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 24, 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 conduct a cognitive interviewing study to examine questions for the Pregnancy Risk Assessment Monitoring System (PRAMS) for the Division of Reproductive Health (DRH), National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP).

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: PRAMS Cognitive Interviewing Study in English and Spanish

PRAMS operates through a cooperative agreement between CDC and states that have been awarded grants on a competitive basis. Currently, 40 states and 1 city are funded to collect data on maternal behaviors and experience that occur before, during, and shortly after pregnancy. The PRAMS is comprised of core questions and standard questions. The core questions cover topics such as attitudes and feelings about the most recent pregnancy, content and source of prenatal care, maternal alcohol and tobacco consumption, physical abuse before and during pregnancy, pregnancy-related morbidity, infant health care, contraceptive use, mother's knowledge of pregnancy-related health issues (adverse effects of tobacco and alcohol; benefits of folic acid; and risks of HIV). The standard questions are developed and coordinated with significant input from state, CDC, and other researchers and address different topics, including social support and services, mental health, and injury prevention. Several of the PRAMS indicators are associated with Healthy People 2020 performance objectives, Title V Maternal Child Health Service Block Grant Performance Measures, or the uptake of health insurance coverage and women's preventive health services in the Affordable Care Act (ACA).

The PRAMS questionnaire, first implemented in 1988, has been revised several times over the life of the project and revisions have been made primarily to capture data on recent public health guidelines or emerging issues concerning maternal and child health and to improve

respondents' comprehension of questions. The QDRL has conducted cognitive interviewing studies for earlier revisions (1999, 2001, 2003, and 2007). Given that the goal of the Phase 8 survey is to ensure collection of high quality data that has practical application, PRAMS will benefit from cognitive testing to improve the validity and reliability of the data. The information gleaned from the cognitive testing will not only improve data collection but also the researchers' experience in analyzing the data.

The English PRAMS questions that we are evaluating appear as Attachment 1a and the Spanish PRAMS questions appear as Attachment 1b. The wording of all of the English language forms contained in this GenIC package have been approved with the exception of project specific information that has been added to the documents, and are contained within our umbrella package. We have included the forms in this GenIC for ease in reviewing the Spanish language forms.

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 50 women (30 English-speaking and 20 Spanish-speaking) aged 18 and over who:

- Had a baby between 2-12 months ago
- From different backgrounds (race, education level, etc.)
- Some who worked outside the home during pregnancy
- Some who breastfed and some who didn't
- Some who used a breast pump
- Some who have used (or are very familiar with) e-cigarettes (potentially have friends or relatives that use, if they don't use)
- Some who have used (or are very familiar with) hookah (potentially have friends or relatives that use, if they don't use)
- Some who smoke cigarettes (or smoked during pregnancy)

Recruitment will be carried out through a combination of a newspaper advertisement, flyers, and word-of-mouth. The advertisement/flyer used to recruit English and Spanish-speaking Mothers is shown in Attachment 2a&b. The telephone screener used to determine eligibility of those English and Spanish Mothers responding to the newspaper advertisement/flyer is shown in Attachment 3a&b (the 5-minute burden for the screener is included in the 1-hour burden).

Interviews will be conducted in either the QDRL or a private room of a community facility with an individual participant and an interviewer for no more than 90 minutes. Interviews conducted in the QDRL 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 (Attachment 4a&b). Respondents will also be asked to fill in their demographic characteristics on the Respondent Data Collection Sheet (Attachment 5a&b).

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:

> *We will be working on some questions that will eventually be added to national health surveys. Before that happens, we like to test them out on a variety of different people. The questions we are testing today are about your health behavior and experiences before and during your pregnancy and early infancy of your child including prenatal care, breastfeeding, health care coverage, employment, tobacco use, non-cigarette tobacco use, health conditions, family history of health conditions, emergency preparedness, and other things that affect your health and the health of your baby. 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 (Attachment 6a&b) signed by Charles J. Rothwell, Director of NCHS, a copy of the informed consent document, and $50.

After the interview, respondents may be asked to read the Special Consent for Expanded Use of Video and Audio Recordings (Attachment 7a&b). 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 $50 for their participation, which is $10 over our standard payment. We hope the extra $10 above our standard $40 payment will be sufficient to entice new mothers of babies 2-12 months of age to come to the QDRL for a 90-minute interview. In a 2007 PRAMS cognitive interviewing study, we found that new mothers had difficulties keeping appointments due to problems with childhood illnesses, baby sitters for older children, and transportation. In total, for this project, the maximum respondent burden will be 75 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	50	1	1.5	75

Attachments (7)
cc:
V. Buie
T. Richardson
DHHS RCO