**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**

February 24, 2020

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. Date 08/31/2021) plans to conduct a cognitive interviewing study to examine occupational health questions for the National Institute for Occupational Safety and Health (NIOSH), Division of Surveillance, Hazard Evaluations, and Field Studies (DSHEFS). This 10-day letter is a revision of the 10-day letter submitted on December 6, 2018 and addresses concerns raised during correspondence with OMB. Attachment 1 contains NIOSH’s full response to the questions raised by OMB across multiple discussions.

We propose to start recruiting for volunteer participants as soon as we receive clearance and to begin interviews as soon as possible after that.

Cognitive Interviewing Methodology

The methodological design of this proposed study is consistent with the design of most NCHS/CCQDER cognitive interviewing studies: the purpose is to identify the various patterns of interpretation that respondents consider when formulating an answer to a survey question as well as any problems experienced. Findings reveal the construct captured by each question, patterns of interpretation across respondent groups, and potential sources of response error. This project will contain iterative rounds of cognitive testing (not to exceed the requested burden detailed in the burden table on page 5 of this letter) to allow questions to be revised and re-tested; thus, creating a full set of validated questions. Interviews are in-depth and semi-structured; analysis is conducted using qualitative methodologies. Findings from all CCQDER studies are documented in a final report and made publicly accessible on a searchable website at <https://wwwn.cdc.gov/QBank>.

Proposed project: Cognitive testing of 2021 Occupational Health Questions

Overview of procedure for the cognitive testing of 2021 Occupational Health Questions

This cognitive interviewing study will evaluate a series of proposed questions for the National Health Interview Survey (NHIS) Occupational Health Supplement (OHS), which is slated to be fielded in 2021. This supplement is sponsored by NIOSH. NIOSH plans to use the 2021 OHS for population-based occupational health surveillance of US workers across all industries, occupations, work arrangements, and demographic subgroups. The proposed questions for the 2021 OHS build on prior NIOSH sponsored occupational health supplements to the NHIS from 2010 and 2015.

*Background for the OHS:* Changes in the economy have led to changes in the structure of work. The service-providing sector constitutes over 80 percent of U.S. jobs, which are now characterized by non-standard work arrangements and schedules. Healthcare and social assistance services comprise 12.2 percent of all jobs and are increasingly relying on on-call work or staffing on demand. NIOSH’s new Healthy Work Design (HWD) and Well-being research program includes a focus on research examining the relationship between work arrangements and worker safety, health, and well-being. Preliminary evidence has suggested that workers in some nonstandard arrangements are more likely to experience increased exposure to poor psychosocial work environments, safety hazards, job stress, lower pay, less access to fringe benefits (including health insurance), financial stress, and poor health-related quality of life. The proposed 2021 NHIS-OHS will help characterize several types of nonstandard work arrangements (e.g. self-employed, contractor or temporary agency worker), work schedules, and related workplace psychosocial exposures (e.g., job insecurity). NIOSH is interested in examining potential associations between worker health and well-being and various work structures and environments. The list of exposures proposed to be measured (e.g. job insecurity) and associated outcomes measured by NIOSH (e.g. general health status) is provided in Attachment 1.

In developing the questions for the 2021 OHS, NIOSH’s DSHEF collaborated with a panel of subject matter experts and participated in the National Academies of Sciences Meeting in June 2019 which was led by the Contingent Work and Alternate Work Arrangements Committee. The 2021 OHS questions will concentrate on characteristics of healthy work design, focusing on detailed characterization of work schedules, work arrangements, and workplace psychosocial exposures. The proposed questions will help characterize several types of nonstandard work arrangements (e.g. self-employed, contractor or temporary agency worker), work schedules, and related workplace psychosocial exposures (e.g., job insecurity). The 2021 NHIS-OHS data will primarily be used to study associations between these job characteristics and select health outcomes in order to determine which elements of work design may be associated with poor health outcomes so that they can be targeted for interventions. Although some of the elements of interest (nonstandard work arrangements, contingent work, and precarious employment) are covered by the NHIS core or rotating core content, the 2021 NHIS-OHS will collect data that will expand our understanding of these concepts. Attachment 1 details the constructs that will be captured in the 2021 NHIS annual or rotating core, the proposed constructs for cognitive testing, as well as the potential associations with health outcomes and occupational safety.

