



HDGEC Participant Research ID

						-				
--	--	--	--	--	--	---	--	--	--	--

**FuRST 2.0 Cognitive Pre-testing Round 2
Cognitive Testing Instructions – Interview Guide**

**Version No. 05
Jun 13, 2019**



HDGEC Participant Research ID

						-				
--	--	--	--	--	--	---	--	--	--	--

1. Consent

- a. Date when Informed Consent was obtained from the HDGEC participant: / /
DD MMM YYYY
- b. Date when Informed Consent was obtained from the companion participant: / /
DD MMM YYYY
- OR N/A

2. Eligibility Criteria

- a. Does the HDGEC participant satisfy all the HDGEC inclusion criteria and exclusion criterion?
Yes No
- b. Does the companion participant satisfy all the companion inclusion criteria and exclusion criterion?
Yes No N/A

3. Who is attending the cognitive testing?

- HDGEC participant only
- HDGEC participant and companion together

Site Principal Investigator/Site Principal Investigator’s Designee
Signature:

Date:

 / /
DD MMM YYYY



						-			
--	--	--	--	--	--	---	--	--	--

Round 2 Cognitive Testing “Interview Guide” for FuRST 2.0 Assessment Tool

Cognitive testing is used to elicit respondents’ interpretations of the items in a survey or other data collection instrument being tested. Our goal is to test both the usability and clarity of the Functional Rating Scale (FuRST) 2.0 questionnaire so that revisions can be made to enhance this tool before putting it into practice for its intended purpose. Cognitive testing for the FuRST 2.0 tool will involve in-depth interviews with study participants. Data will be gathered from interviewers and from study participants to understand any difficulties that study participants may have with understanding the FuRST 2.0 questionnaire. Your patience in conducting these in-depth interviews and recording the cognitive study participants’ responses will be invaluable in making the FuRST 2.0 tool as effective as possible as a way to collect valid patient assessment data from people with Huntington’s disease (HD).

Some of the cognitive tests will be conducted with an HDGEC participant alone while in other tests, the HDGEC participant may be accompanied by a companion participant. In the instructions that follow, “item” refers to one of the 24 items on the FuRST 2.0 questionnaire to be reviewed for understandability and completed by the study participant(s). “Question” generally refers to a cognitive test question requiring a response from either the interviewer or the study participant(s) related to difficulties encountered while completing a FuRST 2.0 questionnaire Item.

All instructions and items that are part of the standard FuRST 2.0 questionnaire are **shaded** in the cognitive test form. All **non-shaded** areas are part of the cognitive test script. The cognitive test instructions and questions **for the interviewer** will appear in a **box**. Cognitive test questions for the study participant(s) are not boxed. In general, after each FuRST 2.0 questionnaire item (duplicated on this cognitive test form), there will be a few cognitive test questions to be completed by the interviewer regarding the interviewer’s observations of any difficulties or questions the study participant(s) had with regard to an item (or to the instructions).. These will be followed by cognitive test questions to be addressed directly to the study participant(s) about their understanding of the FuRST 2.0 item and its response options.

All cognitive test question responses from either the interviewer or the study participant(s) are to be recorded in the space provided. Study participant(s) responses should be captured **in their own words whenever possible**. Please respond to all cognitive test questions or mark them “N/A” if the question is not applicable for any reason. Please indicate whether the response was given by the HDGEC participant or the companion by checking the appropriate check box after each question and also document this in your observations (questions 1.0 and 2.0 of each item).

Responses to cognitive test questions should be documented clearly and legibly by the interviewer. Please review the entire Interview Guide before initiating a cognitive test to ensure you are familiar with the flow of non-shaded cognitive test questions interspersed with shaded FuRST 2.0 questionnaire items.

Please **print a separate copy of this Interview Guide for each test** to be conducted.

Please sign the Interviewer’s Statement at the end of the Interview Guide. The Site Principal Investigator (“Site PI”) will also need to sign the Site PI’s Statement on the last page of this Interview Guide, once the interview is complete.

For the delivery process of the complete, signed and dated CRF, please refer to the “Study Manual”.



