U.S. Food and Drug Administration
Center for Tobacco Products
The Real Cost Campaign Outcomes Evaluation Study: Cohort 3
OMB Control No. 0910-0915
Supporting Statement Part A

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

This information collection supports the U.S. Food and Drug Administration's (FDA) efforts to assess the effectiveness of "The Real Cost" campaigns aimed at reducing tobacco use among youth. FDA's Center for Tobacco Products (CTP) was established under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31; 21 U.S.C. 387 et seq.) which authorizes FDA to educate the public about the dangers of tobacco use and to evaluate the effectiveness of such efforts. CTP's tobacco education mission directly contributes to advancing the goals of Executive Order 14212: Establishing the President's Make America Healthy Again Commission, including the Make Our Children Healthy Again assessment, in three ways. First, CTP works to reduce tobacco use, the leading cause of chronic disease and mortality in the United States. Second, CTP protects the health of children; public education campaigns and other CTP efforts decrease the likelihood that youth initiate or escalate tobacco use. Third, CTP uses gold-standard science to develop, implement, and evaluate its programs.

Tobacco use remains the leading cause of preventable disease and death in the United States. Youth tobacco use continues to be a critical public health concern. In 2024, 7.8% of high school students reported vaping and 10.1% reported use of any tobacco product in the past 30 days (Jamal et al., 2024). From 2019 to 2023, the prevalence of current vaping among young adults aged 18 to 24 increased from 9.3% to 15.3% (Vahratian et al., 2025). In 2021, 17.0% of young adults ages 18 to 24 years were current users of a tobacco product (Cornelius et al., 2023). As a way to reduce the enormous public health burden of tobacco use, the Tobacco Control Act has given the FDA the authority to take action to protect children, encourage smokers to quit, and reduce tobacco-related disease and death. The law also enables FDA to educate the public, especially young people, about the dangers of tobacco products. Research shows that public education mass media campaigns can be used to change attitudes and beliefs about tobacco use and reduce smoking prevalence.

FDA launched "The Real Cost" public education campaigns in 2014 to prevent tobacco use among youth at risk of initiation. These campaigns use evidence-based messaging delivered through multiple channels to communicate the health risks of tobacco use. To ensure that these campaigns are effective and that federal resources are used efficiently, FDA must systematically evaluate campaign reach and impact.

The Real Cost Campaign Outcomes Evaluation Study (ExPECTT) is a longitudinal cohort study designed to assess exposure to campaign messaging and its relationship to changes in tobacco-related beliefs, intentions, and behaviors among youth. The study includes a baseline survey and multiple follow-up waves conducted approximately every 6 to 9 months. The

current request seeks to extend data collection for Cohort 3 to allow continued assessment of campaign effectiveness over time.

The first ExPECTT study (Cohort 1; OMB Control No. 0910-0753) assessed the campaign's impact on outcomes of interest, such as tobacco use behaviors and beliefs, from November 2013 to November 2016. The second ExPECTT study (Cohort 2; OMB Control No. 0910-0753) assessed the campaign's impact on outcomes of interest from June 2018 to August 2022. The third ExPECTT study (Cohort 3; OMB Control No. 0910-0915) has been assessing the campaign's impact on outcomes of interest starting in February 2023. To continue assessing the impact of "The Real Cost" campaigns, FDA intends to extend implementation of the ExPECTT Cohort 3 study. The study consists of multiple waves of data collection, including a baseline survey and three follow-up (FU) surveys prior to the requested extension, and up to five additional FU surveys.

The study will be conducted using web-based surveys that are self-administered to youth on personal computers or web enabled mobile devices. Each survey will take approximately 30 minutes to complete per participant. Each survey will include questions on youth's awareness of campaign advertisements, tobacco-related beliefs, and psychosocial predictors and precursors to tobacco-use behavior. The baseline survey included a supplemental data collection using social media; recruitment during the extension period will not use social media.

Existing national data sources (e.g., NYTS, YRBSS, PATH) do not provide the longitudinal, individual-level data necessary to link exposure to specific campaign messages with subsequent changes in attitudes and behaviors. Without this information collection, FDA would be unable to rigorously evaluate the effectiveness of its public education campaigns or optimize them to better prevent youth tobacco use.

Accordingly, this information collection is necessary for FDA to fulfill its statutory mandate to protect public health and to ensure that its tobacco education campaigns are evidence-based, effective, and responsive to evolving patterns of tobacco use among youth.

