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

March xx, 2019

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. 08/31/2021) plans to conduct a cognitive interviewing study to evaluate questions on intellectual and developmental disabilities (I/DD; as defined in points 1-2 below) for the Department of Health and Human Services (HHS), Administration for Community Living (ACL), Administration on Intellectual and Developmental Disabilities (AIDD). The ultimate goals are to update national prevalence estimates for individuals with I/DD and to gather improved health surveillance data among this population.

Definitions:

1. The DD Act of 2000, (Pub. L. 106-402) defined **Developmental Disability** as a severe, chronic disability that is attributable to a mental and/or physical impairment, is manifested before the individual attains age 22, is likely to continue indefinitely, results in substantial functional limitations in three or more of the following areas of major life activity: self-care, receptive and expressive language, learning, mobility, self-direction, capacity for independent living, and economic self-sufficiency; and reflects the individual's need for a combination and sequence of services and supports."

2. **Intellectual Disability** is defined as, "a disability characterized by significant limitations in both intellectual functioning and in adaptive behavior, which originates before the age of 18" (Schalock et al, 2010). Intellectual functioning, or intelligence, refers to general mental ability including reasoning, planning, solving problems, thinking abstractly, comprehending complex ideas, learning quickly, and learning from experience. Adaptive behavior is the collection of conceptual, social, and practical skills that have been learned and are performed by people in their everyday lives (Schalock et al, 2010).

Study Background and Purpose:

In an effort to better understand the health status and prevalence of people with I/DD, a workgroup comprised of key agencies within HHS[1] and other experts in the field of I/DD convened during the first half of 2018 to review the current landscape and future needs related to health surveillance among this population. The workgroup concluded that national health surveys do not adequately identify people with I/DD, particularly adults. Priority criteria for better identifying adults with IDD relate to measurements of **learning**, **independent living**,

[1] Workgroup participants include representatives from the Administration for Community Living, Centers for Disease Control & Prevention, Centers for Medicare & Medicaid Services, Office of Minority Health (OMH/HHS), and Assistant Secretary for Planning and Evaluation (ASPE/HHS)

and **age of onset**. Thus, the purpose of this cognitive interviewing study is to develop and evaluate questions within these priority areas that can be used – in conjunction with existing survey questions – to update national prevalence estimates of I/DD among adults in the United States.

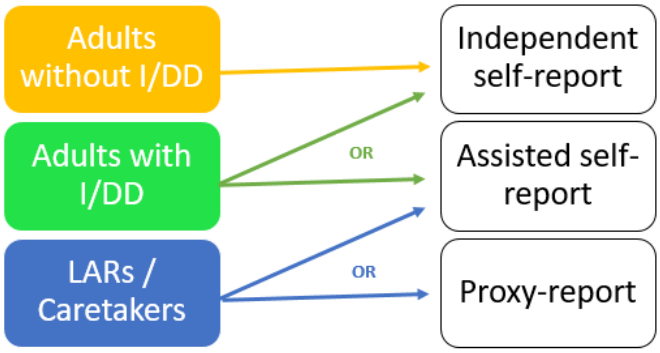
More specifically, the two main goals of this project are to:

1. Identify a small number of questions that can be added to the National Health Interview Survey (NHIS) (OMB No. 0920-0214, Exp. Date 12/31/2020). and other national surveys to better assess prevalence of I/DD, and
2. Evaluate additional questions that may be used for more refined identification of I/DD in future, more specialized health surveys.

Study Protocol:

The disability questions we are evaluating are included as Attachments 1a&b. In addition to questions newly developed for this project, we also test a number of questions derived from existing surveys and pertinent to I/DD. For example, the first 6 questions were developed by the Washington Group on Disability Statistics and are currently in use on the NHIS. Other questions were derived from the American Community Survey (ACS) (OMB No. 0607-0810, Exp. Date 06/30/2021) and the 1994/1995 National Health Interview Survey-Disability Survey (NHIS-D), legally. One item was modified from the Diagnostic Adaptive Behavior Scale (DABS[2]) to apply to an adult population. 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). Staff will adhere to a protocol designed for previous disability projects when screening, selecting, and acquiring informed consent for adults with learning difficulties and adaptive limitations. Specific safeguards for this vulnerable population are described in further detail below. Prior to study commencement, all staff working on the project will participate in a one-hour training session led by professionals in the disability field. In addition to covering study-specific safeguards, the training will provide more general guidance for working with adults with I/DD.

