

B. Statistical Methods

The one-time actual burden figures listed in Part A, Item 12, Table 1 of this supporting statement have been divided by 3 to avoid double counting in the ROCIS system. These figures are listed in parentheses as “annualized” below in this part of the supporting statement.

1. Respondent Universe and Sampling Methods

The primary outcome study will consist of two probability samples: 1) a longitudinal survey of 6,445 youth (2,148 annualized) for the national campaign and 2) a longitudinal survey of 1,575 male youth (525 annualized) for the rural smokeless 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 campaigns are effective, the baseline-to-follow-up changes in outcomes should be larger among individuals exposed to the campaigns more frequently (i.e., dose-response effects). Eligible youth will be aged 11 to 16 at baseline and 13 to 18 by the end of data collection. For the national sample age is the only screening criterion and for the rural smokeless campaign potential respondents will be screened for age and sex as only males are eligible. As the cohort will be aging over this time period, the data collected throughout the study will reflect information from youth aged 11 to 18. For the national sample evaluation, we will begin by taking a probability proportional to size sample of 75 U.S. designated market areas (DMAs) that will represent the full universe of 210 DMAs, geographic areas that constitute television markets. We will select 30 DMAs for data collection for the rural smokeless campaigns. Fifteen will come from the DMAs where the campaign will be targeted. The other 15 will serve as comparison markets/cities. These DMAs are our Primary Sampling Units (PSUs). Within DMAs, our secondary sampling units (SSUs) will be census block groups allocated roughly proportionally across the PSUs.. The census block groups will serve as the areas in which our address sample will be selected. Our size measure for both primary sampling PSUs and SSUs is the number of youth aged 11 to 16.

Our third stage sampling units are addresses from the Computerized Delivery Sequence file (CDS) obtained from Compact Information Systems (CIS), one of two vendors having a license with the U.S. Postal Service. We will sample roughly 100 addresses per selected CBG. To obtain the 4,125 interviews (1,375 annualized) at wave 4 of data collection of the general market campaign evaluation, we will start with 47,817 sampled addresses from a frame of all locatable addresses within the selected census block groups (locatable addresses are those suitable for in-person data collection—PO boxes are not

considered locatable). Based on prior experience with address samples for in-person surveys, we expect 95% of the selected units to be correctly geocoded into the selected census block group and about 85% of those correctly geocoded addresses to be occupied. These are determinations that RTI's field interviewers will make at the start of data collection. Of the approximate 38,612 housing units that the interviewers will visit, we expect that 70%, or 27,028 households will complete the screener. Because we are using targeted address frames that have indicators for addresses with youth in our target population age range, we expect the sample to yield approximately 11,190 eligible households that will have at least one youth in the age range; that is, we expect the households with eligible youth to be roughly double the national average. To be conservative, we have not adjusted here for households that will have multiple youth in the age range (although all will be eligible). We are expecting a 50% interview completion rate at wave 1, which would yield 8,057 (2,686 annualized) completes. Due to the incentives and the option for completing the survey via the Web, we are expecting 80% of those interviewed at one wave to respond at the next wave, which will yield approximately 4,125 (1,375 annualized) completes by wave 4. Exhibit 6 outlines this progression of one-time actual numbers for both components of the campaign evaluation.

Exhibit 6. Addresses and the Associated Assumptions to Yield the Needed Number of Completes

| Activity | Rural Sample (Males) | National Sample (All Youth) |
|----------------------------------|---------------------------------|--|
| Selected addresses | 24,668 | 47,817 |
| Correctly geocoded housing units | 22,201(90%) | 45,426 (95%) |
| Occupied housing units | 18,871 (85%) | 38,612 (85%) |
| Screened households | 13,210 (70%) | 27,028 (70%) |
| Eligible households | 5,469 (41%) | 11,190 (41%) |
| Eligible persons | 2,734 (50%) | 11,190 (100%) |
| Baseline completes | 1,969 (72%) | 8,057 (72%) |
| Wave 2 completes | 1,575 (80%) | 6,445 (80%) |
| Wave 3 completes | 1,260 (80%) | 5,156 (80%) |
| Wave 4 completes | 1,008 (80%) | 4,125 (80%) |

Note: The 50% response rate at the first time point is a product of the person completion rate and the household screening rate (72% * 70%).

