance over time, and provide the ability to pivot and add new survey measures as necessary. Monthly data will also allow us

to obtain timely information on stimuli awareness, perceived effectiveness, and teen attention and processing of the stimuli.

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

3. Use of Information Technology and Burden Reduction

Data collection 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 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. An added benefit is increased data protection by limiting the amount of personally identifiable information (PII) collected from respondents, reducing the risk of data security issues. Finally, the use of a more private data collection method makes reporting on potentially embarrassing or stigmatizing behaviors (e.g., tobacco use) feel less threatening and enhances response validity and response rates.

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 implementation evaluation differs from the longitudinal outcome evaluation 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. Having a separate, monthly implementation evaluation offers several additional benefits:
 - a. The ability to assess receptivity to messages in development among a sample of the intended audience before dissemination. Examining receptivity during the developmental stage allows FDA to ensure future efforts can potentially improve awareness, attention, processing, and receptivity.
 - b. 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 flighting schedule and media buy relate to change in ad awareness.
 - c. 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 Ipsos KnowledgePanel, specific subpopulations or specific professions, 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 one-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 health communication projects, 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 survey 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 data collection, KnowledgePanel members ages 18 to 20 years 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 (Gelinas et al., 2018).

Ipsos, the contractor acting 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., Quantitative Data on Tobacco Products and Communications, OMB Control Number 0910-0810).

To recruit a diverse sample, we want to ensure that we can reach groups who are typically underrepresented in research and have higher rates of tobacco use, including people with low socioeconomic status, LGBTQ+, those with mental health related conditions and symptoms. People from these populations are consistently underrepresented in all types of research studies (Bonevski et al., 2014, Guillory et al., 2018). When applied in a reasonable manner, tokens of appreciation are not an unjust inducement and are not coercive—they are an approach that acknowledges respondents for their participation (Halpern et al., 2004).

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 (Göritz et al., 2006).

Table 1. Token of Appreciation Schedule

Activity	Respondent	Points/Survey & Monetary Equivalent	Total Possible Monetary Equivalent Across 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

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 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 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 for the MIA will consist of a monthly online survey. 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. 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. Ipsos will not collect PII from the child of the adult KnowledgePanel respondent.

The MIA will also collect the following non-PII data, including information relating to a respondent's: (1) race/ethnicity; (2) acculturation; (3) gender identity; (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.

Survey 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, and survey weights.

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 respondent information, including PII. Only Ipsos employees are permitted access to respondent information. Neither FDA nor RTI will have access to survey data files containing PII (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 survey data. Only RTI and FDA project staff directly involved in analysis will have access to the de-identified survey 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. 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 as 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). Ipsos uses a unique case identification number to identify respondents. 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 has in place standard operating procedures based on Ipsos Policy to ensure the security and privacy of recorded information during all phases of the destruction process, including pickup and transport of records from Ipsos' locations to the destruction site. All PII, including electronic PII, will be destroyed as stipulated in the PIA. 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.

Notice and Transparency

All respondents are provided notice regarding the collection and use of the information they provide. The purpose of the study and intended use of the information collected is described on the first page of the screener. Parents are 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 complete the survey. Respondents under the age of 18 years who complete the survey must first read an electronic informed assent form and provide their acceptance before they can complete the survey. 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 the MIA is entirely voluntary. Respondents may choose to not join the study and are free to withdraw at any time without incurring any negative consequences. For 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.

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’ data security procedures for the FIPS moderate network, which is the Ipsos network on which the data from the evaluation will be stored, have been reviewed by a FedRAMP certified Third Party Organization and deemed acceptable. This organization issued an Authorization to Operate (ATO) for the FIPS moderate network. PII will remain on the FIPS-moderate network 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 complete MIA surveys 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 completing the follow-up survey; (2) respondents 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 before they encounter the first survey item; (4) respondents are asked to provide their assent or consent to participate before they encounter the first survey item; and (5) respondents have the option to decline to respond to any item in the survey for any reason. All study staff who handle or analyze data are required to adhere to Ipsos' standard data security policies.

Ipsos maintains restricted access to all data preparation areas (i.e., receipt and coding). All data files on multi-user systems are under the control of a database manager, with access limited to project staff on a "need-to-know" basis. No respondent identifiers will be contained in reports to RTI or FDA, and results will only be presented in aggregate form.

Implementation of data security systems and processes occur as part of the survey 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 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 at Ipsos and then collected and stored on a protected network share on the Ipsos Network. Only authorized Ipsos 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 all surveys will be combined into a summary report so that details of individual surveys 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, sexual orientation, and gender identity are necessary to assess disparities in tobacco use and possible differences in campaign impact across different populations.

