Supporting Statement A Request for Clearance:

# COLLABORATING CENTER FOR QUESTIONNAIRE DESIGN AND EVALUATION RESEARCH

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## Table of Contents



LIST OF ATTACHMENTS

ATTACHMENT I: Sample Respondent data collection sheet
ATTACHMENT J: Sample Advertisement
ATTACHMENT K1 & K2: Distress Protocols
ATTACHMENT L: Sample of an advance letter sent to NHIS respondents
ATTACHMENT M: Sample CCQDER Voice mail script
ATTACHMENT N: Detailed explanation of cognitive interviewing procedure read by interviewer to respondent

- **Goal of the study:** It is the goal of the Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) to evaluate questions for optimal design as well as to provide documentation supporting the validity of NCHS and other agencies' information collections.
- **Intended use of the resulting data**: CCQDER obtains information about the interpretive processes used by respondents to formulate answers to survey questions. Findings are used 1) to ensure question comparability across respondent groups, for example, those across different disability status, income and education groups, 2) to correct any identified problematic questions, for example, those which are vague or ambiguous, cannot be answered readily or accurately by the respondent, or otherwise contribute to the non-sampling errors of the survey, and 3) to provide data usage documentation regarding the phenomena considered by respondents, that is, the specific construct measured by individual questions.
- **Methods to be used to collect**: Data collection includes a mix of qualitative and quantitative methodologies, including cognitive interviewing, focus groups, usability testing, ethnography, and survey field tests/pilot interviews (in-person/telephone/web).
- **Subpopulation to be studied:** In that a primary research goal involves assessment of comparability among potential survey respondents, focus of analysis is across relevant respondent groups, for example, of those across different disability status, income and education groups.
- **How data will be analyzed**: Depending on project needs and data collection methods, a variety of analytic methods may be used and will be explained in the individual information collection requests under this clearance. In general, however, qualitative data will be analyzed using the constant comparative method to identify the presence and comparability of interpretive patterns. Quantitative data will be analyzed using estimation- and correlation-based techniques including hypothesis testing, latent class analysis, and studies of differential item functioning. Regardless of analysis techniques used, findings under this generic clearance serve methodological purposes and are not intended for the production of population estimates.

**Supporting Statement A**

**Collaborating Center for Questionnaire Design and Evaluation Research**

A three-year OMB clearance is requested for the "NCHS Collaborating Center for Questionnaire Design and Evaluation Research". This request is submitted a Reinstatement of a previously approved data collection (OMB No. 0920-0222, Exp. Date 01/31/2026). This generic clearance request encompasses general questionnaire development, pre-testing, and measurement-error reduction activities to be carried out in 2026-2029 in the Division of Research and Methodology, National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC). The activities are to be conducted by the staff of the CCQDER Collaborating Center for Questionnaire Design and Evaluation Research and designated agents, such as contractors, and involve the examination of reliability and validity of items on health-related survey questionnaires.

## A. Justification

### 1. Circumstances Making the Collection of Information Necessary:

Federal statistical agencies have a fundamental obligation to produce valid and reliable data, and more attention on question evaluation and documentation is required. Validation of measures is a particularly complex, methodological problem that requires a mixed-method approach. While quantitative methods are essential for understanding the magnitude and prevalence of error, qualitative methods such as cognitive interviewing are necessary to provide context and information about the interpretation of measures. While projects under this generic clearance may use a wide range of specific qualitative and quantitative methods, including focus groups, ethnography, experimental designs, and psychometric approaches, CCQDER's work relies most heavily on cognitive interviewing and field testing via commercial survey panels.

Cognitive interviewing is a semi-structured qualitative method used to uncover the interpretive processes that ultimately produce survey data. The method additionally allows for the examination of interpretive patterns across various respondent groups to assess comparability. Consequently, cognitive interviewing is an effective method for ensuring the validity of statistical data, and the documented findings from these studies represent tangible evidence of how the question performs.

In 2015, CCQDER began the first of a series of web surveys (referred to as the Research and Development Survey, or RANDS, series) to assess the utility of web panels as a way of augmenting the primarily qualitative program with quantitative methodologies, specifically, with the use of embedded, close-ended probe questions. The quantitative data coupled with the larger sample sizes (in contrast to traditional cognitive interviewing studies) allows for comparing the performance of alternate questions as well as quantitatively assessing their performance across respondent subgroups. If representative (or at least understood in the ways they are not), web panels could become an important platform for investigating question response as a socio-cultural process as well as conceptualizing error quantitatively, significant advancements for the field of survey measurement. Initial assessments of web-panel surveys for use in question evaluation, particularly the use of embedded probing questions, have shown to be successful. Consequently, there is growing interest among CDC and other federal programs to use such platforms for question design-related research. Given its leadership in this area, CCQDER intends to continue RANDS as an ongoing program for methodological research.

