FDA DOCUMENTATION FOR THE CLEARANCE OF FOCUS GROUPS FOR THE TOBACCO USER PANEL

Focus groups do not yield meaningful quantitative findings. They can provide public input, but they do not yield data about public opinion that can be generalized. Thus, they cannot be used to drive the development of policies, programs, and services. Policy makers and educators can use focus groups findings to test and refine their ideas, but they should then conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

TITLE OF INFORMATION COLLECTION: Establishment of a Tobacco User Panel: Focus Group Study (OMB Control Number 0910-0497)

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of Need:**
   The U.S. Food and Drug Administration (FDA), Center for Tobacco Products (CTP), is seeking OMB approval under the generic clearance 0910-0497 to conduct exploratory focus groups, "FDA Tobacco User Panel: Focus Group Study," to assess best strategies for recruiting and managing a web panel of tobacco users. To inform existing and future regulatory actions, FDA-CTP has contracted with RTI International (RTI) to establish a high-quality, probability-based, Web-based panel of 4,000 tobacco users. The contractor will recruit panelists in person to participate in up to 8 studies over a 3-year period to assess consumer perceptions of tobacco products, including their labeling, advertising, and marketing. Other brief period surveys, such as monthly panel maintenance contacts, are planned to ensure engagement with the panel.

   A key benefit of the Web panel approach is that the surveys can include multimedia, such as new and existing warning labels, antismoking print, radio, and television advertisements, and potential reduced harm claims in the form of labels and print advertisements. Although existing Web panels of consumers who use tobacco products exist, they have a number of significant limitations. Most existing consumer panels are drawn from convenience samples that limit the generalizability of study findings (Baker et al., 2010). In addition, although at least two probability-based panels of consumers exist in the United States, there is a concern that responses to these surveys may be biased due to panel conditioning effects (e.g., Coen, Lorch and Piekarski, 2005; Nancarrow and Catwright, 2007). That is, consumers in these panels complete surveys so frequently that their responses may not adequately represent the population as a whole. Panel conditioning has been associated with repeated measurement on the same topic (e.g., Kruse et al., 2009), panel tenure (e.g., Coen, Lorch and Piekarski, 2005), and frequency of the survey request (e.g., Nancarrow and Catwright, 2007).

   This issue is of particular concern for tobacco users who may be subjected to experiments and/or surveys that may bias their responses to future surveys. By establishing a probability-based panel of tobacco users by conducting in-person recruitment of tobacco users, nationally representative and unbiased data on tobacco users can be collected.

To inform the design of the study, in particular the protocols for recruiting panel members and maintaining their active participation over the 3-year period, five focus groups are planned with tobacco users who have demographic characteristics that mirror those of the target population for the national implementation of the Tobacco User Panel. The focus groups will explore methods for gaining cooperation from sampled tobacco users, including various incentive strategies, and options for maintaining their interest between survey contacts.

2. **Intended Use of Information:**
The Tobacco User Panel focus groups will explore potential panel participants' opinions and reactions to strategies for recruiting, participating and remaining active in a Web panel of tobacco users. Specifically, the focus groups will explore: 1) general attitudes about participating in a panel of tobacco users, and potential obstacles that would need to be overcome in a national implementation; 2) participant preferences for length of time in panel and frequency and number of survey contacts; 3) opinions about various incentives that could be offered to minimize attrition and help achieve acceptable response rates to the Web surveys; and 4) reactions to the proposed computing device that would be given to panelists to complete the planned Web surveys, including usability issues identified during a short test of sample Web survey items. The focus groups will also explore methods for maintaining contact with panel members between survey contacts.

