

**U.S. Food and Drug Administration**

**Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications**

**OMB Control No. 0910-0796**

**Part B. DATA COLLECTION & STATISTICAL METHODS**

Data collection will consist of interview, small group, and focus group methodologies, i.e., qualitative methods. In qualitative studies, an individual or small group of people (typically 2-12 individuals) engage in a discussion on selected topics of interest typically directed by a moderator/interviewer who guides the discussion in order to obtain the person or group's opinions, particularly the "whys" and "hows" behind a behavior or attitude at question (Krueger & Casey, 2000; Lindlof & Taylor, 2017). Interviews and focus groups capture the insights of an individual or the collective insight of a group while preserving individual preferences. In groups, participants can describe their experiences and preferences without the limitations of preset response categories. Furthermore, interviews and focus groups produce rich data complete with nuances that often may be obscured in quantitative data collection techniques. The methods are used to produce qualitative data to help develop, design, and interpret quantitative results obtained from surveys or experiments.

Since interviews and focus groups are qualitative research methodologies, statistical methods will not be employed to analyze interview and focus group data. Descriptive data may be reported as appropriate. Typically, qualitative data involve reviewing responses to open-ended questions, emerging approaches, and other types of text or image data. (Carey, 1995; Morgan, 1995; National Cancer Institute, 2002; Webb & Kevern, 2001). Typically, not every participant in a group comments on every issue discussed (Carey, 1995), and the course of discussion will vary across groups, with some topics emerging in one group and not in another (Carey, 1995; Morgan, 1995). Instead, descriptors such as "many," "several," and "few" will be used to qualitatively describe the relative number of participants or groups who expressed a particular view.

**1. Respondent Universe**

Study participants will include members of the general public and stakeholders with an interest in tobacco products. Inclusion and exclusion criteria will vary depending on the research topic. To identify potential variation according to regional differences, information collections may be conducted at multiple sites in the United States when appropriate.

The interviews and focus groups will generate qualitative data, and the results from the interviews and focus groups will not be used to make statements representative of the universe of study, to produce statistical descriptions (careful, repeatable measurements), or to generalize the data beyond the scope of the sample.

Interviews and focus groups are a valuable tool for qualitative data collection; they allow for the efficient collection of information and in-depth exploration of major themes and perspectives, and they help develop new insights. Some of these benefits are not available through traditional quantitative or other experimental data collection methods. The accuracy, reliability, and applicability of the results of these interviews and focus groups will be adequate for this purpose, and for this reason, the samples associated with this collection are not subject to the same scrutiny as quantitative sampling designs where estimates are published or otherwise released to the public. The specific sample planned for each individual collection and the method for soliciting participation will be described fully in each collection request.

## **2. Procedures for Information Collection**

The typical steps for this information collection are as follows.

1. Screen and recruit participants using current and pertinent databases such as local telephone directories and lists maintained by qualitative recruitment vendors or contractors. Prior to group discussion, youth assent and parental consent forms will be signed by all participants as appropriate.
2. Conduct the interview or group discussion, not to exceed 2 hours, under the direction of one or more professionally trained moderators. The discussion will follow OMB-approved guidelines. Discussions are usually audio-recorded to aid data analysis. When needed, discussions will also be streamed from a facility to other locations to allow remote observation. A verbatim transcript will be compiled for each interview or group.

## **3. Methods to Maximize Response Rates**

These are qualitative research methodologies. Participants will be recruited from sources which offer an abundant supply of the target audience. In the past, participants have been recruited from commercial databases or through advertisements placed in a newspaper or online. Since results are not generalizable, appropriate response rates will be flexible based on the target audience and research question(s).

To minimize the possibility of having too few appropriate focus group participants (thereby forcing group cancellation) or too few interview participants, as many as 25 percent more participants are invited than are needed. In the event that too many participants report, excess participants will be dismissed.

## **4. Tests of Procedures or Methods to be Undertaken**

Pretesting of interview and focus group protocols to be used in these qualitative studies may be done with internal staff or a limited number of external colleagues. If the number of pretest respondents exceeds nine members of the public, the agency will submit the pretest focus group protocol for review under this generic clearance.

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

FDA staff will be responsible for developing the moderator guides and screening criteria with advice, if needed, from data collection contractors. FDA staff will work with contractors to develop data analysis plans. Data will be analyzed by contractors, with data quality checks and additional in-depth analyses conducted by FDA staff. Contractors will prepare draft presentations of results, which will be reviewed by FDA staff and approved for presentation to CTP leadership and external stakeholders.