United States Food and Drug Administration
Center for Tobacco Products
"The Real Cost" Monthly Implementation Assessment (MIA)
OMB Control Number 0910-NEW
Supporting Statement Part B

B. Statistical Methods

1. Respondent Universe and Sampling Methods

"The Real Cost" Monthly Implementation Assessment (MIA) consists of a sample drawn from Ipsos' KnowledgePanel and involves quantitative cross-sectional surveys of approximately 2,000 respondents ages 12 – 20 in the United States. Each quantitative survey is administered every 1-2 months (up to 24 waves total). In addition, mixed methods data from up to 400 participants ages 12-20 years in the United States will be collected two to three times a year (up to 8 mixed methods data collections total). RTI International (RTI) is the external contractor responsible for coordinating the study and analyzing data on behalf of FDA. Ipsos is a sub-contractor to RTI responsible for collecting and storing quantitative data on behalf of FDA.

The Ipsos KnowledgePanel, an established national online panel of adults, is solely maintained by Ipsos. Data from the voluntary respondents will be processed by Ipsos to de-identify it before being shared with either RTI or FDA. The KnowledgePanel system 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 system. Neither RTI nor FDA will access it directly. 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 period it is accessible.

Table 1. Eligibility and Exclusion Criteria for Respondents, by Recruitment Source

Recruitment Source	Eligibility Criteria	Exclusion Criteria
Via parent panel member	Must be: ☐ Age 12-20 ☐ U.S. resident	Excluded if: • Age <12 or >20 • Parent does not provide permission • Respondent (age 12-17) does not provide assent • Respondent (age 18-20) does not provide consent
Panel Participant	Must be: • 18-20 (19-20 in AL and NE)	Excluded if: • Age >20

	☐ U.S. resident	• Respondent (age 18-20) does not provide consent

Exhibit 1. Assumptions to Yield the Needed Number of Completes

Activity	Panel Sample (All Respondents)
Screened panel members (parents)	2,457,310
Eligible respondents from parent screeners	1,842,983 (75% of screened panel member)
Completed surveys from screeners	44,698 (87.3% of total completes)
Direct invite to adult panel members	54,577
Eligible respondents from direct invites	40,933 (75% of direct invites)
Completed surveys from direct invites	6,502 (12.7% of total completes)
Total Eligible completes: Entire study period	51,200 (2.0% of panel members)

2. Procedures for the Collection of Information

Recruitment and screening will occur prior to each quantitative survey wave of data collection to recruit up to 2,000 unique respondents each 1-2 months, for a total of 24 waves of survey data collection (48,000 respondents total). Mixed methods data collection under the MIA umbrella generic will be collected approximately every two to three times a year (up to 8 mixed methods data collection total) with each mixed method study recruiting a sample size of up to 400 participants aged 12 to 20 over the course of the data collection, for a total of 3,200 participants. Over the course of the entire study period, Ipsos will email recruitment and screening materials to approximately 194,880 households in order to get approximately 2,457,310 completed screeners and connect directly with 54,577 adult panel members (18 – 20 years old). From those contacts we will identify up to 48,000 eligible respondents who will complete the survey over the course of the data collection period and 3,200 eligible participants who will take part in the mixed methods data collection over the course of the study.

The recruitment and study materials (available in both English and Spanish) will consist of an email invitation and/or SMS message that will be used to invite an adult panel member to access the Ipsos member portal to learn more about the study and begin taking the survey. An adult panel member will complete the online screener, which will determine eligibility. For panel members with eligible children, we will ask the parent/guardian to list all eligible children in their households that can be selected for participation in the study, a process called rostering. If eligibility is determined during the screener, the parent/guardian of potential respondents ages 12 to 20 will be routed to the

parental permission screen when required by the external IRB. After parents give their permission when required by the external IRB, they will be taken to a screen which will instruct them to have the youth (ages 12-17) provide assent through the electronic form before completing the survey. Respondents ages 12 to 17 (or 12 to 18 in Alabama and Nebraska in accordance with state law) will be routed to the assent screen (a random selection of 1 respondent will take the survey if more than 1 in a household qualify). Respondents ages 18 to 20 (or 19 and 20 in Alabama and Nebraska) will be routed to the consent screen. After parental permission and respondent assent/consent is obtained, eligible respondents will begin the survey. The survey responses will be written in real-time directly to Ipsos's server and then stored in a local MS-SQL database. Ipsos has developed a secure transmission and collection protocol, including the use of system passwords, encryptions, and firewalls to prevent unauthorized access to the data collection system.

