

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

Questions on Subjective Cognitive Decline

OMB No. 0920-0222
Expiration Date: 01/31/2026

Contact Information:

Amanda Titus
Behavioral Scientist, Collaborating Center for Questionnaire Design and
Evaluation Research
Division of Research and Methodology
National Center for Health Statistics/CDC
3311 Toledo Road, Room 5451
Hyattsville, MD 20782
301-458-4579
atitus@cdc.gov

7/8/2024

Table of Contents

A. Justification

A.1.	Circumstance Making the Collection of Information Necessary.....	1
A.2.	Purpose and Use of Information Collection.....	1
A.9.	Explanation of Any Payment of Gift to Respondents.....	2
A.10.	Protection of the Privacy and Confidentiality of Information Provided by Respondents.....	2
A.11.	Institutional Review Board (IRB) and Justification for Sensitive Questions.....	3
A.12.	Estimates of Annualized Burden Hours and Costs.....	4

LIST OF ATTACHMENTS

Attachment 1: Questions

Attachment 2: Purpose and Development of Questions

Attachment 3ab: Suspected & Diagnosed Cog Decline Advertisement

Attachment 4: Screening Script

Attachment 5ab: In Person & Virtual Informed Consent Forms

Attachment 6ab: In Person & Virtual Respondent Data Collection Sheet

Attachment 7: Thank You Letter

Attachment 8: Data Retention Policy

Attachment 9: NCHS Non-Disclosure Affidavit

Attachment 10: Distress Guide

Attachment 11: Research Approval Letter

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**

CCQDER conducts exploratory question evaluation studies, for both applied and methodological purposes, with particular focus on question design, measurement, comparability, and response error.

The purpose of the current project is to evaluate the construct validity of questions on self-assessed cognitive decline focusing on thinking, memory, and other daily activities in

collaboration with the National Center for Chronic Disease Prevention & Health Promotion.¹ Questions will be tested with up to 30 English speaking respondents. The questions to be tested in English are included as Attachment 1. 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. Information about the purpose and use of the questions is included as Attachment 2. 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 30 respondents aged 18 or over who believe that they have experienced difficulties with thinking or memory over the past 12 months, including those with differing levels of severity and a few who have not experienced such difficulties, in order to be able to provide a more thorough evaluation of the questions. 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/ethnicity, and educational attainment. Recruitment will be carried out through a combination of advertisements, flyers, social media, word-of-mouth, and the CCQDER Respondent Database. The advertisement/flyer used to recruit respondents is shown in Attachments 3a and 3b.

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 Attachment 4. It is anticipated that as many as 60 individuals may need to be screened to recruit 30 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.

9. Explanation of Any Payment or Gift to Respondents

For this project respondents will be given the standard remuneration of \$50 approved by OMB on January 31, 2023, for CCQDER Generic data collection. For virtual interviews, respondents will be emailed the activation code and link for an \$50 electronic gift card or (if cash is used) sent \$50 in cash via FedEx within 7 business days for remuneration. For in person interviews, respondents will be given \$50 in cash at the end of the interview.

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

Data will be kept private to the extent allowed by law.

¹ [Chronic Disease Center \(NCCDPHP\) | CDC](#)

The CCQDER continues to collect, on a confidential basis, data needed in order to conduct CCQDER studies. 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.”

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 2 years. The information of individuals who did not qualify for the study and opt into our respondent database will be kept

for 2 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 07/08/2024.

12. Estimates of Annualized Burden hours and costs

In January 2023, OMB approved 71,925 total number of respondents and 21,905 total burden hours. This GenIC NCHS is requesting 60 respondents and 35 burden hours.

Table 2: Burden table for Cognitive Decline:

Form Name	Number of Participants	Number of Responses/Participants	Average hours per response	Response Burden (in hours)
Screener (all recruitment methods as described above (Attachment 4)	60	1	5/60	5
Questionnaire	30	1	55/60	27.5
Respondent Data Collection Sheets	30	1	5/60	2.5
Total	60			35