The final product of each study conducted under the auspices of this clearance will consist of a clearly documented and publicly available report. Such documentation serves not only NCHS and other federal programs but also supports data users in their application and interpretation of data. All completed CCQDER testing reports are available on the NCHS website.

Data collection for this project is authorized under 42 U.S.C. 242k (Section 306 of the Public Health Service Act). A copy of the legislation is provided in Attachment A. CDC is requesting terms of clearance identical to previous submissions. CDC will submit individual collections under this generic three-year clearance to OMB. It is requested that OMB continue to provide feedback on the individual collections within 10 working days of the submission. Standard remuneration of cognitive interviewing respondents will be capped at $50.00 for an hour interview, though higher remunerations may be requested with justification for difficult recruitments, such as medical doctors and practitioners, specialized populations, focus groups, etc.

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

NCHS and the Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) conducts question evaluation studies, for both applied and methodological purposes,

with particular focus on question design, measurement, comparability, and error.

The purpose and use of collecting this information fall into four categories:

i. Development and evaluation of specific survey items and questionnaires
ii. Research on the cognitive and interpretive aspects of survey methodology, including the study of comparability and the impact of intersectionality in question design
iii. Usability research
iv. Studies of the optimal design and presentation of statistical graphical and textual material

i. Development and evaluation of specific survey items and questionnaires: The purpose of question evaluation and cognitive testing is not to obtain survey data, but rather to obtain information about the processes people use to answer survey questions as well as to identify any potential problems in the questions, e.g., questions which are vague or ambiguous, cannot be answered readily or accurately by the respondent, or otherwise contribute to the non-sampling errors of the survey. CCQDER typically uses both cognitive interviewing and web probing for this type of work. Because these methods often generate narrative responses rather than statistics, results are typically analyzed qualitatively. The goal of these analyses is to determine the actual functioning of a measure, reveal potential pitfalls or problems for respondents, and therefore allow survey sponsors to mitigate these issues before fielding which improves the overall quality of surveys.

ii. Research on the Cognitive and Interpretive Aspects of Survey Methodology: The second major purpose of the CCQDER's data collection is to conduct research on the cognitive and interpretive aspects of survey methodology. In 2026-2029 NCHS/CCQDER staff plan to continue research on methods evaluation and general questionnaire design research. We envision that over the next three years, NCHS/ CCQDER will work collaboratively with survey researchers from universities and other Federal agencies to define and examine several research areas, including, but not limited to: 1) differences between face-to-face, telephone, and virtual/video-over internet cognitive interviewing, 2) effectiveness of different approaches to cognitive interviewing, such as concurrent and retrospective probing, 3) application of web based techniques, including web probing and discrete choice methods, 4)

social, cultural and linguistic factors in the question response process, and 5) recruitment and respondent participation. These studies will be conducted either by CCQDER staff, DHHS staff, or NCHS contractors. 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.

iii. Research on usability: The third major purpose of this data collection is to conduct usability research on data collection instruments. This type of research examines how survey questions, instructions, and supplemental information are presented to respondents and investigates how their presentation affects the ability of users to effectively use and interact with these instruments. Authors of such 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.

iv. Studies of the optimal design and presentation of graphical and textual material NCHS is the Federal government's principal health statistics agency and is responsible for collecting and disseminating many reports and volumes of data annually. As such, CCQDER is sometimes called upon to research whether statistical publications, products, and releases are understood by their intended audiences. One project, for example, involved the development and testing of a brochure designed by staff of the National Health and Nutrition Examination Survey (NHANES) (OMB. No. 0920-0950, Exp. Date 1/31/2028) to convert refusals to acceptance. Another recent project involved testing and evaluation of different Health Surveillance Map formats (choropleth versus isopleth) to determine if they affect ability to extract information from the maps for the Division of Adult and Community Health/the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), CDC. We anticipate that

there will be more work of this type during 2026-2029.