						-				
--	--	--	--	--	--	---	--	--	--	--

FuRST 2.0 Cognitive Test Form

Site Number: _____

Site Name: _____

Site Interviewer Name: _____

HD Stage (early-manifest or premanifest): _____

Companion Relationship to the HDGEC Participant: _____ or N/A

Visit Date : ____/____/____
 DD MMM YYYY

HDGEC Participant Demographics

Age (years):

Gender: F=Female M=Male

Companion Participant Demographics or N/A

Age (years):

Gender: F=Female M=Male

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Testing Instructions for the Interviewer before giving the study participant(s) the questionnaire:

For the cognitive test, interviewers will have the study participant(s) complete only one question at a time. While the study participant(s) is/are reading the instructions or answering a FuRST 2.0 questionnaire item, the interviewer will observe the study participant(s) to note any difficulties they have interpreting the item or response options. The interviewer will document these observed difficulties in the space provided. After the study participant(s) respond(s) to each item, the interviewer will then pose the cognitive test questions and document the participant(s) response. The interviewer will document who answered each cognitive test question (HDGEC or HDGEC and companion by using the check boxes – H or HC and also document this in observations (questions 1.0 and 2.0 of each item)).

About Cognitive Testing (Interviewer Reads to Study Participant(s)):

Today we are testing and trying to improve the FuRST 2.0 questionnaire which is a tool used to help clinicians understand the impact of HD on the daily life of persons with HD. The goal of this test is to detect any problems that study participants might have understanding the questions we are asking. Thank you for participating with us in this test of the FuRST 2.0 assessment tool.

It is very important to us that you describe any difficulties you have in understanding or responding to particular questions as truthfully as possible. This is not a test of your abilities but of how well we have created an assessment tool that people with HD and their companions can understand easily. If you have difficulty in understanding anything in the questionnaire, you are probably not alone and other people would also have the same difficulty. It is important for us to know this so that we can change the wording and make it easier for everyone to understand and answer consistently. Please do not hesitate to tell me when anything — instructions, questions, response options, or disclaimer statement — is confusing to you, including medical terms.

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Testing Instructions (Interviewer Reads to **Study Participant(s)):**

Please read the instructions on Page 1 and say aloud which parts are confusing to you while you are reading them. After you have read them, I will ask you a few additional questions. Then I will give you further instructions about the cognitive test before you start completing the questionnaire.

Additional Cognitive Testing Instructions (Interviewer Reads to **Companion (if applicable)):**

The instructions on page 1 are written for the study participant you are accompanying. When you see “you” and “your” in the instructions to the scale, this really means the study participant you are accompanying and not you the companion. Please read the instructions on Page 1 and say aloud which parts you think may be confusing to the study participant you are accompanying or to yourself while you are reading them.

Instructions

This questionnaire asks you about difficulties you may have doing your day-to-day activities. People may have several medical issues that impact these activities. Do not worry about separating the effects of different medical issues.

This questionnaire is for you to complete alone. Please read each question carefully and consider all the answers before deciding which answer is best for you. Do not leave any answers blank.

Please follow these guidelines when you are answering the questions:

- If you had no difficulty doing an activity or you have **never** done the activity, please choose option a: No.
- If you had any difficulty doing an activity, please choose options b, c, or d indicating the level of difficulty you had: Mild, Moderate or Severe.
- If you used to do an activity but stopped because of your illness, please choose option d: Severe.

For each question below, please circle letter (a, b, c or d) that best describes how much difficulty you had doing that activity, **on average**, over the **past two weeks**.

Thank you for completing this questionnaire.

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Test Question for the Interviewer

1. What difficulties did you observe or hear voiced while watching the study participant(s) read the questionnaire instructions?

Cognitive Test Questions for the Study Participant(s) Regarding the Questionnaire Instructions

2. How easy or difficult were these instructions for you to understand?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy
H HC

If your rating was less than 6, please provide additional information below

3. Which parts of the instructions were difficult to understand? What was the difficulty?
(Interviewer circles above the difficult parts of the instructions and documents verbal reports in response to the questions below)

H HC

- 3.1 Explain why the language in the instructions made them difficult in the space below

H HC



						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Testing Instructions (Interviewer Reads to HDGEC Study Participant):

Usually, you would fill out the entire FuRST 2.0 questionnaire by yourself before reviewing it with your doctor or nurse. However, today I am going to stop you after you have completed each item to ask you how easy or difficult it was for you to understand the item and to select an appropriate response option. While you are completing the item, please say out loud any problems you may be having with the item or response selection. I will not provide you with any additional information until after you have completed it. Then I will ask you how easy or difficult it was to complete that question and why. Your companion may assist you in answering the questions, as needed.

