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

November 24, 2017

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 Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) (OMB No. 0920-0222, exp. 07/31/2018) plans to conduct a cognitive interviewing study to evaluate English and Spanish questions about food for babies, mothers' health, and Women, Infants and Children (WIC) benefits on the NHANES B24 Month Questionnaire for the Division of Health and Nutrition Examination Surveys (DHNES).

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 Food for Babies and Mothers' Health Questions on the NHANES B24 Month Questionnaire

The National Health and Nutrition Examination Survey (NHANES) is a program of studies designed to assess the health and nutritional status of adults and children in the United States. Findings from this survey are used to determine the prevalence and risk factors for major diseases. The staff of DHNES and the Federal Data Consortium on P/B24 are proposing that the NHANES B24 Month Questionnaire be added onto NHANES cycle years 2019-2022. The B24 Month Questionnaire will ask a maximum of 24 questions for participants about food for babies, birth to 24 months old, and mothers' health. Specifically, the topics will include: 1) "mixed feeding" and "modes of feeding," 2) introduction of first foods with a focus on the five main food groups, 3) maternal pre-pregnancy height and weight for calculating pre-pregnancy BMI of the

mothers, and 4) the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC).

The Federal Data Consortium on P/B24 sought out other experts in the field to explore the existing questionnaires on "mixed feeding" and "modes of feeding" and to consider if those measures have been validated. The consortium found that there are no well-established and validated questionnaires that are designed to measure "mixed feeding" and "modes of feeding" in children 0-24 mo. The questionnaire includes eleven "mixed feeding" and "modes of feeding" questions that were adapted from or informed by four sources – 1) Dr. Matthew Greenhawt, University of Colorado Denver School of Medicine; 2) Dr. Kathleen Rasmussen, Cornell University; 3) Dr. Sheela Geraghty, Cincinnati Children's Hospital Medical Center; and 4) the Infant Feeding Practices Study II (IFPS II). The questionnaire content from IFPS II has been used in ethnically diverse groups. The questionnaire includes seven "introduction of first foods" questions that were developed by the USDA Center for Nutrition Policy and Promotion and the HHS Office of Disease Prevention and Health Promotion. It also includes two "maternal pre-pregnancy height and weight for BMI" questions that were developed by the NIH's Office of Dietary Supplements.

There is an increasing need for nationally representative detailed data on the feeding of babies from birth to 24 months old. The current Dietary Guidelines for Americans focus on persons aged 2 years and older. However, the Dietary Guidelines of 2020-2025 will include dietary recommendations for babies 0-24 months of age. This change in the Dietary Guidelines makes the need for nationally representative data on the feeding of babies from birth to 24 months old even more prominent. NHANES does not currently collect sufficient data to assess and monitor the nutrition and health of babies 0-24 months of age. The proposed NHANES B24 Month Questionnaire will capture the nutrition and health data of 0-24 month old children. As mentioned above, there are no well-established and validated questionnaires that are designed to measure "mixed feeding" and "modes of feeding" in children 0-24 mo. The use of cognitive interviews to evaluate the NHANES B24 Month Questionnaire will progress the federal health statistical system in the development and validation of these essential measures.

The English and Spanish food for babies, mothers' health, and WIC benefits questions we are evaluating are included as Attachment 1a&b. Spanish translation of the questions was performed by DHNES' Contractor, Westat. The testing procedure conforms to the cognitive interviewing techniques that have been described in CCQDER's generic OMB clearance package (No. 0920-0222, exp. 07/31/2018). Aside from exploring different patterns of interpretations typical of cognitive interview projects, an objective of this study is to examine if different caretakers (e.g. mothers, fathers, guardians, other primary caretakers) interpret the NHANES B24 Month questions differently. All respondents will be asked questions that require intimate knowledge about the child from birth as well as the biological mother's health. One research objective for the cognitive interviews is to explore the extent to which the various types of primary caregivers (biological parents, guardians, other family members, or nannies) are knowledgeable on each of the topic areas. These findings will ultimately

inform any skip patterns that are implemented in the B-24 survey. Another objective of this study is to evaluate how recipients of the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) understand and answer the questions.

