

**NCHHSTP Generic Clearance
Formative Research and Tool Development**

OMB No. 0920-0840

Supporting Statement A

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A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests extension of a 3-year of the currently approved generic information collection, “Formative Research and Tool Development” (OMB#0920-0840, exp. 10/31/2021). The information collection supports formative research for the development or improvement of interventions and or tools in Human Immunodeficiency Virus Acquired Immunodeficiency Syndrome (HIV/AIDS), sexually transmitted diseases (STDs), tuberculosis (TB), viral hepatitis, and school and adolescent health. The project activities, scope, and methods that were previously approved will remain the same. This clearance estimates that approximately 3-4 individual projects will be completed each year.

The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, which also includes the Division of School and Adolescent Health (DASH) (NCHHSTP) conducts formative research for developing and or testing new tools and methodologies or to build upon existing tools and methodologies that respond to the changing epidemiology of NCHHSTP’s five areas of responsibility and (4) groups of diseases (HIV/AIDS, STD, TB, and viral hepatitis) that cause 80% of the disease morbidity in the U.S. The extension of this generic clearance mechanism is necessary as it has increased productivity of CDC programs and improved the quality of public health

intervention by streamlining the development of ICRs submitted under this generic and by reducing the processing time. The continued use of this generic ICR will allow the NCHHSTP to further develop collections necessary to help CDC understand the interests, attributes and needs of the various populations and persons within the community. The formative research and tool development activities occur before programs are designed and implemented, or while a program is being conducted. Formative research activities are beneficial in:

- defining and understanding populations at greatest risk for HIV
- creating programs that are specific to the needs of those populations
- ensuring programs are acceptable and feasible to clients before launching
- improving the relationship between clients and agencies that provide necessary services.

Since receiving the last OMB approval, 8 generic information collection requests (GenICs) have been approved under the Formative Research and Tool Development Generic Clearance (**Attachment 10**). There are currently 3 additional genICs in the queue to be reviewed.

Background

CDC conducts surveillance and prevention research projects as part of its response to the domestic HIV/AIDS epidemic, STD prevention, TB elimination, and viral hepatitis control with local partners. National Advisory Committees require evidence for considering revisions to existing prevention and intervention methods, and new recommendations.

The behavioral, clinical, and surveillance research projects implemented by the National Center for HIV/AIDS, Viral Hepatitis, Sexually Transmitted Diseases, Tuberculosis Elimination Programs and the Division of School and Adolescent Health (DASH) are the pillars upon which recommendations and guidelines are revised and updated.

Disease Specific Advisory Committees that debate and approve the national recommendations and guidelines proposed by CDC require that each process and hypothesis is based on scientific evidence and are acceptable to the community and the local health care providers. Formative research is the mechanism by which this evidence is obtained for each of the four (4) priority diseases and school and adolescent health. The data collection and evidence are developed using a multitude of information sources including internal and external subject matter experts, field experience, and consultation with external colleagues, piloting activities, and formal evaluations. The involvement of external and internal subject matter experts produces scientifically valid instruments, interventions, and methods that enable CDC to be responsive to the changing epidemiology and community needs of these four (4) priority diseases and school and adolescent health.

For health communications, target audience members or representatives provide the information for developing clear and influential health messages¹. Provisional versions of the messages must be tested with members of the target audience.²

In order to reduce the burden of HIV, STDs, TB, and viral hepatitis in the United States, CDC invests in public education campaigns and social marketing strategies to integrate population-level interventions. An integrated research effort is needed to fill in the gaps of HIV/AIDS and STD knowledge, awareness, screening, and prevention behaviors and could simultaneously work to

reduce stigma surrounding these topics within special populations, explore cultural issues, and increase the demand for, and uptake of screening by health care providers.

Short term qualitative interviewing and cognitive research techniques have previously proven invaluable in the development of scientifically valid and population-appropriate methods, interventions, and instruments. These activities will continue to inform many aspects of surveillance, communications, health promotion, and research project development for the 4 priority diseases (HIV, STDs, TB, and viral hepatitis and school and adolescent health).

The activities include the utility and acceptability of recruitment methods, intervention contents and delivery, questionnaire domains, individual questions, and interactions with project staff or electronic data collection equipment. These activities will also provide information about how respondents answer questions and ways in which question response bias and error can be reduced. Overall, these development activities are intended to provide information that will increase the success of the surveillance or research project through increasing response rates and decreasing response error thereby decreasing future data collection burden to the public. This ongoing data collection activity benefits the Federal Government by providing the CDC with data to determine how to best manage and improve the health of HIV-infected Americans who receive HIV care, and to monitor the progress in achieving the goals of the National HIV/AIDS Strategy (White House, 2010). These data will also be used to enhance HIV prevention programs designed to reduce high-risk behaviors in persons most likely to transmit HIV, and to test new methodologies and techniques used to increase awareness, testing, and ensure linkage to care.

