U.S. FOOD AND DRUG ADMINISTRATION
NATIONAL PANEL OF TOBACCO CONSUMER STUDIES
SUPPORTING STATEMENT PART B
OMB CONTROL NO. 0910-0815

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PART B: COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1 Respondent Universe and Sampling Methods

This section describes the sample design for establishing the panel, including the four-stage sample design, sample selection at each stage, sample sizes, and precision and statistical power. The section also describes sample replenishment plans for the panel.

B.1.1 Overview of the Sample Design

The target population for the panel is tobacco users aged 18 years and older in housing units and in noninstitutionalized group quarters in the 50 states and the District of Columbia. A stratified four-stage sample design was used, to recruit approximately 4,000 adult tobacco users into the sample panel. Eighty (80) primary sampling units (PSUs) were selected at the first stage, 3 census block groups (CBGs) within each selected PSU at the second stage, approximately 152 housing units (HUs) within each selected CBG at the third stage, and a maximum of one adult tobacco user from an eligible HU at the fourth stage. To successfully recruit 4,000 adult tobacco users for establishing the panel, we selected 43,123 HUs for screening and recruiting. This included 6,852 HUs selected from a reserve sample to increase the number of young adults enrolled in the panel. Full details of the sample design are presented in ***Attachment 5***.

The main goal of the design was to select a sample of all tobacco users in the nation representing the full range in that population with respect to behavior patterns, knowledge, and attitudes. Another objective was to design a sample that was efficient and cost-effective. This was the motivation behind the strategies for stratification, stratum allocation, and PSU design.

B.1.2 Stratified Four-stage Sample Design and Sample Selection

The four-stage sample design and the probabilities proportional to size (PPS) measure selection method applied at the first and second stages, where the number of tobacco users is used as the size measure, ensure a near equal probability selection method (*epsem*) within each of the four design domains:

- 18- to 25-year-olds, low socioeconomic status (SES)
- 18- to 25-year-olds, non-low SES
- 26 years of age or older, low SES

- 26 years of age or older, non-low SES

The *epsem* sample minimizes the unequal weighting effect (UWE), thereby maximizing the precision of estimates for those domains. In addition, selecting the same number of CBGs within a PSU and equally allocating HU samples to each CBG provide for a consistent workload for each field interviewer in every PSU and more efficient field management.

Sampling PSUs at the First Stage: At the first stage, a sample of 80 PSUs in 50 states and Washington, DC, was drawn. Traditionally PSUs have been defined as one county or groups of counties because that is the administrative unit for which Census data are readily available. However, counties have very large variation in population sizes (varies from 82 to 9,818,605 among 3,143 counties) and large variation in number of estimated tobacco users[1] (varies from 17 to 1,074,654). As a result, some large counties were selected in the PSU sample with certainty; certainty PSUs could cause more variation in sample weights. To avoid undesirable effects caused by the large variation in population size or number of estimated tobacco users, we created customized PSUs by combining small contiguous counties and splitting large counties based on the number of estimated tobacco users in each county. Small counties were combined to have at least 2,000[2] tobacco users, while large counties with more than 31,000 tobacco users were divided into areas comprising census tracts within a county. Strata were defined based on various factors related to tobacco use, as well as geography. The 80 PSUs were then allocated proportionally to the strata. The PSU sample with PPS of tobacco users was selected within each stratum, the size measure being the estimated number of adult tobacco users in a PSU.

Sampling CBGs at the Second Stage: At the second stage, CBGs were sampled within the PSUs selected from the first stage. A CBG is a cluster of census blocks generally containing between 600 and 3,000 people, with an average size of about 1,500 people. It is the smallest geographic entity for which the decennial census and American Community Survey (ACS) tabulate and publish sample data. We sampled three CBGs per PSU using the PPS method, with the size measure being the estimated number of adult tobacco users in a CBG.

[1] The number of tobacco users for each county is estimated using the results from the predictive modeling as described in Section 2.1.3.
[2] The cutoff value of 2,000 and 31,000 tobacco users correspond to the 25 percentile and 90 percentile of the distribution of county-level estimated number of tobacco users.

The size measure, namely the number of tobacco users in a PSU or a CBG, is not readily available. A predictive model, shown below, was developed to estimate the tobacco use prevalence rate for each CBG using National Adult Tobacco Survey data including race/ethnicity and SES. The estimated CBG-level tobacco user rate can be used with the population counts in each CBG to estimate the number of tobacco users for each CBG. The number of estimated tobacco users for each CBG can be aggregated to estimate the number of tobacco users for census tracts and counties.

We fit a logistic regression model, using smoking status as the dependent variable and the Census and ACS block group level variables in ***Table 1*** as the independent variables. To fit the model we used SAS software LOGISTIC procedure. The model has the form:

$$\text{logit}(p) = \beta_o + \beta_1 X_1 + \cdots + \beta_n X_n \quad .$$

The independent variables are the *n* variables $(X_1 \cdots X_n)$ that come from the ***Tables 1 and 2*** below.

Table 1. 2010 U.S. Census Data

2010 Census Variable	Variable Type
Population count of the block group	Continuous
Household count of the block group	Continuous
African-American proportion of the block group	Continuous
Hispanic proportion of the block group	Continuous
Rural proportion of the block group	Continuous
Median age of the block group	Continuous
Children per household of the block group	Continuous
Adults per household of the block group	Continuous
Total housing units of the block group	Continuous
Occupied household proportion of the block group	Continuous
Occupied households with a mortgage proportion of the block group	Continuous

Table 2. 2006-2011 American Community Survey (ACS) 5-year Summary File

2006-2011 ACS Variable	Variable Type
Proportion of population with less than a high school degree in the block group	Continuous
Proportion of population with a college degree or higher in the block group	Continuous
Proportion of the population that lived in the same house one year ago in the block group	Continuous
Proportion never married in the block group	Continuous
Proportion now married in the block group	Continuous

To evaluate whether oversampling geographic areas with higher density of tobacco users can significantly improve cost efficiency without unduly decreasing design efficiency, the contractor conducted several simulation experiments of oversampling tobacco-user-concentrated PSUs and/or block groups to optimally balance the cost efficiency and design efficiency. The simulation results showed that oversampling block groups or oversampling both PSUs and block groups achieved small gains in cost savings, but also suffered an associated statistical penalty as loss of design efficiency. Considering the gain of oversampling is relatively small, and the loss of design efficiency due to oversampling, a decision was made not to oversample PSUs and/or CBGs with higher prevalence rates.

Sampling Housing Units at the Third Stage: The third stage involved selecting housing units within the selected second-stage CBGs. The sample of households was drawn from the contractor's in-house, nationally-representative Enhanced Address-based Sampling (ABS) listing of all addresses in the United States. The foundations of this high-quality ABS frame are sourced from commercially available versions of the U.S. Postal Service's (USPS) Computerized Delivery Sequence (CDS) file. The CDS file is available through nonexclusive license agreements with qualified private companies and includes variables such as vacancy/seasonal status, address type (city-style, P.O. box, etc.), single/multifamily, and high-rise. The contractor supplements the CDS file with the No-Stat file that contains over 9 million primarily rural mailing addresses. The union of these files accounts for all postal delivery points, giving near-complete coverage of U.S. addresses (Iannacchione, 2011). The contractor licenses both files from one of only two nationally qualified vendors and receives monthly updates.