3. **Description of Respondents:**
Respondents will participate in one of five focus groups, led by contractor survey methodologist personnel trained in focus group facilitation. The sessions will be conducted at the contractor's headquarters in Research Triangle Park, NC, although one session may be held in a larger metropolitan area (Chicago, IL or Washington, DC) for participant diversity reasons. The groups will be segmented by age (18-25 vs. 26 and older) and socio-economic status (SES), with SES status broken out as household income of less than $30,000 per year (low SES) and $30,000 or more per year (non-low SES). This segmentation is intended to match the sampling domains for the national implementation, including the planned oversampling of 18 – 25 year olds. Each group will include an equal mix of males and females and races/ethnicities that match the sampling goals for the Tobacco User Panel. In addition, there will be one focus group that consists of Spanish-speaking participants, selected by low socio-economic status, an equal mix of males and females, and a mix of ages. ***Table 1*** describes the five groups.

Table 1. Focus Group Segmentation

Focus Group	Respondent Characteristics
1	18-25, Low SES, Mix of Races and genders
2	26 and older, Low SES, Mix of Races and Genders
3	18-25, High SES, Mix of Races and Genders
4	26 and older, High SES, Mix of Races and Genders
5	Spanish speakers, Low SES, Mix of Ages and Genders

The contractor will recruit 10-11 individuals for each focus group discussion, with the expectation of having nine participants attend each session. To be eligible to participate, participants must be able to read, understand, and speak English, except for participants in the Spanish-language focus group. Participants must also be current tobacco users, specifically, cigarette, cigar, and/or smokeless tobacco product users. Additionally, no individual will be included to participate if he/she or a household member ever lobbied on behalf of the tobacco industry or personally represented or worked on behalf of a tobacco company in connection with a tobacco lawsuit. No individual will be included to participate if he/she or a household member worked in the past 5 years for any of the following entities:

- a tobacco or cigarette company;
- a public health or community organization involved in communicating the dangers of smoking or the benefits of quitting;
- a marketing, advertising, or public relations agency or department;
- U.S. Food and Drug Administration (FDA);
- National Institutes of Health (NIH);
- Centers for Disease Control and Prevention (CDC);
- Substance Abuse and Mental Health Services Administration (SAMHSA); and/or
- Centers for Medicare & Medicaid Services (CMS).

4. **Date(s) to be conducted and location(s):**
   The focus groups will be recruited and conducted during a 6-week period in fall 2013, at the contractor's offices in Research Triangle Park, NC, Chicago, IL, and/or Washington, DC.

5. **How the Information is being collected:**
   Focus groups are used to obtain insights into target audience perceptions, beliefs, and attitudes in the early stages of the communication process (i.e., in concept, strategy, and materials development) and to inform the development of quantitative research. Focus groups are usually composed of 8 to 10 people who have characteristics similar to the target audience or subgroups of the target audience. The groups are conducted by a professional moderator who keeps the session on track while allowing respondents to talk openly and spontaneously. The moderator uses a loosely structured discussion outline, which allows him/her to change direction as the discussion unfolds and new topics emerge. Focus groups are valuable in exploring reactions to concepts and design ideas before additional resources are put into development.

   Participants will be required to consent, in writing, to participation in the focus group. With respondent consent, each group will also be audio-recorded to facilitate note-taking after the session. The audio tapes will be destroyed after a report of the focus group findings has been prepared. Participants may also be asked if the session can be unobtrusively observed by another RTI or FDA project staff member, using two-way mirrors in the laboratory setting.

Using a structured moderator's guide, an experienced moderator will lead each group through the discussion, which will revolve around strategies for recruiting panel participants, types of incentives, length of panel participation, frequency of contact and usability issues related to the use of a device that will be given to panel members to complete the surveys online. The moderator will be assisted by a note-taker, also present in the room, to capture comments and questions that are shared by participants. Audio recordings of the sessions, if available, will be used to ensure a complete and accurate summary of participant feedback.

Copies of all focus group materials, including the participant recruitment flyer, recruitment protocol, moderator's guide, informed consent form, example equipment agreement form, and receipt form are provided in Attachment A.

6. Number of focus groups:

There will be five focus groups representing a diverse population.

