



May xx, 2019

Margo Schwab, Ph.D.  
Office of Management and Budget  
725 17th Street, N.W.  
Washington, DC 20503

Dear Dr. Schwab:

The staff of the NCHS Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) (OMB No. 0920-0222, exp. 08/31/2021) plans to conduct a cognitive interviewing study to evaluate National Health Interview Survey (NHIS) questions on adult behaviors, including walking, sleeping, smoking, CT scans, and X-rays of the chest area (OMB No. 0920-0214, Exp. Date 12/31/2020) and CCQDER questions on opioid painkillers. The ultimate goals are to evaluate new and revised questions on adult behaviors in preparation for the 2020 NHIS, and to validate questions on opioid painkillers as part of an ongoing CDC effort to develop a standardized battery of opioid questions.

Study Backgrounds and Purposes:

***NHIS Questions on Adult Behaviors***

The NHIS questions on Adult Behaviors are being tested in preparation for the upcoming 2020 NHIS. Rationales for testing and inclusion are detailed below:

1. Walking

A set of questions about frequency and duration of walking for transportation and leisure are proposed for the rotating core. Walking is a way to meet the recommended physical activity guidelines and is of particular interest to researchers specializing in cancer in the Centers for Disease Control and Prevention's (CDC) National Center for Chronic Disease Prevention and Health Promotion. The proposed questions would allow researchers to calculate the average weekly minutes of walking done by the sample adult. The first five questions were on the NHIS in 2005, 2010, and 2015, but have not been tested. The last two questions about frequency of walking in the sample adult's neighborhood and the type of housing in that neighborhood will be tested as part of a NHIS cancer supplement. This aims to look at the influence the environment has on frequency of walking.

## 2. Sleep

Insufficient sleep, defined as 7 hours of sleep or less, contributes to motor vehicle accidents and is associated with many health conditions including diabetes, cardiovascular disease, stroke, obesity, and depression. In the past, NHIS proposed questions about the average amount of sleep adults receive. The questions were sourced from Behavioral Risk Factor Surveillance System (BRFSS) with the response categories developed by the Division of Health Interview Statistics (DHIS). Previous cognitive testing of these questions showed that adults with variable sleep schedules often had a difficulty reporting exact amounts of time they slept in a given night. In this cognitive testing protocol, the question will have hour ranges that will provide adults with more flexibility in answering.

## 3. Smoking, CT Scans, and X-rays of Chest Area

As part of the cancer-screening supplement, researchers at the CDC's Division of Cancer Prevention and Control (DCPC) would like to examine rates of lung cancer screening for current and former smokers who do not have a history of lung cancer. Questions are proposed to assess knowledge of types of screening tests and determine if current or former smokers are getting recommended screenings by doctors or other health professionals. The questions are taken directly from the CDC's chronic disease indicators (CDI).

### ***CCQDER Question on Opioids***

In 2018, CCQDER tested questions from NHIS and National Survey on Drug Use and Health (NSDUH) questionnaires on opioid use, misuse, impairment, and disorder. As part of an ongoing CDC effort to develop a standardized battery of opioid questions, CCQDER developed a revised set of questions based on findings from the 2018 testing. This new set of questions was tested using cognitive interviews with 20 respondents in December 2018 and January 2019. The questions have been revised and require more testing.

#### Study Protocol:

The NHIS questions on adult behaviors and the CCQDER questions on opioid painkillers are included as Attachment 1. Interviewers will administer all questions to the participants. The testing procedure conforms to the cognitive interviewing techniques that have been described in CCQDER's generic OMB clearance package (OMB No. 0920-0222, Exp. Date 08/31/2021). Staff will adhere to a protocol designed for previous projects when screening, selecting, and acquiring informed consent for adults.

We propose to recruit at least 20 English-speaking adults (aged 18 and over). We will recruit individuals who range in their experiences with the following criteria: those who (1) walk to work or for exercise, (2) currently or previously smoked regularly, (3) have had a CT scan and/or x-ray of chest area, and (4) have taken prescription opioid painkillers in the last 12 months. Recruitment of individuals will be guided first by the criteria listed above. Participants may meet any number of the criteria, including no criteria, and there are no specific combinations of

criteria. Each of the criteria is aligned with a set of questions on the instrument. Also, because qualitative sampling is based on theoretical relevance more than equal cell sizes, on-going analysis may reveal the need to test specific sets of questions more than others. We will recruit up to 20 more English-speaking adults if on-going analysis suggests a need for additional testing.

Secondarily, we aim to recruit respondents with a roughly even mix of age, race, and educational attainment. The initial goal is to recruit groups in equal proportion, to the extent possible; that is, within the constraints of those willing to participate in the study. However, as explained above, qualitative sampling is based on theoretical relevance and on-going analysis may determine a need to recruit more from one group than others. The principal investigator and recruiters will determine if there is a need for more participants of particular age, race, or educational attainment after the first round of testing.

