



May 10, 2016

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

Dear Dr. Schwab:

On October 27, 2015, the GenIC entitled “2017 NHANES Health Behaviors Cognitive Interviewing Study” (OMB No. 0920-0222, exp. 07/31/2018) that recruited English-speaking participants was approved for 60 completed questionnaires. A complimentary GenIC (under the same OMB number) that recruited Spanish-speaking participants was thereafter approved on November 23, 2015 for 20 completed questionnaires. The staff of the NCHS Center for Questionnaire Design and Evaluation Research (CQDER) plans to conduct an additional 30 interviews in order to continue to evaluate questions on alcohol intake and exposure to second-hand e-cigarettes. This supplemental GenIC, entitled “A supplement to the 2017 NHANES Health Behaviors Cognitive Interviewing Study”, is being requested to test the National Health and Nutrition Examination Survey (NHANES, OMB #0920-0950, exp. 12/31/2017) alcohol questions together with alcohol questions from the National Health Interview Survey (NHIS, OMB #0920-0214, exp. 01/31/2019). There have been some changes to the alcohol questions, and additional English-speaking and Spanish-speaking respondents are required.

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 alcohol intake and exposure to second-hand e-cigarettes (English & Spanish language testing).

The 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. The NHIS collects data on a broad range of health topics through household interviews. Questions on alcohol consumption have been

included on previous NHANES and NHIS 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 for both NHANES and NHIS.

The NHANES alcohol questions focus on 12 month exposure to alcohol and were developed in collaboration with the National Institute on Alcohol Abuse and Alcoholism. The NHIS questions focus on a 30 day reference period and come from the current NHIS, from the Behavioral Risk Factor Surveillance System survey or from the National Survey on Drug Use and Health.

The NHANES and NHIS alcohol questions we are evaluating and the NHANES questions on exposure to e-cigarettes are included as Attachment 1a&b. Hand card ALQ1 is included as Attachment 2a&b. 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).

In this GenIC we are requesting thirty respondents (20 English-speaking and 10 Spanish-speaking). We propose to recruit English-speaking and Spanish-speaking adults (aged 18 and over) who consume alcohol or who have consumed alcohol and who live in a household with someone who uses electronic cigarettes or know someone who currently uses electronic cigarettes. The newspaper advertisements/flyers used to recruit respondents are shown in Attachments 3a-d. Note that advertisement (Attachment 3c&d) have not changed since the original approved protocol, but they are included in the amendment for ease of review. The screener used to determine eligibility of individuals responding to the newspaper advertisements/flyers is shown in Attachment 4a&b. Within these constraints, we plan to recruit participants with some demographic variety (particularly in terms of gender, education, and race). 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 96 individuals may need to be screened in order to recruit 30 participants.

Interviews conducted in English will be conducted by CQDER staff members with English-speaking respondents for up to 60 minutes (including the completion of a Respondent Data Collection Sheet). 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 offsite will only be audio recorded. These recordings will allow researchers to insure the quality of their interview notes.

Interviews conducted in Spanish will be conducted by Research Support Services (a frequently used CQDER contractor for conducting Spanish cognitive interviews) with Spanish-speaking respondents for up to 60 minutes (including the completion of a Respondent Data Collection Sheet). Interviews will be conducted in a private room of a community-based organization or at a mutually agreed upon location with an individual respondent and an interviewer. All interviews will be audio recorded. These recordings will allow researchers to insure the quality of their interview notes.

Research Support Services staff conducting the Spanish cognitive interviews will complete NCHS Confidentiality training at http://www.cdc.gov/nchs/about/policy/confidentiality_training/index.html and sign a Nondisclosure Affidavit (provided by NCHS). The contractor will send hardcopies of the NCHS Confidentiality Training certificates and original signed hardcopies of the Nondisclosure Affidavits to Karen Whitaker, Program Specialist, CQDER.

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 (Attachment 5ab). 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 6ab). 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 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 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 (Attachment 7ab/document contained in umbrella package and translated into Spanish for this project) signed by Charles J. Rothwell, Director of NCHS, a copy of the informed consent document, and \$40. After the interview is over, respondents will be asked to read the Special Consent for Expanded Use of Video and Audio Recordings (Attachment 8ab/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 participants \$40 incentives, which is our standard incentive. In total, for this project, the maximum respondent burden will be 38 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	96	1	5/60	8
Questionnaire	30	1	60/60	30

Attachments (8)

cc:

V. Buie

T. Richardson

DHHS RCO