Data collection for this project is authorized under 42 U.S.C. 241, Chapter 6a - Public Health Service; Subchapter II - General Powers and Duties Part A - Research and Investigations (**Attachment 1**).

The information collection activities are limited to formative work that will result in the development of interventions, new or improved tools, methodologies, concept development and or and product development and testing. The types of information collection activities included in this generic package for NCHHSTP's 4 priority diseases are:

- 1) Qualitative interviewing will use volunteer respondents for exploratory and formative research to either develop and or improve upon existing intervention methods, concept, material, and product development and testing. Interviews may be individual or group conducted in-person, on the telephone, or via the internet (i.e. internet focus groups). Results of qualitative interviews will be used to develop and or improve upon population-appropriate methods, interventions, messages, products, campaigns, and data collection materials for current and future projects.
- 2) Cognitive interviewing and in-depth interviews (IDIs) may be conducted among the consumer clients or the implementers. These may be individual interviews or focus group interviews. Cognitive interviews are commonly used for development and testing of specific data collection instruments and frequently involve several rounds of cognitive interviews, with each iteration of the product. Results of cognitive interviews help researchers understand how respondents interpret and answer questions and are therefore

used to make instrument design decisions that minimize response error and reduce burden to the public.

- 3) Methodological research may be conducted with consumers or implementers to evaluate alternative instrument design, non-response, perceptions of enrollment procedures, and other general methodological research questions. 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. The purpose of the research would be to enhance understanding of the psychology of participation and response, to develop better standards for project methodology and instrument design, or to improve data collection and other study procedures.
- 4) Usability testing of technology-based instruments and materials may be conducted with end-users who may be consumers or implementers. This testing would use qualitative and quantitative data collection methods with volunteer respondents in order to assess the design and use of technology-based instruments and materials. The purpose of this testing is to develop new methods that address the rapid evolution of technology-based surveys, interventions, and communications and use those technologies to enhance CDC's projects and reduce burden of future data collections.
- 5) Field testing of new methodologies and materials may be conducted with a small number of participants using the enrollment, study methods and observations by experienced study methodologists. Unlike full pilots of data collection activities, the purpose of a field pilot will be to evaluate project methods and materials not yet used by CDC on a limited scale. Information from field testing can be used to improve methods, materials, and interventions to reduce the burden of future data collections.
- 6) Mental models elicitation and communication frames.

Schema theory from the cognitive sciences describes processes and interpretative mental structures that a person uses to organize their experience. These intrinsic internal representation systems play a role in health decision-making. The purpose of health communication mental modeling is to understand mental models of health by eliciting information on how individual and groups see relationships among health, health determinants, health risk, and good health for specific health topics, and the relationships among health issues and other factors. This enables better message design as one can address more accurately health risk factors and outcomes in terms of, for example: 1) how persons can take action, 2) if health is seen as collectivist or individualistic oriented. By understanding mental models, one can also take into account in message design 3) decision points at-risk individuals (or groups) undergo when they move between internal-based reality (e.g., intra-personal attitudes, knowledge, values, perceived stigma, racism, discrimination, sexism, beliefs and skills) and external-based, actionable reality (e.g., outward behaviors, environmental constraints, health inequity).

A partial list of potential items of information to be collected is provided in **Attachment 3**. The information collected by local implementers may contain personally identifiable information such as, name, address, medical information, referred individuals etc. Projects that involve Respondent Driven Sampling (RDS) or other risk-based surveys or interviews with affected persons will also include personal information that the local implementers will need in order to provide continuity of

service, follow-up of referrals, and other outreach activities. Personally identifiable information will be kept in a separate location and accessible only to the interviewer. This information will be destroyed when the client's contribution to the project has ended.

The information collected for the project will be maintained or stored locally under strict access controls limited to the local project leader/manager or his/her designate without personally identifiable information. Under no circumstances will an individual be identified using a combination of variables such as gender, race, birth date, and/or other descriptors.

Because this request includes a wide range of studies, specific requests will include items of information to be collected and copies of the data collection instruments. Web-based methods for survey or intervention delivery may involve the creation of a website with controlled access. Web-based investigations will include surveys, and components of formative research collecting public evaluations of health communication messages or materials.

2. Purpose and Use of Information Collection

Many questionnaire design recommendations are based on cognitive testing; others are based upon past experience or general principles of questionnaire design. Changes to the structure of a question based on existing theories will make it easier to understand and more efficient to administer. Field experiments where original and alternative versions of a question are each administered to half of a sample are a proven method to test the theory in the environment where the change is needed.