The MIA survey includes measures of demographics; tobacco use behavior; intentions to use tobacco; media use and awareness; environmental questions; and measures of awareness, attention, processing, and receptivity to "The Real Cost" stimuli.

The consent/assent forms and surveys are provided in both English and Spanish. We will not recruit separate English-speaking and Spanish-speaking samples for this study. We will simply provide Spanish-language consent/assent forms and surveys 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. Parents and respondents ages 18-20 are not asked their language preference because exiting panel member preferences are known. Respondents ages 12-17 whose parents give us permission to participate (when required by the IRB) and provide assent will be asked in which language they prefer to take the survey. The virtual discussions will be conducted in English only.

3. Methods to Maximize Response Rates and Deal with Nonresponse

To maximize participation, we will incorporate best practices from similar online panel surveys into our data collection procedures. These include:

- Implementing a soft launch of the online survey to a small number of selected panel members to detect and resolve any technical difficulty.
- Keeping the questionnaire at a reasonable length to minimize breakoffs. Survey waves are modular and will vary each wave, meaning that not all survey items in the supporting questionnaire will be fielded each wave. A typical wave will contain approximately 3-4 stimuli exposure sections, as well as standard tobacco use and demographics modules. Each survey wave is expected to take, at most, 25 minutes for participants to complete; however, we will keep the survey as short as possible, while still ensuring we are collecting the information CTP needs to inform campaign decisions. As part of our internal survey testing, we plan on reviewing the survey completion times to verify our questionnaire is programmed as intended.

- Including a brief introduction to the study that identifies FDA as the sponsor, states the purpose of the study, provides the OMB control number, and provides toll-free telephone numbers for participants to call RTI with any questions about the study or their rights as a study participant.
- Inviting panel members who appear to be eligible based on their member profile. As part of the process of registering with the survey panel, panelists provide information about a range of sociodemographic characteristics, including whether or not they have children, that can be used to target particular groups. Ipsos actively manages panelist profiles, requesting updated information on an ongoing basis to ensure that profile information is up to date.
- To minimize nonresponse, Ipsos will monitor cooperation rates (i.e., total number of completed surveys divided by the total number of respondents invited to complete the survey), incidence levels (i.e., the ratio of people who take the survey vs. qualify for the survey), and participant drop-offs to ensure we can collect the desired number of survey completes. In conjunction with monitoring cooperation rates, we may send out additional reminders to participants. Ipsos and RTI will check in together regularly to monitor these trends and address any deviations from expected response rates (e.g., a teen's parents providing consent but the teen not providing assent).

4. Test of Procedures or Methods to be Undertaken

Prior to launching the wave 1 survey, RTI will field a nine-case cognitive interview pre-test of selected items from the survey instrument, with the exception of a few additional prompting questions, 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 cognitive interviews, Ipsos staff will conduct rigorous internal testing of the online screener and survey instrument prior to fielding the first wave. 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. Ipsos 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, we will use a rotating module approach with each wave to ensure the survey does not exceed 25 minutes on average while collecting the information we need to inform campaign flighting and media buy. For example, in one month we may field questions from Section J of the surveys (see attached) and suppress that section the following month to ask questions from Section H. Further, we may remove 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 campaign stimulus 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. To further ensure that the survey does not exceed the allowable length, the study will use a time tracker tool that estimates the total survey time based on average response per item, number of items, stimuli length, and the number of stimuli asked at a given wave. The tool will be updated each month based on actual survey response times from the prior waves in coordination with the survey vendor (Ipsos).

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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