The major activities outlined above have well-demonstrated practical utility. As a result of CCQDER's mixed method evaluation program, questionnaires may produce substantially less response error than would occur in the absence of this testing. As such, NCHS data users can be confident in the underlying assumptions regarding minimal measurement and non-sample error when using the Center's data.

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

Usually, cognitive interviews will be conducted via video conferencing software, allowing for a more geographically diverse sample than would be possible for in-person-only interviewing. The use of web surveys in CCQDER's RANDS program allows for a relatively cheap and less burdensome approach to field testing than would be possible by using space on the Center's traditional household survey questionnaires and samples.

CCQDER Staff conduct reviews to determine if a survey question has been cognitively tested. This reduces unnecessary testing as well as allows CCQDER to build upon existing knowledge learned from past testing projects. Additionally, each cognitive interview is digitally recorded and stored on an internal, searchable video database. This technology allows CCQDER staff to build upon past projects and, at the same time, it improves the accountability of test findings.

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

The CCQDER at NCHS is the only government facility that currently conducts testing and development of NCHS or other CDC questionnaires. Similar facilities at the Bureau of the Census and the Bureau of Labor Statistics bear the responsibility for testing survey questionnaires associated with their own agencies. The demand for CCQDER activities exceeds available resources. CCQDER reports are accessible online, allowing other agencies to track the work done at NCHS, avoid duplication, and build on existing knowledge.

**5. Impact on Small Businesses and Other Small Entities**

CCQDER testing does not impact small businesses or small entities. If such requests are made, 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 cognitive interviews.

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

Individual projects usually involve one-time data collection activities. There are no legal obstacles to reducing the burden.

**7. Special Circumstances Relating to 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**

A Federal Register notice for this collection was published on September 30, 2022 (Vol. 87, No. 189 p. 59425). The text of the notice is contained in Attachment B. No comments were received related to this notice.

**Consultants outside of CDC:**

The following individuals have been consulted within the past year on survey methodology and/or on a specific project:

**Paul Beatty**
Director, Center for Behavioral Science Research
United States Census Bureau
4600 Silver Hill Rd
Suitland, MD
paul.c.beatty@census.gov

**Alisu Schua-Glusberg**
Research Support Services
906 Ridge Avenue58
Evanston, IL 60602
(847) 864-5677

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**Rebecca Morrison**

Director, Behavioral Science Research Center

Bureau of Labor Statistics

4600 Silver Hill Rd

Suitland, MD

morrison.rebecca@bls.gov

**Consultants within CDC:**

The following individuals have been consulted within the past year on survey methodology and/or on a specific project:

**Jess Jones**

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## 9. Explanation of Any Payment or Gift to Respondents

For most testing projects, cognitive interview respondents receive incentives for several reasons:

- Typically, respondents are recruited for specific characteristics that are related to the subject matter of the survey (e.g., questions 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. Incentives help to attract a greater number of potential respondents.

- 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.
- They may be asked to travel to the laboratory testing site, which involves transportation and parking expenses, as well as additional expenses due to leaving their jobs during business hours.

For a standard cognitive interviewing project in which one-hour interviews are conducted at NCHS and eligibility requirements are of average complexity, respondents will be given $50.00. Higher incentives may be requested on a case-by-case basis for particularly difficult recruitment. For example, in a 2008 & 2009 study, the CCQDER was unable to find epidemiologists willing to be interviewed for less than $75, and in 2011, 2013, and 2016 the CCQDER was unable to find physicians willing to be interviewed for less than $100. On rare occasions, a lower incentive is proposed. Since 2020 CCQDER has used e-gift cards and cash incentives.

It is important to offer incentives sufficient to attract the full range of needed respondent types for cognitive interviewing projects. Inadequate respondent recruitment limits the effectiveness of the questionnaire evaluation. Requests and justification for incentives will be included in each individual collection submission.

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

The NCHS Privacy Act Coordinator has reviewed this request and has determined that the Privacy Act is applicable. The related System of Records Notice is 09-20-0164 Health and Demographic Surveys Conducted in Probability Samples of the U.S. Population.

The CCQDER continues to collect, on a confidential basis, data needed in order to conduct CCQDER studies. The process of informing respondents of the procedures used to keep information confidential begins with the telephone screener and will carry through to the interviewer and all communications with potential respondents. Materials will include all elements of informed consent, including the purpose of the data collection, the voluntary nature of the study, audio or video recording of the interview, and the effect upon the respondent for terminating the interview at any time. Confidentiality provided to respondents is assured by adherence to Section 308(d) of the Public Health Service Act (42 U.S.C. 242m(d)) which states:

> "No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under section...306 (NCHS legislation),...may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose and (1) in the case of information obtained in the course of health statistical or epidemiological activities under section...306, such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form,..."

