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

April 1, 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 Questionnaire Design Research Laboratory (QDRL) (OMB No. 0920-0222, exp. 06/30/2015) plans to continue to evaluate questions on cervical and lung cancer screening questions for CDC's National Center for Chronic Disease Prevention and Health Promotion, (NCCDPHP), Division of Cancer Prevention and Control (DCPC), Epidemiology and Applied Research Branch (EARB).

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 Cervical and Lung Cancer Screening Questions

The QDRL conducted preliminary cognitive testing in 2014 as part of the preparation for the 2015 National Health Interview Survey (NHIS) Cancer Supplement (approved March 15, 2014), and identified several problems with question wording. Examples included whether respondents were able to understand the difference between a screening and diagnostic test, whether respondents were able to accurately report screening with the newer technology, such as lung cancer screening using low-dose computed tomography, and whether respondents understand that certain tests are linked to cancer screening, such as the Pap test for human papillomavirus (HPV)/cervical cancer. For details on each question, see: http://wwwn.cdc.gov/qbank/Home.aspx.

Additional cognitive testing is needed to further improve the measurement of constructs in the cervical and lung cancer screening questions. Valid and reliable question wording is needed for national surveys to accurately determine trends in cervical and lung cancer screening and monitor future progress towards achieving Healthy People 2020 health objectives, such as: C-2 Reduce the lung cancer death rate; C-4 Reduce the death rate from cancer of the uterine cervix; and C-15 Increase the proportion of women who receive a cervical cancer screening based on the most recent guidelines. Question design modifications developed in this project will be proposed for use in future national surveys such as the NHIS and the CDC Behavioral Risk Factor Surveillance System.

The cervical and lung cancer screening questions we are evaluating are included as Attachment 1. The testing procedure conforms to the cognitive interviewing techniques that have been described in QDRL's generic OMB clearance package (No. 0920-0222, exp. 06/30/2015).

We propose to recruit 40 English speaking adults in order to evaluate the questions. Recruitment will include women (aged 18 and over/Attachment 2b) who have had a Pap test, HPV test, and men and women (aged 18 and over; Attachment 2a; aged 55 to 80/Attachment 2c) who have had a Chest CT scan, CAT scan, lung cancer screening with low dose computer tomography, Chest X-ray lung cancer screening.

The newspaper advertisements/flyers used to recruit respondents are shown in Attachments 2a-c. The 5 minute telephone screener used to determine eligibility of individuals responding to the newspaper advertisements/flyers is shown in Attachment 3. Within these constraints, we plan to recruit participants with some demographic variety particularly in terms of gender, education, 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 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 QDRL 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 QDRL 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. 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:

> *Lauren 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 general health and cancer screening exams. 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.

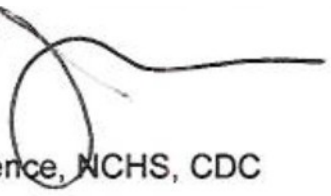
After the interview, respondents will be asked to read the Special Consent for Expanded Use of Video and Audio Recordings (Attachment 5). There will be no coercion and the respondents will be told that they can call and reverse the decision at any time if they change their minds. If respondents do sign 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, 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	1	40

Signature of Senior Departmental Official or Designee



Jennifer H. Madans, Ph.D., Associate Director for Science, NCHS, CDC

Attachments (5)
cc:
V. Buie
T. Richardson
DHHS RCO