Generic Clearance

Assessments of adults' professional experiences for improving programs to decrease sexual risk and related behaviors and adverse health outcomes among youth.

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Supporting Statement Part B

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Supported by:

Division of Adolescent and School Health
Centers for Disease Control and Prevention

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PART B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1. Respondent Universe and Sampling Methods

The respondent universe consists of adults (18 years of age and over) who help implement or oversee programs to prevent HIV, other sexually transmitted diseases (STDs), and pregnancy among youth or influence related risk and protective factors. These adults typically serve in the following types of roles:

- School staff and administrators;
- Staff in state and local education agencies;
- Staff in local health agencies;
- Staff in youth-serving community or national non-governmental organizations;
- Community-based health care providers for youth; and
- School-based health care providers for youth.

Each information collection will target individuals in areas aligned with the purpose of the project. For example, if the project was designed to refine a program being implemented in a specific school district, a respondent sample would be drawn from the universe of relevant adults (e.g., teachers, administrators) working with the program in that particular school district. In addition, respondents may sometimes be drawn from outside the areas of interest if that is required to compile an appropriate control group. Each individual ICR under this generic clearance will include the specific methods for sampling and show alignment with the questions being addressed.

For probability-based sample quantitative questionnaires, the potential participants for each data collection will be selected using the simplest sampling and lowest burden methodology possible to address the question of interest. Methods will be dependent on the sampling frame and characteristics of the specific target population.

a. For data collections designed to refine specific program activities, the sampling frame will consist of adults associated with the program (also referred to as "program implementers") and, for some projects, an additional group of adults in similar roles who are closely matched to the program implementers on a number of relevant factors (e.g., geographic location, race, ethnicity, age, SES, policy environment, length of experience). Sampling frames could be limited to a particular region, community, school district, schools, or even particular classes or professional roles within a school or community, depending on the structure and implementation format of the program being assessed. When feasible, random selection within the sampling frame will be used.

b. For data collections used to inform program design (e.g., needs assessments), the sampling frame will consist of lists of program implementers representing the area where the program is implemented. For example, if the data collection is intended to inform a program in a particular school district, the sampling frame would be limited to the school districts' list of adults associated with the program in that school district. When feasible, random selection within the sampling frame will be used.

Power calculations will be conducted for each data collection to determine appropriate sample sizes based on the specific measure of interest and desired precision. Limits to generalizability of each collection will be clearly described through all reports of the data.

For qualitative interviews or focus groups, purposive non-probability sampling will be used to identify and recruit participants in accordance with the specific target population (e.g., age, race, ethnicity, program experience) and purpose of the project. Participants' recruitment is expected to take place through collaboration with schools, community-based organizations, and/or other groups helping provide program implementation support. As with the quantitative data collection, recruitment methods will vary depending on the group being targeted and the purpose of the project. Eligibility criteria will be established for all focus group participants, and potential participants will be screened using a standard screening process. As many as 7,000 respondents may be anticipated to take part in interviews or focus group discussions each year, with most individual ICRs under this generic clearance averaging no more than 200 qualitative participants.

Each proposed data collection will submit an application for IRB review and approval, which will outline their procedures for participant selection and consent.

B.2. Procedures for the Collection of Information

Quantitative surveys

For the quantitative surveys, data collection methods will be determined by the nature of the survey questions, considerations of respondent privacy and comfort, and the environment in which the respondents will provide data. It is anticipated that data collections will typically be electronic (e.g., computer, tablet, or phone based) in order to take advantage of features such as programmed skip patterns to reduce burden on the respondent. In general, the preference will be for electronic data collection unless logistics or participant characteristics limit the feasibility or effectiveness of such an approach. As many as 30,000 respondents may take part in one of the 20 projects per year for which we are requesting approval, which averages approximately 1,500 respondents per project.

As appropriate, possible survey respondents will be screened for appropriate eligibility characteristics as indicated by the project purpose. Each proposed information collection request will include review and approval by an IRB. The IRB and OMB packages will outline the procedure for participant selection and consent. In addition, each ICR submitted under this generic clearance will provide culturally-appropriate tools for data collection as well as additional details on the data collection methods proposed and the rationale for their selection.

Qualitative interviews/focus groups

Qualitative interviews and focus group discussions will be led by trained interviewers and/or moderators. These data collection discussions may take place in-person, through web-interface or by telephone. With permission from the respondents, discussions will be audio-recorded and transcripts will be prepared from these recordings. Notes will also be taken during the discussions to ensure that records of the conversations exist in the case of audio equipment malfunction.

Each proposed project will submit age- and culturally-appropriate tools for data collection, in the statement provided to OMB. As many as 7,000 respondents may take part in interviews or focus group discussions each year, with most individual requests under this generic clearance averaging no more than 350 qualitative participants.