The quality of the national ABS frame is enhanced by appending ancillary information from public and private sources, including geographic and demographic data from sources such as the U.S. Census Bureau, U.S. Department of Agriculture, National Oceanic and Atmospheric Administration, and U.S. Bureau of Labor Statistics, and hundreds of person-level characteristics sourced from private databases such as Acxiom, updated monthly. These data include elements for each person in the household, including name, age, child age range, race/ethnicity, and SES data such as education and income. There is also a household size variable modeled by Acxiom. Addresses have been geocoded into census geography to develop area information. This allows aggregate neighborhood information (county, zip code, tract, census block group, block) to be created based on the variables collected in the American Community Survey and the Census.

ABS has emerged as a high-coverage, cost-effective sampling frame for in-person, mail, and multimode surveys. It is a much cheaper alternative to the traditional counting and listing method. The ABS coverage in the majority of CBGs is high; however, as expected, the ABS coverage was low in rural CBGs. We estimated the expected ABS coverage rate for each sampled CBG, calculated as the ratio of the number of city-style mailing addresses on the ABS list to the estimated number of HUs in the CBG. If the expected ABS coverage was greater than 50%, the ABS list was supplemented with addresses identified through the Check for Housing Units Missed (CHUM) procedure. The CHUM procedure, developed at RTI (McMichael et al., 2008), is similar in concept to the Half-open Interval procedure in that the interviewers search the selected HU and the prescribed area up to the next HU on the frame, whether or not the next HU is sequentially next on the list. Interviewers also check a subset of sample blocks so that housing units in blocks with no city-style addresses on the Computerized Delivery Sequence have a chance of selection. CHUM takes geocoding error into account and gives every housing unit one chance of selection with known probability. CHUM is most effective when monitored and conducted in a separate field visit from the survey interviewing, but it is far less costly than enhanced listing because only small portions of the geographical areas are searched, while still giving all housing units a chance of selection through the corresponding sample HUs and subsampled blocks. And, because it is conducted after HUs are selected and not at the frame-building stage, the results are more up to date. The CHUM instrument is included in ***Attachment 1***.

The improved list served as the frame for CBGs having coverage rates at or above the coverage threshold. For CBGs having ABS coverage less than the coverage threshold, traditional field enumeration, that is, counting and listing, was used to develop the HU frame. We estimated that ABS and the CHUM would be used in approximately 90% of the CBGs, and counting and listing would be used in the remaining 10% of CBGs. On average, 152 HUs were selected using a systematic random sampling method from each CBG.

Sampling Adult Tobacco Users at the Fourth Stage: At the final stage, we sampled at most one adult tobacco user from an eligible HU into the panel. The target sample of 4,000 and actual sample of 3,893 adult tobacco users were distributed disproportionately to four sampling strata called domains. The four domains were formed by the cross-classification of two age groups (18–25, 26 or older) and two SES categories (low SES, non-low SES). The sample allocation is displayed in ***Exhibit B.1-1***.

Exhibit B.1-1. Sample Sizes in Sampling Domains

	Target Sample Size		Actual Sample Size	
Domain	**N**	**Prop**	**N**	**Prop**
18–25, Low SES[a]	416	10%	394	10%
18–25, Non-Low SES	624	16%	490	13%
26+, Low SES	1,184	30%	1,352	35%
26+, Non-Low SES	1,776	44%	1,657	43%
18–25	1,040	26%	883	23%
26+	2,960	74%	3,010	77%
Low SES	1,600	40%	1,746	45%
Non-Low SES	2,400	60%	2,147	55%
Total	4,000	100%	3,893	100%

[a] Low SES is defined as household income less than $30,000.

We screened household members for SES (combined household income less than $30,000, or greater than or equal to $30,000), age, and tobacco use status.

As shown in ***Exhibit B.1-1***, to achieve the target sample sizes in four domains, adult tobacco users aged 18–25 were oversampled, in particular users aged 18–25 with non-low SES, while tobacco users aged 26 or older were undersampled. The probabilities of an adult tobacco user being selected for the panel are different and they are predetermined. A young adult user

with non-low SES has the highest probability, and an older adult tobacco user with low SES has the lowest probability of being selected in the sample. Poisson sampling was used to determine the rate at which persons in each domain were selected. These sampling rates were continuously monitored and adjusted during data collection to ensure that the target number of tobacco users in each domain were obtained with a minimum amount of screening. When smokeless tobacco users were identified during screening, they were assigned higher probabilities than regular tobacco users in the same domain, therefore increasing their chance of being selected. As noted earlier, no more than one tobacco user was selected from an eligible housing unit.

B.1.3 Recruitment Response Rates

We understand that for the survey data results to be credible, generalizable, and able to withstand scientific scrutiny, high response rates must be obtained. Our recruitment protocol is designed to achieve higher response rates than online panels that recruit by telephone or use opt-in methodology.

Exhibit B.1-2. Actual Panel Recruitment Response Rates

Response Rates	Percentage
Occupied Household Rate (A)	84
Screening Response Rate (B)	79
Eligibility Rate (C)	81
Household Initiation Rate (D)	80

Exhibit B.1-2 shows the actual response rates at each stage in the recruitment process using our currently approved technical approach. The occupied household, screening, eligibility, and household initiation rates reflect our experience in establishing the panel. The Occupied Household Rate (A) indicates the number of dwelling units occupied by residents. The Screening Response Rate (B) reflects the number of households that were successfully screened as eligible or ineligible. The Eligibility Rate (C) is the number of households with an eligible member. The Household Initiation Rate (D) is the number of eligible household members who completed the full enrollment process (enrollment and baseline surveys). We have assumed similar rates for the panel replenishment efforts.

B.1.4 Precision and Statistical Power

This section provides the statistical basis and justification for the original panel size at establishment. These calculations and justifications remain relevant for the replenished panel that

will result from ongoing and future replenishment efforts. Based on the target sample sizes presented in ***Exhibit B.1-1,*** the relative standard error (RSE) and the minimum power of detecting 7% of difference at the 0.05 significance level for proportion estimates within various domains are estimated and displayed in ***Exhibit B.1-3***. To illustrate, we use three proportion estimates ($p = 0.1$, $p = 0.3$, and $p = 0.5$). The average RSE over all proportions in ***Exhibit B.1-3*** is 6.5%; this is considered to be reasonably good for a survey with a total sample size of 4,000. Similarly, the power of detecting a 7% difference within SES, age group, and sex domains is also high. However, the statistical power within race/ethnicity and tobacco product domains is lower because of smaller sample sizes in some of those categories.

Exhibit B.1-3. Relative Standard Errors/Power to Compare Prevalence Estimates

Domain	Sample Size[a]	Estimated Deff[b]	Effective Sample Size	Relative Standard Error for Domain Prevalence Estimates			Minimum Power[c] of Detecting 7% a Difference within Domain (p=0.5)
				p = 0.1	p = 0.3	p = 0.5	
SES Status							
• Low SES	1,440	1.3	1,108	9.0%	4.6%	3.0%	95.3%
• Non-Low SES	2,160	1.3	1,662	7.4%	3.7%	2.5%	
Age Group							
• 18–25	936	1.5	624	12.0%	6.1%	4.0%	
• 26–44	1,241	1.5	827	10.4%	5.3%	3.5%	75.9%
• 45+	1,423	1.5	949	9.7%	5.0%	3.2%	
Race/Ethnicity							
• NH-Black	592	1.5	395	15.1%	7.7%	5.0%	
• NH-Others	2,586	1.5	1,724	7.2%	3.7%	2.4%	44.3%
• Hispanic	422	1.5	281	17.9%	9.1%	6.0%	
Sex							
• Male	1,936	1.5	1,291	8.4%	4.3%	2.8%	93.3%
• Female	1,664	1.5	1,109	9.0%	4.6%	3.0%	
Tobacco Product							
• Cigarette	2,778	1.5	1,852	12.0%	6.1%	4.0%	
• Cigar	759	1.5	506	10.4%	5.3%	3.5%	50.7%
• Smokeless	482	1.5	321	9.7%	5.0%	3.2%	

[a] Assuming a 90% response rate to the survey. Sample sizes for race/ethnicity, sex, and tobacco product were estimated from the 2010 TUS-CPS.

