

Supporting Statement A for Request for Clearance:
**COLLABORATING CENTER FOR QUESTIONNAIRE
DESIGN AND EVALUATION RESEARCH**

RANDS 10 and Accompanying Cognitive Interviews

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A. JUSTIFICATION

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

The NCHS Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) conducts qualitative and mixed method research. CCQDER data collection is authorized under a generic OMB clearance (OMB No. 0920-0222, Exp. Date 01/31/2026) and 42 U.S.C. 242k (Section 306 of the Public Health Service Act).

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

The staff of the National Center for Health Statistics' (NCHS) Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) in the Division of Research and Methodology (DRM) is requesting approval to evaluate several general health-related topics as part of NCHS' Research and Development Survey (RANDS) Program, in collaboration with National Center for Complementary and Integrative Health (NCCIH) at the National Institutes of Health (NIH). This will be a mixed-method evaluation using both cognitive interviews and a multi-mode survey using a commercial survey panel. As with most of the previous rounds of RANDS that have been approved in the past, the survey content for this round will be related to health and will generally mirror content found on the National Health Interview Survey (NHIS), the National Health and Nutrition Examination Survey (NHANES), the Household Pulse Survey, and the Behavioral Risk Factor Surveillance System (BRFSS). The overall goals of this round of

RANDS will be to evaluate potential questions for NCHS surveys and to continue to develop NCHS' statistical and weighting approaches to using commercial survey panel data. The methodological survey will follow the same protocols approved for previous rounds of CCQDER RANDS projects and will use NORC's AmeriSpeak Panel as its sample source. As is typical for RANDS projects, the data will be used by NCHS for methodological purposes only, and public data files will be released along with extensive documentation about the limitations of the data.¹

In addition to the RANDS survey, this proposal also requests approval to conduct accompanying cognitive interviews, allowing CCQDER to evaluate the response processes underlying the RANDS10 questionnaire items and to develop embedded evaluation techniques (such as close-ended probes or experimental designs) as necessary. The cognitive interviewing study will follow CCQDER's typical protocol, using both virtual interviews and in-person cognitive interviews.

We propose to start recruiting participants for cognitive interviews and programming the survey instrument for the methodological survey as soon as we receive IRB and OMB clearance.

Proposed Project: RANDS and Accompanying Cognitive Interviews

As the nation's principal health statistics agency, NCHS is responsible for producing high-quality statistics on the health and wellbeing of the American public and the state of the country's health care system, as well as contributing to the development of survey methodologies that will allow the agency to continue producing these health statistics in the future. As OMB has previously approved in prior RANDS submissions, NCHS uses commercially available, pre-existing survey panels to supplement its ongoing examinations of measurement error and estimation techniques. This methodological survey system—NCHS' RANDS—has allowed the Center to conduct meaningful subgroup analyses of survey response patterns, explore patterns of survey item interpretation and potential reporting errors at a population level, and provides an opportunity to explore how estimates from commercial survey panels might be used in the future to supplement NCHS' official statistics information collections and survey systems. To date, nine separate rounds of RANDS have been conducted.²

The questions we plan to study in the proposed cognitive interviews are included as Attachment 1a. The questionnaire proposed for RANDS10 is in Attachment 1b. In addition to the inclusion of the standard RANDS variables that allow NCHS to calibrate RANDS to the NHIS, this questionnaire covers other topics that will help NCHS and NCCIH advance its methodological research, including:

¹ <https://www.cdc.gov/nchs/rands/data.htm>

² <https://www.cdc.gov/nchs/rands>

Whole Person Health: The NCCIH asked NCHS to consider adding items to the NHIS that could be used to capture the concept of ‘whole person health.’³⁴⁵⁶⁷ As opposed to considering specific conditions or diseases, ‘whole person health’ is a holistic approach that considers multiple factors affecting a person’s health and well-being, and focuses on restoring health, promoting resilience, and preventing diseases across a lifespan. Nine items constituting whole person health are in consideration for the NHIS and relate to: self-rated health, quality of life, social and family connections, diet, physical activity, stress management, sleep, spirituality, and management of health concerns. Questions pertaining to overall self-rated health, quality of life, and diet are well-established and come from the NHIS and NHANES. The other 6 items are newly adapted single items taken from existing scales (social and family connections, physical activity, stress management, sleep, spirituality, and management of health concerns).

