United States Food and Drug Administration
Center for Tobacco Products

The Real Cost Campaign Outcomes Evaluation Study: Cohort 3
OMB Control Number 0910-0915
Supporting Statement Part B

B. Statistical Methods

1. Respondent Universe and Sampling Methods

The Real Cost Campaign Outcome Evaluation Study, also known as the Evaluation of FDA's Public Education Campaign on Teen Tobacco (ExPECTT) study consists of a probability sample involving a longitudinal survey of youth, assessed at baseline and follow-up waves to evaluate "The Real Cost" health education campaign. This longitudinal design allows us to calculate baseline-to-follow-up changes in campaign-targeted outcomes for each study participant. We hypothesize that if the campaign is effective, the baseline-to-follow-up changes in outcomes should be larger among individuals who report greater exposure to the campaign (i.e., dose-response effects). The survey is being conducted by RTI International (RTI), a contractor acting on behalf of FDA.

At baseline (conducted in February 2023), we recruited a sample of 5,354 youth aged 11 to 17 by mail. We used a stratified random sample of addresses selected from RTI's national Address-Based sampling (ABS) frame. Our ABS frame is maintained in-house and based on the U.S. Postal Service's Computerized Delivery Sequence (CDS) file, of which we receive monthly updates, so it is as up to date as possible. Prior to selecting the address sample, the national frame was stratified by both an address's predicted probability of having youth ages 11 to 17 and an address's probability of response. Sample were allocated to these strata to balance data collection costs and statistical precision.

Additionally, at baseline, we recruited a supplemental sample of 1,501 youth ages 14 to 20 via social media. We will not be conducting any additional recruitment or data collection using social media. The supplemental sample recruited via social media is a nonprobability sample and was included to enhance sample size and support subgroup analyses. Analyses intended to produce population-level estimates will rely on the probability-based address-based sampling (ABS) sample and associated survey weights. Data from the social media sample may be analyzed separately or incorporated into analytic models as appropriate, with consideration of differences in selection probabilities and potential biases. Inclusion of this supplemental sample does not affect the validity of probability-based estimates derived from the ABS sample.

Prior to the requested extension period, we have conducted the baseline survey and 3 follow-up surveys. We intend to collect up to five additional follow-up waves of survey data during the extension period. In March-June 2025, as part of the second follow-up survey, we replenished the sample. Replenishing the sample ensures 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 more times during the extension period. Sample replenishment occurs using the same method described above for the baseline mail survey.

For the ExPECTT study, age is the only screening criterion. Eligible youth were aged 11 to 20 at baseline will be 14 to 24 by the end of data collection during the extension period, including respondents recruited through sample replenishments.

2. Procedures for the Collection of Information

Baseline recruitment took place in 2023, primarily via mail. The recruitment sample for the mail-based data collection included youth ages 11 to 17. In addition to the primary mail-based data collection at baseline in 2023, we recruited an additional sample using a social media-based recruitment. We will not be conducting additional recruitment or data collection using social media during the extension period. Because this is a longitudinal study, participants from the social media sample will be retained in the sample because they were members of the original study cohort.

Replenishing the sample ensures we maintain an adequate longitudinal sample at each study wave despite attrition and continue to have representation from younger respondents in our aging sample. We have replenished the sample once as part of the second follow-up survey and intend to replenish the sample up to 2 more times during the extension period. To recruit for the replenishment samples, 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 study 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.

All youth participating in the study complete a survey. The youth survey instrument will include items that measure self-reported exposure to other tobacco use prevention media campaigns. Data from these items, along with demographic and other confounding influences will be included in regression models as controls to help isolate the campaign effect of “The Real Cost,” similar to published analyses evaluating previous cohorts of “The Real Cost” and

other longitudinal media studies (Duke, et al., 2018; Duke, et al., 2019; Farrelly, et al., 2009; Farrelly, et al., 2017; MacMonegle, et al., 2022).

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.

To support estimation of population parameters, survey weights will be constructed for each wave of data collection. Base weights will be calculated as the inverse of the probability of selection at each stage of sampling, including selection of addresses and selection of eligible youth within households. These base weights will be adjusted to account for differential nonresponse at both the household and individual levels. The resulting weights will be calibrated to align with external population benchmarks (e.g., U.S. Census Bureau or American Community Survey estimates) based on demographic characteristics such as age, sex, race/ethnicity, and geographic region. Separate cross-sectional weights will be developed for each wave, as well as longitudinal weights for analyses that require respondents to have participated across multiple waves. Variance estimation will account for the complex sampling design, including stratification and weighting, using appropriate methods such as Taylor series linearization or replicate weights.

Power

We determined the effect sizes for two different research questions:

1. Is there a relationship between amount of exposure of campaign advertising and average score on outcome constructs?
2. Is the effect of awareness of advertising on outcome constructs moderated by the data collection period? (i.e., is there a data collection wave by treatment interaction)?