Estimation procedures

All survey analysis will be conducted under the advice of a statistician/data analyst as needed and may involve generating descriptive statistics and analyses such as t-tests and regression analysis to identify change from pre-test data to post-test data or to identify characteristics predictive of the outcomes of interest. When required, the planned sample strategies will also permit sub-analyses that may include analyzing experiences, knowledge, attitude, behavior, and skill disparities among different sub-populations. Corrections will be made for over/under sampling, non-response, non-standard distributions, or any other unanticipated sampling or measurement error that may skew or bias the information collection and analyses.

Degree of accuracy needed for the purpose described in the justification

The use of simple but scientifically sound sampling methods and power calculations will ensure data are collected with enough accuracy to determine program impact and to inform future program development as well as help CDC/DASH provide appropriate guidance to its funding recipients. Close partnership with organizations participating in data collection (e.g., schools, community-based organizations) will help ensure all activities are conducted in culturally-appropriate ways, and should help ensure sufficient participation levels to reduce non-response bias. The qualitative data collection may also offer useful insight to interpretation of quantitative findings and allow for better understanding of the experiences, knowledge, attitude, behavior, and skill-related results found among participants.

Unusual problems requiring specialized sampling procedures

Unusual problems requiring specialized sampling are expected to be rare and will be disclosed in individual requests under this generic clearance.

Any use of periodic (less frequent than annual) data collection cycles to reduce burden

Use of periodic data collection cycles, e.g. once over the approval term of the generic, for specific projects is likely for many of the qualitative data collections. The periodicity of data

collection will be described in the ICR submitted for each proposed project under this generic clearance. Justification and description for more frequent data collection will be provided if it applies to the proposed project.

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

The following are the examples of the procedures that have proven effective in previous studies and will be used when possible to obtain an adequate response rate:

- Informing respondents of what the project is asking, why it is being asked, who will see the results, and how the results will be used, as well as discussing how respondents will benefit from the results and how the findings will be put into action.
- A token of appreciation for a respondent's time and interest may be given to research participants.
- Addressing data security and anonymity with respondents.
- Minimizing the time needed for participation in the project.
- Informing respondents how much time the project will take so that they know what to expect.
- Utilizing deadlines, reminders, and follow-ups to remind respondents and encourage participation.
- Providing easy access to data collection instruments, regardless of method being utilized. When appropriate for the participants and setting of a specific project, data collection instruments will be designed to be easily accessed by electronic means, from a link in an e-mail or on a website.
- For telephone surveys, outgoing calls that result in no answer, a busy signal, or an answering machine will be automatically rescheduled for subsequent attempts.
- Over-sampling, if necessary, to address potential for non-response.
- Collaborating to collect information with organizations and agencies (e.g., schools, community-based organizations) that serve the target populations.
- Obtaining support for information collections from trusted leaders in the participating organizations/agencies (e.g., school superintendents, school principals, community leaders).

B.4. Test of Procedures or Methods to be Undertaken

CDC/DASH will implement strategies (e.g. pilot testing, key informant interviews) to ensure that all information collection instruments and tools are culturally-appropriate for the populations targeted in each proposed project. The strategies used will be disclosed in each individual submission under this generic clearance.

1. *Quantitative surveys*

As appropriate, validated standard questions from existing questionnaires will be incorporated into the instruments used under this generic clearance. All new or adapted instruments will be pilot tested with 9 or fewer individuals prior to submission to OMB. In addition, if creation of new items becomes a substantial task in any of the proposed projects, one or more of the following procedures may be used to shape item construction:

- Developing protocols, scenarios, and question probes--follow-up questions used to gain more information about respondents' strategies for answering questions.
- Concurrent think-aloud interview--respondents think aloud while answering questions and responses are probed extensively.
- Retrospective think-aloud interview--respondents answer all questions first, then are asked how they arrived at their answers.
- Confidence ratings--respondents relate the degree of confidence they have in the accuracy of their answers.
- Paraphrasing--respondents repeat the questions in their own words.
- Collaboration with community representatives in developing survey instruments

2. *Qualitative Interviews/Focus Groups*

The use of previously validated interview and focus group guides will be encouraged, as appropriate. If previously validated instruments are not available or appropriate for a proposed project, then the instruments and methods of data collection will be pilot tested before information collection is implemented. Lessons from the pilot test will be identified, and changes will be incorporated into the instrument and method, as necessary. All pre-tests will involve no more than nine individuals unless OMB clearance is sought for more than nine participants.

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

The following individuals, including contractors, who may be chosen to review information collection instruments and tools and conduct information collections, will be available to provide advice about the design of statistical and sampling procedures undertaken as part of these data collection activities:

- Catherine Rasberry, PhD, Health Scientist, Division of Adolescent and School Health, CDC
- Leah Robin, PhD, Lead Health Scientist, Division of Adolescent and School Health, CDC
- Catherine Lesesne, PhD, Technical Director, ICF International

CDC/DASH staff will determine if additional consultation is required and will report any individuals consulting on statistical aspects or collecting/analyzing data in the individual packages.