For this study, cognitive interviews will first be conducted to examine the performance of the proposed items. During the interviewing process, wording changes may be made if deemed appropriate to reduce error or respondent confusion. Analysis of interviews will indicate the phenomena (or interpretive patterns) considered by respondents when formulating answers and will provide the basis for construct probes to be embedded in the RANDS10 questionnaire. RANDS10 data will indicate the extent that various patterns exist and the comparability across demographic groups. In addition to the follow-up probe questions, well-established, pre-existing scales items will be included to assess the validity of the single item measures.

Discrimination: NCHS is continuing its work evaluating existing discrimination scales, specifically, the Everyday Discrimination Scale and the Heightened Vigilance Scale. This builds on previously approved studies (for both RANDS and cognitive interviewing) that were conducted in 2022 to inform decisions for including such measures on the NHIS. The analytic purpose of this study is to collect more in-depth data detailing the ways in which respondents experience and interpret specific episodes of discrimination. This will allow us to understand respondents’ perceptions of discrimination more fully as they are shaped by intersectionality, the phenomena (or interpretive patterns) considered by respondents when formulating answers and, ultimately, the validity of the measures. Findings from the cognitive interviews will inform development of construct and error probes to be embedded in the RANDS10 questionnaire. This quantitative data will provide insight into the extent that error and/or construct patterns exist within the discrimination data as well as measurement invariance across demographic groups.

Novel Calibration Variables: To this point, DRM has found success calibrating RANDS data to the NHIS using a combination of demographic and chronic condition variables.

³ <https://journals.sagepub.com/doi/full/10.1177/2164957X221079792>

⁴ <https://www.nccih.nih.gov/about/offices/od/director/past-messages/an-opportunity-to-weigh-in-and-advance-whole-person-research>

⁵ <https://www.nccih.nih.gov/about/offices/od/director/past-messages/zeroing-in-on-the-factors-that-determine-whole-person-health>

⁶ <https://www.nccih.nih.gov/about/offices/od/director/past-messages/including-spirituality-into-a-fuller-picture-of-research-on-whole-person-health>

⁷ <https://www.nccih.nih.gov/about/offices/od/director/past-messages/including-spirituality-into-a-fuller-picture-of-research-on-whole-person-health>

DRM and NCHS' Division of Health Interview Statistics have developed an expanded list of potential calibration variables. Specific items include questions about volunteerism, health care access, internet use, and functional disability. NCHS plans on using the proposed cognitive interviews and RANDS to continue its evaluation of these variables' response patterns and how the inclusion of these variables in its calibration approach affects estimation.

The previous use and development of these items is described in Attachment 2. NCHS understands that OMB approval for evaluation of these questions does not imply or guarantee future approval for use or application of these or similar items.

Cognitive Interviews

The methodological aim of this study is consistent with the design of most NCHS/CCQDER cognitive interviewing studies, that is, to understand the construct captured by each question, identify patterns of interpretation across respondent groups, and explore potential sources of response error. The testing procedure conforms to the cognitive interviewing techniques that have been described in CCQDER's generic clearance package (OMB No. 0920-0222, exp. 01/31/2026). Within that framework, the following procedures are particular to this study:

Recruitment. We propose to recruit up to 80 English-speaking, adult respondents. In addition to those criteria, demographic diversity and intersectionality is also a priority, with the goal of achieving a purposive sample that includes a mix of genders, age, race, and educational attainment. Recruitment will be carried out through a combination of advertisements, flyers, word-of-mouth, and the CCQDER Respondent Database. The advertisement/flyer used to recruit respondents is shown in Attachment 3.

Screening. Respondent screening will conform to the protocol laid out in CCQDER's generic package. The 5-minute screener used to determine eligibility of individuals responding to the advertisements/flyers is shown in Attachments 4a & 4b. It is anticipated that as many as 120 individuals may need to be screened to recruit 80 participants.

