**Information Collection Request**

**NEW**

**Cognitive Testing and Pilot Testing**

**For the National Center for Chronic Disease Prevention**

**and Health Promotion**

**Supporting Statement: Part A**

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* **Goal of the Proposed Project:** The purpose of this effort is to provide a generic information collection request document that covers cognitive testing and pilot testing for the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP). Cognitive testing and pilot testing are used frequently to test survey questions and survey methodologies under consideration by NCCDPHP divisions and programs.
* **Intended use of the resulting data:** Cognitive testing is conducted early in the question proposal process (see Attachment 3 for an example of a process of question adoption used by the NCCDPHP). It is the first step in ensuring that a question is properly worded for inclusion in a survey. Pilot tests are used to determine whether a new approach or data collection methodology may be useful in the near future. They may also be proposed as a potential solution to a data collection issue (such as nonresponse, targeting a specific hard-to-reach population, or determination of the effectiveness of a new calling protocol).
* **Methods to be used to collect data: Cognitive testing**—survey questionnaire development and testing based on cognitive testing using a number of testing modes will be conducted for telephone, web-based (including mobile), paper-and-pencil (mail format) and personal interview modes. **Pilot testing**—NCCDPHP will conduct general methodological research on public health surveillance to ascertain differences in mode of data collection on population prevalence estimation, effectiveness of approaches of data collection methodologies, comparisons of software and other technologies, research on optimal questionnaire design formats and new sampling methods.
* **Populations to be studied**: Rather than studying a population, cognitive testing will examine the questions themselves. Respondents and trained interviewers will look at the context, wording and possible interpretations of questions. Some testing may include minor children and/or international respondents. Pilot tests will be used to inform future survey construction.
* **How data will be analyzed**: The resulting data will be used to determine effectiveness of approaches of data collection methodologies, comparisons of software and other technologies, research on optimal questionnaire formats and new sample methods.

**A. Justification**

1. **Circumstances Making the Collection of Information Necessary**

The Centers for Disease Control and Prevention (CDC) request that the Office of Management and Budget (OMB) approve a generic clearance for cognitive testing and pilot testing of survey questions and methodologies for three years for the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP). Cognitive testing and pilot testing conducted under this authorization will be used to inform data collection and surveillance efforts of the NCCDPHP prior to full implementation of surveys and data collection efforts. Each information collection (IC) under this generic clearance will be submitted separately to OMB for approval. Submissions will include a form (Attachment 9) that provides details on the purpose, use, method and burden. The NCCDPHP will undertake cognitive testing and pilot testing for each IC in order to develop, test and modify questions, test questionnaire formats, software programs, online interview platforms and conduct research on data collection and other methodological processes. Cognitive testing and pilot testing are essential to ensure the quality of public health data. Cognitive testing provides an efficient means to identify issues and problems that would be significantly more difficult to correct during the implementation phase of data collection and pilot testing allows for the determination, on a small scale, whether new methods may be appropriate for adoption for use by NCCCDHP surveillance systems. The collaborative development and testing of survey questions and piloting of surveillance methodologies that are useful to multiple programs within the Center is an activity supported through this generic.

Cognitive testing is used to determine whether survey items are poorly worded or formatted, or pose questions that respondents are not able to answer. Cognitive test results illustrate whether questions are susceptible to item nonresponse or difficult for interviewers to implement. Cognitive tests may also determine whether cultural interpretations affect responses to questions among subsets of the population. In some instances, cognitive tests are necessary to determine whether items used in other surveys are appropriate for surveys collecting data in different modes. For example, questions adopted from an in-person survey may be cognitively tested prior to use on telephone surveys to determine whether respondents need visual cues in order to respond.

Cognitive testing is conducted early in the question proposal process (see Attachment 3 for an example of a process of question adoption used by the NCCDPHP). It is the first step in ensuring that a question is properly worded for inclusion in a survey. Cognitive testing is a discussion between recruited respondents and trained interviewers about interpretations of items to be included in a survey question (see Attachment 5). It includes paradata about the question itself rather than a simple response to the question. Several formats of the question may be tried with the same or several respondents in a controlled setting to determine the optimal question wording and/or format. Following cognitive testing, questions may be sequence reordered or response sets may be changed. In some cases, the questions may need rewording or removal from consideration. Cognitive testing contributes to the understanding of the face validity and reliability of questions under consideration.

