

FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS

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: Qualitative Study on Cigarettes and Smoking: Knowledge, Beliefs, and Misperceptions about cigarettes and cigarette smoking; OMB Control Number 0910-0674

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

The Food and Drug Administration (FDA), Center for Tobacco Products (CTP), is seeking OMB approval under the generic clearance 0910-0674 to conduct exploratory focus groups, “Qualitative Study on Cigarettes and Smoking: Knowledge, Beliefs, and Misperceptions about cigarettes and cigarette smoking,” to assess consumers’ understanding of cigarettes and cigarette smoking. This research will inform the Agency’s efforts to implement the provisions of the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) by understanding how people think about cigarettes and cigarette smoking.

Section 1003(d)(2)(D) of the Food, Drug and Cosmetic Act (21 U.S.C. Section 393(d)(2)(D)) and Sections 2, 3, 105, 201, 204, 904, and 908 of the FD&C Act support the development and implementation of FDA communications and education related to tobacco use. Effective communication requires an understanding of consumer knowledge and beliefs.

2. Intended use of information:

This study is intended to qualitatively explore knowledge and beliefs about cigarettes and smoking. Findings from this formative research will allow FDA to: 1) examine knowledge and beliefs about the harms of smoking; 2) identify potential communication messages; and 3) refine warnings about the harms of smoking to be tested in future studies. Any further work done to create communication messages or develop items for inclusion on national surveys would require additional research prior to execution. Research conducted to inform such efforts will seek OMB approval.

As with all qualitative research, results from this focus group study are not generalizable. As such, FDA will not use findings from this study to directly inform policy.

FDA issued a cigarette graphic health warning (GHW) rule in 2011, which was challenged in court. Ultimately, the rule was vacated in *R.J. Reynolds Tobacco Co. vs. FDA*, and FDA announced that it was planning to undertake research to support a new rule for cigarette graphic health warnings. This focus group project is the first step in that research. The knowledge gained from these groups will be used to refine the text element of warnings which will eventually be paired with color graphics depicting the negative health consequences of smoking” as described in Sec. 201 201(a)(d) of the Tobacco Control Act.

3. Description of respondents:

Respondent Characteristics and Group Segmentation

Respondents will participate in one of 16 focus groups. Focus groups will be conducted in approximately equal numbers in Baltimore, MD, Memphis, TN and Portland, OR. These locations were chosen because they 1) have relatively high rates of cigarette use overall; 2) have relatively high rates of adolescent cigarette use; 3) provide geographic and racial/ethnic diversity. Geographic diversity is achieved by selecting one site on the east coast, one on the west coast and one in the south. Each group will include a mix of ages, races/ethnicities, and education levels.

Because this study is exploratory, it is important to capture a full range of responses from a variety of people. Respondents will be recruited based on characteristics related to differences in smoking behavior. Recruitment characteristics include: age (adolescent, adult) and smoking status (e.g., current user, susceptible to smoking). Respondents are grouped together based on common characteristics (e.g., age and smoking status) to maximize compatibility and facilitate group discussions. Groups will be segmented as follows:

Adolescents: Four groups will be conducted exclusively with adolescents (ages 16-17). The adolescent groups will be segmented by gender (2 male groups and 2 female groups) and smoking status: current users (smoked a cigarette in the past 30 days) and susceptible to smoking (based on a 3-item screener).

Adults: Twelve groups will be conducted with adults (≥ 18 years old). All of these groups will consist of current smokers. Each group will contain an approximately equal number of males and females.

While there will be differences in the characteristics of the groups, this study is not designed to examine differences between the groups. Rather, the analysis will identify major themes across groups.

Recruitment

The contractor will recruit approximately 12 individuals for each focus group discussion, with the expectation of having 8 to 10 participants per group. To be eligible to participate, respondents must be able to understand and speak English and must be comfortable talking in a group of people of a similar age. Respondents cannot have participated in a focus group or a similar study in the past 6 months. Additionally, no adult participant 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 adult participant 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).
- Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF)
- Alcohol and Tobacco Tax and Trade Bureau (TTB)

4. Date(s) to be conducted and location(s):

The focus groups will be conducted in Spring/Summer 2015 pending OMB approval. The focus groups will be conducted in Baltimore, MD, Memphis, TN and Portland, OR.