We propose to recruit 80 English-speaking adults (aged 18 and over). Recruitment of individuals will be guided first by their experience with the learning difficulties and adaptational limitations associated with statutory definitions of I/DD (presented in #1-2 above). We aim to recruit adults who meet these criteria, as well as adults who do not. We will also recruit caretakers of adults with I/DD to either assist with the interview or participate in their own proxy-report interview. The diagram below illustrates the groups we will recruit and the types of interviews they may take part in.



LAR = Legally Authorized Representative

[2] Tassé, M. J., Schalock, R. L., Balboni, G., Bersani, H., Borthwick-Duffy, S. A., & Spreat, S. (2014). Diagnostic adaptive behavior scale (DABS). *Washington, DC: American Association on Intellectual and Developmental Disabilities*

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 and the inclusion criteria of 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.

Recruitment will be carried out through networks of service providers, as well as through a combination of a newspaper advertisement, flyers, word-of-mouth, and CCQDER Respondent Database. The newspaper advertisements/flyers used to recruit respondents with I/DD, their caretakers/proxies, and respondents without I/DD are shown in Attachments 2a, 2b, & 2c, respectively. The 5 minute screener used to determine eligibility of individuals responding to the newspaper advertisements/flyers is shown in Attachment 3a. The 5 minute screener used to determine eligibility of individuals from the CCQDER Respondent Database is shown in Attachment 3b. 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 160 individuals may need to be screened in order to recruit 80 participants.

During the initial telephone screener, individuals will be screened about the nature of their learning and adaptive difficulties.[3] Based on the respondent's difficulties, as well as the flow of the conversation, the CCQDER Recruiter will use their discretion in determining whether consent capacity may be impaired. In cases of questionable or impaired consent capacity, the Recruiter will ask if the individual has a support provider or family member they would like to bring along to the interview. The Recruiter will ask permission to speak with the support person in order to provide further details about the study. If this support person is a legally authorized representative (LAR), we will seek their consent for the prospective respondent to participate in our study. If the support person is not a LAR, we will ask for the LAR's contact information. We will invite the LAR to attend the study session with the respondent.[4] The LAR will be given the option of completing a simultaneous proxy-report interview in a separate room or, alternately, remaining in the room to assist the person with I/DD. If, by chance, an individual is scheduled for a solo interview, but upon arrival indicates that they are having trouble reading and/or understanding the informed consent form, or if the Recruiter suspects that the respondent is having trouble reading or understanding the consent form, the Recruiter will notify the CCQDER Interviewer, who will in turn conduct a formal assessment of consent capacity. Specifically, the Interviewer will ask the following questions, adapted from published instruments measuring consent capacity (Horner-Johnson & Bailey, 2013; Jeste et al., 2007)[5]:

[3] In some cases, initial telephone contact will be made by a support provider such as a family member, legal guardian, case manager, or paid support staff. In these cases, the study will be explained to the support provider and the screening process will only be allowed to continue with the agreement of that provider.

[4] If requested, a caregiver other than the LAR will be allowed to attend the study session with the respondent. In such cases, signed LAR consent forms permitting the respondent with IDD to take part in the study will be received prior to the scheduled interview. Alternatively, the forms may be hand carried by the IDD respondent in a sealed enveloped provided by NCHS, The Laboratory Manager/Staff person will check the forms for completeness and will call the LAR to verify that they have given their permission for the respondent with IDD to participate in the study session. If any of the required forms are missing or incomplete, the respondent will not be allowed to participate in the interview and will not receive remuneration. LARs will be informed of this during the recruiting and screening process.

[5] Horner-Johnson, W., & Bailey, D. (2013). Assessing Understanding and Obtaining Consent from Adults with Intellectual Disabilities for a Health Promotion Study. *Journal of policy and practice in intellectual disabilities*, *10*(3), 10.1111/jppi.12048.

Jeste, D. V., Palmer, B. W., Appelbaum, P. S., Golshan, S., Glorioso, D., Dunn, L. B., ... & Kraemer, H. C. (2007). A new brief instrument for assessing decisional capacity for clinical research. *Archives of general psychiatry*, *64*(8), 966-974.

1. Please tell me, in your own words, what you will be asked to do if you take part in this study?
2. When I say your taking part is completely voluntary, what does that mean to you?