In addition, legislation covering confidentiality is provided according to the Confidential Information Protection and Statistical Efficiency Act or CIPSEA (44 U.S.C. 3561-3583) which states:

> “Whoever, being an officer, employee, or agent of an agency acquiring information for exclusively statistical purposes, having taken and subscribed the oath of office, or having sworn to observe the limitations imposed by this section, comes into possession of such information by reason of his or her being an officer, employee, or agent and, knowing that the disclosure of the specific information is prohibited under the provisions of this subchapter, willfully discloses the information in any manner to a person or agency not entitled to receive it, shall be guilty of a class E felony and imprisoned for not more than 5 years, or fined not more than $250,000, or both.”

Standards for federal government surveys highlight the importance of the interviewers' responsibilities under the Privacy Act of 1974 (5 U.S.C. 552a), the Privacy Act Regulations (34 CFR Part 5b), Section 308(d) of the Public Health Service Act (42 U.S.C. 242m(d)), the Confidential Information Protection and Statistical Efficiency Act or CIPSEA (44 U.S.C. 3561-3583), HIPAA and other regulations.

The CIPSEA legislation authorizes the designation of agents ("designated agents" or "agents") to perform statistical activities on behalf of an agency. These agents function under the supervision of the agency's employees and are subject to the same provisions of law with regard to confidentiality as an agency's employees. A Designated Agent Agreement between the agency and the designated agents (e.g. contractors) must be executed before the agents can acquire information for the agency for exclusively statistical purposes under a pledge of confidentiality. This requirement is outlined in an OMB Notice, published in the Federal Register on June 15, 2007, entitled "Implementation Guidance for Title V of the E-Government Act, Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA)."
NCHS also makes the following Confidentiality Pledge:

Assurance of Confidentiality (shown on all forms collecting PII) – We take your privacy very seriously. All information that relates to or describes identifiable characteristics of individuals, a practice, or an establishment will be used only for statistical purposes. NCHS staff, contractors, and agents will not disclose or release responses in identifiable form without the consent of the individual or establishment in accordance with section 308(d) of the Public Health Service Act (42 U.S.C. 242m(d)) and the Confidential Information Protection and Statistical Efficiency Act or CIPSEA (44 U.S.C. 3561-3583). In accordance with CIPSEA, every NCHS employee, contractor, and agent has taken an oath and is subject to a jail term of up to five years, a fine of up to $250,000, or both if he or she willfully discloses ANY identifiable information about you. In addition to the above cited laws, NCHS complies with Cybersecurity and Infrastructure Security Agency Act of 2018 (6 U.S.C. § 663) which protects federal information systems from cybersecurity risks by screening their networks.

Only those NCHS employees, contract staff, and full research partners who must use the personal information for a specific purpose can access and use such data resulting from the studies. Everyone else who uses the data can do so only after all identifiable information is removed.

A Designated Agent Agreement between NCHS and any CCQDER contractor will be executed if any contractors are hired to acquire information for the NCHS for exclusively statistical purposes under a pledge of confidentiality (i.e. complete any of the five types of activities described in this

generic clearance request). Additionally, the agents (contractors) will be required to complete NCHS Confidentiality Training (https://www.cdc.gov/nchs/training/confidentiality/training/), submit a certificate of completion, and sign a pledge to maintain confidentiality (Nondisclosure Affidavit; see Attachment C) prior to completing CCQDER work. If the CCQDER contractor hires subcontractors to complete CCQDER work, the subcontractors must adhere to the same confidentiality and security requirements as CCQDER staff and contractors.

Data in identifiable form is collected for linkage of various CCQDER forms (informed consent documentation and respondent demographics) and audio and video recordings. The CCQDER also uses some identifiable data (name, phone number, email address) to contact previous respondents for CCQDER studies. The ability to match respondents to other data (informed consent documents, respondent demographics, and audio/video recordings) greatly expands the usefulness of the data at a very low cost.

As outlined in the informed consent form, access to personal information is restricted to CCQDER staff who can only access the personal information for statistical, training and research purposes. Additionally, other NCHS staff, designated agents such as CCQDER contractors, or subcontractors may access the personal information for statistical purposes only after signing a Designated Agent Agreement with NCHS. CCQDER staff, designated agents, and staff from collaborating agencies must complete annual NCHS confidentiality training (https://www.cdc.gov/nchs/training/confidentiality/training/), submit a certificate of completion, and sign the NCHS affidavit of nondisclosure (see Attachment C) prior to being granted access to any personal information.