[b] Deff = design effect, which measures the loss of efficiency resulting from the use of cluster sampling and unequal selection probabilities, instead of simple random sampling.

[c] Differences in percentage estimates will be detected at the 0.05 level of significance.

B.1.5 Panel Replenishment

We recognize that some panel members will leave the panel because of nonresponse at each wave of Web surveys, and have allowed for a 35% yearly attrition rate. To maintain a panel with a constant number of members and the baseline distribution of age group and SES, we are

implementing sample replenishment as needed to address panel attrition. We selected extra CBGs per PSU when the CBG samples were selected for establishing the main panel and use one or two CBGs per PSU each year for the sample replenishment. The estimated yearly sample sizes for sample replenishment are provided in ***Exhibit B.1-4,*** assuming the same recruitment response rates as in ***Exhibit B.1-2*** for the main panel, and are equally allocated when replenishment is conducted. We will set aside a 20% reserve sample yearly (about 2,500 housing units) in the event estimated eligibility and/or response rates are lower than expected during panel replenishment.

Exhibit B.1-4. Estimated Sample Sizes for Yearly Sample Replenishment

Sample	Sample Size
Selected HUs	15,624
Occupied Hus	10,937
Screened Hus	8,749
Eligible Hus	1,750
Selected Tobacco Users	1,750
Recruited Tobacco Users	1,400[a]

[a] Will be allocated to four design domains to maintain the same age group and SES status distribution as for the established panel. The design provides for replenishment to be conducted, as needed, based on panel attrition rates.

The first panel replenishment effort was initiated in July 2019 and is ongoing as the time of this renewal information collection request. While panel member requests to disenroll from the panel have been infrequent since panel establishment, a lower than estimated response rate at Study A and the additional elapsed time expected between Study A and Study B prompted us to initiate the first panel replenishment effort in order to refresh the panel with new members in advance of Study B. As discussed in Section B.3.1, we experienced a lengthy and unanticipated delay between panel establishment in 2016-2017 and the first panel study (Study A) in 2018. This negatively impacted panel member engagement and willingness to respond to the Study A survey request. Section B.3.1 details additional steps we have taken, based on lessons learned, to re-engage establishment panel members in preparation for the launch of Studies B and C.

B.2 Information Collection Procedures

This section describes the procedures for panel recruitment, maintenance, and replenishment, including the weighting plan, panel screening, enrollment, and retention strategies, and efforts to maximize response rates.

B.2.1 Weighting Plan

This section describes the weighting plan for the main panel sample and the individual experimental and observational studies, taking into account the complex sample design, panel replenishment efforts, nonresponse, and attrition from the panel.

B.2.1.1 Weighting the Main Panel Sample

Sample weights are needed to adjust for the sampling approach and nonresponse. They are developed for every member of the main panel, reflecting the varying probability of selection discussed in ***Section B.1***, and adjustments for unit nonresponse, coverage error, and extreme weight values. The weights account for the disproportionate sampling of various subgroups of interest resulting from the sample design, and the bias that can be introduced by screening and interview nonresponse. These weights for the main panel members will be used in all subsequent studies after adjusting them for nonresponse at each study.

B.2.1.2 Weighting the Sample of the First Study

For the first study, the weights for main panel members were adjusted for nonresponse. In addition, to compensate for potential coverage error, a poststratification adjustment was implemented. An adjustment of extreme weights was also implemented.

B.2.1.3 Weighting the Sample of Subsequent Studies

For each subsequent study, sample weights will be developed for both cross-sectional and longitudinal data analyses.

1. **Cross-Sectional Analysis Weights**—In developing the cross-sectional analysis weights for a study, the sample replenishment should be accounted for if recent sample replenishment was implemented. The design weights will be calculated for each new sample member in the same manner as the design weights were computed for the main panel sample. The final weights from the first study or previous study sample, combined with the design weights for the recent sample replenishment, will be the initial weights for post-survey weight adjustments.

These weights will be adjusted for nonresponse and coverage error, with an extreme weight adjustment applied if required. The fully adjusted weights can be used independently of prior studies for cross-sectional analysis at each study.

2. **Longitudinal Analysis Weights**—In addition to the cross-sectional weights for each experimental and observational study, longitudinal weights may be developed for longitudinal and trend analyses. Longitudinal weights differ from cross-sectional weights in that they account for the joint probabilities of response or study combinations. For example, the first and second study longitudinal weights adjust by the joint probability or propensity of responding to both studies. Separate longitudinal weights will be calculated for comparing any two studies. Longitudinal weights can also be computed for simultaneously analyzing all studies or any combination of those studies together. We will work with the contractor to determine the desired set of longitudinal analysis weights as the experimental and observational studies are implemented.

The most current version of NCHS' National Health Interview Survey, will be used at that time as the source for control totals to perform the poststratification adjustment to reduce coverage error and variance of survey estimates (currently 2018). The WTADJUST procedure in SUDAAN (RTI, 2010) can be used for nonresponse, poststratification, and extreme weight adjustments.

B.2.2 Initial Implementation of the Panel

A phased approach to panel recruitment and implementation was followed. During the initial implementation period (approximately the first six weeks), we conducted testing of panel procedures for process improvement. This included evaluating the materials, procedures, and systems used to conduct the CHUM, screen and recruit panel members, review participation requirements and obtain informed consent for Web or mail participation, instruct participants on accessing and completing the baseline survey and subsequent experimental and observational studies via the panel Website or mail, and initiate participation in the panel. The initial implementation period also evaluated procedures for equipping and training select eligible adult tobacco users with loaned tablet computers to facilitate Web survey access while they are in the panel. During this initial implementation period, a portion of the national ABS sample was fielded across two sites with 123 original addresses in each. A total of 17 adult tobacco users were recruited during the initial implementation phase to serve in the first cohort of the panel. These panel members were retained in the panel, and their data were retained for use.

During the 6-week initial implementation period, both the mail and field screening protocols were implemented. For the in-person household visits, field interviewers used panel recruitment materials and protocols to visit sampled addresses, determine whether they serve occupied residential dwelling units, conduct the CHUM procedure, administer the field screening interview to identify eligible adult household members, and, if found, invite the selected eligible household member to join the panel. As part of this process, interviewers administered the enrollment questionnaire to consenting panel members and trained them on procedures for logging in and completing panel studies via the Web, including the initial baseline survey and future experimental and observational studies. Protocols for identifying and enrolling panelists who required mail mode or a loaned tablet computer to facilitate Web participation were also followed.