We propose to recruit up to 45 English-speaking parents/guardians/primary caretakers (aged 18 and over) and up to 20 Spanish-speaking parents/guardians/primary caretakers (aged 18 and over, preferably monolinguals) who live in the same household of babies aged 0-24 months. Recruitment of individuals will be guided first by their experience with being the parent/guardian or primary care taker of a 0-24 month old baby, being a WIC recipient, and caring for the child at home or using daycare. Secondarily, we aim to recruit respondents with a roughly even mix of age, race, and educational attainment. The initial goal is to recruit groups in equal proportion, to the extent possible – that is, within the constraints of those willing to participate in the study. However, because qualitative sampling is based on theoretical relevance more than equal cell sizes, on-going analysis may reveal the need to recruit more from one group than others. The newspaper advertisements/flyers used to recruit respondents are shown in Attachments 2a-d. The language in the Sample Script of CCQDER Voice Mail, (contained in our generic package) where interested English speaking persons express interest and leave contact information, has been modified to remove language indicating that ALL respondents will be called to determine eligibility (Attachment 3). The 5 minute screener used to determine eligibility of individuals responding to the newspaper advertisements/flyers is shown in Attachment 4a&b. 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. The screening script is not directly linked to the instrument. However, the recruiter will inform the interviewer of the respondent's relationship to the baby during scheduling of interviews. The recruiter will ascertain if the potential respondents are primary caregivers that have intimate knowledge of the babies' health and eating patterns. Only primary caregivers (biological mothers or fathers, guardians, other family members, or nannies) with this intimate knowledge will be recruited into this study. It is anticipated that as many as 120 individuals may need to be screened in order to recruit 65 participants. In order to accommodate our research objectives, we intend to include participants with various relationships to the baby, such as parents (both mothers and fathers), guardians, and other primary caregivers (such as other relatives or nannies). We also hope to include participants that are recipients of WIC. Within these constraints, we will also strive for demographic diversity in terms of race and educational attainment.

Interviews averaging 60 minutes (including the completion of a Respondent Data Collection Sheet) will be conducted by CCQDER staff members with English speaking respondents and by Research Support Services (RSS) with Spanish speaking respondents. RSS is a frequently used CCQDER contractor for conducting Spanish cognitive interviews. Interviews conducted in English will be conducted in the Questionnaire Design and Evaluation Research Laboratory as well as at off-site locations. Interviews conducted in Spanish will be conducted in a private room of a community-based organization or a mutually agreed upon location. All English interviews conducted in the Questionnaire Design and Evaluation Research Laboratory will be video and audio recorded to allow researchers to review the behaviors and body language of the respondents. English

Interviews conducted off-site and all Spanish interviews will only be audio recorded. These recordings will allow researchers to ensure the quality of their interview notes.

In the rare case that a study participant initially agrees to audio recording during the telephone screening, but changes their mind and checks "no" to allowing the interview to be recorded on the informed consent document the interview will proceed without audio recording. In this case the interviewer will depend on their handwritten notes when conducting analysis. In addition, individuals who select "yes" for allowing the audio recording on the informed consent form, but "no" for retaining the recording for future research (final text before signatures on informed consent form), will be allowed to participate in the study.

RSS staff conducting the Spanish cognitive interviews will complete NCHS Confidentiality training at https://www.cdc.gov/nchs/training/confidentiality/training/ and sign a Nondisclosure Affidavit (provided by NCHS). The contractor will send hardcopies of the NCHS Confidentiality Training certificates and original signed hardcopies of the Nondisclosure Affidavits to Karen Whitaker, Program Specialist, CCQDER.

After respondents have been briefed on the purpose of the study and the procedures that CCQDER routinely takes to protect human subjects, respondents will be asked to read and sign an Informed Consent (Attachment 5a&b). 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 (Attachment 6a&b). 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 staff 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 people. The questions we are testing today are about are about food for babies, mothers' health, and Women, Infants and Children (WIC) benefits. 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 the Charles J. Rothwell, Director of NCHS (Attachment 7a&b), a copy of the informed consent document, and $40. After the cognitive interview is over respondents will be asked to read the Special Consent for Expanded Use of Video and Audio Recordings (Attachment 8a&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 giving participants $40 incentives, which is our standard incentive. In total, for this project, the maximum respondent burden will be 75 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 (English)	72	1	5/60	6
Screener (Spanish)	48	1	5/60	4
Questionnaire (English)	45	1	1	45
Questionnaire (Spanish)	20	1	1	20

Attachments (10)
cc:
V. Buie
T. Richardson
DHHS RCO