Because of CDC's need to respond rapidly to changes in the epidemiology of the 4 priority diseases through development of new projects, the exact nature of every activity is not always known until just prior to the need for its development. It is most likely that a combination of the listed studies will be employed. For example, focus groups and interviews conducted by recipients of CDC funding or contractors selected to perform specific activities will provide the information to make the changes which then need to be tested both qualitatively and quantitatively to ensure that the changed instrument is acceptable to the target audience but is also more efficient than the existing version in providing the needed information.

- CDC's ability to process and/or integrate the information into an on-going national program in a timely manner. Formative research is an integral part of the operations research and surveillance activities at NCHHSTP because they are dependent upon the consumers and the health department staff to obtain the data needed to monitor changes in disease epidemiology and design more efficient interventions.
- None of the studies proposed intend to produce results that can be generalized beyond the scope of each study. The objective of this request is to enable NCHHSTP to improve the quality of the data collection systems and respond to the needs of the affected persons and the community in a timely manner. The improved timeliness of this development will improve data quality, increase the efficiency of data collection, and decrease burden to the public.

The CDC NCHHSTP has benefitted from this Formative Research and Tools Development Generic Information Collection, OMB #0920-0840. Since receiving the most recent OMB approval in 2018, 9 generic information collection requests (ICRs) have been approved under the Formative Research and Tool Development Generic Clearance (**Attachment 10**). With it, we have been able to conduct formative research to inform the development of and refinement of our HIV prevention

messages, collect information on student and teacher perspectives on sexual health and issues related to sexual health and men who have sex with men (MSM). For example, we have also developed and tested materials to examine jail and prison policies to reduce STD rates. Under this mechanism, we have developed a mobile message intervention for MSM with the purpose of using formative research to develop and assess HIV prevention messages tailored for men who have sex with men (MSM) in the United States, including informational and motivational messages about recent advances in biomedical HIV prevention.. This Generic gives us the opportunity to obtain qualitative feedback that we need to be able to develop and adapt our campaigns, which are vital to the CDC/NCHHSTP mission in a timely manner.

In addition, this generic clearance information collection mechanism has allowed us to conduct a formative research study to address prevention preferences among Adolescent Men Who Have Sex with Men (AMSM). The pilot study evaluated: 1) our ability to reach a viable number of AMSM and Trans youth, particularly Blacks and Latinos and youth 13-17 years old; 2) potential to recruit youth in areas disproportionately affected by HIV/AIDS; 3) ability to address the role of parental permission in the venues as dictated by state and local laws and relevant policies, including corporate policies; 4) potential for harm to participants (i.e., being identified as gay or bisexual to others); 5) potential for respondent bias; 6) calculate an average cost per respondent; 7) knowledge, attitudes, behaviors regarding: acceptability of HIV risk/prevention including risk behaviors, condoms, as well as biomedical interventions such as PrEP, PEP, etc.; 8) access, exposure, attitudes toward: sex education, HIV prevention services in school and community settings. The data collected from this project is used to inform the design of a future surveys of AMSM and Transgender youth and the development of tools and guidance to effect changes in education, health care, and youth services that can reduce AMSM's vulnerability to HIV infection.

Qualitative interviewing for surveillance and research for the development and or improvement of interventions, tools, and materials uses qualitative interviewing methods to identify appropriate project methods, intervention content and delivery, and instrument domains and questions. NCHHSTP will conduct qualitative interviews with volunteer respondents, either individually or in groups, using standardized methods. Results of qualitative interviews will be used in conjunction with other information to develop the most appropriate and successful surveillance or research methods, interventions, and data collection instruments for current and future projects.

Field experience with prototype data collection instruments is crucial for the development and or improvement of methods, interventions, and instruments that may improve surveillance and other research projects. In a few instances, open discussions with members of the target population with opportunities to provide input on project methods, interventions, and instruments assure success in implementation. The combined methods are especially relevant for projects intending to reach vulnerable populations or to explore novel areas in HIV/STD/TB/hepatitis research.

Cognitive interviewing for development of specific data collection instruments uses cognitive interviewing methodology to identify and correct instrument flaws, such as questions which are vague or ambiguous, cannot be answered readily or accurately, or otherwise contribute to the non-sampling errors of the data collection instrument. The methods used will vary depending on the stage of development of the various data collection instruments to be studied. When questions have been used successfully in earlier surveys, testing will evaluate whether the questions function appropriately in the new context. In cases where there is evidence that previously developed questions were not entirely reliable or valid, more extensive evaluation will be conducted. The

most extensive instrument development activities will be applied to untested draft questions and undeveloped lists of data objectives.