The rural smokeless campaign sample differs from the national sample in one major way—only males in the age range will be considered eligible. Also, we are assuming a slightly lower rate of housing units that geocode to the correct census block group (90%) due to prior research showing that geocoding is less accurate in rural areas. Aside from those two modifications, all other assumptions are the same as the national component. We will need to select 24,668 addresses to yield 1,008 (336 annualized) completes by wave 4. Both national and rural surveys will be conducted by RTI.

For the purposes of estimating statistical power for the national sample, we assume that the test statistic evaluating campaign impact will involve a two-tailed hypothesis test with a Type I error rate of 0.05 and a Type II error rate of 0.020, yielding 80% statistical power. Our estimates include an intraclass correlation coefficient (ICC) of 0.01 to account for the geographic clustering of respondents and a variance inflation factor of 1.25 to account for potential imbalance across conditions. To some extent, these factors are offset by parameters that will serve to reduce variation. Those parameters include over-time correlation corrections of 0.75 at the cluster and individual levels as well as a 0.20 reduction at the individual level for the inclusion of demographic and economic covariates that will reduce between-person variations. These parameter estimates are available in the published literature and supported by our experience conducting similar studies (Murray & Short, 1997; Murray & Blitstein, 2003; Janega et al., 2004; Farrelly et al., 2005). Statistical models will be used to assess change in the prevalence of past 30-day tobacco use among youth aged 12 to 17 as the primary impact of the media campaign. An analysis of data from the National Youth Tobacco Survey (NYTS) shows that the current prevalence of tobacco use (i.e., cigarette, cigar, and smokeless tobacco) among this group is 16.7%. A 3-percentage point reduction in this rate of tobacco use

would result in an 18% decline in tobacco use prevalence, or an odds ratio of approximately 0.80. This expectation is reasonable and similar to the change observed as a result of a previous national youth tobacco campaign (Farrelly et al., 2007). Based on these parameters, we anticipate data collection will include complete and repeated measures on approximately 4,125 youth (1,375 annualized) in the target age range. Consistent with theories of behavior change and previous campaign evaluations, we expect larger changes in intermediate outcomes such as intentions to use tobacco, and tobacco-related attitudes and beliefs. As a result, we should have sufficient power to also detect changes in these intermediate outcomes.

Expected effect sizes for the rural smokeless campaign were calculated with relatively little available data for comparative purposes. Data from the 2011 Youth Risk Behavior Survey indicate that the prevalence of 30-day smokeless tobacco use among high school students is approximately 8%. The Tier 1 markets for the rural smokeless campaign are in states with higher than average smokeless tobacco use rates. Additionally, smokeless tobacco use rates are significantly higher among boys than among girls (CDC, 2012). Accordingly, restricting the sampling frame to boys aged 12 to 17 from these rural communities increases the nominal base rate; for our calculations, we assume a 15% base rate for smokeless tobacco use.

For the purposes of estimating statistical power, our primary outcome variable is 30-day prevalence of using smokeless tobacco, and our models estimate the change (pre-test/post-test) in prevalence among rural, male youth aged 12 to 17. We anticipate that the test statistic evaluating the campaign impact will involve a two-tailed hypothesis test with a Type I error rate of 0.05. Our estimates include an ICC of 0.005 to account for the geographic clustering of respondents and a variance inflation factor of 1.5 to account for unequal weighting effects. To some extent, these factors are offset by parameters that will serve to reduce variation. These factors include over-time correlation parameters of 0.75 at the cluster and individual levels as well as a 0.20 reduction at the individual level for the inclusion of demographic and economic covariates that will reduce between-person variations. These parameter estimates are available in the published literature and supported by our experience conducting similar studies (Murray, 1997; Murray & Blitstein, 2003; Janega et al., 2004; Farrelly et al., 2005).