This project is only proposing cognitive testing; however, NIOSH has noted that the analytical sample derived from the 2021 NHIS-OHS quantitative data will be described as workers from a representative sample of the civilian noninstitutionalized population of the U.S. Additional details about the quantitative sample (e.g. impact of sampling error on small subpopulations) are discussed in Attachment 1.

Testing the 2021 OHS will help NIOSH understand the performance of questions on the OHS, including how respondents interpreted questions and any difficulty that respondents had in answering questions or out of scope patterns of interpretation. Study findings will help NHIS and NIOSH to revise and validate the supplement before fielding the 2021 OHS on the NHIS.

The occupational health questions we are evaluating are included as Attachment 2. The testing procedure conforms to the cognitive interviewing techniques that have been described in CCQDER’s generic OMB clearance package (OMB No. 0920-0222, Exp. Date 08/31/2021).

We propose to recruit 20 English speaking adults (aged 18 and over) who are either employed or do volunteer work across different work environments. Specifically, we will be recruiting for respondents who are involved in standard 9 to 5 work as well as those in non-standard work such as shift work, temp work, self-employed, gig work (e.g., uber/lyft), and contractors.

Recruitment will be carried out through a combination of a newspaper advertisement, flyers, special interest groups, and word-of-mouth. The newspaper advertisements/flyers used to recruit respondents are shown in Attachments 3a&b. The 5-minute screener used to determine eligibility of individuals responding to the newspaper advertisements/flyers is shown in Attachment 4a. The 5-minute screener used to determine eligibility of individuals from the CCQDER Respondent Database is shown in Attachment 4b. Note that wording of the templates have been approved and are contained within our umbrella package. Only project specific information has been added to the documents. It is anticipated that as many as 35 individuals may need to be screened in order to recruit 20 participants.

Interviews averaging 60-minutes (including the completion of a Respondent Data Collection Sheet) will be conducted by CCQDER staff members with English-speaking respondents. Interviews will be conducted in the Questionnaire Design Research Laboratory (QDRL) as well as at off-site locations. All interviews, including those conducted in the QDRL and those conducted off-site, will be video and audio recorded to allow researchers to review the behaviors and body language of the respondents. These recordings will also allow researchers to ensure the quality of their interview notes. Recordings will be used in accordance with the CCQDER Data Storage and Access Policy and will depend on what the participant agrees to during the informed consent and special consent process. Researchers from CCQDER, and National Institute for Occupational Safety and Health (NIOSH), Division of Surveillance, Hazard Evaluations, and Field Studies (DSHEFS), who are working on the project, will use the recordings for research purposes. Recordings will remain under CCQDER staff control. NIOSH and DSHEFS staff traveling to the Questionnaire Design Research Laboratory to view the recordings in the QDRL under CCQDER supervision will read and sign a nondisclosure affidavit.

Video or audio recording is required for this project except in the rare case that a study participant initially agrees to be video recorded during the telephone screening, but changes their mind. In that case, they will be asked if they agree to be audio recorded. If they decline to be audio recorded the interview will proceed without recording. In this case the interviewer will depend on their handwritten notes when conducting analysis. In addition, individuals who select “yes” for allowing the 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.

NCHS government issued encrypted laptops will be used to video and audio record the interviews conducted off-site. Due to the size of the video recordings, the internal drive of the encrypted laptop is not sufficient for storage of the recordings. Recordings will be saved to an NCHS government issued encrypted flash drive. The encrypted flash drive is FIPS 140-2 compliant and approved for use by OCISO.

CCQDER staff will also use the NCHS government issued encrypted laptops to input their interviewer notes into Q-Notes. Within 24 hours, a CCQDER staff member will review the 2021 Occupational Health Supplement Questions interview notes and will delete any direct or indirect personal identifiable information (PII) if found.

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. Once the video and audio recordings are transferred to the QDRL Network, the recordings will be deleted from encrypted flash drive. Once deleted, the files are no longer available for use.

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 5). 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 6). 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 your work environment. 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 Jennifer Madans, Acting Director of NCHS (Attachment 7), 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 8). 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.

We propose giving participants $40 incentives, which is our standard incentive. In total, for this project, the maximum respondent burden will be 23 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 (recruited from newspaper/flyer) | 35 | 1 | 5/60 | 3 |
| Questionnaire  | 20 | 1 | 55/60 | 18 |
| Respondent Data Collection Sheet | 20 | 1 | 5/60 | 2 |
| Total | 23 |

Attachments (8)

cc:

V. Buie

J. Zirger

DHHS RCO