DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Road
Hyattsville, Maryland 20782

October 26, 2017

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. 07/31/2018) plans to conduct a cognitive interviewing study to examine questions on injury for the National Health Interview Survey (NHIS OMB No. 0920-0214, expires 1/31/2019).

We propose to start recruiting for volunteer participants as soon as we receive clearance and to start testing as soon as possible after that.

Background Information about Cognitive Testing of Questionnaires

The methodological design of this proposed study is consistent with the design of typical cognitive testing research. As you know, the purpose of cognitive testing is to obtain information about the processes people use to answer survey questions as well as to identify any potential problems in the questions. The analysis will be qualitative.

Proposed project: Cognitive testing of injury questions for the National Health Interview Survey

Since 1997, the National Health Interview Survey has collected data on all medically attended injuries and poisonings occurring to any family member during the 3-month period prior to the interview. Information about the cause of the injury or poisoning episode, activity the person was doing at the time of the injury or poisoning episode, the place of occurrence, whether the person was hospitalized, whether the person missed any days from work or school due to the injury or poisoning, and whether the injury or poisoning episode caused any limitation of activity. There is also narrative text taken verbatim from the respondent describing how the person was injured or poisoned from which ICD-9-CM diagnostic codes and ICD-9-CM external cause codes are created. The current injury data from the NHIS are released as part of an injury episode based file. Data users must currently summarize and merge the episodic injury information onto the NHIS data files for analysis. This can be a difficult task for many data users.

The NHIS is currently in the process of being redesigned and will be fielding a new injury module that would rotate in the NHIS every two out of three years beginning in 2020. One of the main objectives of this new injury module is to create a person-based measure of injuries that will be easier for data users to work with and still provide meaningful information on injuries in the U.S. population.

The National Center for Health Statistics (NCHS) has undertaken several steps to begin developing the new injury module. NCHS consulted with the Bureau of Labor Statistics (BLS) regarding their 2016 testing of the Household Survey of Injuries and Illnesses. Discussions with BLS highlighted the importance of separating repetitive strain type injuries from more acute injuries. We also reviewed surveys around the world that include injury questions. Finally, NCHS conducted three expert panels that included experts from universities and government agencies including the National Institute for Occupational Safety and Health (NIOSH) and the National Center for Injury Prevention and Control (NCIPC) who have either used the existing NHIS injury files or have an interest in conducting analyses of injury data from the NHIS in the future. The panels discussed several injury related topics. One of the key issues that was raised during the expert panels was the nature of the injuries that are captured with an injury module. One view expressed by many experts in the panel was that the NHIS is an important data source for capturing information about injuries that do not lead to visits to an emergency department visit since there are other data sources that capture visits to the emergency department. At the same time, it is important for the NHIS to capture injuries with a certain degree of severity that may lead to a limitation in a person's activities such as needing medical attention or losing a day of work or school.

The main goal for this current round of cognitive testing is to understand the nature of the injuries produced by two different versions of injury screening questions. Half of our respondents will receive one version of the injury questions and half of them will receive the other version of the questionnaire. Respondents will be assigned at random by recruiters into one of the two groups. In one version, we ask "DURING THE PAST 3 MONTHS, did you have an accident or an injury where any part of your body was hurt?" This version only makes reference to accidents or injuries without providing any examples of accidents or injuries. In the second version, we ask "DURING THE PAST 3 MONTHS, did you have a broken bone, sprain, burn, wound, cut, bruise, concussion, animal bite, or any other type of injury?" This version relies on providing examples to help clarify the nature of the injuries that we are capturing. One set of follow-up questions will be used as retrieval cues to prompt respondents about different mechanisms, activities, or locations of injuries that may help a respondent remember an injury that occurred. Another set of follow-up questions will help to determine the seriousness of the injuries by asking about limitations caused by the injuries. A secondary objective for this round of cognitive testing is to understand the extent to which respondents with repetitive strain injuries can separate those injuries from acute injuries.

The injury questions we are evaluating are included as Attachment 1. The testing procedure conforms to the cognitive interviewing techniques that have been described in CCQDER's generic OMB clearance package (No. 0920-0222, exp. 07/31/2018).

We propose to recruit 20 English speaking adults (aged 18 and over) who have a likelihood of injury due to age or occupation. Recruitment needs for this study include having a range of respondents with different experiences to these questions. Therefore, we are targeting both those who have occupations and activities that have likely repetitive strain injuries as well as those that do not. Recruitment will be carried out through a combination of a newspaper advertisement, flyers, special interests groups, and word-of-mouth. The newspaper advertisements/flyers used to recruit respondents are shown in Attachments 2a&b. The 5 minute screener used to determine eligibility of individuals responding to the newspaper advertisements/flyers is shown in Attachment 3. 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. Within these constraints, we plan to recruit participants with some demographic variety (particularly in terms of gender, education, and race/ethnicity). It is anticipated that as many as 48 individuals may need to be screened in order to recruit 20 participants.

Interviews averaging 60 minutes (including the completion of a Respondent Data Collection Sheet) will be conducted by CCQDER staff members with English speaking respondents. Interviews will be conducted in the Questionnaire Design and Evaluation Research Laboratory as well as at off-site locations. All interviews conducted in the Questionnaire Design and Evaluation Research Laboratory will be video and audio recorded to allow researchers to review the behaviors and body language of the respondents. Interviews conducted off-site will only be audio recorded. These recordings will allow researchers to ensure the quality of their interview notes. In the rare case that a study participant initially agrees to audio recording during the telephone screening, but changes their mind and checks “no” to allowing the interview to be recorded on the informed consent document the interview will proceed without audio recording. In this case the interviewer will depend on their handwritten notes when conducting analysis. In addition, individuals who select “yes” for allowing the audio recording on the informed consent form, but “no” for retaining the recording for future research (final text before signatures on informed consent form), will be allowed to participate in the study.

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 (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. The questions we are testing today are about injury. 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 Charles J. Rothwell, Director of NCHS (Attachment 6), a copy of the informed consent document, and $40. After the cognitive interview is over 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 that as well.

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.

We propose giving participants $40 incentives, which is our standard incentive. In total, for this project, the maximum respondent burden will be 24 hours. A burden table for this project is shown below:

Form Name	**Number of Participants**	**Number of Responses/ Participant**	**Average hours per response**	**Response Burden (in hours)**
Screener	48	1	5/60	4
Questionnaire	20	1	60/60	20

Attachments (7)
cc:

V. Buie
T. Richardson
DHHS RCO