At 80% statistical power, the rural smokeless campaign will include 48 rural youth respondents in each of the 21 media markets (N = 1,008), and the resulting analyses will be able to identify changes of 4 percentage points or larger. This effect would result in an odds ratio of approximately 0.70, meaning that boys exposed to the campaign would be 0.70 times less likely to use smokeless tobacco compared with boys not exposed to the campaign. This odds ratio represents a standardized effect size estimate (Cohen's D) of 0.19, which is similar to the effects for media campaigns noted by Snyder and colleagues (2004) in their meta-analysis on the effects of health messages in mass media.

In addition to the primary outcome evaluation, we will conduct three Web-based, cross-sectional media tracking surveys, each with a unique, non-probability sample of 4,000

(1,333 annualized) youth. The media tracking surveys are designed to assess youth's awareness of and receptivity to campaign advertising over time. Surveys will be conducted 4 months after campaign launch and at 8-month intervals throughout the evaluation period. RTI will conduct this study using a sample of youth purchased from the digital data collection company Global Market Insite, Inc. (GMI). GMI will distribute a link to these RTI-programmed Web-based surveys to approximately 40,000 (13,333 annualized) members of their youth panel and track the number of completed surveys remotely until we reach our target of 4,000 (1,333 annualized). Youth will be advised of the privacy of their data and be asked to provide their assent to participate before encountering the first survey question. All data will be disassociated with names, addresses, and other identifying information to ensure respondent privacy to the fullest extent of the law, and all data will be entered directly into secure GMI servers.

Although the primary outcome evaluation will be the source for all public information about the campaign, the media tracking surveys allow FDA to track campaign awareness more frequently. Consistent tracking of campaign awareness and receptivity to its messages is necessary because campaign effects may diminish based on media purchase patterns (Wakefield et al., 20011). In addition, this sample allows FDA to assess awareness at more granular levels, particularly within subpopulation groups. The sample size is calculated based on CTP requirements to assess campaign effects by gender, age (aged 12 to 14 and aged 15 to 17), geographic area (rural and non-rural), and tobacco use susceptibility. Each media tracking survey will provide approximately 250 youth in each of these segments. This sample will yield 80% power within each subgroup to detect changes in campaign awareness and ad-level awareness between waves of 12%.

2. Procedures for the Collection of Information

B.2.1 Outcome Evaluation Baseline Data Collection

This section describes the procedures for baseline data collection. The baseline data will be collected by field interviewers at respondents' homes. To be eligible, youth must be aged 11 to 16 at the time of the baseline data collection. Parents or legal guardians of selected youth will be asked to complete a brief survey about their household to provide context for the data collected from youth.

Before the interviewer's arrival at the sampled dwelling unit (SDU), a lead letter (see Attachment 10) will be mailed to the selected addresses. The lead letter will briefly explain the purpose of the survey and request the cooperation of a parent or legal guardian aged 18 or older in each household. This letter will be printed on project-specific letterhead with the signature of FDA's Project Director and RTI's Project Director.

Upon arrival at each SDU, the interviewer will refer an adult resident to this letter and answer any questions the person might have about the study. If the resident has no knowledge of the lead letter, the interviewer will provide another copy, explain that one

was previously sent, and then answer any questions the person might have. If no one is home during the initial visit to the SDU, the interviewer will have the option to leave a card (see Attachment 13) to inform the residents that the interviewer plans to visit the household at a different time. Further visits will be made as soon as feasible after the initial visit. Interviewers will make at least four additional visits beyond the initial visit to each SDU to complete the screening process and up to another four visits to complete interviews with selected youth, if at least one youth is selected for an interview.

If the interviewer is unable to contact a parent or legal guardian aged 18 or older at the SDU after repeated attempts, the field supervisor may send an unable-to-contact letter (see Attachment 13) to reiterate information provided in the lead letter and ask for participation in the study. If the interviewer is still unable to contact anyone at an SDU, the interviewer might send an additional call-me letter (see Attachment 13) to the SDU. The call-me letter will request that the residents call the field supervisor to set up a screening appointment.

