

Generic Clearance for CDC/ATSDR
Formative Research and Tool Development

Supporting Statement B

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Table of Contents

Collection of Information employing Statistical Methods

1. Respondent Universe and Sampling Methods
2. Procedures for the Collection of Information
3. Methods to Maximize Response Rates and Deal with Nonresponse
4. Tests of Procedures or Methods to be Undertaken
5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

The respondent universe for the proposed data collection includes persons in the general population or from specific subpopulations such as persons with or at risk for certain medical conditions, adolescents and/or adults, males, females, and/or persons of specific races/ethnicities, persons residing in rural and/or urban locations, and/or in specific regions or health jurisdictions. Other respondents may include health care providers, health department personnel, community-based organization personnel and others engaged in public health activities promoted by CDC.

Populations and sampling methods will vary from project to project. Sampling methodologies will include probability sampling methods such as simple or stratified random sampling, or multi-stage random sampling, or nonprobability methods such as respondent-driven sampling, purposive sampling, and convenience sampling.

Information collection requests for each individual project associated with this generic clearance will clearly define the specific goals, respondent population and sampling method.

2. Procedures for the Collection of Information

Because this generic clearance covers a wide range of studies, each individual project submitted under this generic clearance will clearly define the specific data collection methods and procedures. Individual data collections will be time-limited and generally conducted only once, except in the cases of individual interviews conducted during pilot testing of interventions where respondents may have to be approached several times on the same or similar topic under evaluation. No single data collection activity will take longer than 1 year to complete from inception of information collection to the first report of findings. CDC will not receive any personally identifiable information.

Potential respondents will be identified through targeted recruitment efforts or purposive selection of key informants selected from the relevant study population. Screening questions may be used to determine eligibility. All recruitment materials will indicate the voluntary nature of the study.

We anticipate that studies under this generic clearance will use mixed methods for data collection. Some data will be collected by using qualitative open-ended questions. Brief structured surveys that include closed-ended questions will be appropriate for collecting information on age, race/ethnicity, sex, sexual orientation, and socio-economic status (e.g., education, income, employment, housing, health insurance status). Assessments may also collect quantitative data on contextual information, such as behavior or organizations and places where respondents interact. Regardless of the mixture of open-ended and closed-ended questions being used, all data collection methods will be implemented by trained personnel. For in-depth interviews and focus groups, questions may be open-ended so respondents can reply freely of their own accord. For these types of interviews, the trained data collector will guide the discussion with probing questions as needed. The content of open ended questions will vary by each task order. Qualitative interview guides, focus group guides, and brief structured surveys will be submitted with each genIC covered under this generic clearance.

Qualitative or structured interviews may involve individuals or groups, and may be conducted in-person, on the telephone, or via the internet (i.e. internet focus groups). Cognitive and in-depth interviews may involve the consumer clients or data collection implementers and generally involve face-to-face interactions. Methodological research procedures used for this research are similar to testing of surveys and materials, but focus more on the methods of enrollment and administration and less on the content of the materials themselves.

Field testing of new methodologies and materials may also be conducted under this generic ICR, and generally involves a small number of participants. Unlike full pilots of data collection activities, the purpose of field testing will be to evaluate project methods and materials not yet used by CDC. With the verbal consent of the respondents, pilot interviews or interventions may be unobtrusively observed by experienced methodologists who can objectively evaluate the process.

Regardless of methods, informed consent will be obtained before data are collected. The consent will inform potential participants of the private and voluntary nature of the study and provide general information about the study, the topics to be covered in the surveys, potential risks, and the token of appreciation available for completing the study. Screening questions may be asked; the screener includes questions to assess eligibility.

Data collection may be interviewer administered or self-administered. Data collection will generally be computer assisted. Implementers may also collect data with pencil and paper for some studies in certain situations. Data collected will be kept on secure computer servers with access restrictions and/or in locked cabinets in secure locations. All personal identifiable information (PII) required to conduct the study, such as contact information, will be maintained separately from the data collected, either on a server with access restricted to authorized personnel only, or if on paper, in separate locked cabinets from the data or recordings/transcripts. For online surveys, eligible individuals will be invited to participate and asked to click on a hyperlink to launch the consent form and survey on a secure Website. Individuals will indicate their consent online to be screened. Only those who agree to participate will enter the survey. Those who do not consent to be screened will be thanked for their time and asked to close their browser window.

3. Methods to Maximize Response Rates and Deal with No Response

The following procedures will be used to maximize cooperation and to achieve the desired high response rate:

A token of appreciation in cash or gift card, may be provided to respondents - Respondents from the target populations who participate in projects covered under this generic ICR may be provided with a token of appreciation of up to \$40 to encourage their participation, and convey appreciation for contributing to the research study. Incentives will not exceed \$40 per hour for such intensive interviews like focus groups and cognitive interviews unless compelling evidence is provided that recruitment is very difficult for a particular subgroup. Tokens of appreciation may include but are not limited to gift certificates to grocery stores or retail pharmacies and cash. The amount of the token of appreciation will depend on the preferences and needs of the populations in the local study locations.

4. Test of Procedures or Methods to Be Undertaken

Depending on the purpose of the individual study covered under this Generic ICR, tests may be conducted of recruitment and enrollment procedures; study recruitment materials; health messages, products, interventions or campaigns; and data collection methods and instruments.

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

This information collection request does not employ statistical methods.