**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**

September 26, 2016

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 continue to conduct an evaluation of confidentiality pledges for NCHS entitled Cognitive Testing of Confidentiality Pledge, Round 2 . Round 1 of the evaluation of confidentiality pledges for NCHS was described in our letter to you dated June 6, 2016.

 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: Cognitive Testing of Confidentiality Pledges for NCHS

The passage of the Cybersecurity Enhancement Act of 2015 requires the installation of the Department of Homeland Security’s Einstein cybersecurity protection system on all Federal civilian information technology systems by mid-December 2016.  Combined with DHS’ stated policies, it also potentially compromises the absolute nature of the Federal statistical system’s (FSS) confidentiality pledges by no longer enabling statistical agencies to pledge that respondents’ data will be seen only by a statistical agency’s employees or its sworn agents.  Consequently, the FSS needs to develop a revised confidentiality pledge(s) that informs respondents of this change in circumstances.  To optimize the effects of a revised confidentiality pledge(s), we need to cooperatively and carefully design the type and scope of our cognitive research.  CCQDER plans to cognitively test new language for the confidentiality pledge used by the NCHS.

The confidentiality pledge we are evaluating is included as Attachment 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 up to 20 English speaking adults (aged 18 and over). 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 Attachment 2. 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 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 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 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 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 material that will eventually be added to national surveys. Before that happens, we like to test it out on a variety of people. The material we are testing today is about survey research privacy pledges. We are interested in whether and how you understand the material.. I will ask you questions about the material,—whether it makes sense, what you think about when you hear certain words, and so on.*

*After reading the material, please tell me if:*

*there are words you don’t understand,*

*there are phrases that don’t make sense to you,*

*you could interpret it more than one way, or*

*it seems out of order,*

*The more you can tell us, the more useful it will be to us as we try to develop better language. 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, respondents 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 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 | 1 | 20 |

Attachments (7)

cc:

V. Buie

T. Richardson

DHHS RCO