Additional Cognitive Testing Instructions (Interviewer Reads to Companion (if applicable)):

You may assist the study participant you are accompanying, as needed. Note that when you see “you” and “your” in the questionnaire, this really means the study participant you are accompanying and not you the companion.

						-				
--	--	--	--	--	--	---	--	--	--	--

1. Over the past two weeks, did you have difficulty interacting with other people in person or over the phone?
 - a. No: I had no difficulty doing this.
 - b. Mild: I had difficulty doing this but could still do it well.
 - c. Moderate: I had difficulty doing this well.
 - d. Severe: I could barely do this **or** I could not do it at all.

Document the interviewer's answers to cognitive test questions 1 and 2 while the study participant(s) is/are reading/responding to the FuRST 2.0 item.

0.0 Please write in the study participant(s) self-rating here _____

H HC

1.0 What issues with the FuRST 2.0 item did you observe while the study participant(s) was/were reading or interpreting the question?

2.0 What issues with the FuRST 2.0 response options did you observe while the study participant(s) was/were reading or interpreting the response options?

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Test Questions to be used with the *study participant(s)* after they have read and responded to the FuRST 2.0 item:

3.0 Which parts of the question, if any, seemed difficult to understand?
(Interviewer circles above the difficult parts of the question and documents verbal reports in response to the questions below)

H HC

3.1 Please tell me what made them difficult.

H HC

3.2 In your own words, what might be a better way to ask this question?

H HC

4.0 Overall, how easy or difficult was this question for you to understand?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

5.0 What, if anything, made it difficult for you to select an appropriate response option?

H HC

5.1 How might you revise the response options to make selecting a response easier?

H HC

6.0 Overall, how easy or difficult was it for you to select a response option for that question?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

						-			
--	--	--	--	--	--	---	--	--	--

2. Over the past two weeks, did you have difficulty communicating with other people using electronic devices? Some examples are difficulty texting or using email.

- a. No: I had no difficulty doing this **or** I have never done it.
- b. Mild: I had difficulty doing this but could still do it well.
- c. Moderate: I had difficulty doing this well.
- d. Severe: I could barely do this **or** I could not do it at all.

Document the interviewer's answers to cognitive test questions 1 and 2 while the study participant(s) is/are reading/responding to the FuRST 2.0 item.

0.0 Please write in the study participant(s) self-rating here _____

H HC

1.0 What issues with the FuRST 2.0 item did you observe while the study participant(s) was/were reading or interpreting the question?

2.0 What issues with the FuRST 2.0 response options did you observe while the study participant(s) was/were reading or interpreting the response options?

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Test Questions to be used with the *study participant(s)* after they have read and responded to the FuRST 2.0 item:

3.0 Which parts of the question, if any, seemed difficult to understand?
(Interviewer circles above the difficult parts of the question and documents verbal reports in response to the questions below)

H HC

3.1 Please tell me what made them difficult.

H HC

3.2 In your own words, what might be a better way to ask this question?

H HC

4.0 Overall, how easy or difficult was this question for you to understand?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

5.0 What, if anything, made it difficult for you to select an appropriate response option?

H HC

5.1 How might you revise the response options to make selecting a response easier?

H HC

6.0 Overall, how easy or difficult was it for you to select a response option for that question?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

						-				
--	--	--	--	--	--	---	--	--	--	--

3. Over the past two weeks, did you have difficulty doing chores around the house?
- a. No: I had no difficulty doing this.
 - b. Mild: I had difficulty doing this but could still do it well.
 - c. Moderate: I had difficulty doing this well.
 - d. Severe: I could barely do this **or** I could not do it at all.

Document the interviewer's answers to cognitive test questions 1 and 2 while the study participant(s) is/are reading/responding to the FuRST 2.0 item.

0.0 Please write in the study participant(s) self-rating here _____

H HC

1.0 What issues with the FuRST 2.0 item did you observe while the study participant(s) was/were reading or interpreting the question?

2.0 What issues with the FuRST 2.0 response options did you observe while the study participant(s) was/were reading or interpreting the response options?