3. Do you have to answer all of the questions in this study?

4. What can you do if you start the study but don't want to finish it?

If the respondent has difficulty answering a question, that portion of the consent information will be explained again, with rephrasing if needed, and the respondent will be given a second chance to answer the question. The respondent will be encouraged to fully explain their answers and to ask questions if needed. Where any doubt exists about the appropriateness of a response, the Interviewer will err on the side of caution and terminate the study session. The individual will be paid and escorted out of the building.

Interviews will be conducted by CCQDER staff members with English speaking respondents for up to 60 minutes per interview. Interviews will be conducted in the Questionnaire Design and Evaluation Research Laboratory as well as at off-site locations. All interviews conducted in the Questionnaire Design and Evaluation Research Laboratory and off-site will be video and audio recorded to allow researchers to review the behaviors and body language of the respondents. These recordings will allow researchers to ensure the quality of their interview notes. Recordings will only be used by researchers from CCQDER, the Office of Analysis and Epidemiology (OAE), and Health and Human Services, Administration for Community Living, Administration on Intellectual and Developmental Disabilities (HHS/ACL/AIDD) who are working on the project. Recordings will remain under CCQDER staff control. There will be no non-governmental external sharing of the recordings. HHS/ACL/AIDD staff traveling to the Questionnaire Design Research Laboratory (QDRL) to view/listen to 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 I/DD project 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/Informed Assent document[6]. Only project specific information has been added to the document. Different consent documents will be used depending on the type of interview (self-report vs. proxy-report; see Attachments 4a & 4b, respectively). In cases of questionable consent capacity, assessed via procedures described above, a LAR will be asked to sign a consent form permitting the respondent to participate and the respondent will be asked to sign an Informed Assent form (see Attachments 4c & 4d, respectively). All respondents will be asked to fill out the Respondent Data Collection Sheet (Attachment 5). This document is contained in our umbrella package. The burden for completion of this form is captured in the interview. If the LAR has agreed to participate in a proxy-report interview, he/she will then be escorted to a different room and all procedures described here will be carried out by a separate Interviewer, with the LAR serving as the proxy respondent. If the LAR has declined participation in a proxy-report interview, then he/she will be given the option of remaining in the room[7] or waiting in a different room until the person under their care has finished his/her interview.

The interviewer will then ask the respondent to confirm that he/she understands the information in the Informed Consent/Informed Assent, 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 we will want to use with lots of people all around the country. We call that a national survey. Before that happens, we like to test them out on many types of people. You can help us make these questions as good as we can. The questions we are testing today are about health and how easy or hard it is for a person to do things in everyday life, like learning new things, solving problems, and making decisions. We are interested in how you understand and answer the questions. I may also ask you about the questions on the survey—like whether they make sense to you, what you think about when you hear certain words, and so on.*
>
> *So, I will read a question to you, and I'd like you 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],*[8]
> *or if the answer you are looking for is not provided.*
>
> *The more you can tell us, the more it helps us make better questions. Okay? Do you have any questions before we start? If yes, answer questions. If not, let's get started.*

[6] The consent form will be read aloud to the respondent when necessary.
[7] The LAR will be asked to allow the respondent to answer independently to the best of his/her ability, providing assistance only when necessary or specifically requested.
[8] The bracketed material is cognitively complex and will therefore be omitted from the introduction for respondents with I/DD

For all respondents, but especially for those with impaired consent capacity, the Investigator will carefully monitor the respondent's continued understanding of the voluntary nature of their participation and will provide reminders about the right to withdraw without penalty. After the interview, respondents will be given the thank-you letter (document contained in umbrella package) signed by the Acting Director of NCHS (Attachment 6), a copy of the Informed Consent/ Informed Assent documents, and $40 each.[9]

We propose giving participants $40 incentives, which is our standard incentive. In total, for this project, the maximum respondent burden will be 94 hours. A burden table for this project is shown below:

Form Name	**Number of Participants**	**Number of Responses/Participants**	**Average hours per response**	**Response Burden (in hours)**
Screener (recruited from newspaper/flyer)	160	1	5/60	13
Self-Report Questionnaire	40	1	55/60	37
Proxy Questionnaire	40	1	55/60	37
Respondent Data Collection Sheets	80	1	5/60	7
Total				94

Attachments (6)
cc:
V. Buie
J. Zirger
DHHS RCO

[9] When LARs/caretakers complete a proxy respondent interview, the LAR/caretaker will be paid $40. If a LAR/caretaker does not complete a proxy interview and instead chooses to stay in the room with the respondent with IDD, only the respondent with IDD will be paid $40, not the LAR/Caretaker.