

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

**Caregiving**

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](mailto:atitus@cdc.gov)

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## Table of Contents

### A. Justification

|       |   |    |
|-------|---|----|
| A.1.  | Circumstance Making the Collection of Information Necessary.....                                      | 3  |
| A.2.  | Purpose and Use of Information Collection.....  | 4  |
| A.3.  | Use of Improved Information Technology and Burden Reduction.....                                      | 4  |
| A.4.  | Efforts to Identify Duplication and Use of Similar Information.....                                   | 5  |
| A.5.  | Impact on Small Businesses or Other Small Entities.....   | 5  |
| A.6.  | Consequences of Collecting the Information Less Frequently.....                                       | 5  |
| A.7.  | Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....                                 | 5  |
| A.8.  | Comments in Response to the Federal Register Notice and<br>Efforts to Consult Outside the Agency..... | 6  |
| A.9.  | Explanation of Any Payment or Gift to Respondents.....  | 6  |
| A.10. | Protection of the Privacy and Confidentiality of Information Provided<br>by Respondents.....          | 8  |
| A.11. | Institutional Review Board (IRB) and Justification for Sensitive Questions.....                       | 11 |
| A.12. | Estimates of Annualized Burden Hours and Costs.....   | 12 |
| A.13. | Estimates of Other Total Annual Cost Burden to Respondents<br>or Record Keepers.....                  | 12 |
| A.14. | Annualized Cost to the Federal Government.....  | 12 |
| A.15. | Explanation for Program Changes or Adjustments.....   | 12 |
| A.16. | Plans for Tabulation and Publication and Project Time Schedule.....                                   | 12 |
| A.17. | Reason(s) Display of OMB Expiration Date in Inappropriate.....  | 12 |
| A.18. | Exceptions to Certification for Paperwork Reduction Act Submissions.....                              | 12 |

### LIST OF ATTACHMENTS

- Attachment 1: Questions
- Attachment 2: Caregiving Advertisement
- Attachment 3: Caregiving Script
- Attachment 4a-4b: Caregiving Informed Consent
- Attachment 5: Respondent Data Collection Sheet
- Attachment 6: Thank You Letter
- Attachment 7: Data Retention Policy
- Attachment 8: Nondisclosure Affidavit

## Supporting Statement A

### Collaborating Center for Questionnaire Design and Evaluation Research

The staff of the National Center for Health Statistics (NCHS), Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) (OMB No. 0920-0222, exp. 01/31/2026) proposes to conduct a cognitive interviewing study to evaluate questions on caregiving. Recruitment of respondents and interviewing would begin as soon as approval is received.

#### A. JUSTIFICATION

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

The caregiving questions to be evaluated were derived from several sources. Some came from the most recent version of Behavioral Risk Factor Surveillance System (BRFSS) Caregiver Optional Module and from an expert work group tasked by CDC's Alzheimer Disease Team with proposed revisions and improvements to the module (Questions 1, 4, 5, 6, 7, 8, 9, 10, 13 and 14)<sup>1</sup>. Other questions were originally developed by subject matter experts on the CDC's Alzheimer's Disease Team (Questions 2, 3, 11, 12, 15, 16, 17, 20 and 21)<sup>2</sup>. A single question was derived from the National Health and Aging Trends Study (NHATS) (Question 19). While there has been some cognitive testing of questions related to caregiving, this module has not undergone previous cognitive testing. The questions to be tested are included as Attachment 1.

##### **The sources of the caregiving questions are as follows:**

##### **i) Behavioral Risk Factor Surveillance System (BRFSS) Caregiver Module**

These questions are derived from the most recent version of the Behavioral Risk Factor Surveillance System Caregiver Optional Module<sup>3</sup> and from an expert work group tasked by CDC's Alzheimer Disease Team with proposing revisions and improvements to the module. The first version of the BRFSS Caregiver Optional Module was developed in 2005 to estimate the prevalence and burden of informal caregiving across U.S. states and territories. The module was pilot tested and subsequently cognitively tested and implemented as a BRFSS optional module in 2009. The module has undergone several iterations and rounds of cognitive testing<sup>4</sup>. In Spring 2022, CDC convened an expert panel comprised of BRFSS state coordinators and data users, caregiving subject matter experts, methodology experts,

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<sup>1</sup> [Caregiver Module | BRFSS FAQs | Healthy Brain Initiative | Surveillance | Alzheimer's Disease and Healthy Aging | CDC](#)

