

Supporting Statement A for Request for Clearance:  
**COLLABORATING CENTER FOR QUESTIONNAIRE  
DESIGN AND EVALUATION RESEARCH**

**Point of Care Checklist Subproject 1: Conducting in-depth  
interviews among those with intellectual and developmental  
disabilities**

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## Table of Contents

A.	Justification.....	1
A.1.	Circumstances Making the Collection of Information Necessary.....	1
A.2.	Purpose and Use of Information Collection.....	1
A.10.	Protection of the Privacy and Confidentiality of Information Provided by Respondents	6
A.11.	Institutional Review Board (IRB) and Justification for Sensitive Questions.....	7
A.12.	Estimates of Annualized Burden hours and costs.....	7

## LIST OF ATTACHMENTS

- Attachment 1: Topic Guide
- Attachment 2: History and Development
- Attachment 3: Advertisements
- Attachment 4: Screening Script
- Attachment 5: Informed Consent

## Supporting Statement A

### Collaborating Center for Questionnaire Design and Evaluation Research

The staff of the National Center for Health Statistics' (NCHS), Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) (OMB No. 0920-0222, exp. 01/31/2026) proposes to conduct exploratory research, using qualitative ethnographic in-depth interviews with people with an Intellectual and Developmental Disability (ID/DD), on functional difficulties they may experience in everyday life. Recruitment of respondents and interviewing would begin as soon as approval is received.

#### **A. Justification**

##### **A.1. Circumstances Making the Collection of Information Necessary**

The NCHS Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) conducts qualitative and mixed method research. CCQDER data collection is authorized under a generic OMB clearance (OMB No. 0920-0222, Exp. Date 01/31/2026) and 42 U.S.C. 242k (Section 306 of the Public Health Service Act).

##### **A.2. Purpose and Use of Information Collection**

CCQDER conducts exploratory question evaluation studies, for both applied and methodological purposes, with particular focus on question design, measurement, comparability, and error.

The purpose of the current project is to conduct exploratory research using ethnographic in-depth one-on-one interviews with individuals with ID/DD and their support community in collaboration with The Centers for Disease Control and Prevention's (CDC) National Center on Birth Defects and Developmental Disabilities (NCBDDD). The exploratory work will inform the future development of a functional disability checklist that could be used (either as self-reported or by proxy) at point-of-care settings to identify individuals with ID/DD. CCQDER will interview 40 English-speaking respondents<sup>1</sup> with the use of an interview topic guide. The topic guide is included as Attachment 1. History and development of the topic guide is included as Attachment 2. NCHS understands that OMB approval for exploration of these topics does not imply or guarantee future approval for use or application of these or similar items.

The functional disability checklist will be the final product of a multi-phase project recently funded by the Office of the Secretary Patient-Centered Outcomes Research Trust Fund which aims to improve identification and representation of individuals with ID/DD in administrative healthcare data systems used for public health surveillance and allocation of resources.

Consistent representation in healthcare and service data is necessary for improving services and

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<sup>1</sup> Some respondents may utilize text-to-speech augmentative communication software.

outcomes for people with ID/DD.<sup>2,3,4</sup> To fulfil this objective, accurate and complete reporting of ID/DD by the individual, a healthcare provider, or other proxy reporter, is needed at the time of point of care.<sup>5</sup> Functional disability status was recently added as a United States Core Data for Interoperability (USCDI) v3 data element based on the current HHS standard for identifying disability status in federal surveys. Various question sets designed to capture and measure disability, such as the American Community Survey-6 and Washington Group Short Set, have been thoroughly tested and are also available for use. However, these questions were designed for use in surveys and have not been adapted for use in a clinical setting, such as on a clinical intake form. In addition, these established question sets may not cover certain domains relevant to ID/DD and little research has been carried out among those with ID/DD to establish whether there are functional difficulties that they encounter outside of the domains covered by the standard survey disability questions<sup>6</sup>.

