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

July 29, 2014

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 adults with chronic health care needs developed by the National Institutes of Health Clinical Research Center/Rehabilitation Medicine Department.

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 Adults with Chronic Health Care Needs (ACHCN) questions

The ACHCN initiative is analogous to the Children with Special Health Care Needs Initiative and is focused on developing a health consequences based approach to identifying adults with chronic conditions, disabilities, and elevated health service needs. The broad objective of this initiative is to improve the surveillance and monitoring of health care and related service need and use among people with chronic conditions and/or disabilities at the population level; its specific purpose includes the development of a screening instrument to provide the health services research community with the capacity to estimate the size of and measure the subsequent health care needs of and use by this population. Background research for the ACHCN initiative began in 2008. In 2012, the NIH/CC/RMD formed an expert measurement panel to support development of a screener. Cognitive testing of the proposed survey questions is central to the mission of developing a screener and will help to identify the most appropriate question variants to ultimately proceed to field testing.

The adults with chronic health care needs 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 60 respondents (age 18-64) in order to iteratively evaluate the adults with chronic health care needs questions. In addition to ensuring demographic variety (gender, education and race/ethnicity), the recruitment process will identify working age adults over three primary domains, as follows.

A) Health service need and use: A spectrum of health and mental health service use patterns is desired among the participants. This includes primary and specialty care, mental health services and/or related Rx, general prescription medications and over the counter supplements, therapies (including alternative therapies such as acupuncture), and/or DME. We will seek to balance the sample, with some using only routine / preventive care, and others using extensive or complex care from multiple provider types.

B) Chronic condition status: Chronic conditions as broadly defined in this project are those lasting or expected to last 12 months or longer, including both physical (diabetes, cancer, asthma, etc.) and mental (depression, anxiety, addiction, etc.) conditions. While it will not be possible to exhaustively capture all conceivable conditions, a purposive balance will be sought. This will include individuals with no chronic conditions, one such condition, and multiple chronic conditions. It will also include a balance of individuals with physical, versus mental health related conditions.

C) Disability status: Participants will be identified for the cognitive interviews that do have some degree of functional limitations among the 6 areas assessed by this instrument. We thus intend to gather *at least* two individuals in each area of limitation (sight, hearing, cognition, mobility and ADLs/IADLs, respectively).

The newspaper advertisements/flyers used to recruit respondents are shown in Attachment 2a-c. The screener used to determine eligibility of individuals responding to the newspaper advertisements/flyers is shown in Attachment 1 (the 5-minute burden for the screener is included in the 1-hour burden). Note that wording of the document has been approved and is contained within our umbrella package. Only project specific information has been added to the document. Within these constraints, we hope to recruit participants with some demographic variety (particularly in terms of gender, education, race/ethnicity, and income).

Interviews will be conducted by QDRL staff members with English speaking respondents for up to 60 minutes per interview. Interviews will be conducted in the Questionnaire Design Research Laboratory as well as at off-site locations. 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 document. Respondents will also be asked to fill in their demographic characteristics on the Respondent Data Collection Sheet. Note that these documents are contained in our umbrella package.

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.

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 document, and $40.

After the interview, respondents will also be asked to read the Special Consent for Expanded Use of Video and Audio Recordings. Note that this document is contained in our umbrella package. 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 paying participants $40, which is our standard payment. In total, for this project, the maximum respondent burden will be 60 hours of interviewing. A burden table for this project is shown below:

Projects	**Number of Participants**	**Number of Responses/ Participant**	**Average hours per response**	**Response burden**
QDRL Interviews				
2) Other Questionnaire Testing	60	1	1	60

Attachments (2)
cc:
V. Buie
T. Richardson
DHHS RCO