In some cases, cognitive testing is conducted with targeted populations. For example, questions about experiences quitting smoking would be cognitively tested with current or former smokers. Some surveys are implemented for international populations and others may include minor children as subjects. With proper controls for privacy and consent, each package will include methods for ensuring informed and voluntary participation.

Cognitive tests examine the context of the questions as well as the questions themselves. They may determine whether interviewers are having difficulty in presentation of questions, or if interview software programs are functioning properly. Screening scripts, interviewer and respondent instructions and visualization of paper and online surveys are also reviewed during the cognitive testing process.

Although cognitive testing contributes to the overall success of data collection efforts, data from cognitive tests are not included in any public use dataset, nor used internally for rigorous statistical analyses. Cognitive testing outcomes are only used to develop and refine data collection processes. Participation by the public in cognitive testing is voluntary and responses to questions are confidential.

Pilot tests are used to determine whether a new approach or data collection methodology may be useful in the near future. Pilot tests may be proposed as a potential solution to a data collection issue (such as nonresponse, targeting a specific hard-to-reach population, or determination of the effectiveness of a new calling protocol). Pilot tests do not impact nor take the place of regular data collection efforts at the time of their implementation. For the Behavioral Risk Factor Surveillance System (BRFSS), for example, pilot tests may be conducted in a selected number of states without changes in the regular data collection processes of those states. Pilot testing may include testing groups of individuals in order to compare rates of response when differing questionnaire formats or modes of response are provided. Pilot testing may also be used to determine mode effects on a single question, whether and how temporal reminders affect response, bias effects of formats and issues related to sensitive questions. Pilot tests can also be used to test new methods of data collection, sampling or operational protocols for existing surveys. See Attachment7 for an example of a final report from a pilot.

Feasibility testing of methods is a form of pilot testing. For example a test of whether respondents will participate in an online version of a questionnaire may have the sole purpose of determining whether respondents will participate. Question wording and formats may be of lesser interest in such a feasibility test. Feasibility tests are of unique importance as new methods of contact are under review to alleviate issues related to response rate decline.

Pilot testing results are often used to inform future survey construction, sampling, methodologies, interpretation of responses and may often be used for publication and presentation to survey and surveillance methodological audiences. Participation by the public in pilot testing is voluntary and responses to questions are kept private. When international populations or minor children are part of the pilots, methods will include specific steps to ensure that informed consent is obtained.

Cognitive testing and pilot testing are an integral part of public health surveillance. CDC’s surveillance efforts quantify disease and risk factors, identify opportunities for prevention and are central to CDC’s planning and evaluation efforts. CDC will submit individual collections under this generic three-year clearance to OMB. CDC’s authority to collect information for this purpose is provided by the Public Health Service Act (Attachment 1).

1. **Purpose and Use of Information Collection**

The NCCDPHP conducts cognitive testing and pilot testing for a number of its data collection processes. Most notably the BRFSS conducts three to four cognitive tests and one to two pilot tests each year. Other divisions housed within the NCCDPHP contribute questions to the BRFSS and conduct separate surveys that require cognitive and pilot tests and are included in this request. Surveys conducted by NCCDPHP divisions other than the Division of Population Health include, but are not limited to, the Pregnancy Risk Assessment Monitoring System (PRAMS; OMB 0920-0654) and various national and international tobacco surveys conducted by the Office on Smoking and Health. A list of divisions that may propose questions for testing, and/ or conduct pilot tests is included in Attachment 4. In addition, relevant information collections by the Office of the Director of the NCCDPHP may also be requested through this mechanism. Additional information collections may also be considered for submission through this generic clearance if they are relevant to BRFSS and NCCDPHP programs or collaborations. Programs within the NCCDPHP are not restricted to use of this generic ICR and may use other OMB approved information collection methods to cognitively test questions and methods. Information derived from the cognitive and pilot tests will be used for the following purposes:

