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 evaluate questions on high-impact, chronic pain for the National Pain Strategy Workgroup (includes members from the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), Stanford, and others).

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 High-impact, Chronic Pain questions

Publication of the 2011 report by the Institute of Medicine, *Relieving Pain in America*, has led to growing recognition of the impact of pain on the health, productivity, and well-being of the U.S. population. Efforts to lower the impact of chronic pain at the individual and population levels need to be guided by population-based data. According to the workgroup, data are needed on the prevalence, onset, course, impact, and outcomes for most common chronic pain conditions.

The pain assessment tools proposed by the Workgroup use the definitions of chronic pain and high-impact chronic pain, which are based in part on the widely used definition of chronic pain recommended by the International Association for the Study of Pain,[1] modified to account for intermittent pain.

Chronic pain *is pain on at least half the days for six months or more.*
High-impact chronic pain *is associated with substantial restriction of participation in work, social, and self-care activities for six months or more.*

The high-impact, chronic pain questions we are evaluating are included as Attachment 1. The testing procedure conforms to the cognitive interviewing techniques

1 International Association for the Study of Pain. (1986). *Classification of chronic pain. Descriptions of chronic pain syndromes and definitions of pain terms. Pain Suppl, 3*, S1-226.

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 (aged 18 and over) who may or may not have some level of pain that restricts their participation in work, school, social and self-care activities.

The newspaper advertisements/flyers used to recruit respondents are shown in Attachment 2a&b. 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 how pain impacts your health and daily activities. 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.

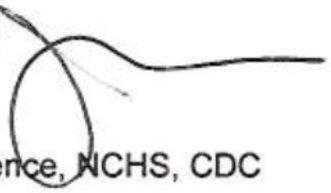
After the interview, respondents will be asked to read the Special Consent for Expanded Use of Video and Audio Recordings (Attachment 5). There will be no coercion and the respondents will be told that they can call and reverse the decision at any time if they change their minds. If respondents do sign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

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