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. In addition, two short handouts will be used to guide discussion. Focus groups are valuable in exploring consumer reactions to message concepts before additional resources are put into development.

For this study, each 90-minute focus group will be conducted at a local marketing research firm. With respondent consent, each group will be digitally audio-recorded. Focus groups may be monitored by FDA representatives from behind a one-way mirror or will be video-streamed such that FDA representatives can view them via a live webcast. Using a structured moderator guide, a professional moderator will lead each group through a discussion, which will revolve around a discussion of knowledge, beliefs and perceptions about cigarettes and cigarette smoking.

6. Number of focus groups:

There will be 16 focus groups representing a diverse population.

7. Amount and justification for any proposed incentive:

Potential participants have competing demands for their time, so incentives are used to encourage participation in focus groups. Incentives must be high enough to cover travel costs, time, and to provide enough incentive to attend the focus group rather than another activity. Focus group studies run by industry offer incentives at much higher levels than those typically allowed by government studies (Fieldwork Denver, personal communication, March 22, 2012), establishing a market rate that makes recruitment more difficult. Additionally, incentives typically are higher for harder-to-recruit populations.¹

The amount of the proposed incentive is \$40 for adolescents, plus \$25 for a parent/guardian that accompanies them to the study facility; and \$75 for adults. Adults

¹ Stewart, D.W., Shamdasani, P.N., Rook, D.W. (2007). *Focus Groups: Theory and Practice*. Thousand Oaks, CA: Sage Publications.

who smoke are a difficult-to-reach population given the low prevalence of smoking in the general population. Similarly, adolescents who smoke—or are susceptible to smoking—are also a minority of the population.

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 time². Given FDA's need to understand consumer perceptions of cigarettes and smoking 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 eligible cigarette users. Thus, in order to obtain the sample of participants required by our study, while also minimizing biases in self-selection and balancing recruitment expenses, it is critical we offer a sufficient level of incentive.

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 education level on the initial screening questionnaire used for recruiting. Potential participants are informed that these questions are asked to ensure that FDA speaks with the kinds of people for whom its messages are intended. Again, respondents are assured that the information they provide is voluntary and will be treated as private and anonymous. 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>).

Because FDA tobacco communications may be concerned with communicating messages about the health risks of smoking this project may involve asking questions about (or discussing) how one perceives his/her own personal risk for serious illness. This information is needed to gain a better understanding of the target audience, so that the messages, strategies, and materials designed will be appropriate and sensitive. Questions of this nature, which are not necessarily as personal as those about sexual behavior, household income, or religious beliefs, still require some sensitivity in how they are worded and approached. In face-to-face data collections, questions of this kind are generally asked later in the interview or group discussion, when respondents are more comfortable with their environment. In this study, participants will be asked about the effects of cigarette smoking on health, and so it is possible that the questions could provoke responses of a personal nature. Participants are informed prior to actual participation about the nature of the activity. Additionally, the moderator makes it clear at the beginning of each group that respondents do not have to respond to any question that makes them uncomfortable.

Raw data from data collections that include sensitive information (for example, screening questionnaires and audio recordings) 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.

² Morgan, D.L. & Scanell, A.U. (1998) *Planning Focus Groups*. Thousand Oaks, CA: Sage Publications.

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. 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 over recruiting 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)
Adolescents (16-17 years old): 4 groups with 12 participants per group			
Initial Screener	720	6	72
Parental Assent	48	5	4
Adolescent Assent	48	5	4
Focus group discussion	48	90	72
Total Adolescents Screened	720		
Adults (≥18 years old): 12 groups with 12 participants per group			
Initial Screener	1,296	6	130
Consent	144	5	12
Focus group discussion - Adults	144	90	216
Total Adults Screened	1,296		
Total Screened	2,016		
Total Participants	192		
Total Burden	2208		510

REQUESTED APPROVAL DATE: April 14, 2015

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FDA CENTER: Center for Tobacco Products (FDA/CTP)