Methodological Research

a) *Research on the effects of alternative instrument designs*

Many instrument design recommendations are based on cognitive testing; others are based upon past experience or general principles of questionnaire design. In any case, it is often advantageous to quantify how these design decisions affect data collection in the field. For example, we may develop theories that certain changes to the structure of a question will make it easier to understand and more efficient to administer. One way to explore this possibility is to conduct field experiments where original and alternative versions of a question are each administered to half of a sample of respondents. In addition to comparing response distributions of the two versions, interviews can be tape recorded and coded so that a variety of interviewer and respondent behaviors can be compared. Such experiments may focus on grammatical structure of questions, number of questions used to measure a particular concept, context of the question, and similar design decisions. This research may be embedded into field surveys, conducted as a separate project, or some combination of the two. Research may also be conducted by comparing survey data to other data sources such as external records or detailed respondent diaries.

b) *Research on cognitive aspects of non-response*

Non-response creates numerous analytic difficulties for surveillance and research projects. Minimizing this problem requires a greater understanding of the cognitive processes that lead respondents to not answer particular questions. NCHHSTP may conduct cognitive interviews using a variety of types of survey questions in order to explore these decision processes further. Survey non-response will be explored through examination of reasons that non-responders provide for their unwillingness or inability to complete surveys. It is also possible that data will be collected through research questionnaires that explore the effect of various design decisions on item non-response.

c) *Respondent perceptions of enrollment procedures*

To encourage participation and protect the rights of respondents in projects, NCHHSTP often utilizes standard consent forms and respondent enrollment procedures. However, it is not known how well they are generally understood and believed by respondents. Therefore, NCHHSTP may conduct interviews to examine comprehension and attitudes regarding respondent enrollment procedures. The results will be used to propose modifications to procedures used to communicate key issues related to informed consent, and to explain the need and purpose for the data collection in a way intended to increase participation.

d) *General methodological research*

NCHHSTP regularly evaluates and refines HIV/AIDS surveillance and research methods, especially in response to advances in current methodologies or changes in the epidemic itself. In order to meet this need, NCHHSTP plans to conduct research on the development of these new methods. The issues examined during these activities may include, but are not limited to: 1) differences between interviewer-administered and self-administered interviewing, 2) differences between in-person interviewing and telephone interviewing, 3) reactions of both survey

respondents and survey interviewers to the use of different forms of survey administration, and 4) social, cultural and linguistic factors in the response process. Procedures for each of these activities will be similar to those applied in the usual testing of survey questions. For example, current questionnaires may be evaluated using several of the techniques described above. Different versions of a survey question could also be developed and the variants administered to separate groups of respondents in order to study the cognitive processes that account for the differences in responses obtained across different versions. The results of these studies will be applied to our specific questionnaire development activities in order to improve the methods that we use to conduct questionnaire testing, and to guide questionnaire design in general.

Usability testing of technology-based instruments and materials research examines how questions, instructions, and supplemental information are presented on computer instruments (e.g., Computer Assisted Personal Interview (CAPI), Computer Assisted Self Interview (CASI), or Web-based instruments), and investigates how the presentation affects the ability of users to effectively utilize these instruments. Authors of computer-assisted instruments make numerous design decisions: how to position the survey question on a computer screen; how to display interviewer instructions that are not to be read to respondents; the maximum amount of information that can be effectively presented on one screen; how supplemental information such as “help screens” should be accessed; whether to use different colors for different types of information presented on the screen; and so on. Research has shown that these decisions can have a significant effect on the time required to administer survey questions, the accuracy of question-reading, the accuracy of data entry, and the full exploitation of resources available to help the user complete his or her task.

Usability testing has many similarities and shares the same main purpose as does questionnaire-based cognitive interviewing, since it focuses on the ability of individuals to understand and process information in order to accurately complete survey data collection. It is also somewhat different, in that the typical user can be a staff interviewer (in the case of CAPI instruments) as well as a survey respondent (in the case of CASI or Web-based instruments). It also focuses more heavily on matters of formatting and presentation of information than traditional cognitive testing does.

Field testing of new methodologies and materials is used to conduct field tests of new methods, interventions and data collection instruments; also referred to as pilot testing. Pilot testing in this instance is defined as the evaluation of methods proposed by subject matter experts or published articles but new to CDC. The objective of such pilot studies would be to evaluate the feasibility of the ‘new’ strategies in CDC-funded projects. The pilot may also include two different versions of particular questions or novel intervention components of interest, in order to determine which version functions better in the actual field environment. With verbal consent of the respondents, pilot interviews or interventions may be unobtrusively observed by experienced methodologists who can objectively evaluate the process (e.g. proper survey/intervention administration and interviewer-respondent interaction). Information from pilot testing can be used to improve the existing instruments, interviewer training materials, or survey methodologies that would reduce the public burden

Testing of Communication Mental Models is used to develop and test mental modeling methodologies and protocols for qualitative methods that may include: elicitation guides, Q methodology, mental models expressionism (e.g., hexagons, causal diagrams and flow

diagrams), card sorts, feedback, single, or double-loop learning and health risk or health prevention vignettes. The information collected will be used to revise, augment or finalize communication campaign platforms and systems within the context of the audiences' sense of reality and how they may decide to act in accordance with how they plan to act.

