Generic Clearance for CDC/ATSDR
Formative Research and Tool Development

October 17, 2016

Contact Information:

Shari Steinberg
ICRO – OADS
Centers for Disease Control and Prevention (CDC)
404-639-4942

Table of Contents

Section

A. Justification

Attachments

- The goal of this generic information collection request is to enable CDC/ATSDR to conduct formative research for developing new tools and methodologies supporting CDC/ATSDR's research, surveillance, and program evaluation activities, and the development and assessment of multi-use tools when practicable. Information collection will include short term qualitative interviewing and cognitive research techniques to develop scientifically valid and population-appropriate methods, interventions, and instruments that are up-to-date with respect to terminology, health care practice, etc.
- The resulting data will benefit the federal government in the development of interventions, new or improved tools, methodologies, concept development and/or product development and testing. In some cases a variety of similar questions are in use by various CDC/ATSDR programs and partner organizations. Formative research and instrument testing will help CDC/ATSDR clarify how respondents interpret questions and response options; compare respondent perceptions of different versions of similar questions or response options; and inform the selection of which version of a question to use in a specific information collection context (mode of data collection, subpopulation, or research/surveillance/program evaluation activity). Formative research and cognitive testing may also be conducted to support the translation of questions, instruments or supplementary materials (e.g., consent forms) into a variety of languages.
- The methods used to collect the information will include qualitative interviews, cognitive and in-depth interviews among the consumer clients or the implementers - individual interviews or focus group interviews, methodological research, usability testing of technology-based instruments and materials, field testing of new methodologies and materials and or testing of communication mental models.
- Respondents include 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 transgender persons, persons of specific races/ethnicities, and 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 and others engaged in public health activities promoted by CDC.
- The data will be analyzed using various methods to be further defined for individual projects submitted under the Generic Clearance.
- In addition to submission of the instruments utilized, all collections submitted under this generic pathway will also include a full supporting statement Part A that describes the tool/method/intervention under development, identifies the targeted respondent populations, includes a justification for any incentives offered, assesses applicability of the Privacy Act and includes a complete Privacy Impact Assessment if necessary, and an accompanying Supporting Statement Part B if any statistical methods are employed for sampling or analyses in the study.
- Outcomes collected under this generic pathway are intended for internal CDC/ATSDR use only and will not be generalized beyond the scope of each study or to broader populations.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests 3 years of approval for a generic information collection entitled Generic Clearance for CDC/ATSDR Formative Research and Tool Development. The information collection supports formative research for the development or improvement of interventions and tools for CDC/ATSDR. We estimate that approximately 20 individual projects will be completed each year.

CDC conducts formative research for developing and testing new tools and methodologies or to build upon existing tools and methodologies that are used in response to public health issues. The use of this generic mechanism will allow CDC to further develop collections necessary to help CDC understand the interests, attributes and needs of the various populations and persons that we serve 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 specific health issues
- 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.

Background

CDC conducts surveillance and prevention research projects as part of its response to current public health issues. Many of these projects provide the basis for the recommendations and guidelines that CDC provides.

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. The data collection and evidence are developed using various information sources including internal and external subject matter experts, field experience, 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 the affected populations.

For health communications, target audience members or representatives provide the information for developing clear and influential health messages. Health message development is typically an iterative process that begins with formative research to identify the priorities, concerns, themes or gaps in knowledge that are most relevant to a target population and the development of message platforms and the overall health communication plan. During the initial formative phase of message development CDC may also collect information to assess which communication channels are most likely to be effective in reaching the target audience, as well as demographic information to assess whether needs vary across subpopulations. Successive phases of message development include testing of provisional versions of the message(s) with members of the target audience,

and/or testing of draft messages for dissemination through various communication channels including television, radio, print, and social media.

To reduce the burden of disease, 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 knowledge, awareness, screening, and prevention behaviors and 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 be used to inform many aspects of surveillance, communications, health promotion, and research project development. The activities include determining the utility and acceptability of recruitment methods, assessing intervention contents and delivery, identifying questionnaire domains and individual questions, documenting interactions with project staff and/or ascertaining 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 developmental 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 CDC with data to determine how to best manage and improve the health of persons with various health conditions. These data also will be used to enhance disease prevention programs and to test new methodologies and techniques used to increase awareness and testing.