When contact is made with an adult member of an SDU and introductory information about the study is communicated, the interviewer will present a Question & Answer Fact Sheet (see Attachment 11) that provides answers to commonly asked questions. When a potential respondent refuses to complete the household screening procedures, the interviewer will rely on their training and experience to accept the refusal in a positive manner. This technique will reduce the potential for creating an adversarial relationship between the residents and the interviewer that could preclude future visits. The supervisor might then request a refusal letter (see Attachment 13) be sent to the residence. The refusal letter will be tailored to the specific concerns expressed by the potential respondent and ask him or her to reconsider participating in the study. Refusal letters will also include the supervisor's telephone number, in case the potential respondent has questions or would like to set up an appointment with the interviewer. Unless the respondent calls the supervisor or RTI's office to refuse participation in the study, one further attempt to enlist the household's cooperation will be made by specially selected interviewers with experience in addressing initial refusals. Specially trained interviewers will also be selected based on their proximity to the case to minimize travel costs.

When an adult resident of a household agrees to cooperate with the study procedures, the interviewer will begin the SDU screening procedures using a tablet computer. Survey data will be collected from adult respondents immediately following the screener (Attachment 3), after respondents have been found eligible and have consented to participate. As many eligible youth aged 11 to 16 as currently reside in the household will be selected to complete the interview. A maximum of two adult parents or legal guardians will be selected to complete the interview, should there be eligible youth with different parents or legal guardians.

For each youth selected to complete the baseline interview, the interviewer will follow these steps:

- The interviewer will obtain verbal consent from the parent or legal guardian for themselves and for the selected youth before approaching the youth for participation in the study.
- The interviewer will then administer a brief screener and parent survey using a tablet computer, to collect data specific to youth media use and household characteristics. A subset of the adult questions will be asked of each participating youth; the household questions will be asked once. If there are multiple adult respondents, the first adult to complete the survey will complete the household questions on behalf of the household; these questions will be omitted from the survey of the second adult respondent.
- When parent or guardian permission has been obtained, the interviewer will obtain verbal assent from selected youth respondents. The assent form, which will appear as the first visible screen on the laptop, will be designed to communicate the goals and procedures to youth aged 11 to 16 (Attachment 6). The interviewer will also read the assent language to the youth before beginning the interview, to assure them that what they report will be kept confidential and to communicate the voluntary nature of participation and their right to refuse to answer any question asked.
- When both consent and assent have been obtained, the interviewer will administer the first portion of the youth interview in a prescribed and uniform manner. For the self-completed portion of the youth interview, the interviewer will then turn the computer over to the youth to read the survey questions and enter responses to the questions directly into the computer.

After the interview is completed and before the verification information is collected, youth respondents will be offered an incentive of \$20.00 each for participation. For verification purposes, one parent of each youth respondent will be contacted via telephone after the interview. The verification interviews will ask the parent to answer a few questions confirming that the interview took place, that proper procedures were followed, and that the amount of time required to administer the interview was within the expected duration. Verification letters will be mailed to respondent addresses when telephone numbers are unavailable (see Attachment 12).

All interview data will be transmitted at least daily via secure encrypted data transmission to RTI's offices, where the data will be subsequently processed and prepared for analysis, reporting, and data file delivery. Upon transmission to RTI, all data will be automatically wiped from all data collection devices used in the field.

B.2.2 Outcome Evaluation Follow-Up Data Collection Waves

After the baseline data collection, three follow-up surveys will be conducted in 8-month intervals. This design will produce data for the same youth over a 2-year period. This study design will provide a more accurate and thorough understanding of tobacco initiation, prevalence, and cessation among the campaign's target audience of youth aged 12 to 17. Eligible youth will be aged 11 to 16 at the baseline survey and 13 to 18 at the

fourth and final survey wave. As the cohort will be aging over this time period, the data collected throughout the study will reflect information from youth aged 11 to 18. Like the baseline survey, most of the follow-up surveys will be conducted in person by interviewers. Youth respondents will also be offered the option to complete the follow-up surveys via a Web-based application. The expected proportion of in-person surveys for each follow-up wave is 70%, with the remaining 30% completed via the Web.

