



December 3, 2014

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 Questionnaire Design Research Laboratory (QDRL) (OMB No. 0920-0222, exp. 06/30/2015) plans to evaluate 2016 NHIS Diabetes Primary Prevention questions.

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: 2016 NHIS Diabetes Primary Prevention Questions

The 2016 NHIS Diabetes Primary Prevention questions have been drafted to address the following objectives:

- Assess the levels of screening, testing, and detection of prediabetes and diabetes currently underway in the U.S.
- Examine levels of selected diabetes risk factors
- Examine levels of referral, uptake, and participation in structured diabetes prevention programs, community weight loss and exercise programs
- Identify adults with type 1 diabetes among those with diagnosed diabetes

The 2016 NHIS Diabetes Primary Prevention questions that we are evaluating appear as Attachment 1.

In order to iteratively evaluate the questions, we propose to recruit 45 respondents (18 years of age and older) through newspaper advertisements, flyers, word-of-mouth, or by contacting respondents from past QDRL projects who have expressed interest in participating in upcoming projects. The testing procedure conforms to the cognitive interviewing techniques that have been described in QDRL's generic OMB clearance package (No. 0920-0222, exp. 06/30/2015).

Recruitment will include individuals who have diabetes, have been told they might have diabetes, think they might have diabetes, or do not have diabetes. The newspaper advertisement/flyer used to recruit respondents who have diabetes, have been told they might have diabetes, or think they might have diabetes is shown in Attachment 2. The telephone screener used to determine eligibility of individuals responding to the newspaper advertisements/flyers is shown in Attachment 3a and the telephone screener for individuals contacted through the QDRL Respondent Database is shown in Attachment 3b. It is anticipated that as many as 72 individuals may need to be screened in order to recruit 45 participants. Note that wording of the document has been approved and is contained within our umbrella package. Only project specific information has been added to the document. Within these constraints, we hope to recruit participants with some demographic variety (particularly in terms of gender, education, race/ethnicity, and income).

Interviews will be conducted by QDRL staff members with English speaking respondents. All interviews conducted in the Questionnaire Design Research Laboratory will be video and audio recorded to allow researchers to review the behaviors and body language of the respondents. Interviews conducted offsite will only be audio recorded. These recordings will allow researchers to insure the quality of their interview notes.

After respondents have been briefed on the purpose of the study and the procedures that QDRL 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. 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:

Lauren 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 different people. The questions we are testing today focus on diabetes. 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 Charles J. Rothwell, Director of NCHS, a copy of the informed consent document, and \$40.

After the interview, respondents will also be asked to read the Special Consent for Expanded Use of Video and Audio Recordings. Note that this document is contained in our umbrella package. 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 paying participants \$40, which is our standard payment. In total, for this project, the maximum respondent burden will be 51 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
Screener	72	1	5/60.	6
Questionnaire	45	1	1	45

Attachments (4)