Focus Groups as Used by the Food and Drug Administration (All FDA-regulated Products)

0910-0497
SUPPORTING STATEMENT

B. Statistical Methods (used for collection of information employing statistical methods)

You should be prepared to justify your decision not to use statistical methods in any case where such methods might reduce burden or improve accuracy of results.

1. Respondent Universe and Sampling Methods

Describe (including a numerical estimate) the potential respondent universe and any sampling or other respondent selection method to be used, including the following.

- Data on the number of entities (e.g., establishments, State and local government units, households, or persons) in the universe covered by the collection and in the corresponding sample. Provide these in tabular form for the universe as a whole and for each of the units in the proposed sample.
- Indicate expected response rates for the collection as a whole. If the collection had been conducted previously, include the actual response rate achieved during the last collection. If virtually the same study has been done in the past few years, you may use that experience as the basis for the expected response rate to the proposed data collection activity, provided techniques used in the earlier experience are not changed in the proposed activity.
- As a general rule for obtaining OMB approval, the minimum acceptable response rate for a statistical survey is 75 percent. You must provide a special justification for a response rate less than 75 percent. Do not obtain statistical data collection for activities with an expected response rate of fewer than 50 percent.

2. Procedures for the Collection of Information

Describe the procedures for collecting the information including:

- statistical methodology for collection and sample selection;
- estimation procedure;
- degree of accuracy needed for the purpose described in the justification;
- unusual problems requiring specialized sampling procedures, and;
- any use of periodic (less frequent than annual) data collection cycles to reduce burden.

Keep the following in mind when discussing your procedures for the information collection.

- A probability sample is always preferred. When a probability sample is not used, explain the rationale for the procedures to be used in the proposed non-probability sample.

- Include precision requirements for estimates from sample surveys There should be enough detail to allow a reviewer to determine whether proposed sample sizes are sufficient to satisfy the stated requirements.
- It is important to provide sufficient information about the types of individuals, and any special qualifications they may have. Explain who will collect the information and how it will be collected so that it is clear how the sampling plan and data collection instruments are implemented to provide the resultant data.
- Include any response cards or other visual aids that are used with respondents.
- Describe any advance appointments that are made prior to visit of an interviewer or if any advance letters are sent to respondents. Include copies for review and approval.
- Describe any quality control procedures that you will implement as part of the fieldwork or review of data coding and preparation. If respondents are re-interviewed or re-contacted, include that data collection instrument or script, along with any additional burden.
- Discuss plans for imputation of missing data (handling of non response data). Describe the estimation (including variance estimation) procedures that you will use. If commercially available packages will be used for variance computations, identify the name of the computer program.

Note: Any response advance letters, cards, or other visual aids used with repondents must be included in the submission as attachments.

3. Methods to Maximize Response Rates and Deal with Non-response

   Describe the methods you are using to maximize response rates and to deal with issues of non-response.

   You must show that the accuracy and reliability of information collected is adequate for its intended uses.

   For collections based on sampling, provide a special justification for any collection that will not yield "reliable" data that can be generalized to the universe studied.

   For most data collections OMB requires that response rates be at least 80%. You must provide convincing evidence to support your estimated response rates. If virtually the same study has been done in the past few years, it is appropriate to use that experience as the basis for the expected response rate to the proposed study. Describe the follow-up procedures you will use when first attempts fail to reach respondents (e.g., the number of repeat telephone calls or letters and their content.)

4. Test of Procedures or Methods to be Undertaken

   Testing is encouraged as an effective means of refining collections of information to minimize burden and improve quality.

   - Tests and pretests require OMB approval if you are asking identical questions from 10 or more respondents. You may submit a request for OMB approval of a proposed

test or set of tests separately or in combination with the main collection of information.

- Submit a pretest separately from the main survey for OMB approval if it is designed to make significant decisions about data collection method, content, timing or other major aspect of the effort.
- If only "fine tuning" changes to the data collection activity are expected as a result of the pretest, you can ask for a combined approval for the pretest and the main survey.
- You must inform OMB of any changes to the survey procedures or data collection instruments with a final version before actual data collection begins.

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

   Provide the name and telephone number of individuals consulted on statistical aspects of the design. Include the name of the FDA unit, contractor(s), grantee(s), or other person(s) who will actually collect and/or analyze the information for the agency.