Recruitment will be carried out through a combination of a newspaper advertisement(s), flyers, word-of-mouth, and the CCQDER Respondent Database. The newspaper advertisements/flyers used to recruit respondents are shown in Attachments 2a and 2b. The 5-minute screener used to determine eligibility of individuals responding to the newspaper advertisements/flyers is shown in Attachment 3a. The 5-minute screener used to determine eligibility of individuals from the CCQDER Respondent Database is shown in Attachment 3b. Note that wording of the template has been approved and is contained within our umbrella package. Only project specific information has been added to the document. It is anticipated that as many as 80 individuals may need to be screened in order to recruit 40 participants. Within these constraints, we plan to recruit participants with some demographic variety (particularly in terms of gender, education, and race/ethnicity).

Interviews will be conducted by CCQDER staff members and researchers from Substance Abuse & Mental Health Services Administration (SAMHSA) with English-speaking respondents for up to 60 minutes per interview. Interviews will be conducted in the Questionnaire Design and Evaluation Research Laboratory (QDRL) as well as at off-site locations. SAMHSA researchers will not conduct interviews off-site. All interviews conducted in the QDRL and off-site will be video and audio recorded to allow researchers to review the behaviors and body language of the respondents. These recordings will allow researchers to ensure the quality of their interview notes. Recordings will only be used by researchers from CCQDER, SAMHSA, and DHIS who are working on the project. Recordings will remain under CCQDER staff control. There will be no external sharing of the recordings. SAMHSA researchers and DHIS staff will have read and signed a non-disclosure affidavit before viewing/listening to recordings in the QDRL under CCQDER supervision.

Video or audio recording is required for this project except in the rare case that a study participant initially agrees to be video recorded during the telephone screening, but changes their mind. In that case, they will be asked if they agree to be audio recorded. If they decline to be audio recorded the interview will proceed without recording. In this case the interviewer will depend on their handwritten notes when conducting analysis.

NCHS government issued encrypted laptops will be used to video and audio record the interviews conducted off-site. 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. Within 24 hours, a CCQDER staff member will review NHIS Questions on Adult Behaviors and CCQDER Questions on Opioids interview notes and will delete any direct or indirect personal identifiable information (PII) if found.

CCQDER staff and SAMHSA researchers will use the NCHS government issued encrypted laptops to input their interviewer notes into Q-Notes. SAMHSA interviewers will be assigned to CCQDER secured space, a CCQDER workstation, and NCHS encrypted laptop while they are onsite at NCHS conducting interviews and inputting their interviewer notes into Q-Notes. Interviewer notes in Q-Notes are only accessible to those individuals assigned to a particular project. Hence, SAMHSA researchers conducting interviews onsite at NCHS will be assigned to the Cognitive Testing of NHIS Questions on Adult Behaviors and CCQDER Questions on Opioids project within Q-Notes. Within 24 hours, a CCQDER staff member will review NHIS Questions on Adult Behaviors and CCQDER Questions on Opioids 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 off-site. 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.

After respondents have been briefed on the purpose of the study and the procedures that CCQDER routinely takes to protect human subjects, respondents will be asked to read and sign an Informed Consent document (Attachment 4). Only project specific information has been added to the document. Respondents will also be asked to fill in their demographic characteristics on the Respondent Data Collection Sheet (Attachment 5). This document is contained in our umbrella package. The burden for completion of this form is captured in the interview.

The interviewer will then ask the respondent to confirm that he/she understands the information in the Informed Consent, and then state that we would like to record the interview. The recorder will be turned on once it is clear that the procedures are understood and agreed upon.

The interviewer will then orient the respondent to the cognitive interview with the following introduction:

*[fill staff name] may have told you that we will be working on some questions that will eventually be added to national surveys. Before that happens, we like to test them out on a variety of people. Before that happens, we like to test them out on a variety of people. The questions we are testing today are about walking, sleeping, smoking, CT scans and x-rays of the chest area, and taking prescription opioid painkillers. We are interested in your answers, but also in how you go about making them. I may also ask you questions about the questions*

—whether they make sense, what you think about when you hear certain words, and so on.

*I will read each question to you, and I'd like you to answer as best you can. Please try to tell me what you are thinking as you figure out how to answer. Also, please tell me if:  
there are words you don't understand,  
the question doesn't make sense to you,  
you could interpret it more than one way,  
it seems out of order,  
or if the answer you are looking for is not provided.*

*The more you can tell us, the more useful it will be to us as we try to develop better questions. Okay? Do you have any questions before we start? If yes, answer questions. If not, let's get started.*

After the interview, respondents will be given the thank-you letter (document contained in umbrella package) signed by the Director of NCHS (Attachment 6), a copy of the informed consent document, and \$40.

After the interview, respondents will be asked to read the Special Consent for Expanded Use of Video and Audio Recordings (Attachment 7). There will be no coercion and the respondents will be told that they can call and reverse the decision at any time if they change their minds. If respondents do sign the special consent form they will be given a copy of it.

We propose giving respondents \$40 incentives, which is our standard incentive. In total, for this project, the maximum respondent burden will be 49 hours. A burden table for this project is shown below:

<b>Form Name</b>	<b>Number of Participants</b>	<b>Number of Responses per Participant</b>	<b>Average hours per response</b>	<b>Response Burden (in hours)</b>
Screener (recruited from newspaper/flyer)	40	1	5/60	4
Screener (recruited from CCQDER Respondent Database)	40	1	5/60	4
Questionnaire	40	1	55/60	37
Respondent Data Collection Sheets	40	1	5/60	4
Total				49

Attachments (7)

cc:

V. Buie  
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DHHS RCO