The first phase in this multi-phase project, and for which this application is being made, involves working directly with those with ID/DD and their support community by conducting exploratory research to help inform the initial design of the point-of-care checklist instrument. The aim of this exploratory research phase is to provide information not only on potential content of the instrument to be developed, but also information on the different ways in which respondents with ID/DD best communicate, to include where possible those who use non-verbal communications<sup>7</sup>, such that the instrument can be made accessible.

Unlike CCQDER cognitive interviewing projects, this project will not test specific questions. The interviewers will use a topic guide, wherein the interviewer has a range of topics to cover, but no specific order or question wording. Indeed, the discussion will be respondent driven, and will focus on the topics most salient to the respondent's life experiences.

The methodological aim of this study is consistent with the design of NCHS/CCQDER ethnographic interviews, that is, to understand social context, interactions, and practices so that questions about the study topic may better reflect how people perceive and interact with the world. The testing procedure conforms to the ethnographic interview techniques that have been described in CCQDER's generic clearance package (OMB No. 0920-0222, exp. 01/31/2026). Within that framework, the following procedures are particular to this study:

### Recruitment

We propose to recruit up to 40 English speaking, community dwelling,<sup>8</sup> adult (18+) respondents. Up to 40 ethnographic in-depth interviews will be conducted, most as proxy/respondent dyads.

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2 Developmental disabilities are a group of conditions due to an impairment in physical, learning, language, or behavior areas beginning before age 22, during a person's development. Intellectual disability is a type of developmental disability which is characterized by limitations in intellectual functioning and adaptive behavior that begin during the developmental period of a person's life.

3 [Facts About Intellectual Disability | CDC](#)

4 [Developmental Disabilities | CDC](#)

5 Point-of-care is defined as a place where medical care is received and where people with disabilities may present for services or supports, e.g., medical clinic or education programs.

6 [WG Short Set on Functioning \(WG-SS\) - The Washington Group on Disability Statistics \(washingtongroup-disability.com\)](#)

7 Non-verbal communicators who use an assistive device to communicate.

8 To include group homes

We will recruit self-reporting respondents with intellectual or developmental disabilities.<sup>9</sup> The sample will include adults with primary diagnosis of intellectual disability, primary diagnosis of the developmental disability of autism spectrum disorder (ASD)<sup>10</sup> (who may or may not have an intellectual disability), and those with the primary diagnosis of the developmental disability Cerebral Palsy (CP)<sup>11</sup> (who may or may not have an intellectual disability). The inclusion of people with these diagnoses in the sample will reflect a range of conditions associated with ID/DD. This is because ID, ASD, and CP are common DDs that are typically diagnosed early in someone's life, expected to be lifelong, and affect multiple domains of functioning (as opposed to other common DDs like vision and hearing loss).<sup>12</sup> We will aim to recruit a mix of respondents who might be considered have mild, moderate, and severe ID/DD. This severity assessment will be included in the screener and is based on the level of support respondents receive with daily life activities.<sup>13</sup> We will also aim to include a few people with ID/DD who are non-verbal communicators, to account for communication differences across the ID/DD community. Additionally, we will recruit aides or caregivers of adults with ID/DD to participate in their own interview as one half of a respondent-proxy dyad (discussed in more detail below). In addition, demographic diversity and intersectionality is also a priority, with the goal of achieving a purposive sample that includes a mix of genders, age, and race/ethnicity. We also aim to recruit respondents from different geographical locations around the country.

Some respondents may prefer to have a support person sit with them during the interview to help with communication. This support person, most will be chosen by the respondent, but where possible, will not be the person interviewed as part of the proxy respondent-dyads. This is because in previous studies we have found that the presence of the proxy respondent can influence the way in which respondents engage with the interview process.