2. Purpose and Use of the Information

The information obtained from this data collection will be used to inform FDA, policy makers in the United States, prevention practitioners, and researchers about: (a) the extent of youth's exposure to campaign messages, and (b) the extent to which this exposure is associated with changes in intended outcomes. While not exhaustive, the list below illustrates a range of purposes and uses for the information collection:

- Provide critical data on the reach of the campaign among youth in the United States; particularly estimates of the proportion of the youth population that was exposed to the campaign.
- Understand the influence of the campaign on specific beliefs targeted by messages (message-targeted beliefs).

- Understand the impact of the campaign on psychosocial predictors and precursors of tobacco use behavior, such as:
    - Health and addiction risk perceptions
    - Perceived loss of control or threat to freedom expected from tobacco use
    - Anticipated guilt, shame, and regret from tobacco use
    - Tobacco use susceptibility
    - Intention or willingness to use tobacco
    - Intention to quit and/or reduce daily consumption
- Understand the impact of the campaign on tobacco use behaviors such as initiation, escalation, and cessation.

We are using survey testing and subject matter expert (SME) input to aid in survey clarity (e.g., address typos and decrease confusing wording) and skip pattern testing. Based on survey testing and SME input received prior to follow-up waves, some items may be updated non-substantively for clarity or for accuracy given the evolving science around the health harms of e-cigarette use (e.g., changing "will" to "may" when stating possible health harms of e-cigarette use). Based on skip pattern testing and instrument length, some items may be excluded.

3. Use of Information Technology and Burden Reduction

The study survey 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 that the answers will remain private. In addition, using a web-based survey will allow for more participants 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 participants, reducing the risk of data security issues. Finally, as noted above, this technology permits respondents to complete the survey in privacy. 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

FDA's "The Real Cost" campaign includes specific messages delivered through a variety of advertisements. There are no existing data sources that contain measures on awareness of and exposure to these campaign messages on an ongoing basis, a requirement for determining the impact of campaign exposure on intended campaign outcomes. 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 evaluation 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 evaluate the potential effects of the campaign. This information collection therefore does not duplicate previous efforts.

5. Impact on Small Businesses or Other Small Entities

Respondents in this study will be members of the general public, specific subpopulations, or specific professions, not business entities. No impact on small businesses or other small entities is anticipated.

6. Consequence of Collecting the Information Less Frequently

Participants in this evaluation study are surveyed approximately every 6 to 9 months. There are no legal obstacles to reduce burden, but the lack of information needed to evaluate the FDA's youth tobacco education campaign may impede the federal government's efforts to improve public health. Without the information collection requested for this evaluation study, it would be difficult to determine the value or impact of the campaign on the lives of the people it is intended to serve. Failure to collect these data could reduce effective use of FDA's program resources to benefit youth in the United States. Careful consideration has been given to how frequently the campaign's intended audience should be surveyed for evaluation purposes. We believe the longitudinal evaluation design will provide sufficient data to evaluate the campaign effectively.

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

There are no special circumstances for this collection of information that require the data collection to be conducted in a manner inconsistent with 5 CRF 1320.5(d)(2). The message testing activities fully comply with the guidelines in 5 CFR 1320.5.

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of July 14, 2025. FDA received 1 PRA related comment.

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

In the *Federal Register* of July 14, 2025 (90 FR 31229), FDA published a 60-day notice requesting public comment on the proposed collection of information. One PRA-related comment was received.

(Comment) The commenter strongly supported FDA's proposed "Real Cost" Campaign Outcomes Evaluation Study (Cohort 3), emphasizing the campaign's proven effectiveness and urges continued funding of the campaigns and evaluation studies. The comment highlights that "'The Real Cost" Youth E-Cigarette Prevention Campaign has been "instrumental in reversing the trajectory of youth vaping, driving rates down from a peak of 5.4 million in 2019 to about 1.6 million today" and that "The Real Cost" Youth Cigarette Prevention Campaign demonstrated exceptional cost-effectiveness by generating "$180 in savings for every dollar of the nearly $250 million invested in its first two years." The commenter recommends that the proposed information collection reaches communities historically targeted by the tobacco industry. Finally, the commenter advocated for inclusion of questions related to gender in the information collection.

(FDA Response) FDA appreciates the comment in response to the 60-day notice. FDA agrees with the commenter that continued campaign evaluation is "crucial to maintaining the ongoing success of 'The Real Cost'" campaigns through rigorous gold standard research, and that this information collection has strong practical utility. Specifically, the proposed information collection will continue to assess the campaign's impact on reducing chronic disease among youth through decreased tobacco initiation and identify opportunities to enhance program effectiveness and adapt to changing public health challenges. The proposed information collection is designed to collect high-quality data with a longitudinal cohort design that will follow youth participants over time to assess changes in tobacco-relevant outcomes due to campaign exposure. The data collected has strong practical utility and will provide essential insights for campaign optimization by identifying messages that are most effective in preventing and reducing youth tobacco use and while providing vital campaign evaluation data to ensure FDA is advancing public health goals in protecting children from the harmful effects of tobacco use.

