**dhhs_logoDEPARTMENT OF HEALTH & HUMAN SERVICES** **Public Health Service**

**Centers for Disease Control and Prevention**

**National Center for Health Statistics**

**3311 Toledo Road**

**Hyattsville, Maryland 20782**

April 7, 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 Center for Questionnaire Design and Evaluation Research (CQDER) (OMB No. 0920-0222, exp. 07/31/2018) plans to conduct a cognitive interviewing study to examine Impaired Driving questions developed by CDC’s National Center for Injury Prevention and Control (NCIPC) for possible inclusion on the Behavioral Risk Factor Surveillance System (BRFSS).

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: Evaluation of Impaired Driving questions for CDC’s National Center for Injury Prevention and Control (NCIPC)

In the United States the number of self-reported marijuana users is increasing. Drugged driving is a complex issue because it is not usually reported and contains many complicated and changing variables. According to a 2013-2014 National Highway Traffic Safety Administration roadside survey, 22% of all nighttime, weekend drivers tested positive for drugs. Approximately 31% of fatal crashes in 2014 (n = 9,967) involved an alcohol-impaired driver.  Currently there are not accurate drug impaired driving estimates for fatal crashes.  Due to the changing legal landscape of medical and non-medical marijuana and the increases in prescription drug overdoses, the development and cognitive testing of self-reported drug use, driving after drug use, and driving while impaired by drug questions is necessary to determine prevalence of and be able to track changes in prevalence over time.

There are several objectives specific to this study.  The first pertains to the use of various substances within a specific timeframe and frequency.  Probing will focus on recall issues to determine whether (and to what extent) respondents have specific recollections about when and how often they used the substances, as well as their conceptualizations of those substances.  A second issue centers on perceptions of impairment.  Respondents will be asked to explain their understandings of impairment in general and with regard to specific questions.  For example, questions use phrases and words such as, “under the influence,” “high,” “experiencing side effect” or “perhaps had too much.”  Respondents will be asked to discuss how they interpret those meanings in the context of specific questions.  The goal of probing is to reveal respondents’ understandings and the potential for response error through a discussion of their personal experiences.  The ultimate objective of this study is to determine the actual phenomena that respondents consider when answering the questions.  By diagraming the specific construct captured by each question, survey designers (e.g. NCIPC) are better positioned to make informed decisions about which questions to include in their questionnaire.  Of note, findings of this study will be posted to Q-Bank, a searchable database of tested questions with links to evaluation reports, so that this documentation is publically accessible.

Additionally, because of the sensitive nature of the topic, a certain amount of socially desirable answers are expected.  That is, respondents may provide answers to the survey questions that they believe reflect well on them.  This phenomenon will be explored with the constant comparative method of data analysis.  For example, analysis of the congruence between answers provided to the survey question and respondent narratives regarding their experiences will reveal the extent to which respondents answer the questions in accordance with their experiences or according to notions of socially desirable behavior. Although we have not tested these questions specifically, we have much experience testing sensitive questions.  Those final reports are in Q-Bank (see, for example, <https://wwwn.cdc.gov/QBank/Report.aspx?1161>).  For the most part, we have found the analytic approach to be successful.

The Impaired Driving questions we are evaluating are included as Attachment 1. The proposed questions for cognitive testing have appeared on the Fall Styles Consumer 2015 Survey (non-government consumer survey/<http://www.porternovelli.com/offerings/services/>); however they have not been cognitively tested. 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 40 respondents aged 18 and over who have used alcohol, marijuana/hash, prescription medications, or cocaine in the last 30 days.

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-c. 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. It is anticipated that as many as 72 individuals may need to be screened in order to recruit 40 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. 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 as well as 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 CQDER 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 impaired driving. 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, adult respondents/parents/guardians 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 46 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 | 72 | 1 | 5/60 | 6 |
| Questionnaire | 40 | 1 | 60/60 | 40 |

Attachments (7)

cc:

V. Buie

T. Richardson

DHHS RCO