The objectives of the testing during this initial implementation period were to improve panel recruitment and implementation processes. This included:

- Examining the effectiveness of the recruitment materials and protocols in gaining cooperation and addressing questions that prospective panel members may have about their participation.
- Identifying any software or hardware problems interviewers experience during the recruitment process, including adding missed housing units through the CHUM, doorstep screening of households, and administration of the enrollment questionnaire (in both English and Spanish) to recruited panel members.
- Gauging the ease or difficulty with which respondents access and complete the baseline survey online, if participating via Web, with particular attention paid to the effectiveness of the training delivered by the interviewer and any usability issues panel members experience in logging into the panel Website and navigating through the Web survey application.
- Testing the procedures for ensuring that panel members are Web-enabled, including being able to receive panel emails and other information.
- Identifying respondent concerns about the informed consent protocol, incentive protocol, or other aspects of the panel recruitment process that may hinder long-term commitment. This includes concerns about the tablet equipment agreement if the panel member is being offered the loan of a tablet computer to facilitate Web access while in the panel.
- Launching the first self-administered survey (the baseline survey) and monitoring responsiveness.

- Evaluating the effectiveness of initial nonresponse prompting protocols.

At the conclusion of the initial implementation period, a telephone debriefing was conducted with interviewers to discuss lessons learned, problems experienced in the field, and ways to mitigate them during the remainder of the panel recruiting effort. Information gathered informed any needed refinements to the English and Spanish recruiting and screening protocols. FDA submitted a nonsubstantive change request to OMB for changes to the protocol, materials, and survey instruments. OMB was informed of the package prior to submission. As noted above, participants recruited during this initial implementation period were retained in the panel, and their data were retained for use. They receive the same study requests as all other panel members.

B.2.3 Panel Recruitment and Replenishment

The array of respondent materials used during panel establishment, including lead letters, a study brochure, consent forms, nonresponse letters, and various reminder postcards and other forms, will be used during panel replenishment and maintenance. These are provided in ***Attachment 3*** (English-language versions) and ***Attachment 4*** (Spanish-language versions). A custom-designed panel logo has also been created for use on all respondent materials and the study Website to help panel members easily recognize study correspondence and materials through a form of "brand" recognition.

B.2.3.1 Panel Screening and Recruitment

As noted in ***Section A.2.3***, eligibility screening of prospective households for the panel is conducted in two phases. Sampled households first receive a brief mail screener designed to determine whether there are any age-eligible adult tobacco users residing in the home. The mail screening operation is designed to reduce the number of sampled addresses that require an in-person screening visit, thereby reducing data collection costs. The mail screening instrument includes a cover letter explaining the purpose of the survey contact and requesting the household complete and return the questionnaire in the enclosed postage-paid envelope. The letter and mail screener are printed in both English and Spanish. As a token of appreciation for completing the mail screening survey, the mail screening package includes a $2 prepaid cash incentive. Following this initial mailing, a post-card reminder is sent to all nonresponding households to serve as both a reminder and a thank you for completing the survey. A second mail screener

questionnaire is sent to any remaining nonresponding households following the postcard reminder. This additional survey mailing does not include the $2 prepaid cash incentive. Based on our experience at panel establishment, we anticipate achieving at minimum a 25% response rate for the mail screening questionnaire.

An in-person field screening visit is made by an interviewer to all households that report one or more eligible adult tobacco users in their completed mail screener. Additionally, all nonresponding households are visited in an effort to complete the screening in-person and collect the data needed to assess eligibility. Households that complete the mail screener but report no adult tobacco users are eliminated from the field screening operation. However, as a quality control check of the mail screening results, a 10% sample of these households is selected for an in-person visit in an effort to validate the mail screening data. Households with eligible sample members identified during the quality control check are considered for the panel. Field screening is conducted using the interviewer's tablet computer.

Lead letters are mailed to all sampled addresses that require in-person screening, including those that do not return the mail screener. When making in-person visits, field interviewers provide a copy of the lead letter (if needed) and study brochure to legitimize his/her visit and help answer questions posed by the household. The lead letter and study brochure are available in English and Spanish. As needed, the interviewer also presents his/her letter of authorization to verify he/she is working legitimately for the contractor. When attempting contact, field interviewers leave "Sorry I Missed You" (SIMY) cards when encountering situations where no one is home at the time of their visit.

If a household is found to include one or more eligible adult members, the field screening application may select one eligible adult to receive the panel invitation. The interviewer then administers the enrollment interview to verify the demographic and tobacco use data collected in the screener, review the panel participation requirements, including length of commitment, frequency of contact, and incentives participants can expect to receive while in the panel, obtain informed consent to join the panel, and collect detailed contact information to facilitate subsequent contact while in the panel. Data from the enrollment interview, specifically information about access to and comfort level with computers and availability of Internet access in the home or on a personal computing device, informs the decisions about the mode of

participation (Web or mail) that should be offered to the sampled adult. Once received by the contractor, the enrollment data are also used to identify and select the subset of eligible adults who are not Internet-capable and are disinterested in mail mode participation, but who may be successful Web panelists if provided with a reliable means of accessing the Internet and thus the panel Website. Appointment reminder cards are provided to eligible adults who are not immediately available but instead request a future appointment for the panel enrollment interview. Appointments cards are available in English and Spanish.

Once enrolled, the interviewer instructs the panel member on the procedures for accessing the panel Website (if participating via Web) and completing the baseline survey on his/her own. The baseline survey includes a brief tutorial that allows the panel member to practice answering sample survey questions. For those panelists who are enrolled as mail participants (maximum of 800 panelists), the baseline survey is administered by the field interviewer using his/her tablet computer. The interviewer may also administer the survey to those panelists offered the loan of the tablet, if needed. All screening, enrollment, and baseline instruments are available in both English and Spanish.

In the event reliable Internet connectivity cannot be established during the enrollment visits to the home, interviewers are equipped with paper back-up copies of the baseline survey to record the panel member's answers. This allows the interviewer to complete the enrollment process with the panel member. The interviewer subsequently transfers the information from the paper questionnaire into the Web survey and returns the paper form to the contractor for receipt and secure storage.

As noted in ***Section A.2.1***, we anticipate offering the loan of a Web-enabled tablet computer to a subset of the eligible adult tobacco users who are likely to be successful Web participants but who do not have the means—that is, no access to a computer, data-plan-enabled cellular device, or the Internet in their home. Providing access to a tablet computer while in the panel allows these panel members to participate online. This is an important step in mitigating coverage and nonresponse bias and helps maximize the number of panelists who can receive stimuli (e.g., media images) electronically for the experimental and observational studies. We have allowed for a maximum of 400 panel members, or approximately 10% of the panel, to participate using a tablet computer loaned by the project. These adults are identified from

screening and enrollment data collected by the field interviewer and subsampled by contractor statisticians. We will enroll a maximum of 800 mail mode participants if we find a higher percentage of panel members express a preference for this mode.

Those eligible to receive the tablet computer offer are contacted again in-person to discuss the tablet option and attempt to complete the enrollment process. As part of this effort, the interviewer completes the panel consent process, delivers the tablet, provides a short training on the use of the device, and has the panel member review and complete the equipment agreement form governing the use and care of the device and the protocol for returning the tablet at the end of their panel participation. The interviewer instructs the panelist on how to log into the panel website with the tablet computer and assists with completion of the baseline survey, as needed. The interviewer is available to answer any questions the panel member may have about navigating the website or completing the self-administered survey. All panel members receive a "cheat sheet" which includes tips for accessing the panel Website. Additionally, panel members who receive a tablet computer loan are provided with a tablet user "cheat sheet" which contains general use guidance. Both of these documents are available in English and Spanish.

As described in Section A.2.3, interviewers complete a short observation questionnaire at the conclusion of the enrollment process and upon leaving the panel member's home. About one week after enrollment, panel members are also contacted by the contractor to thank them for their participation in the panel. The contact mode varies based on the panel member's participation mode. For example, Web participants receive an email or text message from the contractor, while mail mode participants receive a thank you letter. Panel members who are using a loaned tablet are called by the recruiting interviewer to thank them for enrolling and to help address any problems they may have experienced with the device.