The goal of the current information collection is to assess the reach and impact of "The Real Cost" Youth E-Cigarette and Cigarette Prevention campaigns for the general population of youth (aged 12-17) in the United States who are at risk of tobacco use. This information collection focuses on all U.S. youth (ages 12-17) because, as the commenter states, the tobacco industry has historically targeted young people in their marketing strategies (U.S. DHHS, 2012), and most adult tobacco users begin using during this critical age range (U.S. DHHS, 2014).

FDA's approach to this evaluation study is conducted in full compliance with all applicable Executive Orders and current Administration priorities regarding federal research and data collection activities. Preventing tobacco initiation among U.S. youth is essential to combat the chronic disease caused by tobacco use. The focus of this proposed information collection is the general population U.S. youth. While examining specific racial, ethnic, or demographic subgroups is not a primary aim of the study, FDA is able to assess campaign reach and impact for various population segments among the youth sample. The study collects demographic data that can support examination of campaign effectiveness among different groups of youth who

may be at varying levels of risk for tobacco initiation and use. For example, the survey collects data on participant race and ethnicity items in compliance of Office of Management and Budget's Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity.

Additionally, the commenter requests for the inclusion of survey items to assess gender in the information collection, which would not be in compliance with Executive Order 14168 "Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government." FDA does not assess or examine gender or gender identity in this study. To be in compliance with Executive Order 14168 "Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government," we are unable to assess or examine gender or gender identity in this study. We include one item on sexual orientation: "Which of the following best represents how you think of yourself?" (Response options: Straight or heterosexual, Bisexual, Gay or lesbian). We also include one item on sex: "Are you female or male?" (Response options: Male, Female). The inclusion of these two items enables us to examine differences in exposure and responses to campaign messages among demographic groups in a manner that is compliant with Executive Orders.

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 National Institutes of Health National Cancer Institute (NIH/NCI). These affiliations serve as information channels, help prevent redundancy, and promote use of consistent measures of effectiveness. Coordination activities include:

- Review of proposed messages for advertisements;
- 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

For each wave of follow-up data collection during the extension period, youth respondents who participate in the data collection will be offered a $25 incentive for an estimated average time of 30 minutes for taking the survey. If a respondent completes the survey during the approximately three-week early release period, they will receive a $5 bonus (Table 1). Respondents can choose whether to receive their incentive (with or without the bonus) in the form of cash or a Visa gift card. In addition, the study will use procedures designed to maximize respondent participation, such as e-mail, text, and mail (paper letter) reminders, encouraging messages, attention check items, and a landing page to encourage engagement.

The proposed incentive allows us to treat participants justly and with respect by acknowledging competing demands for their time and the effort they spend participating (Gelinas et al., 2018). RTI International (RTI), the contractor acting on behalf of FDA, has experience conducting over 35 different recruitment campaigns specifically with youth. Their observations indicate that incentives minimize non-response bias, help to complete data collection goals in a timely manner, reduce overall burden, and reduce costs. Both the scientific literature (Martinson et al., 2000; Festinger et al., 2005) and RTI's experience indicate that research participants are more likely to complete surveys at higher incentive amounts. Achieving high participant retention in this study will allow us to maximize the national representativeness of our sample; for this reason, we are seeking to retain as much of our cohort in follow-up waves as possible as they get older. Other studies have used similar incentive amounts to the proposed incentive for this study. The National Study for Drug Use and Health (NSDUH; OMB Control Number 0930-0110), currently uses an incentive (including cash or gift card) for youth ages 12 to 17. The study experienced an increase in the weighted overall response rate (screening * interviewing) from 67% to 71% from 2001 to 2002 when the incentive was increased to $30. ExPECTT (OMB Control Number 0910-0753) provided similar incentives for the first two cohorts of The Real Cost evaluation. In 2013, a $20 incentive was offered for the first cohort which, adjusted for inflation, is $25.35 in 2022 USD (U.S. Bureau of Labor Statistics, 2022) and in 2020, an increased incentive of $25 (and a $5 bonus for responding during the early release period) was offered for the second cohort of the study.

In order to recruit a diverse sample, we want to ensure that we can reach socially disadvantaged groups, including people with low socioeconomic status. People with low socioeconomic status are consistently underrepresented in all types of research studies (Bonevski et al., 2014). When applied in a reasonable manner, incentives are not an unjust inducement—they are an approach that acknowledges participants for their participation (Halpern et al., 2004).