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Test Questions to be used with the *study participant(s)* after they have read and responded to the FuRST 2.0 item:

3.0 Which parts of the question, if any, seemed difficult to understand?
(Interviewer circles above the difficult parts of the question and documents verbal reports in response to the questions below)

<input type="checkbox"/>	<input type="checkbox"/>
H	HC
<input type="checkbox"/>	<input type="checkbox"/>
H	HC

3.1 Please tell me what made them difficult.

<input type="checkbox"/>	<input type="checkbox"/>
H	HC

3.2 In your own words, what might be a better way to ask this question?

<input type="checkbox"/>	<input type="checkbox"/>
H	HC

4.0 Overall, how easy or difficult was this question for you to understand?
(Check the box on left of the applicable number)

Very difficult	<input type="checkbox"/>	1	<input type="checkbox"/>	2	<input type="checkbox"/>	3	<input type="checkbox"/>	4	<input type="checkbox"/>	5	<input type="checkbox"/>	6	Very Easy	<input type="checkbox"/>	<input type="checkbox"/>
	H													H	HC

5.0 What, if anything, made it difficult for you to select an appropriate response option?

<input type="checkbox"/>	<input type="checkbox"/>
H	HC

5.1 How might you revise the response options to make selecting a response easier?

H	HC
---	----

6.0 Overall, how easy or difficult was it for you to select a response option for that question?
(Check the box on left of the applicable number)

Very difficult	<input type="checkbox"/>	1	<input type="checkbox"/>	2	<input type="checkbox"/>	3	<input type="checkbox"/>	4	<input type="checkbox"/>	5	<input type="checkbox"/>	6	Very Easy	<input type="checkbox"/>	<input type="checkbox"/>
	H													H	HC

						-				
--	--	--	--	--	--	---	--	--	--	--

4. Over the past two weeks, did you have difficulty working at your job? Some examples are making mistakes or not finishing everything.

- a. No: I had no difficulty doing this **or** I have never done it.
- b. Mild: I had difficulty doing this but could still do it well.
- c. Moderate: I had difficulty doing this well.
- d. Severe: I could barely do this **or** I could not do it at all.

Document the interviewer's answers to cognitive test questions 1 and 2 while the study participant(s) is/are reading/responding to the FuRST 2.0 item.

0.0 Please write in the study participant(s) self-rating here _____

H HC

1.0 What issues with the FuRST 2.0 item did you observe while the study participant(s) was/were reading or interpreting the question?

2.0 What issues with the FuRST 2.0 response options did you observe while the study participant(s) was/were reading or interpreting the response options?

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Test Questions to be used with the *study participant(s)* after they have read and responded to the FuRST 2.0 item:

3.0 Which parts of the question, if any, seemed difficult to understand?
(Interviewer circles above the difficult parts of the question and documents verbal reports in response to the questions below)

3.1 Please tell me what made them difficult.
H HC

3.2 In your own words, what might be a better way to ask this question?
H HC

4.0 Overall, how easy or difficult was this question for you to understand?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy
H HC

5.0 What, if anything, made it difficult for you to select an appropriate response option?
H HC

5.1 How might you revise the response options to make selecting a response easier?
H HC

6.0 Overall, how easy or difficult was it for you to select a response option for that question?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy
H HC

						-			
--	--	--	--	--	--	---	--	--	--

5. Over the past two weeks did you have difficulty using cash or credit cards? Some examples are difficulty remembering PIN numbers, finding your credit cards or taking money out of your pocket, wallet or handbag.

- a. No: I had no difficulty doing this.
- b. Mild: I had difficulty doing this but could still do it well.
- c. Moderate: I had difficulty doing this well.
- d. Severe: I could barely do this **or** I could not do it at all.

Document the interviewer's answers to cognitive test questions 1 and 2 while the study participant(s) is/are reading/responding to the FuRST 2.0 item.

0.0 Please write in the study participant(s) self-rating here _____

H HC

1.0 What issues with the FuRST 2.0 item did you observe while the study participant(s) was/were reading or interpreting the question?

2.0 What issues with the FuRST 2.0 response options did you observe while the study participant(s) was/were reading or interpreting the response options?

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Test Questions to be used with the *study participant(s)* after they have read and responded to the FuRST 2.0 item:

3.0 Which parts of the question, if any, seemed difficult to understand?
(Interviewer circles above the difficult parts of the question and documents verbal reports in response to the questions below)

3.1 Please tell me what made them difficult. H HC

3.2 In your own words, what might be a better way to ask this question? H HC

4.0 Overall, how easy or difficult was this question for you to understand?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy H HC

5.0 What, if anything, made it difficult for you to select an appropriate response option? H HC

5.1 How might you revise the response options to make selecting a response easier? H HC

6.0 Overall, how easy or difficult was it for you to select a response option for that question?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy H HC

						-				
--	--	--	--	--	--	---	--	--	--	--

6. Over the past two weeks did you have difficulty managing your finances? Some examples are difficulty keeping track of your bank accounts or paying your bills.