B.2.3.2 Informed Consent Procedures

Verbal consent for the field screening interview is obtained from a knowledgeable adult household member who agrees to respond to housing unit eligibility screening questions. Adult tobacco users who are selected for and agree to enroll in the panel undergo a more comprehensive 3-step consent process. This includes (1) obtaining verbal consent for the enrollment interview, (2) obtaining verbal consent for the use of computer audio recorded interviewing (CARI) during portions of the enrollment interview, and (3) obtaining written

consent for the 3-year panel participation (Web or mail). For those adults offered the loan of a tablet computer while in the panel, the consent process also includes review and completion of the equipment agreement form. Consent forms are available in both English and Spanish.

Consent will also be obtained for each of the experimental and observational studies conducted with the panel. The Web questionnaires will include an introductory question that requires panelists to actively consent (answer "yes" or "no") to participate in each study. Mail mode participants will be informed that their completion and return of the mail survey form indicates their consent to participate.

Near the end of their 3-year panel commitment period, panel members may be invited to continue their participation in the TCS for up to three years through a web/mail re-consent process. Web re-consent would involve reading the re-consent script and actively consenting (answering "yes" or "no") to continue participation in the panel. Mail re-consent would involve signing and returning the re-consent form to the contractor. As part of their panel enrollment consent, and the re-consent process (if implemented), panel members will be informed that a Certificate of Confidentiality exists for this research. Panel members will also be informed that TCS researchers may use, share, or release their deidentified panel data for similar research in the future without obtaining additional informed consent.

B.2.3.3 Interview Content

Two questionnaires are used in the eligibility screening of prospective households. The mail screener, estimated at 2 minutes in length, collects high-level information about the number of adult household members and their current use of cigarettes, cigars or little cigars, and smokeless tobacco. Enumeration of the household and selection of an eligible tobacco user is accomplished as part of the subsequent in-person field screening visit. The field screening questionnaire, which averages 9 minutes to complete, is used to verify that the address serves an occupied housing unit, determine if there are any missed housing units within the structure, enumerate adult members of the household, and determine whether any of the rostered adults are current tobacco users. The questionnaire collects data on adult household members' current tobacco use (cigarettes, cigars or little cigars, and smokeless tobacco) for panel eligibility purposes, and basic demographic information about each adult household member to inform sample selection, including the oversampling of young adults 18-25 years of age. The screening

information determines whether an adult is selected from the household and invited to join the panel.

The enrollment questionnaire, which averages 18 minutes to complete, collects data to verify eligibility information collected during screening, establish the panel participation mode (Web, mail, Web via loaned tablet), obtain informed consent, and maintain contact with the panel member over time. Data from the survey is also used to inform future support needs and to establish important benchmarks for subsequent analyses, including examination of demographic characteristics of survey nonrespondents and panel members who attrite over time.

The baseline questionnaire, which averages 6 minutes to complete, collects more detailed information about the panel member's tobacco use history to establish important tobacco use benchmarks for subsequent analyses. The questionnaire also collects additional information to gauge panel members' comfort level with computers. The baseline survey provides important covariates for nonresponse adjustments, to correct for bias due to wave nonresponse.

The interviewer observation questionnaire captures the interviewer's observations about the panelist's enrollment process and risk of attrition from the panel. The questionnaire also captures any questions or issues reported by panel members using loaned tablets.

Panelists are asked to confirm or update their contact information, including name, address, telephone number, and contact information for up to two people named in the enrollment survey as being able to help locate them if they move. These requests for contact information are folded into experimental and observational studies or other forms of planned, non-survey contacts (see Section B.2.4). Up to 8 experimental and observational studies will be conducted with the panel. The study questionnaires, which are expected to average 15–20 minutes in length and vary in content, will assess tobacco consumers' responses to new and existing warning statements and labels on product packaging and in advertisements; communication about harmful and potential harmful constituents in tobacco products; and perceptions of tobacco products, advertising, and marketing. The first of these panel studies, Study A "Brands and Purchasing Behavior," was included in the currently approved information collection request. Study A focused on consumer purchasing behavior, tobacco brands, and use of coupons and price promotions for tobacco products. The purpose of the study was to collect information about panel member's tobacco product brand loyalty and more accurate measures of

their tobacco product consumption. Study B "Coupons and Free Samples" and Study C "Consumer Perceptions of Product Standards" are included in this renewal information collection request. Study B will be an observational study offered to all panelists that will provide a more in-depth examination of tobacco product promotions, namely free samples and coupons, after the ban on distribution of free samples of tobacco products (with the exception of certain smokeless tobacco exemptions) that went into effect when FDA finalized the "Deeming Rule" on August 8, 2016 that extended FDA's regulatory authority to all tobacco products. Study C will be an experimental study examining how a hypothetical tobacco product standard may impact consumers' perceptions, attitudes, and tobacco use behavioral intentions.

Several additional questionnaires are used to support the data collection operations. These include a Tracing/Nonresponse Follow-up Questionnaire completed by field interviewers who conduct in-person tracing or nonresponse follow-up of panel members, and brief telephone verification surveys for use in verifying the quality of field interviewer performance during the panel screening and enrollment operations.

Attachment 1 includes copies of the English-language versions of the screening, enrollment, baseline, interviewer observation, and Study B-C questionnaires. The questionnaires used for in-person tracing/nonresponse follow-up and telephone verification of field interviewer performance are also included. ***Attachment 2*** provides copies of the Spanish-language questionnaires.

B.2.3.4 Spanish Translation

All questionnaires and panel member materials (e.g., lead letters, brochures, consent forms, FAQs) are available in both English and Spanish. The contractor's translation professionals are native speakers from Mexico, Peru, Venezuela, and other countries who are skilled at producing Spanish translations that are grammatically and terminologically accurate. The goal in performing the translations is to produce materials that remain true to the intent of the English documents yet provide the information to non-English speakers in both a linguistically and culturally appropriate way. A multistep, forward translation procedure that involved a careful review of the source documents, examination of key terminology and research of any unfamiliar vocabulary, translation, editing by a second native-speaking translation

professional, proofreading, and final quality control review was used for the translation of panel participant materials.

In addition to providing Spanish-language translation services, contractor language specialists also conduct the training of bilingual field interviewers, conduct quality control reviews of Spanish-language interviews, and support calls to the panel's toll-free number from Spanish-speaking panel members.

B.2.4 Panel Maintenance

Maintaining frequent contact and providing readily available support to panel members throughout their time in the panel is critical to minimizing attrition and achieving high response rates for each study. The literature on panel maintenance is growing, but there is still much to be learned about optimal strategies for maintaining a healthy and productive panel, especially one that is focused on a subpopulation such as tobacco users. A comprehensive, multipronged approach is being used to maintain the panel and minimize attrition throughout the study period.

Panel maintenance activities, conducted in non-study months, involve the following types of contacts: email, text, mail, or telephone correspondence from the contractor to ensure contact information is accurate, provide study updates and findings, or announce upcoming study requests.

An extensive support network is deployed for the data collection and panel maintenance operations to assure respondents that we are invested in them and provide prompt response to time-sensitive survey requests. This includes:

- Ongoing sampling support to select survey samples, replace sample members who attrite, and refresh the sample as needed.
- Ongoing programmer support to maintain the survey control and case management systems, send e-mail and text prompts and automatic survey notifications by telephone, and troubleshoot system issues in the field.
- Ongoing triage support available through e-mail or a toll-free number that rings to a help desk operated during normal business hours, and in-house referral to project staff who can address questions about the survey content or process, or to technical support staff who can respond to hardware, connectivity, or other technical issues.
- Follow-up by contractor technical support personnel for more challenging problems that require further investigation.