In general, empirical studies show that incentives can increase response rates and reduce attrition in longitudinal surveys within some respondent populations (Scharff et al., 2010; Becker et al., 2019; Pejtersen, 2020) and cash incentives are more effective than non-cash

incentives (Martinson et al., 2000; Festinger et al., 2005; 2008; Becker et al., 2019). 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 incentives within the context of a web-based survey. For example, a 2006 meta-analysis of 32 studies indicates that incentives increase the odds that potential respondents will begin a web survey, and a second meta-analysis of 26 studies shows that incentives increase the odds of completing a web survey once respondents have begun it (Göritz et al., 2006).

We will replenish the sample up to 2 times during the extension period (see Section 12a: *Replenishment Recruitment During Extension Period* for additional information) to account for attrition from the longitudinal sample and ensure we continue to have younger respondents included in the sample. Each household that receives a package of screening materials as part of the replenishments will receive a $1 cash pre-incentive as part of that package, which studies suggest can increase response rates and reduce cost and nonresponse (Dillman et al., 2014; Marlar and Schreiner, 2010; Singer & Ye, 2013). The youth's parent or guardian does not receive an incentive for completing the screener and household roster interview that occurs during replenishment recruitment. Youth who are enrolled in the study during the replenishment receive the same compensation for study participation as youth who have been participating as part of the existing longitudinal cohort.

Table 1. Incentive Schedule for Extension Period

Type of Incentive	**Participant**	**Amount/Value**	**Total Amount if Completing All Waves During the Extension***
Youth Survey incentive- Early Release Period: Completion during the Early Release period of data collection	All longitudinal panel members who complete the survey	$30/survey	$150
Youth Survey incentive- Completion after Early Release Period expires	All longitudinal panel members who complete the survey	$25/survey	$125
Household pre-incentive for replenishment recruitment	Replenishment households	$1/household	$1

*Participants who complete fewer waves will receive a lower total amount, commensurate with the number of waves completed.

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 participants 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 and assigned PTA ID 2060996.

PII Collection

As part of this study, RTI is collecting and maintaining personally identifiable information (PII) about participants who complete the online surveys and online screener (for the replenishment samples). This study has a completed and approved PIA on file: FDA - ExPECTT III - QTR3 - 2023 - FDA2113339 which details the types of PII collected and how that information is protected. The PII we will be collecting from youth participants as part of the follow-up surveys during this extension period are first and last name, date of birth, home address, and phone number. Youth participants are also asked to provide their email address, physical address and phone number at each wave so the study team can send them a Visa gift card or cash incentive (per their preference) for completing the survey at that wave. The following non-PII is also collected from youth: media use, sexual orientation, sex, and grade level. We may also obtain the following PII from parents during follow-up waves: first and last name, email address, phone number, mailing address, and IP address. As part of the online screener process to confirm eligibility for the replenishment sample, parents are asked to provide the following PII about themselves: mailing address, first and last name, e-mail address, and phone number. The following non-PII is also collected from parents during screening for sample replenishment: age, number of people in the home by age, education level, race/ethnicity, spoken language, household income, home ownership status, access to internet, food stamp status, and smoking status. For the purposes of data analysis, we separate PII from non-PII survey responses and only store non-PII on the Federal Information Processing Standards (FIPS)-low server.

All PII will be collected using Blaise (survey programming software) hosted on RTI's secure servers. Data are encrypted using https protocols and stored on secure Structured Query Language (SQL) databases. RTI is using a unique alphanumeric variable to connect screener data and survey data and to determine if a participant has completed the survey. The unique alphanumeric variable, participant responses to the screener, and responses to the body of the survey will be stored by RTI in a Blaise server. As needed, RTI analysts will extract the data to a secure project network location for processing. All data files (PII, screener data for the replenishment sample, and survey data (unique variable but no other PII)) will be stored together temporarily in Blaise (which has restricted access and requires credentials to access) before daily transfer to RTI's FIPS-moderate network. At the completion of data collection, the databases will be deleted from RTI's web server and remain only on RTI's FIPS-moderate network server. Data files containing PII will be stored on the FIPS-moderate network server for at least three years after the project has ended. The FIPS moderate network is not accessible through the internet. It requires specified users with username and password to access a Hosted Virtual Network to access the data.

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. RTI will notify participants 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 purpose of the study is to evaluate “The Real Cost” public education campaign to reduce and prevent tobacco use being conducted by CTP in support of its mandate to positively impact public health. The PII is necessary in order to invite youth participants to take the follow-up surveys, determine household eligibility for replenishment samples, contact parents for parental permission, conduct quality control checks, and distribute incentives.