As mentioned above, aides or caregivers of adults with ID/DD may participate in their own interview. For the purposes of this application, we will refer to these support persons as proxy respondents or proxy reports. In this scenario, proxy-report interviews will be conducted if the corresponding self-report interview is also scheduled and conducted and will not be attempted in cases where there is no corresponding self-report interview. The proxy respondent will know the person with ID/DD well and will provide close personal support for that person. These interviews will be conducted separately from that with the person with ID/DD. The proxy-report person may be an aide or caregiver, someone with firsthand knowledge of the person with

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<sup>9</sup>Developmental disabilities are a group of conditions due to an impairment in physical, learning, language, or behavior areas beginning before age 22, during a person's development. Intellectual disability is a type of developmental disability which is characterized by limitations in intellectual functioning and adaptive behavior that begin during the developmental period of a person's life.

<sup>10</sup> [Autism Spectrum Disorder \(ASD\) | Autism | NCBDDD | CDC](#)

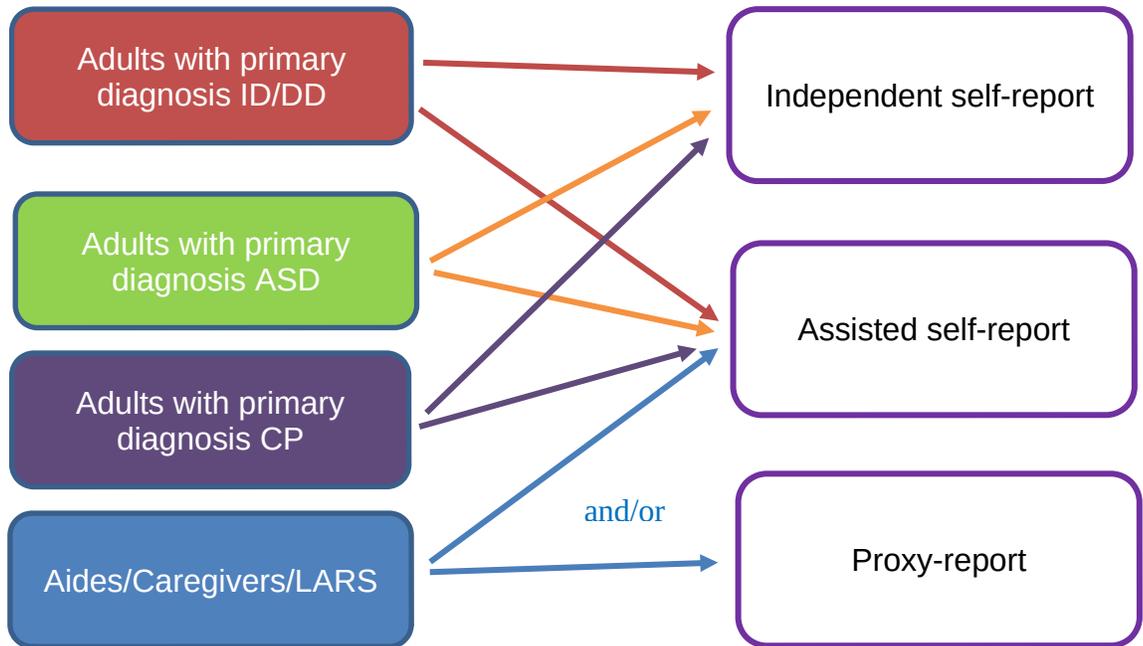
<sup>11</sup> [What is Cerebral Palsy? | CDC](#)

<sup>12</sup> Van Naarden Braun K, Christensen D, Doernberg N, Schieve L, Rice C, Wiggins L, Schendel D, Yeargin-Allsopp M. Trends in the prevalence of autism spectrum disorder, cerebral palsy, hearing loss, intellectual disability, and vision impairment, metropolitan Atlanta, 1991–2010. *PloS one*. 2015 Apr 29;10(4):e0124120. [journals.plos.org/plosone/article?id=10.1371/journal.pone.0124120](https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0124120)

<sup>13</sup> Tassé MJ, Balboni G, Navas P, Luckasson R, Nygren MA, Belacchi C, Bonichini S, Reed GM, Kogan CS. Developing behavioural indicators for intellectual functioning and adaptive behaviour for ICD-11 disorders of intellectual development. *J Intellect Disabil Res*. 2019 May;63(5):386-407. doi: 10.1111/jir.12582. Epub 2019 Jan 9. PMID: 30628126.