<sup>2</sup> [BRFSS Statistical Brief: Caregiver Optional Module \(cdc.gov\)](#)

<sup>3</sup> [Caregiver Module | BRFSS FAQs | Healthy Brain Initiative | Surveillance | Alzheimer's Disease and Healthy Aging | CDC](#)

<sup>4</sup> [BRFSS Statistical Brief: Caregiver Optional Module \(cdc.gov\)](#)

and relevant non-profit stakeholders to consider the ongoing usefulness of the module, existing gaps, and framing and language of the questions. Through 4 extensive work group sessions and intersession assignments, the group came to a consensus around a proposed a revised set of questions. The revised set of questions has not yet undergone cognitive testing and a subset of these proposed questions is expected to be fielded after 2023. The questions intended to be included for NHANES cognitive testing mirror those proposed by the expert workgroup and prioritized by CDC. Relevant questions: 1, 4, 5, 6, 7, 8, 9, 10, 13, 14

**ii) Consumer Styles survey**

These questions were initially developed by subject matter experts on the CDC’s Alzheimer’s Disease Team. Input and review were also obtained from key stakeholders, including national partner organizations and external experts. These questions are being fielded on various Styles surveys implemented by Porter Novelli during 2022-2023. In addition to these questions, the Styles surveys will also include the BRFSS Caregiver module questions as outlined above. Note that Styles surveys allow more flexible question formats (e.g., “select all that apply”, Likert scales etc.). The Styles survey caregiver questions that used these formats have been modified below to align with formats used in federal survey questionnaires (e.g., multiple choice, yes/no). Relevant questions: 3, 11, 12, 16, 17 (format revised), 18 (format revised), 20 (format revised), 21 (format revised)

**iii) National Health and Aging Trends Study (NHATS)**

One proposed question was derived from the NHATS. Begun in 2011, the NHATS gathers information on a nationally representative sample of Medicare beneficiaries ages 65 and older. It is conducted through annual, in-person interviews. Relevant question: 19

**iv) New questions**

Two proposed questions were newly developed by the CDC’s Alzheimer’s Disease Team based on subject matter expertise and known challenges with existing survey questions. Relevant question: 2, 15

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

NCHS’ 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 is for the:

Development and testing of specific survey items on Caregiving for the National Center for Chronic Disease Prevention and Health Promotion.

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

Cognitive interviews for this project will be conducted in-person or virtually using ZOOM video conferencing software. CCQDER continues to maintain and use Q-Bank, a publicly accessible

searchable data base question-evaluation studies, to determine if a survey question has been previously studied. The regular use of Q-Bank reduces unnecessary testing as well as allows CCQDER to build upon existing knowledge learned from past testing projects. Furthermore, each cognitive interview is digitally recorded and stored on an internal, searchable video database. Like Q-Bank, 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.

In order to identify duplication across federal agencies, CCQDER hosts a publicly accessible online searchable database, Q-Bank, that contains all CCQDER evaluation reports. CCQDER encourages all agencies to submit their evaluation reports so that it is possible to track the work done across agencies as well as to build in existing knowledge.

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

This data collection does not impact small business or other small entities.

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

This is a one-time data collection activity.

#### **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 the CCQDER Generic data collection was published on September 30, 2022 (Vol. 87, No. 189, p. 59425). No additional comment period is required for GENICs submitted under this generic.

##### **Consultants:**

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

John D. Omura, MD, MPH (he/him)

Medical Officer

Alzheimer's Disease Team

Healthy Aging Branch | Division of Population Health

National Center for Chronic Disease Prevention and Health Promotion

Centers for Disease Control and Prevention

Phone: 770.488.6339 | Email: ydk8@cdc.gov

## **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 for an \$50 electronic gift card as remuneration. For in-person interviews, respondent will be sent \$50 in cash via FedEx within 7 business days.

## **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; see Attachment 8) 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 8) 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**

The NCHS CCQDER Data Storage and Access policy (Attachment 7) governs retention of interviews, their viewing audience, the data kept, and the length of time before retention of interviews is reassessed. The data retention period for recordings of interviews that do not have consent for future use is until the completion of the project (upon completion of a final product or final sponsor briefing). Upon project completion, these non-retained recordings will be destroyed by designated CCQDER staff.