Parents will receive advance letters, fact sheets and a copy of the parent permission form before the start of each follow-up wave of data collection. These advance letters will inform parents and youth about the study's purpose and background, explain the survey procedures, and provide information to the respondent on participating via the Web or with an interviewer in their home. The letters will provide the Web address for the online version of the survey and the user ID and password each sample member will need to enter the survey application. Respondents who provide an e-mail address in the baseline survey will also receive an e-mail invitation to complete each follow-up surveys via the Web. The follow-up lead letter and text for the follow-up e-mail invitation are shown in Attachment 10. Participation via the Web will provide flexibility and convenience to sample members who can complete the survey online. Completion of the Web-based survey will be tracked closely during each follow-up wave, to identify respondents who will need an interviewer visit to their home to complete the interview in-person.

Before interviewers make any in-person contact with sample members and their parents, reminder letters and e-mails will be sent to respondents who have not completed the survey via the Web. The reminders will encourage sample members to complete the survey via the Web and remind them about the option of having an interviewer visit their homes to complete the survey.

The outcome surveys will include the same set of items at baseline and in all follow-up surveys with the exception of items regarding each campaign and its materials, which will vary over the course of the campaigns (e.g., television ads, print materials) (Attachment 2). Minor revisions to surveys may be necessary given the media development process and the possibility of changes in campaign implementation, but every effort has been made to minimize the possibility of instrument changes. The youth survey instrument includes measures of demographics; tobacco use behavior; intentions to use tobacco; self-efficacy; cessation intentions; cessation behaviors; tobacco-related attitudes, beliefs, and risk perceptions; social norms; media use and awareness; and environmental questions. The youth outcome follow-up surveys will include measures of audience awareness of and exposure to the campaigns' advertisements as well as the aforementioned outcome variables of interest (see Attachment 2 and 2a). The parent baseline survey instrument includes measures of the household media environment, other household environment items, demographics, tobacco use by parent/guardians, cessation by parent/guardians, and communication with the selected youth (see Attachment 3).

B.2.3 Media Tracking Data Collection

This section describes the procedures for the media tracking data collection. Cross-sectional media tracking data will be collected through a Web-based system by RTI, with sample purchased from the digital data collection company GMI. The survey will be administered three times over the course of the campaign evaluation at 8-month intervals, occurring at 4, 12, and 20 months post-campaign launch. Sample size for each wave of data collection will be 4,000, resulting in a total of 12,000 unique respondents over the course of the campaign evaluation. These sample sizes will make it possible to produce estimates for sixteen youth segments. For the purposes of estimating statistical power, we assume that the test statistic evaluating subpopulation differences in campaign awareness will involve a two-tailed hypothesis test with a Type I error rate of 0.05 and a Type II error rate of 0.020, yielding 80% statistical power. The sample will be a non-random convenience sample consisting of youth members of the GMI online panel. Respondents will be aged 13 through 17.

RTI will program the media tracking survey instruments, which, as noted above, will differ only in terms of the specific advertisements they are designed to measure. The sample will be purchased from GMI. GMI invites youth panel participants to complete the survey through an invitation to their parents, who provide consent for their child to participate. Respondent anonymity is guarded by assigning each a unique alphanumeric variable. Participants log onto GMI's secure server to complete the survey, using a link provided by GMI and their unique identifier. No name or other identifying information is associated with survey data. Survey data are entered directly into and housed in GMI's server. Upon completing the survey, respondents will receive reimbursement from GMI. Respondents are reimbursed by GMI using "MarketPoints," a non-monetary incentive that may be exchanged for goods with certain GMI partner vendors, and have a value of approximately \$10 per survey.

The primary purpose of the media tracking survey is to monitor youth awareness of and receptivity to the campaigns and specific campaign advertisements (see Attachment 4a). For this reason, the survey instruments will measure the following: awareness of any tobacco-focused mass media campaign, including the FDA's Tobacco Public Education campaign; awareness of specific campaign advertisements; reactions to the campaigns and to specific advertisements; tobacco-related beliefs, attitudes, intentions, and behavior; and demographic information. Items used to measure campaigns and ad awareness will necessarily change depending on what media is airing at the time of the survey. We expect to measure exposure to advertisements from other tobacco-related media campaigns and possibly other tobacco-related pharmaceutical company ads. Items used to measure tobacco-related beliefs, attitudes, intentions, and behaviors and demographic variables are subsets of those used in the outcome baseline survey (see Attachment 4).