1. Determination of questions for adoption on currently implemented surveys. Cognitive testing results are used to determine whether questions are appropriate for adoption on the BRFSS and other surveys conducted by the NCCDPHP and its data partners.
2. Determination of the use of different modes of data collection for surveys currently in use. Surveys which are currently collecting data by telephone surveys or by using in-person interviews may use cognitive or pilot tests to determine whether mailed surveys or mailed invitations to web-based surveys would be feasible alternatives to collecting information using the same questions but collected by different modes.
3. Evaluation of questions for optimal design. Questions undergoing cognitive testing will evaluated on the basis of placement/order on the questionnaire, sequence of response items, instructions to the interviewer and/or respondent and other questionnaire design items.
4. Determination of appropriate response sets. Response sets may be adjusted to ensure that the most appropriate distinctions in health behaviors can be made after data collection, while ensuring that respondents are capable of differentiating from among response choices. Appropriate response sets also minimize item nonresponse in the final dataset.
5. Evaluation of questionnaire bias. Words and phrases within questions will be examined for cultural bias.
6. Evaluation of presentation bias. Visual bias and usability of items will be tested for paper, online and personal computer/mobile versions of survey instruments.
7. Testing software usability. Computer assisted telephone interview (CATI), computer assisted self-interview (CASI), computer assisted personal interview (CAPI), and other software applications will be tested.
8. Examination of phrasing. Testing of wording on existing questions for outmoded phrasing or inclusion of new wording, as in the case of new standards for preventive testing, or new wording of smoking devices (such as e-cigarettes).
9. Improvement in data collection processes. Cognitive testing and pilot testing results in cost and time efficiencies during the data collection phase of surveillance projects. While it may be difficult to quantify, it is clear that cost savings are associated with noting the needs for changes early in the data collection process.
10. Research on respondent cognitive processes. Qualitative research using paradata on how respondents select answers to questions posed on surveys will be conducted.
11. Providing information on bias among subpopulations. Cognitive testing of questions among members of subpopulations and hard-to-reach populations, in different languages, or in modified dialects of the standard language of the questionnaire can reveal a cultural bias in the survey results.
12. Production of methodological research. Tests may reveal the best times at which to call respondents in telephone surveys, procedures to randomize respondents in household surveys, approaches to probing for responses, optimal length of surveys for telephone or web, or other survey method research questions.
13. Tests of the use of new samples. Surveys which use telephone samples may pilot test the use of Address-Based Samples (ABS) or other geographic-based samples to determine whether new sampling methodologies would result in improved response rates or reduced sampling bias.

No data from cognitive or pilot testing will be used for population prevalence estimation or rigorous analysis of health data. Data will be analyzed to compare presentations of question formats, mode, sample, wording, response sets, subject recruitment and refusal conversion, visualization of questionnaires and similar issues related to data collection methodologies.

Overall results of the cognitive testing and pilot testing processes are linked to improved data quality and efficiency in the data collection process. Without pretesting of questions and processes provided in cognitive testing and pilot testing, respondent burden would be increased and data quality would suffer. The practice of testing questions and procedures is standard for all large-scale data collection systems such as the BRFSS and other data collection systems housed within the NCCDPHP.

1. **Use of Improved Information Technology and Burden Reduction**

CATI, CAPI, CASI and other software programs will be used to facilitate the interview process and reduce the time burden on respondents during cognitive testing when appropriate. In many cases (such as when testing changes in the BRFSS on the phone), only those parts of surveys which will be undergoing changes will be tested, thereby reducing respondent burden.

Cognitive interviews may be recorded for review by staff who have interest in outcomes of the testing. Programs and agencies which request questions to be included on surveys are required to submit information on previous cognitive testing and use on other surveys. Programs and agencies requesting questions to be included on the BRFSS and other surveys are also asked to submit any studies of validity and/or reliability of the questions under consideration as part of their proposals for consideration (see Attachment 3). The use of other research on the questions under consideration limits the scope of additional cognitive testing necessary, thereby also reducing respondent burden.

