

B. Collection of Information Employing Statistical Methods If statistical methods will not be used to select respondents and item 17 on Form 83-I is checked "No" use this section to describe data collection procedures.

The agency should be prepared to justify its decision not to use statistical methods in any case where such methods might reduce burden or improve accuracy of results. When item 17 on the Form OMB 83-I is checked "Yes," the following documentation should be included in the supporting statement to the extent that it applies to the methods proposed:

1. Respondent Universe and Sampling Methods

Describe (including numerical estimates) the potential respondent universe and any sampling or other respondent selection method to be used. 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 are to be provided in tabular form for the universe as a whole and for each of the strata in the proposed sample. Indicate expected response rates for the collection as a whole. If the collection has been conducted previously, include the actual response rate achieved during the last collection period. Include statistical justification for all sample sizes. If you plan to survey the entire universe, explain why this is preferable to using a sample.

2. Procedures for the Collection of Information

Describe the procedures for the collection of information including:

- Statistical methodology for stratification 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. Information should be given about who will collect the information and how it will be done, so that a reviewer can fully understand how the sampling plan and data collection instruments will be implemented. For example: Are interviewers trained? Do the respondents have advance notice or appointments?

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

Quality control procedures to be implemented as part of the field work or review of data coding and preparation should be described. If respondents are re-interviewed or re-contacted for validation, the data collection instrument or script for that re-contact must also be included as an attachment and the burden included. If the specific data collection plans are not yet known and only **concept clearance** is being sought, the Statement of Work and deliverables for the project should be referenced and attached. For experimental designs, include a table (or graphs) showing statistical power at different sample sizes. Requests for approval to conduct case-control and cohort studies must include a complete discussion of detectable differences, sample size and expected statistical power analysis which takes into consideration the following:

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- the size of the difference you want to detect.
- frequency of the outcome or exposure in the control group.
- the level of Type I (alpha) error or the significance level.
- the value of Type II (beta) error.

Prepare the sample size and statistical power discussion as it would appear in a research protocol. There should be sufficient information about the sample design and the expected numbers and characteristics of sample persons or units to enable reviewers to ascertain the adequacy of the sample for the types of planned analyses and uses to be made of the resulting data. If the specific data collection plans are not yet known and only concept clearance is being sought, the contract statement of work and deliverable for the project should be attached and referenced.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Describe methods to maximize response rates, and to deal with issues of nonresponse. The accuracy and reliability of information collected must be shown to be adequate for intended uses. For collections based on sampling, a special justification must be provided 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 had 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. Tests of Procedures or Methods to be Undertaken

Describe any tests of procedures or methods to be undertaken. Pilot testing is encouraged as an effective means of refining questions to minimize burden and improve utility. **Pilot tests must be OMB approved if they call for answers to identical questions from 10 or more respondents.** A proposed pilot test or set of pilot tests may be submitted for approval separately or in combination with the main collection of information. Ensure that all data forms and data collection procedures that you submit for clearance have been pilot tested. Pilot tests involving fewer than 10 respondents are within OMB exemptions for clearance. However, larger pilot tests must first have OMB approval. If the proposed data collection instruments have been used in previous studies, state the source of the study and, if appropriate, the OMB number and expiration date, if known. Also, if only portions of the proposed instrument have been previously used (and/or approved by OMB), it is very much in your best interest to reference those portions in this section. A pretest or pilot test designed to make significant decisions about data collection method, content, timing or other major aspect of the effort should be submitted for approval separately from the main survey. If only **minor** changes are expected as a result of the pretest, it is reasonable to seek

a combined approval for the pretest and the main survey. OMB should be informed of any changes to the survey procedures or data collection instruments as quickly as possible before data collection begins. The intent to inform OMB of such changes should be mentioned in this portion of the Supporting Statement.

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

Provide the name, telephone number, and e-mail addresses of individuals consulted on statistical aspects of the design and the name of the agency unit, contractor(s), grantee(s), or other person(s) who will actually collect and/or analyze the information for the agency. If the persons collecting or analyzing the data are contractors, list their names in addition to the names of the agency personnel responsible for receiving and approving contract deliverables.

Specifically note the person who:

- 1) designed the data collection;
- 2) will collect the data, and;
- 3) will analyze the data.