The collection of information in identifiable form requires strong measures to ensure that private information is not disclosed in a breach of confidentiality. Storage of confidential data is protected through procedures such as an internal QDRL LAN, passwords and restricted access.

**Confidentiality of responses and safeguarding of data at NCHS**

The CCQDER has a routine set of administrative, technical, and physical measures to safeguard confidentiality, including the following:

1. Storage of confidential data (informed consent form, respondent database, video and audio recordings) on the QDRL LAN are protected through procedures such as

an internal QDRL LAN, passwords, and carefully restricted access;

2. The QDRL LAN is not located on the NCHS LAN, the QDRL LAN is inaccessible to others (not CCQDER staff) inside or outside NCHS;

3. All CCQDER personnel (including CCQDER contractors/designated agents) who have access to confidential data (informed consent form, respondent database, video and audio recordings) complete NCHS Confidentiality Training (https://www.cdc.gov/nchs/training/confidentiality/training/), submit a certificate of completion, and sign a pledge to maintain confidentiality (Nondisclosure Affidavit; see Attachment C), and are given instruction by the CCQDER Laboratory Manager on the requirement to protect confidentiality. Contracted personnel send hardcopies of the NCHS Confidentiality Training certificates and original signed hardcopies of the Nondisclosure Affidavits to Kristian Gregory-Lee, CCQDER Behavioral Scientist/Contracting Officer Representative (COR);

4. Only such authorized CCQDER personnel are allowed access to confidential data (informed consent form, respondent database, video and audio recordings) and only when their work requires it. CCQDER Personnel holding proper passwords may access the QDRL LAN through their CCQDER Computer Desktop which is hardwired to the QDRL LAN;

5. Data (informed consent form, audio recordings) from cognitive interviews and focus groups that are conducted off-site are stored in a secured travel case to ensure that there is no loss in transit until returned to NCHS, at which point the data is stored in secure conditions (CCQDER Control Room or locked staff office in a locked drawer) until the recordings can be manually ingested and consent documents scanned into the secure CCQDER LAN or NCHS CIPSEA server;

6. Restricted signage (see below) is placed on the external doors of the CCQDER with point of contact information and phone numbers of whom to contact during and after business hours.

CCQDER Lab Access Protocol: This Lab is a restricted access secure facility. Access is by CCQDER staff or by CCQDER staff escort only. All respondents receive a copy of Attachment D, Informed Consent Form, which describes the procedures by which confidentiality of data identifying individuals is maintained.

Video Access Protocol: Only NCHS onsite CCQDER staff and contractors with PIV cards and proper passwords have access to the digitized video/audio application that captures, stores, and indexes the video and audio of a cognitive interview at the questionnaire level in a digitized database. Video data are housed on the CCQDER LAN or NCHS CIPSEA server. The CCQDER LAN is located in the secured CCQDER Control Room within CCQDER's secured space (authorized keycard access only),

and video data are isolated on the CCQDER LAN, which has no outside connectivity, including no connectivity to the NCHS LAN, CDC, or the internet. It is inaccessible to anyone who is not a CCQDER staff member or CCQDER contractor. Access to the NCHS CIPSEA Server is via a username and password and is limited to NCHS staff and contractors who have taken specialized training. Furthermore, access to CCQDER data on the NCHS CIPSEA server is limited to CCQDER and NCHS staff directly working on CCQDER projects.

Records Retention Schedule for Cognitive Interviews: The cognitive interview's retention is based on the approved retention policy (Attachment E). An interview's Retention Status is determined by several project and interview-level factors. Thus, each interview has its own individual retention status. Only interviews in which the respondent has consented to their interview being used for future research will be retained after the completion of the project. Future research consists only of work directly related to the survey questions discussed in the interview but not necessarily tied to the current specific project. In most cases, retention is used to verify the accuracy of findings stated in final reports and allows for re-investigation of such findings. For those interviews being maintained for future use, the data retention period for storing the interview recording will begin after the conclusion of each project. The CCQDER retention

The factors determining retention status include the type of consent agreed upon by the respondent and whether it is considered to be a restricted or unrestricted interview. Interviews become restricted depending on the type of respondent (e.g. < 18 years old) as well as the interview topic (e.g. illegal behaviors clearly defined by law and are punishable if disclosed). Restricted interviews require enhanced protection for data storage and retention. Interviews that are given the restricted designation are stripped of video (upon submission of the final report) and maintained only in audio format. The audience for restricted interviews is limited, and the interviews are reviewed every two years to determine whether the interview continues to have qualitative value for use in federal question evaluation research projects or activities.