1. **Efforts to Identify Duplication and Use of Similar Information**

Work carried out under this clearance will be designed to address the needs of the NCCDPHP and is not duplicative of other evaluation or testing known.

1. **Impact on Small Businesses or Other Small Entities**

This effort will not have any impact on small businesses or other small entities.

1. **Consequences of Collecting the Information Less Frequently**

Since many of the surveys used by surveillance systems within the NCCDPHP, including the BRFSS, are adapted on an annual basis, cognitive testing and pilot testing are also required to be completed annually. Collecting testing data on a less frequent basis would result in survey items being implemented without cognitive or pilot testing, thereby increasing the potential for error, bias and respondent burden.

1. **Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

No special circumstances apply.

1. **Comments in Response to the Federal Register Notice/Outside Consultation**

**Section 8A:**

As required be 5 CFR 1320.8(d), a 60-day Federal Register Notice (see Attachment 2) was published in the *Federal Register* on August 13, 2019 (Vol 84 No. 156 FR 40061-40062). A single public comment was received. A copy of the comment and response is provided in Attachment 8.

**Section 8B:**

Whenever it is methodologically sound and appropriate to do so, the NCCDPHP may obtain technical assistance from experts within other federal agencies, state health departments and/or outside the federal government to implement cognitive and/or pilot testing procedures. In some instances, statistical expertise will be available from among NCCDPHP partners or contractors.

1. **Explanation of any Payment/Gift to Respondents**

For most testing projects, cognitive interview respondents receive incentives for participation. Typically, respondents are recruited to take part in cognitive testing in an office setting. This requires both travel and time on the part of cognitive testing participants. 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 any ambiguities, and describe why they answered the questions the way they did (see Attachment 5). Persons participating in cognitive testing will likely be compensated for their time and effort. It is standard industry practice for such compensation (see Attachment 5). Current industry practices include standard incentives of approximately $40. It is sometimes important to offer incentives sufficient to attract the full range of needed respondent types, and compensation may exceed this amount for hard-to-reach targeted participants. Incentives increase response rates and are provided to show appreciation for the time and effort involved in participating in cognitive testing. Information on incentives will be included in each individual collection submitted.

### **Privacy Impact Assessment Information**

Privacy Act Determination

The Privacy Act does not apply. No data will be collected, filed or retrieved by the name of the individual or other unique respondent identifier such as social security number.

Items of Information to be Collected

In both cognitive testing and pilot testing, general demographic characteristics of respondents will be collected and associated with paradata on questions posed to participants and question responses. For example, cognitive testing may indicate that some questions are more difficult for minority respondents to interpret or that younger respondents associate different connotative definitions of words included in questions than do older respondents. Cognitive testing conducted in person may not be completely anonymous, as groups of volunteers may discuss issues with questions in an open office setting. Neither cognitive nor pilot testing respondents would disclose their names or addresses as part of the question process. As is noted below, if participants receive incentives, such information may be provided, but it would not be associated with any responses.

Other items of information will include paradata on questionnaire, questions, responses, formats, and other aspects of surveys presented to the participants.

How Information Will Be Shared and For What Purpose

In many cases cognitive testing for NCCDPHP surveys will be undertaken by private vendors. These vendors will be responsible for production of reports outlining their findings including question specific suggestions for improvement, problems with interpretation of question wording, suggestions for ordering of questions. An example of a cognitive testing report is provided in Attachment 5. Cognitive testing results for large surveys such as the BRFSS will be shared with CDC programs which propose questions and /or with state or local partners who participate in data collection systems. Results may also be used to prepare and present methodological research papers at professional conferences or for peer reviewed journals. No data from the cognitive tests or from the pilot tests will be used to produce prevalence estimates or analyze public health status.

Impact of the Proposed Collection on Respondents’ Privacy

The pilot and cognitive test sample files may include phone numbers or addresses (if the pilot tests are for phone or address based surveys, respectively). Persons who are recruited for in-person cognitive testing may report their addresses during the recruitment process and if incentives for their time and effort is provided by the vendor. CDC will not retain any individually identifiable information and will not maintain sample files of phone numbers or addresses. Sample files are kept separate from response files and are not connected to responses. If recordings are made of cognitive interviews, no personally identifying information will be connected with recordings and they will be retained only for the time needed for research purposes. They will be stored in secure locations.

