



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 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 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 proposed evaluation of the smoking behavior questions is consistent with the Department's efforts and approach for cognitive testing new questions. Participants from the Electronic Nicotine Delivery System (ENDS) work group in HHS have reviewed the questions on second hand e-cigarette exposure and the relationship of these questions on NHANES to serum cotinine.

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 (English 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 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).

We propose to recruit 60 English speaking adults (aged 18 and over) who live in a household with 2 or more people, are responsible for meal planning, consume alcohol, 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 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 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 60 participants.

Interviews averaging 60 minutes (including the completion of a Respondent Data Collection Sheet) will be conducted by CQDER 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 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. 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:

[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) signed by Charles J. Rothwell, Director of NCHS, 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 5). 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 68 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	60	1	60/60	60

Attachments (5)

cc:

V. Buie

T. Richardson

DHHS RCO