Unrestricted interviews contain questions about behaviors that are not illegal, and in some projects, could be deemed as embarrassing or disconcerting. Unrestricted interviews can be maintained in audio and/or video format depending on respondent's consent. The audience for unrestricted interviews is broader than restricted interviews and may include sharing the interviews in a classroom setting if respondent's consent was provided. Unrestricted interviews are reviewed every five years to determine whether the interview continues to have qualitative value for use in federal question evaluation research projects or activities.

If the restricted or unrestricted interview continues to be of value (defined as ongoing use by research staff, topic relevance, likely use for federal questions evaluation research), reassessment of the recording will occur again in either 2 years (for restricted interviews) or 5 years (for unrestricted interviews).

Informed Consent documents: Informed consent documents are stored by project in a separate drawer in a locked filing cabinet in the locked office of the CCQDER Recruiter or CCQDER staff member working on the project until the informed consent documents can be electronically scanned and moved to the CCQDER LAN or NCHS CIPSEA Server.

CCQDER Respondent Database: A custom-designed CCQDER Respondent Database contains personal identifiable information and demographic information on respondents who have participated in past CCQDER studies such as name, phone number, email address, age, marital status, ethnicity, race, education, employment status, and household income. The CCQDER Respondent Database is used to produce periodic tabulations and reports on database characteristics and response rates. The CCQDER Respondent Database is also used to conduct computerized searches to locate computer records of past respondents having salient characteristics for use in future studies. The CCQDER Respondent Database is housed on the secure NCHS CIPSEA Server. Access to the server is restricted to members of CCQDER's Operations Team that have undergone training in handling and protection of personal identifiable information.

Reports and publications: No respondent names or other personal identifying information is included in any reports or publications of cognitive testing results.

Presentations: No respondent names or other identifying information is included in any presentations of cognitive testing results.

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

Each individual project under this generic clearance will be reviewed and approved by the CDC Human Research Protection Office and, for non-excepted projects, the CDC Institutional Review Board (Attachment F).

**Informed Consent and Voluntary Nature**

**CCQDER respondents/interviews conducted off-site**[1]: Sometimes interviewers must travel to conduct cognitive interviews in these cases, a mutually agreeable location will be chosen. In all cases, extreme care is taken with audio and video recordings and any materials that contain personal identifiers such as the Informed Consent Form are then transported to the CCQDER, where standard procedures are followed.

**CCQDER respondents/interviews conducted virtually:** Respondents are recruited through media advertisements, flyers, and word-of-mouth, and either call the CCQDER voice mail system or contact a person coordinating the recruitment.

During the telephone screener (Attachment G), potential respondents are informed that answering the telephone screener questions to determine their eligibility for the study is completely voluntary. They are informed that we are required by law to use the information they provided in the telephone screener for statistical research only and to keep it confidential, and that the law prohibits us from giving anyone any information that may identify them without their consent. In addition, respondents who are determined to be eligible for the study are informed during the telephone screener that the information they provide during the cognitive interview is confidential.

Prior to the start of the cognitive interview, CCQDER respondents read and sign Attachment D, template 1, Informed Consent Form (written at an 8th grade reading level). The consent form states that participation is voluntary, they are free to terminate the interview at any time, and if they do so, they will still receive the incentive. The consent form describes the purpose of the interview and recording, specifies that the recordings may be played for other staff working

[1] Off-site interviews fall into two categories. First, it is not always feasible for individuals to travel to the CCQDER, or it may be more efficient for interviewers to travel to a particular site. Second, we occasionally conduct establishment studies where a visit to the business location is pertinent to data collection.

closely on that project, that voice and face identifiers will remain on the recording, and that they may be recognized by a staff member viewing or listening to the recording. After the interview has concluded respondents will be given the thank-you letter signed by Director of NCHS (Attachment H), their incentive, and a copy of the informed consent document (Attachment D, template 1), which contains contact information for the CCQDER Laboratory Manager, the NCHS Research Ethics Review Board (ERB), and the NCHS Confidentiality Officer.