3. Use of Improved Information Technology and Burden Reduction

Testing may be conducted using the most current modes of survey data collection, including CAPI/CASI, ACASI, web-based surveys, or other modes applied to specific national surveys. Though these technologies will be used by many of the individual projects in this data collection, the nature of many of these proposed activities typically requires direct interaction between respondents and project staff, especially in the case of qualitative interviewing and cognitive testing. In situations where an electronic survey can be used, projects will reduce burden because this approach ensures data quality but decreases respondent burden with built-in skip logic. The extent (% of responses), the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (e.g., permitting electronic submission of responses) and the reason for adopting this means of collection will be thoroughly discussed as projects are submitted.

4. Efforts to Identify Duplication and Use of Similar Information

CDC has two generic collections that are related to the proposed collection. The Collaborating Center for Questionnaire Design and Evaluation Research, OMB # 0920-0222, that expires 08/31/2021 provides survey questionnaire development and testing based on cognitive interviewing methodology to be used in CDC, other federal agencies, or other academic or professional institutions. The CDC and ATSDR Health Message Testing System (HMTS, OMB Control Number 0920-0572, expiration 08/31/2021) is designed to refine message concepts and to test draft materials for clarity, salience, appeal, and persuasiveness with external audiences. While there may be overlap or duplication of specific projects from NCHHSTP with the NCHS QDRL collection these projects cannot be accommodated within the QDRL burden and will be submitted under this proposed collection. NCHHSTP has verified through RegInfo.gov that there are no other federal generic collections that duplicate the six study types included in this request.

5. Impact on Small Businesses or Other Small Entities

Some HIV/AIDS surveillance or research activities involve data collection from small business (e.g. medical offices) or small governmental entities; therefore, methods and instrument development activities may also be conducted with these groups. If such activities are conducted, these businesses will be approached in the same manner as the individuals we normally recruit: we will ask the organization to identify the appropriate staff members with whom to conduct the activities. In some studies, no small businesses will be involved in the data collection activities. The methods used to minimize burden on small businesses or other small entities will be explained in each study submitted under this generic.

6. Consequences of Collecting the Information Less Frequently

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. There are no legal obstacles to reducing the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agencies

The Federal Register notice was published for this collection on February 12, 2021, Vol. 86, No. 28 pp. 9346-9348 (See **Attachment 2**) One public non-substantive comment was received (**Attachment 2a**). The standard CDC response was sent to say thank you for your interest.

No other public contacts and opportunities for public comments were received. The following CDC employees were consulted for the development of this request:

<p>Jeanne Bertolli, PhD Associate Chief for Science Behavioral and Clinical Surveillance Branch NCHHSTP, CDC 1600 Clifton Road NE, MS-E46 Atlanta, GA 30333 (404) 639-8500 Email: JBertolli@cdc.gov</p>	<p>Leigh A. Willis, PhD, MPH Behavioral Scientist Health Communication Science Office NCHHSTP, CDC 1600 Clifton Road NE, MS-E45 Atlanta, GA 30333 (404) 639-8447 Email: LWillis@cdc.gov</p>
<p>Constance Bonds, MPH, MPA NCHHSTP PRA Coordinator CDC/NCHHSTP 1600 Clifton Road NE, MS-E07 Atlanta, GA 30333 (404) 718-8548 Email: cbonds@cdc.gov</p>	<p>Natasha Ptomey, MPH OMB PRA Contact ORAU CDC/NCHHSTP/DHAP 1600 Clifton Road NE, MS-D21 Atlanta, GA 30333 (404) 639-1569 Email: NPtomey@cdc.gov</p>

9. Explanation of Any Payment or Gift to Respondents

A review of survey methodologists and practitioners in October, 1992, The “Symposium on Providing Incentives to Survey Respondents,” sponsored jointly by OMB and the Council of Professional Associations on Federal Statistics (COPAFS), considered a number of incentive-related issues, including the impacts on response rates, biases, and incentive types, recommended OMB “seriously consider the use of incentives” for surveys that target difficult-to-engage respondent populations, surveys that are long or time consuming, surveys with items that are

potentially sensitive or require detailed record keeping, surveys for which relatives serve as gatekeepers to respondent access, and surveys that are part of longitudinal panels.”