Likewise, any potentially sensitive information gathered from participants in association with their PII is limited to that which is essential for the study, such as tobacco use and home tobacco environment. Items such as media use and sensation seeking are collected because they are established risk factors for tobacco use in youth.

FDA and RTI have minimized the risk of unnecessary access, disclosure, use or proliferation of PII about participants. RTI maintains all study records containing PII, and only as long as required (until at least 3 years after the project has ended). RTI uses a unique case identification number to identify participants. 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. RTI has in place standard operating procedures based on RTI Policy to ensure the security and privacy of recorded information during all phases of the destruction process, including pickup and transport of records from RTI’s 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 RTI to FDA. No PII will be sent to or be accessible by FDA at any time.

Parents of the youth participants who complete the online survey provide their phone number to receive text reminders, their email address to receive email reminders, and their mailing address so that their child can receive an incentive for participation. RTI study staff will provide an encrypted file with the participants' mailing addresses to the incentive provider group at RTI (Division of Research Services Respondent Incentive Group) so that incentives can be distributed via mail. RTI does not share this information with FDA. RTI shares Case ID, password, parent first and last names, youth first name, and household mailing addresses with the print vendor for the invitation letters, reminder letters, and postcard reminders for follow-up waves of the survey. This information is sent to the printer vendor via encrypted files. RTI does not share this information with FDA. The print vendor does not have access to any other PII or non-PII from the study. RTI International will not share PII gathered via this collection with any other individuals or entities.

Notice and Transparency

All participants are provided notice regarding the collection and use of the information they provide. Youth participants who complete the follow-up surveys must first read an electronic informed assent form and provide their acceptance before they can complete the survey. Youth participants who turn 18 during the course of the study must read an electronic informed consent form and provide their acceptance. In addition, the purpose of the study and intended use of the information collected is described on the first page of the web screeners for replenishment samples. In that web screener, parents are told that the information collected would determine their household's eligibility for the study and must provide their permission for their child to complete the survey. All study materials and website pages clearly state that the study is being sponsored by the FDA.

Individual Participation and Control

Participation in the ExPECTT study: Cohort 3 is entirely voluntary. Participants may choose to not join the study and are free to withdraw at any time without incurring any negative consequences. For all parent permission, youth assent and youth consent forms, affirmative assent or consent is obtained electronically. The parent/youth respondent receives a prompt with information about the study and is then asked if they agree to allow their child to participate (if parent) or if they themselves agree to participate (if youth) and can select either "Yes" or "No" on their personal mobile device, tablet, or laptop. Respondents cannot move forward in the survey unless they provide assent/consent. This process is required at all waves of data collection, including baseline, follow-up, and replenishment.

Third-Party Accountability

RTI is held accountable for complying with privacy and security procedures (including reporting data breaches) by its contract with FDA, which requires that RTI 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 the 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

RTI International's data security procedures for the FIPS moderate network, which is the RTI 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, 5a, 5b, 6, 7, 8) for the Outcomes Evaluation Study. These forms include language for parental permission and youth assent (under age 18; under age 19 in AL/NE) or consent (18 or older; 19 or older in AL/NE). The IRB's primary concern is protecting respondents' rights, one of which is maintaining the privacy of respondent information to the fullest extent of the law.

Concern for privacy and protection of respondents' rights plays a central part in the implementation of the ExPECTT study: Cohort 3 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 youth 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 Personally Identifiable Information (PII) will not be disclosed. Parental permission is obtained from the youth's parent or guardian for those that are ages 11 to 13; subsequently, youth assent is requested. RTI has received a waiver of parental permission from Advarra IRB for youth ages 14 to 17. Youth who turn 18 during the course of the study (19 in AL/NE) provide their own consent. Signed consent and assent are waived in this study.

Names, email addresses, phone numbers, and mailing addresses are never transmitted to FDA/CTP. Only authorized RTI staff will have access to this information on a need-to-know basis. Security for youth participants who complete the online surveys is assured in a number of ways: (1) parental permission is required for all eligible youth ages 11 to 13 prior to completing the follow-up survey; (2) participants log onto the study's secure server hosted by RTI using a unique identifier and password; (3) participants 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) participants 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 RTI's standard data security policies.

To ensure data security, all RTI project staff are required to adhere to strict standards. RTI 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 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 RTI and then collected and stored on a protected network share on the RTI Network. Only authorized RTI project staff members have access to the data on the secure network share.
- Participants access the online surveys with a unique Case ID and password 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 participant. The data will be kept private to the extent allowed by law.