NCHS government issued encrypted laptops will be used to video and audio record the interviews. Interviewers can then securely upload their interview into **CDC's Secure Access Management Services (**SAMS**)** which has been approved by the ISSO **to securely exchange electronic files containing confidential information**. Interviews can then be downloaded by the SAMS/Q-Video Administrator onto an encrypted flash drive and then transferred to the CCQDER LAN. The recordings will then be deleted from SAMS. Alternatively, interviewers can use their NCHS government issued encrypted flash drive to transfer the recordings from the interviewer's laptop to the CCQDER's secure LAN. The encrypted flash drive is FIPS 140-2 compliant and approved for use by OCISO.

CCQDER staff will also use the NCHS government issued encrypted laptops to input their interviewer notes into Q-Notes. Within 24 hours, a CCQDER staff member will review project specific interview notes and will delete any direct or indirect personal identifiable information (PII) if found.

Extreme care will be taken with all recordings and paperwork from the interviews conducted virtually. Recordings and identifying paperwork will be stored in a secured travel case until returned to NCHS, at which point they will be transferred to the usual secured locked storage cabinets. Once the video and audio recordings are transferred to the CCQDER Network, the recordings will be deleted from encrypted flash drive. Once deleted, the files are no longer available for use.

**Focus groups:** In focus group settings, participants are together and obviously can hear each other's comments, statements, and questions. Participants are told in their initial telephone screening interview that they will be participating in a discussion group with other volunteers.

Before the group discussion begins, participants sign the Informed Consent Form (Attachment D Template 3) which is tailored to specify that they will be participating in a focus group. The Informed Consent also states that they will be asked to pick a name and put it on a name tag, and that they do not have to use their real name. It is the responsibility of the interviewer (usually referred to as a moderator when conducting a focus group) to instruct the group that the information discussed will be held confidential by NCHS staff and should be treated confidentially by all respondents. Participants are strongly urged to respect the privacy of the other respondents and not to discuss with others what was discussed by the group.

**Contractor conducted interviews:** On the rare occasion when contractors (designated agents) are used to collect data as part of CCQDER projects, they are contractually bound by NCHS confidentiality provisions and must submit documentation concerning their safeguarding practices to NCHS prior to data collection. The documentation is reviewed by the NCHS Confidentiality Officer and the NCHS Information Systems Security Officer. This is standard NCHS practice and does not reflect a special CCQDER procedure. If recordings are to be shared with the contractor, a contract as well as a Designated Agent Agreement will be developed. The contractor employee will view the NCHS confidentiality training (https://www.cdc.gov/nchs/training/confidentiality/training/), submit a certificate of completion and sign the NCHS non-disclosure statement (see Attachment C) before starting work on the project.

**Field Tests/Pilot Interviews:** For field test/pilot interviews of household and telephone respondents, standard operating procedures regarding informed consent and survey administration procedures specific to the survey being tested will be followed.

Most of the questionnaires currently proposed for study generally do not contain questions that are highly sensitive in nature. National Health Interview Survey (NHIS) (OMB No. 0920-0214, Exp. Date 12/31/2026) questions on income and National Health and Nutrition Examination Survey (NHANES) OMB No. 0920-0950, Exp. Date 1/31/2028) questions on sexual behavior. Again, one purpose of pre-testing such questions is to determine means for fashioning these questions in such a way that sensitivity is minimized, and responses are valid.

**12. Estimates of Annualized Burden hours and costs:**

**A.** An average of 55,900 respondents participate in CCQDER activities in a given year, and the average annual respondent burden is estimated to be 14,100 hours. Annualized estimates of respondent burden for each of the questionnaire development studies, over the course of data collection, are provided below. For most questionnaire development studies, it is anticipated that interviews will last one hour. In some questionnaire development studies, questionnaire administration is anticipated to frequently require less than an hour of a respondent's time (e.g., a 15-minute interview), and in rare cases, the burden may exceed 1 hour. Because the hours per response in questionnaire development studies are expected to vary, we will select the final sample size for each project in such a way that the total burden hours do not exceed the estimate listed above. For focus groups, the usual time is 90 minutes (1.5 hours), including instructions and ancillary paperwork.

For interviews in the laboratory, time required to travel to the lab is not covered, because distances and modes of transportation are unknown. No retrieval of information by respondents is anticipated; however, at some point, validation of data may require respondents to check records, likely those kept at home. In that case, the study will be designed so that the response time includes record retrieval. All estimates are based on NCHS' experience (1988 through 2022).