If a respondent requests that their recording be destroyed at the end of the project (virtual), the recording will be destroyed at the end of the project which is defined as when a report has been cleared by NCHS and submitted to Q-Bank. If the respondent gives future consent, after the initial retention period, the recordings will be re-evaluated by the CCQDER Director to determine relevance, ongoing usefulness, and qualitative value for likely use in question evaluation research. If it is determined by the CCQDER Director in conjunction with CCQDER project-relevant staff that there is no valid reason to retain the recording, it will be destroyed by designated CCQDER staff. If the 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 2 years.

#### *After the interview:*

The recruiter will send the respondent a “thank you” email, informing them that they will receive a hard copy “thank you” letter (Attachment 6) and their remuneration amount (\$50) in cash via FedEx within 7 business days. If electronic gift cards are used for remuneration, the respondent will be emailed the activation code for the gift card and an electronic copy of the “thank you” letter (Attachment 6).

#### *Deletion of information:*

Once the interview and follow-up call (if conducted) are complete and the remuneration has been sent, all email, phone call and calendar records for the respondent will be deleted.

#### *Interview Notes:*

CCQDER staff and RSS contractors 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 interview notes and will delete any direct or indirect personal identifiable information (PII) if found.

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

NCHS Ethics Review Board (ERB) and CDC Human Research Protection Office (HRPO) approved this data collection on 04/26/2023.

### **Informed Consent and Voluntary Nature**

**CCQDER respondents/interviews conducted at NCHS**

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. Data collection for this project is authorized under 42 U.S.C. 242k (Section 306 of the Public Health Service Act).

During the telephone screener (Attachment 3), 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 4a-4b, Informed Consent Form (written at an 8<sup>th</sup> 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 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. Cognitive interviews deemed to be about illegal behaviors will not be video recorded, only audio recorded. Respondents are given a copy of the consent form, which contains contact information for the CCQDER Laboratory Manager, the NCHS Research Ethics Review Board (ERB), and the NCHS Confidentiality Officer.

**CCQDER respondents/interviews conducted off-site**<sup>5</sup>: 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 or the Special Consent for Expanded Use of Video and Audio Recordings. Materials 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 3), potential respondents are informed that answering the telephone screener questions to determine their eligibility for the study is completely

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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.

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 4a-4b. 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 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 6), their incentive, and a copy of the informed consent document (Attachment 4a-4b), 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. Due to the size of the video recordings, the internal drive of the encrypted laptop is not sufficient for storage of the recordings. Recordings will be saved to an NCHS government issued encrypted flash drive. 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.

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 QDRL Network, the recordings will be deleted from encrypted flash drive. Once deleted, the files are no longer available for use.

### **Contractor conducted interviews**

Sometimes 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 8) before starting work on the project.

**12. Estimates of Annualized Burden hours and costs (Table 1 was OMB approved on January 31, 2023 for CCQDER Generic data collection.)**

Table 1: Estimated Annualized Burden Table: (Approved hours under OMB. No. 0920-0222)

| <b>Types of Respondents</b> | <b>Form Name</b>                 | <b>Number of Respondents</b> | <b>Number of Responses per Respondent</b> | <b>Average hours per response (in hours)</b> | <b>Total Burden Hours</b> |
|-----------------------------|----------------------------------|------------------------------|---|--|---------------------------|
| Individuals or households   | Eligibility Screeners            | 4,400                        | 1   | 5/60   | 367                       |
| Individuals or households   | Developmental Questionnaires     | 8,750                        | 1   | 55/60  | 8,021                     |
| Individuals or households   | Respondent Data Collection Sheet | 8,750                        | 1   | 5/60   | 729                       |
| <b>Total</b>                |                                  | <b>9,190</b>                 |   |  | <b>9,117</b>              |

Table 2: Burden table for the Caregiver Project:

| <b>Form Name</b>  | <b>Number of Participants</b> | <b>Number of Responses/Participants</b> | <b>Average hours per response</b> | <b>Response Burden (in hours)</b> |
|---|-------------------------------|---|-----------------------------------|-----------------------------------|
| Screeners (all recruitment methods as described above (Attachment 3)) | 45                            | 1                                       | 5/60                              | 4                                 |
| Questionnaire   | 30                            | 1                                       | 55/60                             | 28                                |
| Respondent Data Collection Sheets                                     | 30                            | 1                                       | 5/60                              | 3                                 |
| <b>Total</b>  |                               |   |                                   | <b>35</b>                         |

**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 for the Caregiver Project is \$70,000. It consists mainly of the salaries of the CCQDER and contracted 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.

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

This is a generic IC. This one-time data collection will use 35 hours.

**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. The majority of 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 in order 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.

**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.