Respondents participate on a voluntary basis. The voluntary nature of the information collection is described in the key information section of the parent permission form (Attachment 4), assent/consent forms (Attachments 5a, 5b, 6, 7, 8) and the lead letter (Attachment 11a).

<u>Data Suppression Techniques</u>

An additional approach to secure sensitive data will be to employ data suppression techniques to protect any PII data from survey respondents in the evaluation. Data suppression is a readily applied technique where estimates are not reported if they could result in disclosure of a participant's identity or are deemed to be unstable (i.e., low precision).

Based on well-established guidelines followed by the Center for Tobacco Products (CTP) Office of Science (OS) guidelines, as well as the National Center for Health Statistics (NCHS), data suppression will be used if any of the following conditions are met: (1) The coefficient of variation of the proportion or estimate is > 30% and/or (2) $n < 50$, where n is the unweighted sample size in the denominator of the estimated proportion or the denominator used for calculating the estimate.

To further reduce disclosure, we will follow further established guidance from CTP/OS:

- Each estimate (or table cell) must be generated based on a numerator of 3. This includes means, total, numerators of proportions, all table cell counts, and marginal counts. If an estimate is based on a numerator of 1 or 2, it will be combined with another category.
- We will work to ensure table differencing (i.e., calculating the sample size of a small cell from cells of another related table) does not occur by using consistent categories across tables.
- Continuous/ordered variables will be presented so that extreme values pertaining to an individual are not evident.

11. Justification for Sensitive Questions

The majority of 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 participants may perceive them to be sensitive. Additionally, some demographic information, such as race and ethnicity, could also be considered sensitive, but are necessary in order to assess differences in prevalence of tobacco use and possible differences in campaign impact across different populations (e.g., differences by race/ethnicity [Harlow et al., 2019; Odani et al, 2018] and sexual orientation [Johnson et al, 2019; McCabe et al., 2018]).

To address any concerns about inadvertent disclosure of sensitive information, participants will be fully informed of the applicable privacy safeguards. The informed consent protocol will notify participants that these topics will be covered in the 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:

- Participants 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.
- Participants will be provided with a phone number and email address for the Principal Investigator should they have any questions or concerns about the study.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

The estimated burden for the total study, including baseline and up to eight continuing follow-up surveys, is 114,945[1] hours. The baseline and first two follow-up studies are complete with total actualized burden of 49,428 hours, and a third follow-up study will be completed prior to the extension period with an estimated burden of 5,717 hours.

An estimated one-time reporting burden for the data collection during the extension period will be approximately 59,799 hours (Table 2). This includes the time burden associated with continued follow-up surveys and informed consent, as well as replenishing the sample up to twice during the extension (i.e., the replenishment recruitment materials, parent and youth screeners, household roster).

We detail below the activities that occurred prior to the extension period and activities that will occur during the extension period.

Data Collection Prior to Extension Period

Four waves of data collection are scheduled to be conducted prior to the start of the extension period. Specifically, we recruited youth at the baseline survey primarily through mail-based recruitment and have completed two follow-up surveys, including replenishing the sample one time. As a supplemental data collection at baseline, we administered an online survey with participants recruited through social media; however, no additional social media recruitment has or will be conducted. One additional follow up survey will be fielded in Spring 2026 prior to the extension period. Each of these surveys take approximately 30 minutes to complete per participant.

Youth Survey Materials for Follow-Up Waves in Extension Period

As this is a longitudinal data collection, participants who were recruited into the study at baseline or at any replenishment wave will be recontacted for each subsequent follow-up wave. During the proposed extension period, we will send invitations and study materials to sample respondents for up to five follow-up waves (10 minutes per respondent). Including youth recruited in the replenishment, this will be up to 14,053 youth at each wave. At each of the follow-up waves, respondents are estimated to provide assent (5 minutes per respondent) and complete the survey (30 minutes per respondent). Where required, we will ask the

[1] There was an error in the household screener burden total hour calculation in the 60-day FRN. We corrected that error in this calculation resulting in 1,011 fewer burden hours for the overall study as compared to the published burden in the 60-day FRN.

parent/guardian to provide permission (5 minutes per respondent) for the youth to participate in the study. For youth who complete the survey, we will also mail an incentive letter (1 minute per respondent).