- a. No: I had no difficulty doing this **or** I have never done it.
- b. Mild: I had difficulty doing this but could still do it well.
- c. Moderate: I had difficulty doing this well.
- d. Severe: I could barely do this **or** I could not do it at all.

Document the interviewer's answers to cognitive test questions 1 and 2 while the study participant(s) is/are reading/responding to the FuRST 2.0 item.

0.0 Please write in the study participant(s) self-rating here _____

H HC

1.0 What issues with the FuRST 2.0 item did you observe while the study participant(s) was/were reading or interpreting the question?

2.0 What issues with the FuRST 2.0 response options did you observe while the study participant(s) was/were reading or interpreting the response options?

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Test Questions to be used with the *study participant(s)* after they have read and responded to the FuRST 2.0 item:

3.0 Which parts of the question, if any, seemed difficult to understand?
(Interviewer circles above the difficult parts of the question and documents verbal reports in response to the questions below)

<input type="checkbox"/>	<input type="checkbox"/>
H	HC
<input type="checkbox"/>	<input type="checkbox"/>
H	HC

3.1 Please tell me what made them difficult.

3.2 In your own words, what might be a better way to ask this question?

<input type="checkbox"/>	<input type="checkbox"/>
H	HC

4.0 Overall, how easy or difficult was this question for you to understand?
(Check the box on left of the applicable number)

Very difficult	<input type="checkbox"/>	Very Easy	<input type="checkbox"/>	<input type="checkbox"/>					
	H							H	HC

5.0 What, if anything, made it difficult for you to select an appropriate response option?

<input type="checkbox"/>	<input type="checkbox"/>
H	HC

5.1 How might you revise the response options to make selecting a response easier?
H HC

6.0 Overall, how easy or difficult was it for you to select a response option for that question?
(Check the box on left of the applicable number)

Very difficult	<input type="checkbox"/>	Very Easy	<input type="checkbox"/>	<input type="checkbox"/>					
	H							H	HC

						-				
--	--	--	--	--	--	---	--	--	--	--

7. Over the past two weeks, did you have difficulty **planning** your day-to-day activities?

- a. No: I had no difficulty doing this.
- b. Mild: I had difficulty doing this but could still do it well.
- c. Moderate: I had difficulty doing this well.
- d. Severe: I could barely do this **or** I could not do it at all.

Document the interviewer's answers to cognitive test questions 1 and 2 while the study participant(s) is/are reading/responding to the FuRST 2.0 item.

0.0 Please write in the study participant(s) self-rating here _____

H HC

1.0 What issues with the FuRST 2.0 item did you observe while the study participant(s) was/were reading or interpreting the question?

2.0 What issues with the FuRST 2.0 response options did you observe while the study participant(s) was/were reading or interpreting the response options?

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Test Questions to be used with the *study participant(s)* after they have read and responded to the FuRST 2.0 item:

3.0 Which parts of the question, if any, seemed difficult to understand?
(Interviewer circles above the difficult parts of the question and documents verbal reports in response to the questions below)

<input type="checkbox"/>	<input type="checkbox"/>
H	HC
<input type="checkbox"/>	<input type="checkbox"/>
H	HC

3.1 Please tell me what made them difficult.

3.2 In your own words, what might be a better way to ask this question?

<input type="checkbox"/>	<input type="checkbox"/>
H	HC

4.0 Overall, how easy or difficult was this question for you to understand?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

<input type="checkbox"/>	<input type="checkbox"/>
H	HC

5.0 What, if anything, made it difficult for you to select an appropriate response option?

<input type="checkbox"/>	<input type="checkbox"/>
H	HC

5.1 How might you revise the response options to make selecting a response easier?

H	HC
---	----

6.0 Overall, how easy or difficult was it for you to select a response option for that question?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

<input type="checkbox"/>	<input type="checkbox"/>
H	HC

						-				
--	--	--	--	--	--	---	--	--	--	--

8. Over the past two weeks did you have difficulty **getting started** with your day-to-day activities?

- a. No: I had no difficulty doing this.
- b. Mild: I had difficulty doing this but could still do it well.
- c. Moderate: I had difficulty doing this well.
- d. Severe: I could barely do this **or** I could not do it at all.

Document the interviewer's answers to cognitive test questions 1 and 2 while the study participant(s) is/are reading/responding to the FuRST 2.0 item.