How Individuals Are Informed That Providing Information Is Voluntary Or Mandatory

Individuals participating in the cognitive tests will be voluntarily recruited but will be reminded that they may refuse to answer specific questions. In all cognitive tests where a telephone interview is conducted, protocols for voluntary screening will be used that match procedures for the surveys that are being tested. Attachment 6 provides an example of a telephone screener for the BRFSS cognitive tests conducted by phone. This screener informs respondents that they do not have to participate and that they may refuse to answer any question. Individuals participating in the cognitive testing by phone are also informed of the voluntary nature of their participation in an introduction (Attachment 6).

Opportunities to Consent

Verbal consent is obtained from participants during the initial contact and/or screening process (see Attachment 6) or by application to the vendor for participation by responding to an advertisement. In all cognitive tests conducted by phone an introductory script, including the voluntary nature of the survey, precedes the survey questions. Specific text of verbal consent language will be included in each IC request submitted under this generic approval.

How Information Will Be Secured

Access to cognitive test data set will be limited to the entity (CDC, a contracted vendor or a data collection partner, such as a state health department) conducting the test and CDC staff who assist in the test. Access to data for cognitive tests will be limited to the program staff members who are reviewing questions for inclusion on a questionnaire and any contracted vendor or data collection partner, as described in each IC request. Security measures include: 1) Physical controls: CDC facilities are secure, ID accessed buildings. Data will not be stored in hard copy formats; and 2) Technical controls: All electronic data are stored on secured servers protected with firewalls and passwords. All employees are trained on data security measures by taking appropriate HHS courses online. All data collection and records management practices and systems adhere to HHS and CDC IT policies and procedures. Individual procedures for data security will be outlined in each request submitted to OMB.

1. **Justification for Sensitive Questions**

It is possible that in developing questions and data collection procedures, potentially sensitive questions may be included in cognitive testing. One outcome of cognitive testing and pilot testing is to determine the degree to which respondents find questions to be sensitive and offer them in the optimal method of presentation. If questions of a sensitive nature are proposed, this will be noted, and a justification will be included in the materials submitted to OMB for review and approval in the specific request that includes the sensitive questions.

1. **Estimates of Annualized Hour and Cost Burden**

Table 12A shows the estimated annualized burden hours of this generic clearance, for both the cognitive tests and the pilot testing of the NCCDPHP. It is anticipated that the total number of hours may vary from year to year. On average 1-3 requests are anticipated each year, although in some years the number may be up to 5 ICs in a single year. The actual number of requests will be determines by the needs of programs within the NCCDPHP.

In-person cognitive testing is anticipated to take up to 1 hour of each respondent’s time, as it includes discussions between participants and interviewers, as well as the respondents’ reactions to questions in a number of formats. This would include cognitive tests of online (including mobile) formats, which would be conducted in a controlled environment. The only exception to that would be cognitive tests conducted by phone, which are anticipated to be shortened to 45 minutes. Pilot tests are estimated at thirty minutes per participant. Pilot testing of mail and web formats will differ by the length of the questionnaire by are also not likely to be longer than 30 minutes on average. Screening questions for pilot tests are shorter, but a larger number of persons will go through the screening process in order to acquire a sufficient sample for cognitive and pilot testing. Since this is a new generic request, the estimates presented in Table 12A for cognitive tests in person and by phone as well as pilot tests by phone are based principally on experience with the BRFSS. The distribution with types of tests may be adjusted across categories as specific testing needs arise.