ID/DD, but not necessarily their Legally Authorized Representative (LAR). In cases where the support person helping with communications during the respondent interview is also the proxy respondent, we will interview the proxy respondent first so that they are not primed as to the discussion topics in advance of their interview. Although we expect that most interviews will be dyad pairs, there may be cases where a respondent does not have an aide or caregiver. In this scenario the respondent may still qualify to take part in a solo interview.

The diagram below illustrates the groups we will recruit and the types of interviews they may take part in.



Recruitment will be carried out through networks of service providers such as Special Olympics,<sup>14</sup> as well as a combination of advertisements, social media, flyers, word-of-mouth, and the CCQDER Respondent Database, if needed. The advertisements/flyers used to recruit respondents are shown in Attachment 3.

Screening and scheduling procedures

Respondent screening will conform to the protocol laid out in CCQDER’s generic package. The 5-minute screener used to determine eligibility of individuals responding to the advertisements/flyers is shown in Attachment 4. It is anticipated that as many as 60<sup>15</sup> individuals may need to be screened in order to recruit 40 participants.

Interview methods

14 [Special Olympics](#)

15 Our experience is that when recruiting is focused through organizations that support a particular community fewer screenings are recruited than is typical to achieve the required sample.

In-depth, or unstructured, interviews are one of the main methods of data collection used in qualitative research (Legard et al, 2006).<sup>16</sup> An in-depth interview can be considered as a form of guided conversation. A topic guide will be used by the interviewer. The topic guide sets out the key topics and issues to be covered during the interview. The aim is for the interviewer to guide, but not lead, the conversation, and explore, in-depth, factors that are most salient to the respondent, within the context of their own life experiences.

The ethnographic, in-depth interviews will be conducted by CCQDER staff in accordance with the protocol described in CCQDER's generic package. The informed consent documents specific to this project are included as Attachments 5a and 5b. Most of the interviews will be conducted using remote-video but the option to conduct in-person interviews is available.

We expect the interviews to generally take about an hour. However, we are asking for up to 75 minutes. This is because, less structured research interviews, particularly those conducted with people who may have receptive or expressive language difficulties, such as those with ID/DD, may be more variable in length than, for example, a typical semi-structured cognitive interview. There are a number of factors that contribute to this greater variability of interview length due to the nature of the disability and the heterogeneity of the group of people with ID/DD. These factors include: the possibility of a longer set-up time if the interview is being conducted remotely and the respondent needs support; a potentially longer time required to obtain informed consent/assent to ensure that respondents understand what they are consenting to; more time needed on the part of the interviewer to ensure privacy for the interview if other people are around; longer processing times and memory issues related to their disability<sup>17</sup>, and the need for the interviewer to be flexible and adapt their techniques to suit the individual, which means the way in which the interviewer asks questions will vary person-to-person. Interviewers may need to slow down their speech, or repeat what they have said if necessary, and they may need to be sympathetic to the fact that respondents may need to take a break occasionally<sup>18</sup>. Alternatively, the interviewer may find that due to respondent fatigue they need to finish the interview sooner. In previous research we also found that those interviewed on behalf of the person with ID/DD, known as proxy respondents, took time to tell the interviewer in detail about their experiences caring for a person with ID/DD which were not always relevant to the subject matter of the interview, but which the interviewer did not feel appropriate or would be disrespectful to close down too quickly. In addition, in cases where a respondent may use non-verbal communications, and using an augmentative/alternative communication (AAC) device, the interview will unfold at a slower pace due to the time required to operate the device. Allowing some additional time means that these respondents will have the opportunity to fully express themselves.

**Note:** Some documents associated with this project do not vary from those approved in CCQDER's generic OMB package and are, therefore, not included as attachments to this document. These documents are the Respondent Data Collection Sheet, the Thank you Letter, CCQDER's Data Storage and Access Policy and the Nondisclosure Affidavit.

