

**Assessments to Inform Program Refinement for HIV, other STD, and Pregnancy
Prevention among Middle and High-School Aged Youth
0920-1235**

Request for OMB Approval of a “Generic Clearance” Data Collection

EXTENSION

Supporting Statement B

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Assessing the Impact of Interventions to Decrease Sexual Risk Behaviors and Adverse Health Outcomes among Middle and High-School Aged Youth

Request for OMB Approval of a Generic Clearance for Data Collection

PART B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1. Respondent Universe and Sampling Methods

The respondent universe consists of (1) adolescents of middle and high school age who are participating in, or can inform, interventions to prevent HIV, other STDs, and pregnancy, and (2) parents of adolescents of middle and high school age who are participating in, or can inform, interventions to prevent HIV, other STDs, and pregnancy. 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 students participating in 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 GenIC 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 adolescents or parents/caregivers associated with the program and, for some projects, an additional group of adolescents or parents/caregivers who are closely matched to the program participants on a number of relevant factors (e.g., geographic location, race, ethnicity, age, SES, policy environment). Sampling frames could be limited to a particular region, community, school district, schools, or even particular classes, clubs, or groups 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 adolescents or parents/caregivers representing the area in which a program would be 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 students and parents/caregivers in that school district. When feasible, random selection within the sampling frame will be used.

For data collections that are intended to represent populations that are often hard-to-reach or hard-to-identify, slightly varied methods may be used. In some instances, as has been previously done, surveys might be distributed to a census of adolescents or parents in a given sampling frame in order to ensure safe and full inclusion of the hard-to-identify groups. In other instances, a snowball sampling approach might be used with entry points provided through or in venues where the relevant target group may be visiting or received services (e.g., community-based organization that serve key sub-groups of youth).

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 exposure) and purpose of the project. Participants' recruitment will take place through collaboration with schools, community-based organizations, and/or other groups reaching members of the target participant pool. In some instances, recruitment might take place via online techniques (e.g., social media outreach or advertising). 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 3,000 adolescent and 3,000 adult respondents are anticipated to take part in interviews or focus group discussions each year, with most individual ICRs under this GenIC averaging no more than 200 qualitative participants.

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

B.2. Procedures for the Collection of Information

General approaches to sample selection have been outlined above in section B.1, but each specific ICR submitted under this generic clearance will include detailed information about statistical methods for stratification and sample selection as well as estimation procedures, any unusual problems that impact sampling, and data collection cycle schedules to reduce burden.

It is expected that data collected for ICRs that are submitted under this generic clearance may be collected by CDC staff or fellows, partners funded through CDC/DASH cooperative agreements or contracts, or non-funded partners that are working on specific program-focused programs with CDC/DASH. Details about the data collectors and the data collection protocols will be provided with any specific ICRs submitted under this generic package. These protocols will describe any processes for training data collectors, for the timing and nature of data collection, for the recruitment of the participants, and for communications used in recruitment and gaining informed assent and/or consent for participation.

Overall, the participants in data collection under this generic clearance may include:

- Adolescents (11-19 years old) of middle and high school age who are participating in, or can inform, interventions to prevent HIV, other STDs, and pregnancy; and

- Parents and/or caregivers of adolescents of middle and high school age. For the purposes of this generic package, parents/caregivers include the adult primary caregiver(s) for a child's basic needs (e.g., food, shelter, and safety). This includes biological parents; other biological relatives such as grandparents, aunts, uncles, or siblings; and non-biological parents such as adoptive, foster, or stepparents.

The participants for this data collection are considered to be the “beneficiaries” of the types of programs that are funded by CDC/DASH. Typically, CDC/DASH programs are intended to have direct impact on proximal indicators such as sexual health-related knowledge, attitudes, perceptions, and behaviors. Furthermore, CDC/DASH currently recommends its funded partners use parent engagement as a strategy for improving sexual health outcomes among youth, and therefore, it is critical to also be able to collect data from parents who may themselves be receiving programs, materials, or services intended to have a cascading reach to their children.

The types of information collection activities included in this generic package are expected to include quantitative and qualitative data collections.