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 product development and testing. The types of information collection activities included in this generic package 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 carried out with individuals or groups, 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, focus group interviews, or online interviews, usually conducted in a controlled setting. 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. Questionnaire development includes testing of non-English language translations or testing of phrasing, order, response options, or other question design elements. Results of cognitive interviews help researchers understand how respondents interpret and answer questions and are used to make instrument design decisions that minimize response error and reduce burden to the public. Cognitive testing may also be conducted to inform the optimal order of questions in an interview or optimal placement of questions on a data collection form.

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 is 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. Cognitive tests and field tests may help CDC/ATSDR determine whether cultural interpretations affect responses to questions; whether items already in use are appropriate for use in multiple modes of information collection; or whether questions developed for a personal interview format can be successfully used in telephone interviews.

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 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. Usability testing may be conducted to evaluate presentation bias or visual bias.

5) Field testing is typically conducted after formative research and cognitive testing. 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, instructions to interviewers or other data collectors, technical documentation, 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 individuals 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).

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 include personal information that the local implementers will need 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 project-specific research staff. This information will be destroyed when the client's contribution to the project has ended.

The information collected for a project will be maintained or stored locally under strict access controls limited to the local project leader/manager or his/her designate. 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. Under no circumstances will CDC sponsored websites be directed at children under 13 years of age. Individual collection requests submitted under this generic approval will describe any web-based material involved.

2. Purpose and Use of Information Collection

Many questionnaire design recommendations are based on cognitive testing; others are based on past experience or general principles of questionnaire design. Changes to the structure of a question based on existing theories 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. For example, cognitive testing and field testing may be conducted to help CDC/ATSDR promote collaborative efforts and efficient use of surveillance infrastructure.

Because of CDC's need to respond rapidly to changes in the epidemiology of various 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 likely that a combination of the listed methods 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 needs the ability to process and/or integrate information into on-going national programs in a timely manner. Formative research is an integral part of the operations research and surveillance

activities at CDC 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 CDC 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.

An analogous generic clearance (0920-0840) has allowed CDC to conduct formative research studies to develop and pilot test a new health communication intervention tool using an HIV and STD themed motion comic designed to reduce HIV/AIDS among young people and identify the mobile technology needs of users, mobile application design preferences, and the barriers and facilitators that prohibit or encourage the uptake and sustained use of mobile apps for HIV prevention. CDC has used this clearance mechanism to conduct in-depth interviews with health care providers and social service providers for the development of the Prevention Is Care (PIC) social marketing campaign to develop and pretest draft materials for the PIC campaign and to obtain reactions regarding appropriateness, usability, and relevance of the materials to the participant's clinical practice. In addition to developing and testing messages and materials, investigating new technology to promote public health and disseminate information, this mechanism facilitates self-testing, treatment, and linkage to care activities among at-risk populations.

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. CDC will conduct qualitative interviews with volunteer respondents, either individually or in groups, using standardized methods. Results of qualitative interviews are 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 of 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. 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. CDC 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, CDC often uses standard consent forms and respondent enrollment procedures. However, it is not known how well they are generally understood and believed by respondents. CDC 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*

CDC regularly evaluates and refines surveillance and research methods, especially in response to advances in current methodologies or changes in the epidemic itself. In order to meet this need, CDC may 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 be developed and the variants administered to separate groups of respondents to study the cognitive processes that account for the differences in responses from different versions. The results of these studies will be applied to our specific questionnaire development activities 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), Audio Computer Assisted Self Interview (ACASI), or Web-based instruments), and investigates how the presentation affects the ability of users to effectively use 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/CATI, 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 some cases cognitive interviews may be recorded to assist in the review and interpretation of findings. 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 three approved generic collections related to the proposed collection. The NCHS Laboratory-based Questionnaire Research (0920-0222, exp. 07/31/2018) 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 /ATSDR Health Message Testing System (0920-0572, exp. 03/31/2018) is designed to refine message concepts and to test draft materials for clarity, salience, appeal, and persuasiveness with external audiences. NCHSTP's Formative Research and Tool Development (0920-0840, exp. 1/31/2019) is the clearance on which this generic ICR is based. It has been a successful mechanism for the Center to conduct formative research to inform the development of campaigns for AIDS prevention activities. Other Centers at CDC/ATSDR would like to have a similar mechanism to facilitate and expedite their research.