To determine the effect sizes, we simulated data that had the structure and effective sample size of the proposed design. We used data from ExPECTT Cohort 2 to estimate patterns of treatment effects and correlations within primary sampling units and across individuals.

Analysis 1. The proposed study has 80% power to detect a relationship between awareness of advertising and outcome constructs if the effect size is 0.12; this is considered a small effect size. Exhibit 1 displays the relationship between outcome constructs we can detect given the level of advertising awareness using mean values. The population standard deviations with each level of awareness are 1. Adding a constant to each value will not affect the power.

Exhibit 1. Mean value of outcome construct given the level of advertising awareness.

	Awareness of advertising				
	0	**1**	**2**	**3**	**4**
Outcome Construct	2.938	2.969	3.000	3.031	3.062

Analysis 2. Simulation approach

The proposed study has 80% power to detect an interaction between awareness of advertising and data collection wave in a model that predicts the outcome construct when the coefficient of the interaction is 0.03 and the population standard deviation of the outcome is 1. The following formula describes the relationship that has 80% power:

$$\text{E-cigarette outcome construct} = 3 + 0.03 * \text{wave} * \text{awareness} + N(0,1)$$

where N (0,1) is a random variable from a standard normal distribution. Adding a constant to this equation will not affect the power. Exhibit 2 displays the relationship between the outcome construct given the level of advertising awareness we can detect with 80% power.

Data Suppression Techniques

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), 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 the potential for 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.

3. Methods to Maximize Response Rates and Deal with Nonresponse

The ability to recruit potential respondents for the baseline survey and maintain their participation across all survey waves will be important to the success of this study.

At each wave of follow-up data collection during the extension period, youth respondents will be offered a $30 incentive to complete the survey during an early release period that will run for approximately three weeks. Subsequently, youth respondents will be offered a $25

incentive to complete the survey after the early release period. Studies suggest that this incentive approach can increase response rates and reduce costs and nonresponse (Brown et al., 2016; Dillman et al., 2014; Lasky-Fink & Rogers, 2020; Marlar and Schreiner, 2010; McGonagle et al, 2023; Singer & Ye, 2013). In addition, the study will use procedures designed to maximize respondent participation. For example, e-mail reminders and text messages will be sent to encourage participants to complete the survey. We will direct respondents to a website that may be updated at each wave to show progress and encourage engagement.

For longitudinal analyses, the sample is limited to those who have completed each wave. Probability weights are generated for the longitudinal sample as well as for the full sample in each wave and are calibrated to help mitigate non-response bias. Methods such as data imputation may also be used to maximize the data and address nonresponse bias.

In addition to efforts to maximize response rates, analyses will be conducted to assess and address potential nonresponse bias. Respondents and nonrespondents will be compared using available sampling frame variables (e.g., geographic and demographic characteristics associated with sampled addresses) to evaluate differences that may indicate nonresponse bias. For longitudinal analyses, patterns of attrition across waves will be examined to identify systematic differences between respondents who remain in the study and those who drop out. Survey weights will incorporate adjustments to mitigate the effects of nonresponse and attrition, and statistical techniques such as imputation or inverse probability weighting may be employed, as appropriate, to reduce potential bias and maximize use of available data.

4. Test of Procedures or Methods to be Undertaken

Prior to launching the follow up surveys, we may field a usability test of the screening procedure and instrument with 9 individuals. This usability testing will provide the study team with feedback from respondents who are similar to the target sample and help us understand if the procedure needs to be adjusted to improve response rates for screening. We may add instructions to the screener or adjust how documents are presented on the web based on this feedback.

Additionally, with a separate sample of 9 individuals, we will field a cognitive interview pre-test of selected items from the survey instrument to assess overall clarity of instrument questions and respondents' opinions on aspects of the survey that are unclear. The purpose of the cognitive interviews is to identify areas of the survey that are either unclear or difficult to understand.

In addition to usability testing and cognitive interviews, RTI staff will conduct rigorous internal testing of the online screener and survey instrument prior to fielding. Evaluators will review the online test version of the instrument used to verify that instrument skip patterns function properly, multimedia included in the survey is functioning properly, and all survey questions are worded correctly and in accordance with the instrument approved by OMB. We will review diagnostic data on average time of survey completion, survey completion patterns

(e.g., are there any concentrations of missing data?), and other aspects related to the proper function of the survey.

Finally, minor revisions to the survey may be necessary given the media development process and possibility of changes in campaign implementation. We may remove a small number of items or response options from the survey if we find they are no longer relevant at the time of data collection. For example, items pertaining to a particular ad that is no longer on air may be removed. Other examples include if a particular tobacco product is no longer on the market or if a particular type of streaming service is no longer available; these items would be removed from the survey as they are no longer relevant. However, every effort will be made to minimize changes to the survey.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The following individuals inside the agency have been consulted on the design and statistical aspects of this information collection as well as plans for data analysis:

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The following individuals outside the agency have been consulted on the survey development, statistical aspects of the design, plans for data analysis, and will conduct data collection and analysis:

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