Decades of research has shown significant disparities in tobacco use by race and ethnicity (e.g., Harlow et al., 2019; Odani et al, 2018), gender identity (e.g., Johnson et al, 2019; Delahanty et al, 2019), and sexual orientation (e.g., Johnson et al, 2019; McCabe et al., 2018). Data from the 2021 National Youth Tobacco Survey demonstrates that 6.0% of heterosexual teens reported ever experimenting with cigarettes, compared to 10.9% of gay or lesbian teens, 15.6% of bisexual male teens, 14.0% of bisexual female teens, and 11.2% of teens who are transgender. Furthermore, 17.9% of heterosexual teens reported ever using e-cigarettes, compared to 27.3% of bisexual male teens, 29.6% of bisexual female teens, and 30.7% of teens who are transgender. Therefore, collecting detailed information on these demographic characteristics will allow us to measure these differences with the goal of reducing these disparities.

Multiple studies of youth and young adults have reported approximately 12-15% of the sample identified as gender non-conforming/non-binary (e.g., The Human Rights Campaign 2018 LGBTQ+ Youth Report [Kahn et al., 2018]; The Trevor Project 2020 National Survey on LGBTQ Youth Mental Health [The Trevor Project, 2020]; CTP's evaluation of "This Free Life" campaign [Crankshaw et al., 2022]) and have concluded that gender non-conforming/non-binary response options are necessary to identify and assess tobacco use and campaign effectiveness among this population. Gender identity questions with genderqueer/gender non-conforming/non-binary response options have been approved by OMB for ExPECTT (0910-0753), RESPECT (0910-0808), and Formative Research Support: Outcomes and Awareness Measurement Research (0910-0810).

Along with the extensive and increasing body of literature showing tobacco use disparities among LGBTQ+ populations, the White House issued the Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals, which includes obligations for federal agencies to collect SOGI data. The order states that, "advancing equity and full inclusion for LGBTQI+ individuals requires that the Federal Government use evidence and data to measure and address the disparities that LGBTQI+ individuals, families, and households face." It also states that federal agencies must "describe disparities faced by LGBTQI+ individuals that could be better understood through Federal statistics and data collection" (White House, 2022).

FDA cannot support LGBTQ+ populations via its programming and resources (i.e., public education campaigns) if it is not aware of how risk factors (such as attitudes, beliefs, and behaviors) may be associated with tobacco use among LGBTQ+ individuals. To support the health and safety of LGBTQ+ populations, FDA needs to be knowledgeable about their specific needs.

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 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 237,866 hours (Table 2). This includes the time burden associated with the recruitment materials, parent screeners, consent and assent, and survey. Our goal is to obtain a sample size of up to 2,000 unique respondents at each wave of data collection, for a total of 24 waves of data collection.

Data collection for the MIA is a repeated cross-sectional design and will consist of administering a monthly survey to up to 2,000 unique respondents aged 12 to 20 at each month over the course of the data collection, for a total of 48,000 respondents. We will need to screen (3 minutes per response) approximately 2,338,560 KnowledgePanel members who may be the parent of an eligible youth over the entire study period (97,440 screeners at each wave, over 24 waves of data collection). We will also directly invite 54,096 adult panel members (ages 18-20 years) to participate in the survey. 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 1,753,920 of the parents who complete the screener will provide their permission for their teen to complete the online survey (approximately 75 percent of the 2,338,560 screened). From those contacted, either

through parents or directly, we estimate 27,936 eligible teens will provide their assent (3 minutes per response) to participate in the online survey (25 minutes per response), and estimate 20,064 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 48,000 completed surveys will come from respondents aged 18 to 20 (19 to 20 in Alabama and Nebraska).

Over the course of the study period, the 48,000 respondents will receive an invitation email (1 minute) and six reminder emails (2 minutes each, 12 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.

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	2,338,560	1	2,338,560	0.05 (3 minutes)	116,928
Parent Permission	1,753,920	1	1,753,920	0.05 (3 minutes)	87,696
Invitation Emails (Respondents ages 18-20)	54,096	1	54,096	0.02 (1 minute)	1,082
Assent (Respondents ages 12-17)	27,936	1	27,936	0.05 (3 minutes)	1,397
Consent (Respondents ages 18-20)	20,064	1	20,064	0.05 (3 minutes)	1,003
Online Survey	48,000	1	48,000	0.42 (25 minutes)	20,160
Reminder Emails	48,000	1	48,000	0.20 (12 minutes)	9,600
Total	2,434,557				237,866

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 \$27.78 was used for young adults (ages 18-20). The youth costs represent the minimum wage, and the young 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 2022 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, and approximately 25 minutes per respondent for the online surveys. Thus, assuming an average hourly wage of \$7.25 and \$27.78 (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 young adult \$55.56, the estimated one-time cost to respondents is estimated to be \$12,330,706. 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	116,928	\$55.56	\$6,496,520
Parent Permission	87,696	\$55.56	\$4,872,390
Invitation Emails (Respondents ages 18-20)	1,082	\$55.56	\$60,116
Assent (Respondents ages 12-17)	1,397	\$14.50	\$20,257
Consent (Respondents ages 18-20)	1,003	\$55.56	\$55,727
Online Survey	20,160	\$14.50	\$292,320
Reminder Emails	9,600	\$55.56	\$533,376
Total			\$12,330,706

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 two 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. 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 2024 to July 2026 (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

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.

