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 monthly cross-sectional surveys of approximately 2,000 respondents ages 12 – 20 in the United States each wave (for up to 24 waves). 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 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:<br>• Age 12-20<br>• U.S. resident | Excluded if:<br>• Age <12 or >20<br>• Parent does not provide permission<br>• Respondent (age 12-17) does not provide assent<br>• Respondent (age 18-20) does not provide consent |
| Panel Participant | Must be:<br>• 18-20 (19-20 in AL and NE)<br>• U.S. resident | Excluded if:<br>• Age >20<br>• 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 | 2,338,560 |
| Direct invite panel members | 54,096 |
| Eligible respondents from parent screeners | 1,753,920 (75% of screened panel member) |
| Eligible respondents from screeners | 3,492 (87.3%) |
| Eligible respondents from direct invitations | 508 (12.7%) |
| Eligible respondents from direct invites | 40,572 (75% of direct invites) |
| Eligible completes: Entire study period | 48,000 (2.7% of eligible respondents) |

## 2. Procedures for the Collection of Information

Recruitment and screening will occur prior to each wave of data collection to recruit up to 2,000 unique respondents each month, for 24 waves of data collection (48,000 respondents total). 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 2,338,560 completed screeners and connect directly with 54,096 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 study.

The recruitment and study materials will consist of an email invitation and/or SMS message that will be used to invite an adult panel member to access the 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.

## 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.
- Including a brief introduction to the study that identifies FDA as the sponsor, states the purpose of the study, 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 conduct ongoing monitoring of response levels and drop-off rates. Ipsos will work with RTI project staff to address any problems that arise throughout the course of the collection of information.

## 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 from month to month 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.

## 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, and plans for data analysis:

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