12A. Estimated Annualized Burden (Hours)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Type of Respondent | Form Name | Number of Respondents | Number of Responses per Respondent | Average Burden per Response (in hours) | Total Burden (in hrs.) |
| General U.S. Population or Selected Subpopulation | Screening for cognitive testing | 2,500 | 1 | 15/60 | 625 |
| Screening for pilot testing | 2,400 | 1 | 15/60 | 600 |
| Cognitive testing in person | 1,500 | 1 | 60/60 | 1,500 |
| Cognitive testingby phone | 1,500 | 1 | 45/60 | 1,125 |
| Cognitive testing by ABS/mail/web | 600 | 1 | 60/60 | 600 |
| Pilot testing in person | 1,000 | 1 | 30/60 | 500 |
| Pilot testingby phone | 3,000 | 1 | 30/60 | 1,500 |
| Pilot testing by ABS/mail/ web | 5,000 | 1 | 30/60 | 2,500 |
| Total | 17,500 |  | 8,950 |

 **12B**. **Costs to respondents.**

No costs to pilot test respondents are anticipated, other than their time to participate. Incentives provided to respondents during cognitive testing are designed to compensate them for their effort and any out-of-pocket costs, such as travel to the cognitive test site for those participating in the in-person testing. Table 12B shows the estimated cost burden over 3 years, based on the respondent’s time to participate in these research activities. The total cost burden is estimated to be $658,900.

**Estimated Annualized Burden Costs**

|  |
| --- |
| Table 12BEstimated Three Year Respondent Burden by Response Type  |
| Type of Information Collection | Total Annual Burden Hours | Three Year Burden Hours | Average Hourly Wage Rate\* | Total (Three Year) Cost Burden |
| Screening for cognitive testing | 625 | 1,875 | $24.54 | $46,013 |
| Screening for pilot testing | 600 | 1,800 | $24.54 | $44,172 |
| Cognitive testing in person | 1,500 | 4,500 | $24.54 | $110,430 |
| Cognitive testingby phone | 1,125 | 3,375 | $24.54 | $82,823 |
| Cognitive testing by ABS/mail/web | 600 | 1,800 | $24.54 | $44,172 |
| Pilot testing in person | 500 | 1,500 | $24.54 | $36,810 |
| Pilot testingby phone | 1,500 | 4,500 | $24.54 | $110,430 |
| Pilot testing by ABS/mail/web | 2,500 | 7,500 | $24.54 | $184,050 |
| Total | $658,900 |

\*Based upon the average hourly earnings for October 2012 from the Current Employment Statistics survey conducted by the Bureau of labor Statistics (available at <http://data.bls.gov/cgi-bin/surveymost>).

1. **Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs**

There are no direct costs to respondents other than their time and travel to participate in the in-person cognitive testing, which is provided for by incentives.

1. **Annualized Cost to Federal Government**

Costs to the federal government would vary by specific cognitive and pilot test activity and would be included for each of the submissions to OMB separately. In some cases, cognitive testing will be undertaken by a private vendor contracted by CDC.

The table below illustrates highest annual anticipated cost for individual pilot tests and cognitive testing. Costs for specific ICs may vary due to the nature of each IC undertaken. Overall, the maximum annual cost to the government for all activities will be $807,632.

|  |
| --- |
| Estimated Annual Costs by Pilot and Cognitive Testing |
| Pilot testing |
| Administrative Costs | Including CDC personnel/ project oversight, report writing | $10,132GS 13 X 200 hours ($50.66/hour) |
| Data Collection Costs | Including contractor costs, interviewer costs, printing, postage. | $675,000(9,000 completes at $75/complete) |
| Cognitive Testing |
| Cognitive Testing | Including CDC personnel/ project oversight, report writing | $10,132GS 13/$50.566 x 200 hours  |
| Contractor Costs | Including recruitment of participants, focus groups, participant incentives | $112,500($7,500 per question x 15 questions) |
| Total  |  | $807,632 |

1. **Explanation for Program Changes or Adjustments**

N/A.

1. **Plans for Tabulation, Publication, and Project Time Schedule**

Analyses plans will be provided for each information collection under this generic clearance at the time that the specific information collection is submitted to OMB. Information collection will not begin until OMB has been notified of a proposed activity and approved of the activity.

1. **Reason(s) Display of OMB Expiration Date is Inappropriate**

Not applicable.

1. **Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the PRA.