References

- Bonevski, B., Randell, M., Paul, C. et al. Reaching the hard-to-reach: a systematic review of strategies for improving health and medical research with socially disadvantaged groups. *BMC Med Res Methodol* 14, 42 (2014). <https://doi.org/10.1186/1471-2288-14-42>
- Crankshaw, E., Gaber, J., Guillory, J., et al. (2022). Final Evaluation Findings for This Free Life, a 3-Year, Multi-Market Tobacco Public Education Campaign for Gender and Sexual Minority Young Adults in the United States, *Nicotine & Tobacco Research*, Volume 24, Issue 1, Pages 109–117, <https://doi.org/10.1093/ntr/ntab146>.
- Delahanty, J., Ganz, O., Hoffman, L., Guillory, J., Crankshaw, E., & Farrelly, M. (2019). Tobacco use among lesbian, gay, bisexual and transgender young adults varies by sexual and gender identity. *Drug and alcohol dependence*, 201, 161-170.
- Gelinas L, Largent EA, Cohen IG, Kornetsky S, Bierer BE, Fernandez Lynch H. A Framework for Ethical Payment to Research Participants. *N Engl J Med*. 2018;378(8):766-771. doi:10.1056/NEJMs1710591
- Göriz AS. (2006). Incentives in web studies: methodological issues and a review. *Int J Internet Science*. 1(1), 58-70.
- Guillory J, Wiant KF, Farrelly M, Fiocco L, Alam I, Hoffman L, Crankshaw E, Delahanty J, Alexander TN. Recruiting Hard-to-Reach Populations for Survey Research: Using Facebook and Instagram Advertisements and In-Person Intercept in LGBT Bars and Nightclubs to Recruit LGBT Young Adults. *J Med Internet Res* 2018;20(6):e197doi: 10.2196/jmir.9461
- Halpern, SD., Karlawish, JH., Casarett, D., Berlin, JA., Asch, DA. Empirical assessment of whether moderate payments are undue or unjust inducements for participation in clinical trials. *Archives of Internal Medicine*. 2004; 164(7), 801-803.
- Harlow, A. F., Stokes, A., & Brooks, D. R. (2019). Socioeconomic and racial/ethnic differences in e-cigarette uptake among cigarette smokers: longitudinal analysis of the population assessment of tobacco and health (PATH) study. *Nicotine and Tobacco Research*, 21(10), 1385-1393.
- Johnson SE, O'Brien EK, Coleman B, Tessman GK, Hoffman L, Delahanty J. Sexual and gender minority U.S. youth tobacco use: Population Assessment of Tobacco and Health (PATH) Study Wave 3, 2015-2016. *Am J Prev Med*. 2019;57(2):256-61. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/31326009>. DOI: 10.1016/j.amepre.2019.03.021
- Kahn, E., Johnson, A., Lee, M., & Miranda, L. (2018). Human Rights Campaign 2018 LGBTQ Youth Report. The Human Rights Campaign Foundation.
- McCabe, S. E., Matthews, A. K., Lee, J. G., Veliz, P., Hughes, T. L., & Boyd, C. J. (2018).

- Tobacco use and sexual orientation in a national cross-sectional study: age, race/ethnicity, and sexual identity–attraction differences. *American journal of preventive medicine*, 54(6), 736-745.
- Odani, S., Armour, B. S., & Agaku, I. T. (2018). Racial/ethnic disparities in tobacco product use among middle and high school students—United States, 2014–2017. *Morbidity and Mortality Weekly Report*, 67(34), 952.
- The Trevor Project. (2020). 2020 National Survey on LGBTQ Youth Mental Health. New York, New York; The Trevor Project.
- U.S. Bureau of Labor Statistics. (2022). All items in U.S. city average, all urban consumers, not seasonally adjusted. https://www.bls.gov/data/inflation_calculator.htm. Retrieved October 26, 2022.
- The White House. (2022). Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals. Retrieved from <https://www.whitehouse.gov/briefing-room/presidential-actions/2022/06/15/executive-order-on-advancing-equality-for-lesbian-gay-bisexual-transgender-queer-and-intersex-individuals/>