In many cases incentives will not be necessary, but when they are, 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 be offered in cash or kind for these activities for several reasons:

- Eligibility criteria for respondents are usually very specific. Some of these criteria are determined by the subject matter of the survey or intervention study (e.g., questions or interventions may be relevant only to people with certain health conditions). The more specific the subject matter, the more difficult it is to recruit eligible respondents; tokens of appreciation may help to attract them.
- Qualitative and cognitive interviews require an unusual level of mental effort, as respondents are asked to explain their mental processes as they hear the question, discuss its meaning and point out any ambiguities, and evaluate the acceptability of response options that are provided.
- Respondents are usually asked to travel to an interview site, which involves transportation and parking expenses. Many respondents may also incur additional expenses such as leaving their jobs during business hours or making arrangements for child care. This may be especially true of some key respondents who may be economically disadvantaged but would provide valuable information in the development of these projects.
- Some major metropolitan areas may be highly saturated with other research activities (e.g., academic research initiatives), which typically provide remuneration and may compete for respondents’ time.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.

The Privacy Act does not apply to this Generic information collection request. Personally identifiable information (PII) may be collected under the subsequent ICRs submitted under this generic clearance. Privacy Impact Assessments will be conducted for those submissions. It is expected that some of the individual data collections may require respondents to provide identifying or potentially identifying information to local project staff and answer sensitive questions. This information will be removed from any data sent to CDC, and CDC will, at no time, have access to any local data that contains identifiers. CDC will not maintain a system of records with any identifiers or with records retrievable by PII elements. Local project staff will verify that any individually identifiable information that has been collected during the course of their business activities has been removed from information transmitted to or shared with CDC.

Personally identifiable information (PII) may be collected by awardees of cooperative agreements such as local and state health departments, or contractors implementing surveillance with diagnostic testing. In these projects, state and local health departments will de-identify PII from the databases, encrypt and, transmit the data to CDC using the secure data network. Some activities may include a unique identification number that will not allow CDC to link back to a specific person, but allow for the tracking of a respondent throughout project activities only.

The databases created for CDC will not include personal information. Project generated identification numbers independent of any personal identity of the participants will be used to protect the participant and no identifiable links will be shared with or accessible to the CDC.

The proposed activities may also be part of the development of the HIV surveillance systems and, as such, are covered under the HIV Surveillance Assurance of Confidentiality (**Attachment 8**) awarded under CDC's statutory authority according to section 308(d) of the Public Health Service Act (42 USC 242m). Certificates of confidentiality may be sought for individual data collection activities that involve sensitive and potentially identifiable information at the local project level but are not covered by the HIV Surveillance Assurance of Confidentiality (e.g., some prevention or epidemiologic research development activities).

Because methods and materials may differ between individual projects, appropriate human subjects review procedures will be conducted for each project as they are developed. Projects that need IRB approval will be submitted with a copy of the approval document. "CDC will treat data/information in a secure manner and will not disclose, unless otherwise compelled by law." In addition, projects submitted under this Generic will under a privacy impact assessment (PIA) that will determine the privacy act applicability and if necessary, provide a system of records notice (SORN) providing additional protections for the collected information.

Participation in development activities is strictly voluntary. Respondents will be provided with an informed consent form prior to the start of information collection, and will be allowed to ask questions about the project before deciding whether to participate or not (**Attachment 9**). Any variation from these templates will be included in each individual collection request. The consent form describes the purpose of the study, sponsorship and collaborating parties, specifies specific procedures that will be conducted, and describes protections for the respondent's privacy.

On occasion, interviewing respondents may be asked questions about sensitive topics (e.g., HIV testing behaviors, sexual orientation and gender identity (SOGI) or sexual behaviors). Collection of these identifiers may place the respondent at risk of potential harm resulting from breach of confidentiality. In these cases, a waiver of documentation of informed consent is requested (i.e., no respondent signatures on a consent form), but the same consent and confidentiality protection information is still imparted to the respondent.

Respondents of HIV surveillance and incidence projects receive **Attachment 8**, the Assurance of Confidentiality and a consent form (**Attachment 9**), which describes the procedures by which confidentiality of information will be maintained. Formative research projects in STD, TB and Viral hepatitis and behavioral research projects for HIV prevention will use Certificates of Confidentiality as appropriate.

Persons participating in all projects conducted or sponsored by NCHHSTP, will be informed that their data will be maintained in a secure manner, and that the data will only be used for purposes stated in the consent form. Although the identities of respondents may be known to local project personnel who conduct interviews and interact with respondents, data will not be stored or accessed in a Privacy Act system of records, and the respondents' identifying information will not be

submitted to CDC. Only authorized project staff will be allowed to have access to study information (whether identifiable or not) and all information will be kept in a locked cabinet and/or locked office with limited access.