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16 Legard, R., Keegan, J. & Ward, K. (2003). In-depth interviews. In Ritchie, J. & Lewis J. (Eds) *Qualitative Research Practice: A guide for Social Sciences Students and Researchers*. SAGE Publications.

17 [sisguidelinesforinterviewing.pdf \(aaid.org\)](#)

18 Wilmot, A., MacFadyen, A. (2021) Conducting Cognitive Interviews with People with Intellectual Disabilities. NCHS' Division of Research Methodology, Research Memo, 2021-1E. August 10, 2021.

## **A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents**

Data will be kept private to the extent allowed by law.

The CCQDER continues to collect, on a confidential basis, data needed in order to conduct CCQDER studies. Confidentiality provided to respondents is assured by adherence to Section 308(d) of the Public Health Service Act (42 U.S.C. 242m). In addition, legislation covering confidentiality is provided according to the Confidential Information Protection and Statistical Efficiency Act or CIPSEA (44 U.S.C. 3561-3583), which states:

“Whoever, being an officer, employee, or agent of an agency acquiring information for exclusively statistical purposes, having taken and subscribed the oath of office, or having sworn to observe the limitations imposed by this section, comes into possession of such information by reason of his or her being an officer, employee, or agent and, knowing that the disclosure of the specific information is prohibited under the provisions of this subchapter, willfully discloses the information in any manner to a person or agency not entitled to receive it, shall be guilty of a class E felony and imprisoned for not more than 5 years, or fined not more than \$250,000, or both.”

### **Confidentiality of responses and safeguarding of data at NCHS**

The CCQDER has a routine set of administrative, technical, and physical measures to safeguard confidentiality. Specific protocol for storage of confidential data, QDRL Lab, Q-video, Q-Notes, and Q-Bank access is described in CCQDER’s generic clearance package. (OMB No. 0920-0222, exp. 01/31/2026)

### **Records Retention Schedule for In-depth Interviews**

Storage and retention of CCQDER data is guided by the CCQDER Data Storage and Access Policy which governs retention of interviews, their viewing audience, the data kept, and the length of time before retention of interviews is reassessed. The Data Storage and Access Policy has been approved by the NCHS ERB and is included in CCQDER’s generic OMB package. In accordance with this policy, data from the current project will be re-evaluated by the CCQDER Director to determine relevance, ongoing usefulness and qualitative value for likely use in question evaluation research after an initial retention period of 2 years. The information of individuals who did not qualify for the study and opt into our respondent database will be kept for 5 years. Removal from the database can be requested by emailing [recruitmentteam@cdc.gov](mailto:recruitmentteam@cdc.gov)

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individuals who did not qualify for the study and opt into our respondent database will be kept for 5 years. Removal from the database can be requested by emailing [recruitmentteam@cdc.gov](mailto:recruitmentteam@cdc.gov).

**A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions**

NCHS Ethics Review Board (ERB) and CDC Human Research Protection Office (HRPO) approved this data collection on 01/08/2024.

**A.12. Estimates of Annualized Burden Hours and Costs**

In January 2023, OMB approved 71,925 total number of respondents and 21,450 total burden hours. This GenIC NCHS is requesting 60 respondents and 61 total burden hours.

Burden Table for Point of Care Checklist Subproject

Table 1: Burden table for Point of Care Checklist Subproject <b>Form Name</b>	<b>Number of Participants</b>	<b>Number of Responses/ Participants</b>	<b>Average hours per response</b>	<b>Response Burden (in hours)</b>
Screener (all recruitment methods as described above (Attachment 3a and 3b)	60	1	5/60	5
Virtual interview Zoom set up support *	40	1	5/60	3
Self-report interview	24	1	1.25	30
Proxy-report interview	16	1	1.25	20
Respondent Data Collection Sheets	40	1	5/60	3
<b>Total</b>	<b>180</b>			<b>61</b>

*\*The maximum is shown but some respondents may not need support and some interviews may be conducted in person in which case there would be no additional time for remote set up added.*