- In-person follow-up by field interviewers to help troubleshoot technical problems in person, including providing retraining on procedures for accessing and completing the Web surveys.

Increased support is also provided to panel members who experience technical difficulties during the initial weeks of the panel or who are perceived by interviewers as being at greater risk of attrition, in particular due to perceived discomfort with the Internet, computers, or the initial self-administered survey task (baseline survey). Increased support is also provided to the subset of panelists who are loaned tablet computers to facilitate online survey completion. This may include a telephone call or visit from the field interviewer within 2–3 days after recruitment to confirm that the panel member is able to log in to the panel Website successfully on his/her own and to inquire about any technical or usability issues. Panel members are also provided with answers to frequently asked questions (FAQs), a troubleshooting guide ("cheat sheet") that allows them to investigate and resolve more common technical problems on their own, and contact information for contractor support personnel during recruitment. Copies of these items are included in ***Attachments 3 and 4*** with other panel member materials. Additionally, links on the panel Website provide ready access to the FAQs online as well as a quick means of e-mailing contractor support staff with questions or technical support inquiries.

At an early point in the planning process, the question arose as to whether to retain or drop panelists who stop using tobacco. Because of recidivism rates, it was decided to retain all enrolled panel members regardless of changes in their tobacco use patterns. Subsampling of panelists may be implemented, however, for specific experimental and observational studies that are intended solely for current users of one or more specific tobacco products.

B.3 Methods to Maximize Response Rates and Assess Non-Response Bias

B.3.1 Response Rates

The incentive strategy, described in detail in ***Section A.9*** and ***Attachment 6***, is a key component of our overall approach to maximizing response rates. We believe that incentives are critical to recruiting the desired number of panel members, obtaining their commitment for the full 3-year period, and maintaining their active involvement in the experimental and observation studies while in the panel. Moreover, providing older, less technically savvy adults with an alternative means to comfortably participate (mail mode) is also important to gaining and maintaining cooperation long-term. Additionally, loaning a select group of eligible adults a Web-

enabled tablet computer for use while in the panel is a practical, effective, and reliable means of minimizing bias while maximizing response via Web to the planned studies.

Several additional strategies are used for reducing nonresponse, the primary one being in-person recruitment of panel members which we believe leads to significantly larger recruitment rates than would be achieved if sample members were contacted via mail, telephone, or web. Others include:

- Training field interviewers thoroughly on panel recruitment methods and available resources and processes to (1) overcome respondent objections, (2) resolve restricted access problems, (3) safely and successfully work in dangerous neighborhoods, and (4) reach difficult-to-contact respondents such as those seldom at home.
- Use of the study logo on all respondent materials and panel Website to maximize brand recognition.
- Using lead letters, study brochures, e-mails, and text messages to address frequently asked questions about the panel or individual studies.
- Emphasizing privacy in all aspects of the panel experience.
- Using tailored nonresponse letters addressing specific reasons for nonparticipation (see Attachments 3 and 4) at both the screening level as well as during the enrollment phase.
- Implementing field supervisor review and approval of all noninterview cases.
- Hiring sufficient numbers of bilingual interviewers so cases are rarely lost because of a Spanish-language barrier.
- Designing study protocols and questionnaires that simplify the respondent task.
- Providing easy access to project and information technology (IT) staff to address technical or other questions (see, for example, online technical support request form and password reset scripts in Attachments 3 and 4).

Tracking of movers is also critical to achieving high response rates and maintaining the panel. Detailed contact information is collected and maintained for each panel member by the panel contractor, including name, address, e-mail addresses, telephone numbers, and contact information for relatives or friends who will know how to reach the panel member in the event of a move. A unique 8-digit identification number is assigned to each sample member and used for storage and retrieval (see A.10: Assurance of Privacy Provided to Respondents for more detail). The locator data are updated periodically as part of each experimental or observational study.

Panel members are also provided with a means to update their contact information on the panel Website at any time, and encouraged to notify the contractor about upcoming moves or name, address, or telephone number changes via the panel Website. Additionally, forwarding information and address corrections are requested with any communications provided to panel members via the U.S. Postal Service.

The contractor deploys both centralized tracing and in-person field tracing to maximize location rates and minimize sample attrition. Tracing professionals in the contractor's call center track hard-to-locate sample members using an extensive array of interactive tracing databases and other resources to generate new leads and contact panelists who have relocated. Field interviewers are trained on in-person tracing techniques, including strategies for generating new contact leads from current residents and neighbors of the panelist's last known address, as well as relatives and other contact persons, postal carriers, and other local, community sources. Field staff training sessions include reviews of general tracing procedures and locating strategies that are tailored to specific populations, such as low-income and minority populations.

The overall unweighted enrollment response rate for panel establishment was 82.1%. The response rates varied by panel member demographic characteristics, and ranged from a low of 72.3% for the 65 years and older subgroup to a high of 90.8% for the African American (non-Hispanic) population. We expect to achieve similar response rates for the current replenishment sample as well as for future replenishments.

As described earlier in Section B.1.5, there was a lengthy and unanticipated delay between the establishment of the panel and the launch of the first panel study. This extended period of panel member inactivity had a negative impact on panel member engagement and their responsiveness to the Study A survey request. Despite extensive panel member nonresponse prompting and tracing, including telephone and field interviewer prompting, many panel members were unwilling to complete the web or mail survey. As a result, the overall unweighted response rate for Study A (43.3%) was lower than originally estimated.

We have taken several important steps to address the challenges experienced in Study A and those anticipated with the delay between Study A and Study B, including implementing measures to re-engage panel members and reduce the time between future survey requests. First, we have developed and included in this renewal request several new respondent materials

designed to legitimize and reinforce the importance of this research for panel members. These materials will be used as part of the contractor's overall panel outreach and prompting approach. In addition, we have included the next two experimental and observational studies (Studies B and C) in this renewal request so they can be conducted in quick succession over the next 12 months (October 2019 – September 2020). Providing panel members with an opportunity to receive the $15 cash incentive for multiple surveys in a relatively short amount of time will be an additional means of re-engagement. Approximately one week before each study launches, all panel members will receive a heads-up email, text, auto-call, or letter alerting them to the upcoming study and encouraging them to share any updates to their contact information in advance of the study. As part of each study, all panel members will also be given an opportunity to confirm or update their contact information to facilitate the mailing of the incentive payment as well as subsequent panel communications.

We are also currently conducting an extensive advance tracing operation for establishment panel members prior to the launch of Study B. This includes telephone tracing by the contractor's Call Center and tracing operations personnel, Call Center interactive database tracing to identify new location leads, and in-person tracing by the contractor's field interviewers. The goal of this effort is to reconnect with each panel member and confirm or update their contact information in advance of Study B. When panel members are located, they are being updated on the timeline for the upcoming panel studies and reminded about how to participate online (if web mode participant) or by mail. Panel member tracing, nonresponse prompting, and Helpdesk support will continue throughout Study B and C data collections to maximize participation for each survey.