7. Amount and justification for any proposed incentive:

Potential focus group participants have competing demands for their time and may incur costs in order to participate in focus groups. Empirical studies have shown that incentives can significantly increase participation in data collection (Shettle & Mooney, 1999; Singer et al. 2000). Similarly, incentives can motivate individuals to participate in focus groups because they encourage them to attend rather than participate in another activity. Incentives also increase participation because they cover out-of-pocket expenses that individuals incur when they participate in focus groups. This may include transportation costs incurred when participants drive to the central location where the focus group is being held or child care costs they incur while participating in the discussion.

The proposed incentive amount for the Tobacco User Panel focus groups is $40. For incentives to have their desired effect of increasing participation, they must be high enough to cover potential participants' transportation costs and time. Further, the incentive amount must be tailored to the population that is being sought. Incentives are typically higher for harder-to-recruit populations (Stewart, Shamdasani, and Rook, 2007). Adults who use tobacco products are a difficult-to-reach population given the prevalence of tobacco use in the general population. Additional challenges in recruiting participants will result from the study's need to collect data from diverse segments of the tobacco-using population, including current users of specific tobacco products, and those in low socioeconomic status and Spanish-speaking groups. Having the perspectives of these varied groups is critical to designing effective panel recruitment procedures for the national study.

An insufficient incentive level increases recruitment difficulty (thereby reducing cost efficiency) and increases the likelihood that recruits who do agree to participate in groups

will end up not showing up for the discussion. Low participation may result in inadequate data collection, or, in the worst cases, cancellation of groups and loss of costs associated with facility rentals, recruitment, travel costs, and moderator and observer time (Morgan and Scanell, 1998). Further, an insufficient incentive amount may limit the ability of certain demographic groups (e.g., low socioeconomic groups, those with children) to participate in the focus group, potentially biasing the results of the focus groups.

Given FDA's need to enroll a nationally representative panel of tobacco consumers from among varied and vulnerable populations, it is critical to this data collection that we provide adequate incentives to encourage participation among the limited number of potential adult tobacco users. The incentive must therefore be sufficient to obtain the sample of participants required by our study, while also balancing recruitment expenses and minimizing biases in self-selection.

8. Questions of a Sensitive Nature:

Some studies require the inclusion of people who match selected characteristics of the target audience that FDA is trying to reach. This may require asking a question about race/ethnicity and income on the initial screening questionnaire used for recruiting. Respondents are assured that the information they provide is voluntary and will be treated as private and anonymous to the fullest extent allowed by law. All information on race/ethnicity will comply fully with the standards of OMB Statistical Policy Directive No. 15, October 1997 (http://www.whitehouse.gov/omb/fedreg/1997standards.html).

Raw data from data collections that include sensitive information (for example, screening questionnaires and audio tapes) are not retained once the data have been extracted and aggregated. The information never becomes part of a system of records containing permanent identifiers that can be used for retrieval.

9. Description of Statistical Methods (i.e., Sample Size & Method of Selection):

In general, focus group research relies on qualitative methods and is not intended to yield results that are statistically projectable. However, the findings from this study will be used to inform the design of the Tobacco User Panel protocols for recruitment and maintenance of the national panel, specifically recruitment strategies, incentive protocols, length of time in panel and number of survey contacts, and panel management strategies. Quota sampling will be used to select a convenience sample of individuals who meet certain qualifications that reflect characteristics typical of the target audience. Response rate is not applicable to quota sampling because this type of sampling results in a nonprobability sample that is not representative of the population. For this focus group study, all respondents will be initially contacted by telephone, and some overrecruiting may be done to compensate for nonrespondents (i.e., no shows).

BURDEN HOUR COMPUTATION *(Number of respondents X estimated response or participation time in minutes/60 = annual burden hours):*

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
1 (18-25, Low SES)	9	90	13.5
2 (26 and older, Low SES)	9	90	13.5
3 (18-25, Non-Low SES)	9	90	13.5
4 (26 and older, Non-Low SES)	9	90	13.5
5 (Spanish speakers, Low SES)	9	90	13.5
Total	45		67.5

REQUESTED APPROVAL DATE: September 24, 2013

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