

United States Food and Drug Administration

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

OMB Control No. 0910-0796

SUPPORTING STATEMENT

Part B. Statistical Methods

Data collection will consist of qualitative methods (e.g., interviews, small group, and focus group methodologies) that may be conducted either synchronously or asynchronously (e.g., via online discussion boards or online journals). 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, discussion boards, 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, qualitative approaches 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. While these studies will employ qualitative methodologies studies may also include collection of individual level quantitative or psychometric data (e.g., eye tracking data) to complement and enhance the analysis of qualitative data.

Analysis will principally be qualitative utilizing thematic coding. Descriptive data may be reported as appropriate.

1. Respondent Universe

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

Data from these studies will primarily be qualitative and 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.

Qualitative research methods 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 qualitative studies 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.

- a. Screen and recruit participants using current and pertinent databases maintained by qualitative recruitment vendors, panels, or contractors and/or through ad postings on social media or other venues. Prior to participation in the research, participant consent (adults) or assent (youth) and parental consent (for youth) forms will be signed by all participants as appropriate.
- b. Conduct the qualitative research (e.g., focus group discussion, usability study, cognitive interview, discussion board, naturalistic observation, and ethnographic studies etc.), under the direction of one or more professionally trained discussion moderators or observers. The discussion will follow OMB-approved guidelines. Synchronous discussions are usually audio-recorded, and then transcribed, to aid data analysis. A verbatim transcript may be compiled for each interview, group, and collection. Asynchronous discussions are downloaded and transcribed for data analysis.

3. Methods to Maximize Response Rates

These are qualitative research methodologies. Participants will be recruited from sources which offer an abundant supply of members of the intended audience. In the past, participants have been recruited from commercial databases or through advertisements placed on social media. 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 participants (thereby forcing group cancellation or leading to failure to reach saturation), as many as 50 percent more participants will be invited than are needed. If too many participants report, excess participants will be dismissed. In addition, focus groups may be pivoted to in-depth interviews, if needed.

4. Tests of Procedures or Methods to be Undertaken

Pretesting of discussion/interview 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 work with contractors to develop data analysis plans. Data will be analyzed by contractors, with data quality checks and additional in-depth analyses (e.g., thematic coding) conducted by FDA staff. Contractors will prepare draft presentations of results, which will be reviewed by FDA staff. FDA staff will approve all final reports and work with contractors to prepare presentations to CTP leadership and external stakeholders.