If individually identifiable information will be accessed by the Division of TB elimination, syphilis, name based HIV reports, AIDS cases, the collections would most likely fall under the following SORNs 09-20-0089 (Studies of Treatment of Tuberculosis and other Mycobacterioses. HHS/CDC/NCHSTP), 09-20-0103 (Alien Tuberculosis Follow-up Program. HHS/CDC/NCID.), CDC has additional SORNs to cover the various collections of information related to public health; 09-20-0160 (Records of Subjects in Health Promotion and Education Studies, HHS/CDC/NCCDPHP.) and 09-20-0136 (Epidemiologic Studies and Surveillance of Disease Problems. HHS/CDC). The appropriate SORN will be used on projects submitted under this Generic Clearance if applicable.

For the most part, state and local health department personnel who conduct HIV/AIDS surveillance activities are subject to the data security policies described in the CDC Centers for Disease Control and Prevention. Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action. (<http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf>). In order to provide for maximal and comparable data security, all project personnel for any of the proposed development activities will be subject to the same requirement as the HIV/AIDS surveillance programs.

All CDC permanent employees and contractors who are involved in HIV/AIDS surveillance activities will be required to attend annual security and privacy training, to sign a nondisclosure agreement and notice about data use policies, and to update their security and privacy agreements and training on an annual basis. In addition, non-surveillance development activities (i.e., research and intervention development) conducted under this generic approval will also adhere to these same security standards.

Information might be collected electronically or on paper (depending on the individual information collection request). Electronic means include handheld devices, computer-assisted self-interview (ACASI), computer assisted telephone interview (CATI), web-based surveys, or other point of service collection devices. Paper copies are the common mode for Focus group interviews.

Electronic data collection and data management systems used for these activities will comply with the current encryption security standards from National Institute of Standards and Technology (NIST) Federal Information Processing Standards (FIPS), which meet or exceed Advanced Encryption Standards (AES). Each individual request under this generic clearance will provide adequate descriptions of information systems that will be used in their study.

The Privacy Act will not apply as the CDC will not receive any personally identifiable information. All individually identifiable information collected by local partners would be unlinked or stripped from the data base that is submitted to CDC. Web-based methods for survey or intervention delivery may also be evaluated under this generic approval, and may involve the hosting of a website in order to conduct the evaluation. There will be no websites or internet content directed at children under the age of 13. Individual collection requests submitted under this generic approval will describe any web-based material involved.

If CDC, or its representative is receiving and or storing personal identifiable information, then the Privacy Act may apply. Each sub collection will be evaluated separately.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

Studies submitted under this Formative Research and Tool Development Generic Clearance ICR can consist of activities involving or not involving human subjects. Each subsequent ICR will address human subject participation and IRB approval. Because methods and materials may differ between individual projects, appropriate human subjects review procedures will be conducted for each project as they are developed. Projects that need IRB approval will be submitted with a copy of the approval document. If the study has been determined to be exempt from IRB, a copy of the exemption determination will be attached. If the appropriate CDC NCHHSTP official has determined that the data/ information collection is not research involving human subjects, the information collection submitted under this generic clearance will state that IRB approval is not required and a copy of the NCHHSTP research determination form will be attached.

Sensitive Questions

The 4 priority diseases that will be covered by this information collection request involve sexual attitudes and practices, use of illegal substances and, other matters that are commonly considered private. Race and ethnicity data, as well as diagnoses of medical conditions that may affect employability or insurability (e.g., HIV/AIDS) may also be viewed as sensitive or even threatening by a portion of respondents. The reasons for collection of sensitive information and their application for the improvement of CDC's prevention efforts for the specific population sub-group will be addressed in specific requests. The procedures used to obtain consent and the content of the consent form will also be explained and justified. In no case will a participant's social security number be obtained.

Collection of sensitive data will be used to understand barriers to engaging in protective behaviors and to using prevention services.

A.12. Estimates of Annualized Burden Hours and Costs

The annualized response burden is estimated at 46,516 hours. Exhibits A.12.A provides details about how this estimate was calculated. Timings were conducted during instrument development process in previous studies to support the overall burden per respondent. Participants are combined and reflect 70% General Public and 30% healthcare providers. Administration of the screening instrument is estimated to take 10 minutes. A participant reading and signing the consent form is estimated to take 5 minutes. Participation in an interview is estimated to take 1 hour and participation in a group interview is estimated to take 2 hours. It is estimated that during a single year, 10 different studies are likely to use 81200 screening questionnaires (13,533 hours), complete 30000 individual surveys (15000 hours), 40600 consent form (3,383 hours) 6600 individual interviews taking 1 hour each (6,600 hours) and 4,000 focus group respondents at 2 hours (8000 hours), totaling 46,516 hours.