Data will be used to determine whether the campaigns are functioning as expected and may inform mid-campaign adjustments. For example, these data will provide information about whether the campaigns are reaching population subgroups of interest and may provide insights into which specific advertisements are most noticed and liked by youth. This information may allow media buyers to air more effective advertisements in heavier

rotation, while phasing out less effective ads. Media tracking data are not nationally representative and will not be used to evaluate overall campaign effectiveness.

3. Methods to Maximize Response Rates and Deal with Nonresponse

The ability to obtain the cooperation of potential respondents in the baseline survey and maintain their participation across all survey waves will be important to the success of this study. In preparation for launching the baseline data collection, we will review procedures for enlisting respondent cooperation across a wide range of surveys, incorporate best practices from those surveys into the data collection procedures, and adapt the procedures through continuous improvement across the survey waves.

The incentive for completion of the youth baseline survey is \$20. At follow-up youth respondents will be offered a \$25 incentive to complete the survey online during an early release period that will run through July 21st. Subsequently, youth respondents will be offered a \$20 incentive to complete the survey either online or in person. Studies suggest that this incentive approach can increase response rates and reduce costs and nonresponse. In addition, the study will use procedures designed to maximize respondent participation. Data collection procedures will begin with assignment of SDUs to specific interviewers at the start of data collection. When assigning cases, supervisors will take into account which interviewers are in closest proximity to the work, interviewer skill sets, and basic information such as demographics and size of each sampled area. Supervisors will assign cases to interviewers in ways designed to maximize production.

When interviewers transmit their data from completed household screenings and interviews, the data will be summarized in daily reports posted to a Web-based case management system accessed by field supervisors and RTI's data collection managers. On a daily basis, supervisors will use these reports to review response rates, production levels, and record of call information. This information will allow supervisors to determine each interviewer's progress toward weekly production goals, when interviewers should attempt further contacts with SDUs, and how to handle challenging situations such as households that initially refuse to participate or households where the interviewer has been unable to contact anyone. Supervisors will discuss information and challenges with their interviewers each week. When feasible, cases will be transferred to other interviewers with different skill sets to assist with converting initial refusals into participating households. Cases might also be transferred among interviewers to improve production in areas where the original interviewer is not meeting response rate goals.

As noted in Section B.2, interviewers will use a Sorry I Missed You Card (Attachment 13) and the Question and Answer Fact Sheet (Attachment 11) when needed to contact respondents and encourage participation. To assist efforts to convert households that initially refuse to participate, refusal letters (Attachment 13) tailored to specific refusal reasons will be used. Similarly, an unable-to-contact letter (Attachment 13) will be sent to an SDU if the interviewer has been unable to contact an adult resident after multiple attempts. When interviewers have been unable to gain access one or more SDUs due to

an access barrier, such as a locked gate or doorman, controlled access letters (Attachment 13) will be sent to the appropriate person or organization to obtain assistance in gaining access to these SDUs.

4. Test of Procedures or Methods to be Undertaken

Prior to launching the baseline survey, we will field an eight-case pretest of the survey instrument. This survey will be identical to the instrument that will be used in this evaluation and approved by OMB with the exception of a few additional questions to assess overall clarity of instrument questions and respondents' opinions on any aspects of the survey that were not clear. The purpose of the pretest will be twofold: (1) to assess technical aspects and functionality of the survey instrument, and (2) to identify areas of the survey that were either unclear or difficult to understand. 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. We will also examine data on pilot test measures that will be used to assess the clarity of item wording and ease of understanding.

In addition to the aforementioned 8-case pretest, the evaluation contractor RTI will conduct rigorous internal testing of the online survey instrument prior to its fielding. Evaluators will review the online test version of the instrument that we will use to verify that instrument skip patterns are functioning properly, delivery of campaign media materials is working properly, and that all survey questions are worded correctly and are in accordance with the instrument approved by OMB.

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 of the agency have been consulted on the questionnaire development, statistical aspects of the design, and plans for data analysis:

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