Attachments 3-7 provide sample instruments (both quantitative and qualitative) with a sample of questions reflecting the type that might be used by studies included in this request. Attachments 3 and 5 include are sample instruments from projects with OMB approval under previous ICRs. Attachment 8 includes a broader set of example questions pulled from studies found in the literature.

As previously stated, data collection instruments used with adolescents will include questions on experiences with programs and services to reduce the risk of HIV and other STD transmission, and knowledge, attitudes, behaviors, and skills related to sexual risk and protective factors on the individual, interpersonal, and community levels. For parents and caregivers, data collection instruments will include questions on parents'/caregivers' (1) perceptions about programs and services provided to adolescents; (2) knowledge, attitudes, and perceptions about their adolescents' health risk and protective behaviors; and (3) parenting knowledge, attitudes, behaviors, and skills.

Because this request includes a wide range of possible data collection instruments, specific requests will include items of information to be collected and copies of data collection instruments. It is expected that all data collection instruments will be pilot-tested, and will be culturally, developmentally, and age appropriate for the adolescent populations included. Similarly, parent data collection instruments will be pilot-tested, and the data collection instruments will reflect the culture, developmental stage, and age of the parents' adolescent children.

Quantitative surveys

Quantitative data collection conducted in-person or remotely through electronic (via computers, tablets, other mobile devices, etc.), telephone, or paper questionnaires to gather information about programmatic and service activities related to sexual risk reduction or adverse health outcomes among adolescents of middle- and high-school age. Data collection for adolescents includes questions relating to demographic and social characteristics, including those that may be linked to increased HIV and STD risk; experiences with programs and services to reduce the risk

of HIV and other STD transmission and adolescents' knowledge, attitudes, behaviors, and skills related to sexual risk and protective factors on the individual, interpersonal, and community levels. Data collected from parents may reflect demographic characteristics of the parents or their adolescents; parents' perceptions about programs and services provided to adolescents; parents' knowledge, attitudes, and perceptions about their adolescents' health risk and protective behaviors; and parents' parenting knowledge, attitudes, behaviors, and skills.

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. For example, in surveys of adolescents participating in programs in schools, surveys will likely be given in paper-and-pencil format because computer availability in schools can be limited (for example, students may have to a computer lab or other similar area for all students to be on a computer at the same time) and electronic data collections cannot always be set up to ensure privacy (for example, in a typical computer lab, students can easily see each other's screens). In other settings, electronic data collection (e.g., computer, tablet, or phone based) will likely be used in order to take advantage of features such as programmed skip patterns and reduce burden on the respondent. In general, the preference will be for electronic data collection unless logistics or participant characteristics limit the feasibility or safety of such an approach. As many as 30,000 respondents may take place in one of the 15 projects per year for which we are requesting approval, which averages approximately 2,000 students 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 GenIC will provide age- and 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 data collection conducted in-person or remotely through electronic (via computers, tablets, other mobile devices, etc.), telephone, or paper means to gather information about programmatic and service activities related to sexual risk reduction or prevention of adverse health outcomes among adolescents of middle- and high-school age. Qualitative data collection may involve focus groups and/or in-depth individual or groups interviews. Questions for adolescents will be related to experiences of programs and services to reduce the risk of HIV and other STD transmission, and knowledge, attitudes, behaviors, and skills related to sexual risk and protective factors on individual, interpersonal, and community levels. Data collected from parents may reflect their perceptions about programs and services provided to adolescents; their knowledge, attitudes, and perceptions about their adolescents' health risk and protective behaviors; and their parenting knowledge, attitudes, behaviors, and skills.

Qualitative interviews and focus group discussions will be led by trained interviewers and/or moderators. These data collections 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 3,000 adolescent and 3,000 adult respondents are anticipated to take part in interviews or focus group discussions each year, with most individual requests under this GenIC averaging no more than 200 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 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 funded partners. Close partnership with organizations participating in data collection (e.g., schools, community-based organizations) will help ensure all activities are conducted in age- and 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 knowledge, attitude, behavior, and skill-related results found among adolescents and their parents/caregivers.

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 GenIC. 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 Non-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.
- Using bilingual consent documents to maximize response rates among youth whose parents may not be fluent in English.
- 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 age- and 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 GenIC. All new or adapted instruments will be piloted 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.