Exhibit A.12.A Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Hours Per Response	Total Response Burden (Hours)
General public	Screener Att6	56840	1	10/60	9473
Health care providers	Screener Att6	24360	1	10/60	4060
General public	Consent Forms Att9	28420	1	5/60	2368
Health care providers	Consent Forms Att9	12180	1	5/60	1015
General public	Individual Interview Att4	4620	1	1	4620
Health care providers	Individual Interview Att4	1980	1	1	1980
General public	Focus Group Interview Att7	2800	1	2	5600
Health care providers	Focus Group Interview Att7	1200	1	2	2400
General public	Survey of Individual Att5	21000	1	30/60	10500
Health care providers	Survey of Individual Att5	9000	1	30/60	4500
Total					46516

A.12.B Estimated Annualized Costs

Collections by health jurisdictions are generally funded through cooperative grants and these will be noted in the specific collection requests. During the past 2 years 70% of the projects from NCHHSTP requiring PRA compliance have involved the general public and 30% private health care provider. The annualized cost to the respondent is segmented accordingly in Exhibit A.12.B.

The United States Bureau of Labor Statistics’ employment and wages estimates from May, 2019 (<https://www.bls.gov/oes/current/oes193022.htm>) were used to estimate the hourly wage rate for

the general public and providers for the purpose of this request. Each project will have cost specific to the category of the respondents. Because it is not known what the wage rate category will be appropriate for the specific projects (or even whether they will be employed at all), the figure of \$23.86 per hour was used as an estimate of average hourly wage across the country. For private physicians, an average cost of 112.65 per hour is used as the mean hourly wage for physicians and surgeons. Thus, the total anticipated annual cost to participants for collections of information for all study types will be \$2,348,936.21. In addition, because we are using averages, the hourly rates will remain unchanged.

Exhibit A.12.B. Annualized Cost to Respondents

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Screener Public (70%)	9473	\$23.86	\$226,025.78
Screener Provider (30%)	4060	\$112.65	\$457,359.00
Consent Forms Public (70%)	2368	\$23.86	\$56,500.48
Consent Forms Provider (30%)	1015	\$112.65	\$114,339.75
Individual Interviews Public (70%) Att4	4620	\$23.86	\$110,233
Individual Interviews Provider (30%) Att4	1980	\$112.65	\$223,047
Group Interview Public (70%) Att7	5600	\$23.86	\$133,616
Group Interview Provider (30%) Att7	2400	\$112.65	\$270,360
Surveys Public (70%) Att5	10500	\$23.86	\$250,530
Surveys Provider (30%) Att5	4500	\$112.65	\$506,925
Total	46516		\$2,348,936

A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

CDC does not anticipate providing start up or other related costs to private entities.

A.14. Annualized Costs to the Government

Actual annualized costs to the government will vary depending on the specific needs of the individual information collection activity. Generally, each development activity will involve participation of at least one CDC project officer (GS-12, 13 or 14 levels) who will be responsible for the project design, obtaining IRB approvals, providing project oversight, and analysis and

dissemination of the results. The CDC project officer will provide remote and onsite technical assistance to the local areas implementing the data collection. Travel may be required to provide this technical assistance. In some cases, a CDC data manager’s (typically a contractor equivalent to GS-9) time may also be required. An estimated average cost per individual activity is listed below, but detailed costs will be submitted with each individual collection request.

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government		
	CDC Project Officer (GS-12/13, 0.5 FTE)	\$156,000
	CDC Data Manager (GS-9/10, 0.25 FTE)	\$48,000
	CDC Travel (15 trips)	\$45,000
	Subtotal, Direct costs	\$249,000
Cooperative Agreement or Contract	Cooperative Agreements, Task orders, or Contracts for implementation or information management	\$325,500
	TOTAL COST TO THE GOVERNMENT	\$574,500

A.15. Explanation for Program Changes or Adjustments

There are no changes to the burden from the burden shown in the current inventory.

A.16. Plans for Tabulation and Publication and Project Time Schedule

Individual data collections under this generic approval 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. Proposed timelines will be submitted for each individual data collection activity.

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate..

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

- ¹ Delong, D.W., & Fahey, L. (2000) Diagnosing cultural barriers to knowledge management. *The Academy of Management Executive*, 14(4): 113-127.
- ² . Black, D.R., Blue, C.L., & Coster, D.C. (2001) Using social marketing to develop and test tailored messages. *American Journal of Health Behavior*, 25(3): 260-271.