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Estimated Annualized Burden Table

| Types of Respondents | Form Name | Number of Respondents | Number of Responses per Respondent | Average hours per response (in hours) | Total Burden Hours |
|---|---|---|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| Individuals or households | Eligibility Screeners | 6,000 | 1 | 5/60 | 500 |
| Individuals or households | Developmental Questionnaires | 1,000 | 1 | 55/60 | 917 |
| Individuals or households | Respondent Data Collection Sheet (Attachment I) | 1,000 | 1 | 5/60 | 83 |
| Individuals or households | Focus Group Respondents | 100 | 1 | 1.5 | 150 |
| Individuals or households | RANDS (Methodological Survey) | 49,800 | 1 | 15/60 | 12,450 |
| Total | | | | | 14,100 |

Estimated Annualized Burden Costs to Respondents.

The average annual response burden cost for the CCQDER is estimated to be $517,047. The hourly wage estimate is based on the Bureau of Labor Statistics May 2025 National Occupational Employment and Wage Estimates (http://www.bls.gov/oes/current/oes_nat.htm). There is no cost to respondents other than their time to participate.

| Type of Respondent | Form Name | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|---|---|---|---|---|
| Individuals or households | Eligibility Screeners | 500 | $36.67 | $18,335 |

| | | | | |
|---|---|---|---|---|
| Individuals or households | Developmental Questionnaires | 917 | $36.67 | $33,626.39 |
| Individuals or households | Respondent Data Collection Sheet (Attachment I) | 83 | $36.67 | $3,043.61 |
| Individuals or households | Focus Group Documents | 150 | $36.67 | $5,500.50 |
| Individuals or households | RANDS (Methodological Survey) | 12,450 | $36.67 | $456,541.5 |
| Total | | | | $517,047 |

**13. Estimates of Other Total Annual Cost Burden to Respondents and Record keepers**

There is no annual capital or maintenance costs to the respondent resulting from this collection of information.

**14. Annualized Costs to the Federal Government**

The cost to the government consists mainly of the salaries of the CCQDER staff that will (1) assist the questionnaire designers in the design of appropriate laboratory instruments, (2) recruit, schedule, and assist in interviewing volunteer respondents, and (3) assist in the analysis of the results and recommend changes in questionnaire wording.

Total annualized project costs are as follows:

NCHS costs for CCQDER staff to plan, conduct, and analyze the outcomes of the questionnaire development activities:

| | | |
|---|---|---|
| Staffing | 11.0 FTEs | $1,897,625.00 |
| Incentives for CCQDER | 1000 cognitive interviews @ $50 and 100 focus | $60,000 |

| | | |
|---|---|---|
| respondents | group respondents @ $100. (Pilot Household and web panel tests do not include incentives) | |
| Contract Staff (CCQDER Support) | | $925,250.00 |
| Materials | | $500 |
| Flyers | | $200 |
| Advertisements | | $24,750 |
| Hardware and Software Upgrades | | $50,000 |
| **Annual Total** | | **$2,958,325** |

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

This generic clearance requests 14,100 annualized burden hours, totaling 42,300 burden hours over a three-year period. No substantive changes have been made since the previous submission, other than a reduction of 7,805 burden hours. The decrease reflects a lower projected number of focus groups and individual or household respondents.

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

This clearance request is for questionnaire development activities to be conducted prior to survey production and for developmental work that will guide future questionnaire design. Most laboratory investigations will be analyzed qualitatively. The survey designers and lab staff serve as interviewers and use detailed notes and transcriptions from the in-depth cognitive interviews to conduct analyses. Final reports will be written that document how the question performed in the interviews, including question problems as well as the phenomena captured by the survey question. All reports will be placed on Q-Bank for public access. Reports are used to provide necessary information to guide designs for redesigning a question prior to fielding as well as to assist end users when analyzing the survey data. For field tests/pilot interviewing activities, qualitative and quantitative analysis will be performed on samples of observational data from household interviews to determine where additional problems occur. Because NCHS is using state-of-the-art questionnaire development techniques, methodological papers will be written which may include descriptions of response problems, recall strategies used, and quantitative

analysis of frequency counts of several classes of problems that are uncovered through the cognitive interview and observation techniques. Each individually submitted information collection will include a project time schedule specific to that project.

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

The expiration date will be displayed.

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

The certifications are included in this submission.