Replenishment Recruitment During Extension Period

Between baseline and the second follow-up wave of the original study period, we lost 27% of our original sample, or 13.5% averaged across the follow-ups. We estimate that we will continue to lose a similar percentage of our sample at each follow-up. Replenishing the sample will ensure we maintain an adequate longitudinal sample at each study wave and continue to have representation from younger respondents in our aging sample. We will replenish the sample up to 2 times during the extension period. We will send out recruitment/study material packages to an additional 305,000 households in total (3 minutes per response) over the course of the extension period. We expect to receive an estimated 65,000 completed screeners (5 minutes per response). For households identified as eligible for the study during the replenishment screening process (i.e., the presence of 1 or more youth ages 11 to 17), we will ask the parent/guardian to list all eligible youth in their households for study selection, a process called rostering (5 minutes per response). We will randomly select up to 2 eligible youth per household. We will ask parents to provide permission for each eligible youth to participate in the study (5 minutes). If more than one youth is selected, parental permission will be required for each child. In some cases, where the adult taking the screener is not the parent of the eligible youth(s), we will reach out by email and/or letter with a notice of eligibility (2 minutes) and a request to provide parental permission. All youth with parental permission will be sent an invitation email to participate in the study (1 minute). We will also send reminder emails and texts out to eligible youth during data collection who have not yet completed the survey (2 minutes). We will not use social media to recruit any respondents for the replenishment samples.

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 consent/assent forms and surveys for participants 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[1,2]

Respondent/Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Household Recruitment Study Materials--Mail: Baseline Recruitment & Follow-up Replenishments	305,000	1	305,000	0.05 (9 mins)	15,250
Household Screener--Mail: Baseline Recruitment & Follow-up Replenishments	65,000	1	65,000	0.08 (5 mins)	5,200

Household Roster--Mail: Baseline Recruitment & Follow-up Replenishments	7,661	1	7,661	0.08 (5 mins)	613
Parent Permission at Recruitment-Mail: Baseline Recruitment & Follow-up Replenishments	12,245	1	12,245	0.08 (5 mins)	980
Invitation Emails-Mail: Baseline Recruitment & Follow-up Replenishments	9,738	1	9,738	0.02 (1 min)	195
Eligibility Letter/Emails-Mail: Baseline Recruitment & Follow-up Replenishments	280	1	280	0.03 (2 mins)	8
Email/Text Reminder-Mail: Baseline Recruitment & Follow-up Replenishments	9,738	1	9,738	0.03 (2 mins)	292
Invitations and Study Materials: Follow-up waves	57,729	1	57,729	0.17 (10 mins)	9,814
Youth Assent: Baseline and Follow-up waves	44,768	1	44,768	0.08 (5 mins)	3,581
Parent Permission at Recontact: Follow-up waves	7,336	1	7,336	0.08 (5 mins)	587
Youth Survey: Baseline and Follow-up waves	44,768	1	44,768	0.50 (30 mins)	22,384
Youth Incentive Thank You Letter: Baseline and Follow-up waves	44,768	1	44,768	0.02 (1 min)	895
Total					**59,799**

*We received a waiver of parental permission from IRB for youth 14+, so not all respondents require parental permission at recontact.

[1]Note that all values in the table are rounded to the nearest hundredths place (for the Average Burden per Response column) or to the nearest whole number (for all other columns); therefore, sums may not equal the exact totals due to rounding.

[2] Note that values in the table are not annualized. These values reflect the full burden hours required for the study.

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 and $31.08 was used for young adults. 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 (https://www.bls.gov/oes/current/oes_nat.htm#19-0000; May 2024 data). There are no direct costs to respondents associated with participation in this information collection. RTI has conducted many smoking-related surveys of similar length among youth and adults. We have examined diagnostic data from each of these prior surveys and estimate that data collection for this study will take, on average, 5 minutes per respondent for screening during replenishment recruitment, 5 minutes per respondent for assenting/consenting, and approximately 30 minutes per respondent for the online surveys. Thus, assuming an average hourly wage of $7.25 and $31.08 (youth and adult, respectively) and doubling this to account for benefits and overhead, yielding an hourly wage rate of $14.50

for youth and $62.16 for adults, the estimated one-time cost to participants is estimated to be $2,436,939.82. The estimated value of respondents' time for participating in the information collection is summarized below.

Table 3. Annualized Cost Burden

Type of Respondent	Activity	Annual Burden Hours	Hourly Wage Rate	Total Cost[1] (Assuming 5 follow-up waves, including 2 replenishments)
Parents of Youth aged 11-17	Recruitment Study Materials – Mail	15,250	$62.16	$947,940.05
	Household Screening – Mail	5,200	$62.16	$323,232.00
	Household Rostering – Mail	613	$62.16	$38,098.76
	Parent Permission – Mail (BL/Replen)	980	$62.16	$60,892.10
	Invitation Emails – Mail (BL/Replen)	195	$62.16	$12,105.77
	Eligibility Letter/Emails – Mail (BL/Replen)	8	$62.16	$522.25
	Email/Text Reminder – Mail (BL/Replen)	292	$62.16	$18,158.65
	Invitation & Study Materials (Follow-up)	9,814	$62.16	$610,033.89
	Parent Permission – Mail (Follow-up)	587	$62.16	$36,478.43
Youth aged 11-20	Youth Assent – Mail	3,581	$14.50	$51,930.39
	Online Survey – Mail	22,384	$14.50	$324,564.93
	Youth Incentive Thank you Letter – Mail	895	$14.50	$12,982.60
Total				**$2,436,940**