Beyond these measures, and as noted in Section B.1.5, we are currently undertaking the first panel replenishment effort to replace panel members who have attrited. The newly enrolled panel members will receive their initial panel survey (Study B), followed by Study C, within a few months of their enrollment. These panel members will also receive the heads-up announcements alerting them to the impending launch of each study. We believe the combination of these measures will position us to achieve higher response rates in subsequent studies, and have assumed an 80% response rate for Studies B and C.

B.3.2 Nonresponse Bias Assessment

We studied and measured nonresponse bias at the original recruitment stage, at Study A, and plan to do so for each panel replenishment phase. We will also assess nonresponse bias for at least several future experimental or observational studies. Extensive analysis of nonresponse cases and panel members who leave the panel early will be conducted to inform subsequent refusal conversion and panel replenishment activities. This includes development of propensity models predicting the likelihood of panel attrition as a function of demographic characteristics, interviewer observations of the recruitment experience and likelihood of attrition, and historic panel behavior to identify cases that may need additional contacts and/or interviewer effort to remain in the panel.

We recognize that some panel members will request to end their participation in the panel early, before the end of their 3-year period. We will respect panel members' decisions to leave the panel early and will provide them a formal disenrollment letter thanking them for their participation and will send any outstanding incentive payments they are owed at the time of their withdrawal. Other panel members may demonstrate their lack of continued interest through a pattern of nonresponse across multiple studies or lack of responsiveness to panel maintenance or nonresponse follow-up contacts. We will assess each situation individually and make case-level decisions about whether or when to cease contact. If a decision is made to halt further contact efforts, the panel member will be sent a disenrollment letter along with any outstanding incentive payments they are owed. English and Spanish-language versions of the disenrollment letters are provided in Attachments 3-44, 3-45, 4-44, and 4-45.

There are two contributing components to the nonresponse bias, nonresponse rate and the difference between responses from respondents and nonrespondents (Kish, 1965). If both components are small, then the bias should be negligible. For bias to be significant, a large nonresponse rate should exist, and/or a large difference between the responses between respondents and nonrespondents. For example, the nonresponse bias would be large if older respondents tend not to respond and their tobacco use patterns are different from younger respondents.

Although response rates have been used as a key measure of data quality (Biemer & Lyberg, 2003), low response rates are not generally predictive of the nonresponse bias (Groves &

Peytcheva, 2008). Researchers have explored alternative indicators to detect nonresponse bias (Wagner, 2012). We use the standard methods for assessing the nonresponse bias due to the unit nonresponse: response rate subgroup analysis, indirect comparisons of survey outcomes, and comparison of sample survey outcomes with corresponding population benchmarks. (Wagner, 2012). We believe that these three approaches identify major sources of nonresponse bias and suggest corrective strategies. There are several stages involved in developing and maintaining the panel. The stage most at risk for nonresponse bias is the original recruitment which is expected to experience the lowest response rate. Consequently, this is the stage on which we focus most of our efforts, especially since all subsequent panel surveys and estimates are based on the original recruitment stage. However, we reiterate that a strictly representative panel is not required for the majority of the work that is currently planned.

B.3.2.1 Compare Response Rates for Subgroups

In this first method, we calculate and compare response rates for some key characteristics (e.g., household size, socioeconomic status, race/ethnicity, geographic location, urbanicity) that are available for both respondents and nonrespondents in the frame files. Because the contractor's maintained frame is ABS-based with considerable amount of appended data, we have an ample supply of indicators to be used in this analysis.

Response rate differences in those key characteristics provide insights into possible nonresponse bias to the extent those attribute characteristics are correlated with the survey outcomes. We also use those characteristics as independent variables and the response indicator as the dependent variable to fit a logistic regression model. The predicted response probability/propensity is estimated from the model, and the weighted (design-based weights is used) standard deviation of the estimated response propensities is calculated, S(p). Then the R-indicator (Schouten et al., 2009) is calculated as $R(p) = 1-2S(p)$, where 1 indicates good representativeness and 0 indicates poor representativeness.

B.3.2.2 Compare Differences of Survey Outcomes Indirectly

For the second method, we use two approaches to assess the nonresponse bias by comparing survey outcomes between respondents and nonrespondents indirectly. Some nonresponse models suggest that those units that require more efforts to respond—for example, more callbacks, incentives, refusal conversion—are similar to the units that do not respond (Lin

& Schaeffer, 1995). Thus, the first approach involves categorizing the respondents according to the level of efforts (LOE), such as number of contact attempts, ever refused, early or late responder, and comparing survey estimates (weighted by design-based weights) for each category. The differences among LOE categories can give a reasonable indicator of the magnitude and direction of nonresponse bias.

The second approach is based on the findings of stochastic nonresponse models that nonresponse bias of a mean is a function of the correlation between response propensity and the survey variables of interest (Bethlehem, 2002). We use logistic regression to estimate the response propensities for all respondents and examine the correlation between the predicted propensity and the survey outcome variables. Each respondent has a propensity score as well as a value for major outcome variables; correlation between propensity and outcome variable suggests presence of nonresponse bias. Another approach is to divide the response units into various propensity groups according to their response propensities and compare the survey estimates over propensity groups. Either high correlation between survey outcomes and predicted propensities or differences of survey estimates among different propensity groups may suggest nonresponse bias exists in the panel data.

B.3.3 Compare Respondent and Population Benchmarks

We also measure nonresponse bias directly by comparing our panel participants' distributions with distributions based on the corresponding target population. In this case, since we are dealing with the specific population of tobacco users, we use benchmark data from a major national survey such as the NHIS. This serves as the source of our gold-standard distributions and we measure the extent to which our panel participants approximate those target distributions. We use unweighted data to make these comparisons. For example, we compare the distribution of the panel characteristics with the corresponding NHIS distribution of tobacco users. This analysis jointly evaluates gender, age, socioeconomic status, race/ethnicity, and region. Significant differences on any of these variables indicates presence of nonresponse bias which should be flagged and quantified. Furthermore, once we identify differences in the joint characteristics of the two populations, we are in a position to use those variables for calculating adjustment weights. A final comparison of weighted panel distributions with benchmark targets confirms that the weighting process has brought the sample data in line with the gold standards

and thus eliminated the bias associated with the variables used in the weighting process. As described in Section B.3.5, analysis of the original panel points to very low levels of nonresponse bias using unweighted survey data, and that low level becomes even smaller when we use weighted data.

B.3.4 Weight Adjustment to Minimize Nonresponse Bias

The results of nonresponse bias analyses inform whether nonresponse bias exists, the magnitude of the bias if it exists, and possible methods for reducing the bias. The design weights are adjusted for nonresponse, and nonresponse adjusted weights are further poststratified to ACS total population and housing unit counts for important characteristics. We calculate weights using the contractor's proprietary software SUDAAN which uses generalized exponential modeling (Folsom & Singh, 2000) to adjust design weights for nonresponse and coverage imbalance to control all the variables that show different response rates or variables that relate to the survey outcome variables. We expect that the nonresponse and poststratification adjustments to the weights reduces the nonresponse bias. However, we recognize that the nonresponse and poststratification adjustments cannot eliminate nonresponse bias completely and thus will take that into consideration in analysis of the study data.

B.3.5 Nonresponse Bias Assessment Results

Based on our analyses at panel establishment, we concluded that the response rates were relatively high across most domains, leaving limited room for significant nonresponse bias. We also concluded that there is little evidence of significant nonresponse bias in the distribution patterns of the sample population. Users can be confident that the impact of nonresponse bias on analyses involving the entire sample was relatively minor. However, for some of the smaller domains (e.g., Asians), the response rate was relatively low and there is more room for nonresponse bias.

