



October 14, 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 Center for Questionnaire Design and Evaluation Research (CQDER) (OMB No. 0920-0222, exp. 07/31/2018) plans to evaluate 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 Phase 8 Supplemental Questions (English version)

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 NCHS' Center for Questionnaire Design and Evaluation Research (CQDER) has conducted cognitive interviewing studies for earlier revisions (1999, 2001, 2003, 2007, and 2014). Given that the goal of the Phase 8 survey is to ensure collection of high quality data that has practical application, PRAMS Phase 8 supplemental questions 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 PRAMS Phase 8 supplemental questions we are evaluating are included as Appendix 1a. Appendix 1b lists the questions and the rationale for their selection and/or response options relative to other surveys. 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 20 English-speaking women (aged 18 and over) who:

- Had a baby between 2-12 months ago
- Some who have a family history of breast and ovarian cancer
- Some who had genetic counseling for cancer risk
- Some who used/taken prescription and non-prescription drugs before and during pregnancy

Recruitment will be carried out through a combination of a newspaper advertisement, flyers, and word-of-mouth. The newspaper advertisement/flyer used to recruit respondents are shown in Appendices 2a-c. Flyers may be posted at locations such as Social Service centers, WIC programs, women and children shelters, churches, rehabilitation centers, health care centers, treatment centers for chronic pain, and child care centers. The 5 minute screener to be used to determine eligibility of individuals responding to the newspaper advertisements/flyers/word-of-mouth is shown in Appendix 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.

Recruitment of respondents may be done in coordination with Social Service centers, WIC programs, women and children shelters, churches, rehabilitation centers, health care centers, treatment centers for chronic pain, and child care centers. The contacted centers will read a statement about CQDER's study (Appendix 2d). If the respondent is interested in participating in the PRAMS Phase 8 study, the potential respondent will contact CQDER staff members [in person/over the phone] to set-up an appointment.

Interviews averaging 90 minutes (including the completion of the 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 or a private room of a community facility with an individual participant and an interviewer. All interviews conducted in the Questionnaire Design and Evaluation Research Laboratory and off-site will be audio recorded. These recordings will allow researchers to insure the quality of their interview notes. Audio recordings will only be used by researchers from the Center for Questionnaire Design and Evaluation Research (CQDER) and the Centers for Disease Control and Prevention, who are

working on the project. Audio recordings will remain under CQDR staff control at all time. There will be no external sharing of the audio recordings.

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 (Appendix 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:

[Fill name] 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 are about your health behavior and experiences before and during your pregnancy and early infancy of your child including family history of health conditions, genetic counseling for cancer risk, prescription and non-prescription drugs, and environmental exposures.

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.

The interviewer will follow the interview protocol, but will also ask emergent probes to better understand the question-response process. Examples of the sorts of probes that may be asked at the interviewer's discretion include:

- Could you tell me what [term] means to you?
- Why did you answer that way?
- In your own words, could you tell me what you think this question is asking?
- Was this question easy or hard to answer? Why?
- How sure are you about your answer?

Interviewers may use some or all of these probes, depending upon the content of the interview and how much information the respondents reveal without being prompted. All probes will be administered after the respondent has completed the questionnaire.

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 \$50.

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 participate in the 90-minute interview. In a 2014 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 34 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	90/60	30

Attachments (4)

cc:

V. Buie

T. Richardson

DHHS RCO