[1] Cost was 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 total cost to the Federal Government for this information collection is $2,110,158 (= $153,119 federal cost + $1,957,039 contractor cost). Our estimated cost reflects the allocation of 4 full time equivalent (FTE) employees at 5-20% to monitor the conduct and progress of the studies (e.g., protocol oversight, data quality assurance, regulatory compliance, documentation review).

Using 2025 Washington DC-Metropolitan area salary and wage data, found at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/25Tables/html/DCB.aspx for a GS-12, Step 5 employee, we calculate a total annual salary of $114,923. Doubling this figure to account for benefits and overhead, and applying the 5% time allocation, we calculate a total cost of $11,493. Using the same data source for the two GS-13, Step 5 employees, we calculate a total annual salary of $136,658. Doubling this figure to account for benefits and overhead, and applying the 20% time allocation, we calculate a total cost of $54,664 for each GS-13 employee ($109,328 total for 2 employees). Using the same data source for a GS-14 Step 5 employee, we calculate a total annual salary of $161,486. Doubling this figure to account for benefits and overhead, and applying the 10% time allocation, we calculate a total cost of $32,298 for the GS-14 employee. Total federal annual salary costs are $153,119.

The estimated total cost also includes an annualized cost of $1,957,039 for a contractor to assist in the conduct of the collection of information, project planning and analysis, coordination with FDA, instrument development, reporting, IRB management, project management and progress reporting. This information collection for the extension period will occur from 2026 through 2029.

Annualized Cost to the Federal Government			
Government Personnel	**Time Commitment**	**Average Annual Salary**	**Total[1]**
GS-12	5%	$114,923	$11,493[2]
GS-13	20%	$136,658	$54,664[2]
GS-13	20%	$136,658	$54,664[2]
GS-14	10%	$161,486	$32,298[2]
		Total Annual Salary Costs	$153,119
Annual Contract Cost			$1,957,039
Total Annual Cost			**$2,110,158**

[1] Costs were rounded up to the next dollar. [2]Costs were calculated using Step 5 employee salary data for each grade. Total salary costs were doubled to account for benefits and overhead.

15. Explanation for Program Changes or Adjustments

To align with Executive Order 14168, Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government, we are revising this information collection to remove questions relating to gender. For the extension, we are proposing up to 2 additional follow-up waves of data collections, including up to 2 additional replenishment samples. Additional waves are needed for this study to evaluate the influence of future "The Real Cost" public education messages on tobacco-related knowledge, attitudes, and behaviors (e.g., preventing youth from using e-cigarettes). Replenishing the sample will ensure we maintain an adequate longitudinal sample at each study wave and continue to have representation from younger respondents in our aging sample.

In addition, we updated the estimated burden per response based on past data collections for the baseline and first follow-up wave. Our estimated burden for the information collection reflects an overall decrease of 55,600 hours and an increase of 247,285 responses.

16. Plans for Reporting and Project Time Schedule

Data from this information collection will be used to estimate awareness of the campaign among youth and model the effects of exposure to the campaign on a variety of intended psychosocial outcomes and predictors of tobacco use behaviors. Estimates will take the form of descriptive data on survey items, such as self-reported ad recognition and recall, that assess basic exposure as well as frequency of ad exposure. Data will also be used to examine statistical associations between exposure to the campaign and pre-post changes in specific outcomes of interest. This will be accomplished with the use of multivariate models that estimate follow-up measures of each relevant outcome as a function of prior self-reported exposure to the campaign, controlling for individual and other characteristics that may confound the relationship between campaign exposure and changes in outcomes. We hypothesize that there should be larger changes in intended outcomes among individuals who report greater exposure to the campaign (i.e., dose-response effects).

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 awareness of and campaign outcomes, (2) data analyses summarized in a report format (e.g., PowerPoint presentations, data dashboards, etc.), and (3) report writing for various audiences, which could include briefings, written reports, and/or peer-reviewed journal articles that document the relationships between campaign exposure and changes in the aforementioned outcomes of interest. The key events after each round of data collection are listed below.

Approximate Project Schedule During Extension Period

Project Activity	Date
Survey Preparation and Data Collection	July 2026 to September 2029 (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.

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