Interview methods. Cognitive interviews will be conducted by CCQDER staff and RSS contractors in accordance with the protocol described in CCQDER's generic package. The informed consent documents specific to this project are included as Attachments 5a and 5b.

RANDS 10

As with previous rounds of RANDS, DRM proposes that RANDS 10 function as a methodological study to provide a testbed for NCHS' estimation and question evaluation research. The design of RANDS 10 will conform to the survey techniques that have been described in CCQDER's generic clearance package (OMB No. 0920-0222, exp. 01/31/2026). Within that framework, the following procedures are particular to this study:

Sample. This round of RANDS will be administered by NORC at the University of Chicago (NORC) across both web and phone modes, according to panelist preference

(approximately 10% of the AmeriSpeak panelists are “phone-only” respondents who only take surveys via a phone interviewer). We are requesting approval to obtain 6,600 complete responses from the AmeriSpeak panel, including 6,000 web responses and 600 phone responses for one round of data collection. Previous rounds of RANDS that have used both phone and web AmeriSpeak panel respondents have obtained sample completion rates averaging 72.5%.

Survey Administration. The proposed RANDS10 will be conducted as soon as IRB and OMB clearances are granted. For one round, NORC anticipates a field period of approximately 1 month. As with previous rounds, the RANDS 10 survey will begin with an introduction screen (or introduction text for telephone respondents) like what is seen at the beginning of Attachment 1b, explaining the general purpose of the survey and providing the consent, confidentiality, and Paperwork Reduction Act language. As signed consent is not possible for internet surveys where the population of respondents is anonymous to NCHS, as in a commercial panel, a waiver of signed consent from the CDC IRB will be obtained (as has been the case in all previous rounds of RANDS). The introduction page will require the respondent to manually click through to the first page of questions (or agree to continue and not hang up for telephone respondents); this action therefore implies consent. As with all previously approved rounds of RANDS that used NORC’s AmeriSpeak panel, NCHS will not provide an incentive to panelists participating in RANDS, though NORC does provide non-cash incentives in the form of “AmeriPoints” that panelists can accumulate and exchange for items such as gift cards. The full RANDS 10 survey is expected to take 20 minutes to complete.

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

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) 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."

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)."

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) 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 are 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 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. Specific protocol for storage of confidential data, QDRL Lab, Q-video, Q-Notes, and Q-Bank access is described in CCQDER's generic clearance package. (OMB No. 0920-0222, exp. 01/31/2026)

Records Retention Schedule for Cognitive Interviews

Storage and retention of CCQDER data is guided by the CCQDER Data Storage and Access Policy which governs retention of interviews, their viewing audience, the data kept, and the length of time before retention of interviews is reassessed. The Data Storage and Access Policy has been approved by the NCHS ERB and is included in CCQDER's generic OMB package. In accordance with this policy, data from the current project will be re-evaluated by the CCQDER Director to determine relevance, ongoing usefulness and qualitative value for likely use in question evaluation research after an initial retention period of 5 years (see data retention policy). The information of individuals who did not qualify for the study and opt into our respondent database will be kept for 5 years. Removal from our database can be requested by emailing recruitmentteam@cdc.gov.

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

NCHS and CDC Institutional Review Board (IRB) approved this data collection on 01/08/2024.

12. Estimates of Annualized Burden hours and costs

In January 2023, OMB approved 71,925 total number of respondents and 21,450 total burden hours. For this GenIC NCHS is requesting 6,720 respondents and 2,290 burden hours.

Burden table for RANDS 10 and Accompanying Cognitive Interviews:

Form Name	Number of Participants	Number of Responses/Participants	Average hours per	Response Burden (in
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			response	hours)
Screener (all recruitment methods as described above (Attachment 4)	120	1	5/60	10
Questionnaire	80	1	55/60	73
Respondent Data Collection Sheets	80	1	5/60	7
Methodological Survey	6,600	1	20/60	2,200
Total				2,290