5. Impact on Small Businesses or Other Small Entities

Some 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 July 18, 2016, Vol. 81, No. 137, pp. 46680. (See **Attachment 2**) No public comments were received.

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

Renita Macaluso, Information Collection Review Office

Verita Buie, DrPH, National Center for Health Statistics.

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.

Depending on the specifics of the individual data collection project, the Privacy Act may or may not apply to an information collection. Although personally identifiable information (PII) may be collected, in some instances CDC will not receive any identifiable information from any of the individual projects. In such cases, when the individual data collection activities do require respondents to provide identifying or potentially identifying information to local project staff and/or answer sensitive questions, the 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. Local project staff will verify that any individually identifiable information that has been collected during the course of their activities has been removed from information transmitted to or shared with CDC.

If CDC or its representative is receiving and/or storing personal identifiable information as a part of a specific project, then the Privacy Act may apply and the specific actions required to ensure the security of that information will be discussed in the documentation for each project submission.

Certificates of confidentiality may be sought for individual data collection activities that involve sensitive and potentially identifiable information at the local project level. Also, depending on the specifics of the project, the assurance of confidentiality afforded in accordance with Section 308(d) of the Public Health Service Act (42USC242m) and the Confidential Information Protection and Statistical Efficiency Act (PL-107-347) may apply.

As methods and materials may differ between individual projects, appropriate human subjects review procedures will be conducted for each project as they are developed. Projects will acquire IRB approval when appropriate and submit documentation.

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. These forms will be included in each individual collection request. The consent form describes the purpose of the study, specifies specific procedures that will be conducted, and describes protections for the respondent's privacy and confidentiality.

On occasion, interviewing respondents about sensitive topics requires that we do not collect personal identifiers at any point. 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.

Persons participating in all projects conducted or sponsored by CDC 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 collected regarding such sensitive topics 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.

Information might be collected electronically or on paper (depending on the individual information collection request). Electronic means include handheld devices, computer-assisted self-interview (CASI), audio 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.

If CDC, or its representative, receives and/or stores personal identifiable information, then the Privacy Act may or may not apply. Each individual collection will be evaluated separately. Generally 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.

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 individual project 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 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.

Sensitive Questions

At times the diseases that will be covered by these information collections may involve sexual attitudes and practices, use of illegal substances or other matters that are commonly considered

private. Race and ethnicity data, as well as diagnoses of medical conditions that may affect employability or insurability 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.

A.12. Estimates of Annualized Burden Hours and Costs

The annualized response burden is estimated at 20,000 hours.

We anticipate approximately 20 information collections per year. These may include eligibility screening collections, surveys or interviews, and focus groups.

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 or health care practitioners	Screener	5,000	1	15/60	1,250
	Interview	5,000	1	1	5,000
	Focus Group Interview	5,000	1	2	10,000
	Survey	5,000	1	30/60	2,500
Total		**20,000**			**18,750**

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. The annualized cost to the respondent is segmented accordingly in Exhibit A.12.B.

The United States Department of Labor, Bureau of Labor Statistics May,2015 http://www.bls.gov/oes/current/oes291069.htm.) data were used to estimate the hourly wage rate for the general public and for private providers for the purpose of this generic 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 $20.00 per hour was used as an estimate of average hourly wage across the country.

Exhibit A.12.B. Annualized Cost to Respondents

Activity	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Cost**
Data collection	18,750	$20.00	$375,000

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)	$40,641
	CDC Data Manager (GS-9/10, 0.25 FTE)	$13,450
	CDC Travel (10 trips)	$20,000
	Subtotal, Direct costs	$74,091
Cooperative Agreement or Contract	Cooperative Agreements, Task orders, or Contracts for implementation or information management	$400,000
	TOTAL COST TO THE GOVERNMENT	$474,091

A.15. Explanation for Program Changes or Adjustments

This is a new generic information collection.

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.

REFERENCE

Office of Management and Budget, Statistical Policy Directive No. 2: Standards and Guidelines for Statistical Surveys; Addendum: Standards and Guidelines for Cognitive Interviews. Published in the Federal Register, October 12, 2016, vol. 81, no. 197, pp. 70586.