



October 2, 2015

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 Center for Questionnaire Design and Evaluation Research (CQDER) (OMB No. 0920-0222, exp. 06/30/2015) plans to evaluate Spanish language questions of the National Health and Nutrition Examination Survey (NHANES, OMB #0920-0950) on consumer behavior, alcohol intake, and exposure to second-hand e-cigarettes. The questions proposed for the Spanish language testing are exactly the same as the English language testing submitted to you on October 2, 2015

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: Testing of National Health and Nutrition Examination Survey (NHANES) questions on consumer behavior, alcohol intake and exposure to second-hand e-cigarettes (Spanish language testing)

The National Health and Nutrition Examination Survey (NHANES) is a program of studies designed to assess the health and nutritional status of adults and children in the United States. Findings from this survey are used to determine the prevalence of major diseases and risk factors for diseases. Data from this survey also inform public health policy and health programs. Questions on consumer behavior and alcohol consumption have been included on previous NHANES surveys, but are being updated. Questions on second-hand e-cigarette exposure are new (as smoking e-cigarettes is a relatively new behavior). Questions are to be tested as part of the process of updating old questions and designing new questions.

The Spanish language consumer behavior, alcohol intake and exposure to second-hand e-cigarettes questions we are evaluating are included as Appendix 1. The testing procedure conforms to the cognitive interviewing techniques that have been described in CQDER's generic OMB

clearance package (No. 0920-0222, exp. 07/31/2018) and follow the exact procedures as used in the English language testing described in our letter to you on October 2, 2015

We propose to recruit 20 Spanish speaking adults (aged 18 and over) who live in a household with 2 or more people, are responsible for meal planning, consumes alcohol, lives in a household with someone who uses electronic cigarettes or knows someone who currently uses electronic cigarettes.

The newspaper advertisements/flyers used to recruit Spanish speaking respondents are shown in Appendix 2a&b. The 5 minute telephone screener used to determine eligibility of individuals responding to the newspaper advertisements/flyers is shown in Appendix 3. Within these constraints, we plan to recruit participants with some demographic variety particularly in terms of gender, and race/ethnicity. Note that wording of the English language template has been approved and is contained within our umbrella package. Only project specific information has been added to the document and the entire document translated into Spanish. 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 CQDER staff members with 20 Spanish 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 insure the quality of their interview notes.

After respondents have been briefed on the purpose of the study and the procedures that CQDER routinely takes to protect human subjects, respondents will be asked to read and sign an Informed Consent (Appendix 4). Only project specific information has been added to the document and the entire document translated into Spanish. Respondents will also be asked to fill in their demographic characteristics on the Respondent Data Collection Sheet (Appendix 5). 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 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 different people. The questions we are testing today focus on consumer behavior, alcohol intake and exposure to second-hand e-cigarette. 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 and translated into Spanish for this project) signed by Charles J. Rothwell, Director of NCHS (Appendix 6), a copy of the informed consent, 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 (Appendix 7/ translated into Spanish for this project). 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 Spanish speaking 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 (5)

cc:

V. Buie

T. Richardson

DHHS RCO