At panel establishment, we first measured response rates at two stages—screening and enrollment—for the total sample and for various demographic domains. The results indicated that at both stages the overall and domain response rates were approximately 80%. Some domains (e.g., Asians) had lower response rates at the enrollment stage, but in general the response rates were relatively high, thus mitigating the risk of nonresponse bias.

We then measured nonresponse bias at the screening and enrollment stages. For the screening interview, we compared the set of screening respondents and their demographic distributions with comparable distributions for the entire population using data from the ACS (2011-2015). Statistical tests of the TCS-ACS difference were not significant at the 5% level.

During the enrollment stage, the sample size was limited to those who answered the field screening questionnaire, were deemed eligible for the panel, and agreed to join the panel. For these cases, we had a two-pronged strategy for measuring nonresponse bias. We first compared respondents with any nonrespondents for whom we had basic demographic information from the screener. There is little evidence of significant nonresponse bias introduced at this point in the panel creation process. The weighted results tell a very similar story.

We then compared the final panel of responders with the comparable set of responders on the 2015 NHIS. In this case, we focused on cigarette users for two reasons: (1) they represented the vast majority of our panel, and (2) we could readily obtain NHIS data for that population. The underlying distributions of cigarette smokers in the TCS panel very closely track the corresponding distributions from the NHIS. In looking at weighted results, we found that the weighted estimates more closely resemble the NHIS benchmarks than do the unweighted estimates. This is a direct result of the weighting procedure which aims to bring the weighted sample results in line with known population benchmarks.

It is important to note that our analysis focused only on demographic dimensions of nonresponse bias. Differences in demographic characteristics do not necessarily suggest there may be nonresponse bias in substantive variables (Groves and Peytcheva, 2008; Peytcheva and Groves, 2009). Moreover, such differences are mitigated through poststratification adjustments, and are therefore ignorable nonresponse bias. To study nonresponse bias with respect to substantive variables related to tobacco use, we will use data from the planned experimental and observational studies.

To study nonresponse bias for Study A, we compared the weighted distribution (weighted by panel weights) of the respondents and nonrespondents across several basic demographic characteristics from the field screener: race/ethnicity, gender, age, education, employment status, and region. The two distributions looked similar with some differences in the magnitude of proportions. For race/ethnicity, Study A both overrepresented Whites and underrepresented

Asians. Even though the distributions of respondents and nonrespondents looked similar, statistical tests (Wald Chi-square test) indicated that there were some discrepancies by these characteristics, except for employment status. It is thus highly recommended that nonresponse adjustments, through weighting, be included as part of any analysis.

We also compared the weighted distributions between Study A respondents only and all panel members (including Study A nonrespondents). The weighted distributions of Study A respondents were calculated using final analysis weights that have been adjusted to account for Study A nonrespondents. The weighted distributions of the whole panel were calculated using the original TCS analysis weights. The two distributions looked very similar, and this comparison indicated that weighting for nonresponse adjustments may reduce potential nonresponse bias in the survey estimates or analyses that are produced with the Study A respondents' survey data.[1]

In addition to the comparisons with the TCS panel members above, we also compared the Study A respondents with respondents from the 2017 NHIS on survey items that indicate current use of cigarettes. In both surveys, we defined the current users of cigarettes as respondents who ever smoked 100 cigarettes or more during their lifetime and currently smoked every day or some days (questions S1A1 = 1, and S1A1a = 1 or 2 in Study A). We calculated distributions of current users of cigarettes in Study A and in the 2017 NHIS, calculated standard errors in both, and performed comparisons through Bonferroni statistical tests. Only Asian and Other race groups indicated statistical differences (*p*-values smaller than 0.01). The two groups of respondents were similar with regard to other characteristics.

Based on our analyses, we concluded that there could be potential nonresponse bias because of low response rates, especially when Study A respondents were analyzed using the original panel weights. Although distributions of Study A respondents and nonrespondents are statistically different, we did not find these differences to be of practical importance. Our adjustments to the panel weights indicate that the use of adjusted weights (i.e., Study A final analyses weights) reduces the potential nonresponse bias when analyzing data from the survey.

[1]

B.4 Tests of Procedures

Focus groups (OMB Control No. 0910-0497), involving 49 adult tobacco users with varying demographic characteristics, were used to develop and refine protocols for recruiting panel members and maintaining their interest and involvement during their tenure in the panel. This included issues such as length of time in the panel, number and frequency of study requests, panel member incentive strategies, and various panel maintenance methods. Participants were asked to provide feedback on possible approaches and to complete several sample questionnaire items on two tablet computers being considered for the panel. The focus group sessions explored the following topics:

- General reactions to the creation of a panel of tobacco users, including willingness to participate and concerns participants may have
- Willingness to commit for a 2- or 3-year period, and preferences of participants
- Reaction to the planned monthly contacts to maintain participant interest in the panel
- Information needed to make an informed decision to join the panel, and how the information should be delivered
- Reaction to proposed incentives, including cash incentives, tablet computers, and other possible cash or non-cash incentives for study participation
- Feedback on elements of the equipment agreement associated with the tablet computers
- Additional methods and materials that could be used to maintain interest in the panel

Feedback from focus group participants (OMB Control No. 0910-0497), as well as discussions with an external consultant on Web panel data collection and senior contractor methodology, survey, and IT personnel informed the final design recommendations for the panel. Key recommendations adopted for the panel included:

- Implementing a cash-based incentive protocol rather than a tablet-based one for most panelists;
- Utilizing a mixed-mode design to provide an alternative data collection option for those sample members who are technology adverse or who will not (or cannot) access the Internet, and
- Subsampling of nonrespondents to address potential coverage and bias concerns through the limited offer of a study tablet computer (for use while in the panel).

More extensive testing of the panel procedures was conducted through the initial panel implementation period described in ***Section B.2.2***. The initial panel implementation period provided an opportunity for testing all field interviewer training protocols, data collection systems, and panel screening and recruitment protocols. FDA and its contractor remain committed to continuous improvement throughout the life of the panel.

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

The sample design for the panel was developed by senior statisticians in the contractor's organization, in consultation with FDA statisticians. Contact information for the statistical consultants and FDA statisticians is provided below.

Karol Krotki, PhD Senior Research Statistician	**RTI International** Division of Statistical and Data Sciences 701 13th St. NW, Suite 750 Washington, DC 20005-3967 Ph. 202-728-2485
Patrick Chen, PhD Senior Research Statistician	**RTI International** Division of Statistical and Data Sciences 3040 Cornwallis Rd Research Triangle Park, NC 27709 Ph. 919-541-6309
Antonio Paredes Statistician	**Food and Drug Administration** **Center for Tobacco Products** Office of Science Division of Population Health Science 10903 New Hampshire Ave Silver Spring, MD 20993 Ph. 301-796-3866
Nikolas Pharris-Ciuej Statistician	**Food and Drug Administration** **Center for Tobacco Products** Office of Science Division of Population Health Science 10903 New Hampshire Ave Silver Spring, MD 20993 Ph. 301-796-8875

As discussed in Part A, to inform the design of the panel recruitment and retention strategies, the contractor also engaged the services of a Web survey panel expert in the research

community. The consultant participated in discussions with the contractor to review focus group findings (OMB Control No. 0910-0497) discussed above and provided feedback on strategies for recruiting and engaging panel members long-term. Consultant contact information is provided below.

Scott Crawford Founder, Chief Executive Officer	**Survey Sciences Group, LLC** 950 Victors Way, Suite 50 Ann Arbor, Michigan 48108 Ph. 734-527-2150

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