0.0 Please write in the study participant(s) self-rating here _____

H HC

1.0 What issues with the FuRST 2.0 item did you observe while the study participant(s) was/were reading or interpreting the question?

2.0 What issues with the FuRST 2.0 response options did you observe while the study participant(s) was/were reading or interpreting the response options?

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Test Questions to be used with the *study participant(s)* after they have read and responded to the FuRST 2.0 item:

3.0 Which parts of the question, if any, seemed difficult to understand?
(Interviewer circles above the difficult parts of the question and documents verbal reports in response to the questions below)

H HC

3.1 Please tell me what made them difficult.

H HC

3.2 In your own words, what might be a better way to ask this question?

H HC

4.0 Overall, how easy or difficult was this question for you to understand?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

5.0 What, if anything, made it difficult for you to select an appropriate response option?

H HC

5.1 How might you revise the response options to make selecting a response easier?
H HC

6.0 Overall, how easy or difficult was it for you to select a response option for that question?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

						-				
--	--	--	--	--	--	---	--	--	--	--

9. Over the past two weeks did you have difficulty getting to where you needed to go without assistance? Some examples are difficulty getting in or out of a car, bus or train, or difficulty knowing how to get somewhere.

- a. No: I had no difficulty doing this.
- b. Mild: I had difficulty doing this but could still do it well.
- c. Moderate: I had difficulty doing this well.
- d. Severe: I could barely do this **or** I could not do it at all.

Document the interviewer's answers to cognitive test questions 1 and 2 while the study participant(s) is/are reading/responding to the FuRST 2.0 item.

0.0 Please write in the study participant(s) self-rating here _____

H HC

1.0 What issues with the FuRST 2.0 item did you observe while the study participant(s) was/were reading or interpreting the question?

2.0 What issues with the FuRST 2.0 response options did you observe while the study participant(s) was/were reading or interpreting the response options?

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Test Questions to be used with the *study participant(s)* after they have read and responded to the FuRST 2.0 item:

3.0 Which parts of the question, if any, seemed difficult to understand?
(Interviewer circles above the difficult parts of the question and documents verbal reports in response to the questions below)

H HC

3.1 Please tell me what made them difficult.

H HC

3.2 In your own words, what might be a better way to ask this question?

H HC

4.0 Overall, how easy or difficult was this question for you to understand?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

5.0 What, if anything, made it difficult for you to select an appropriate response option?

H HC

5.1 How might you revise the response options to make selecting a response easier?
H HC

6.0 Overall, how easy or difficult was it for you to select a response option for that question?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

						-			
--	--	--	--	--	--	---	--	--	--

10. Over the past two weeks did you have difficulty walking? Some examples are difficulty feeling steady on your feet, going up or down stairs, or walking smoothly.

- a. No: I had no difficulty doing this.
- b. Mild: I had difficulty doing this but could still do it well.
- c. Moderate: I had difficulty doing this well.
- d. Severe: I could barely do this **or** I could not do it at all.

Document the interviewer's answers to cognitive test questions 1 and 2 while the study participant(s) is/are reading/responding to the FuRST 2.0 item.

0.0 Please write in the study participant(s) self-rating here _____

H HC

1.0 What issues with the FuRST 2.0 item did you observe while the study participant(s) was/were reading or interpreting the question?

2.0 What issues with the FuRST 2.0 response options did you observe while the study participant(s) was/were reading or interpreting the response options?

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Test Questions to be used with the *study participant(s)* after they have read and responded to the FuRST 2.0 item:

3.0 Which parts of the question, if any, seemed difficult to understand?
(Interviewer circles above the difficult parts of the question and documents verbal reports in response to the questions below)

H HC

3.1 Please tell me what made them difficult.

H HC

3.2 In your own words, what might be a better way to ask this question?

H HC

4.0 Overall, how easy or difficult was this question for you to understand?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

5.0 What, if anything, made it difficult for you to select an appropriate response option?

H HC

5.1 How might you revise the response options to make selecting a response easier?
H HC

6.0 Overall, how easy or difficult was it for you to select a response option for that question?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

						-				
--	--	--	--	--	--	---	--	--	--	--

11. Over the past two weeks did you have difficulty doing activities you enjoy?
- a. No: I had no difficulty doing this.
 - b. Mild: I had difficulty doing this but could still do it well.
 - c. Moderate: I had difficulty doing this well.
 - d. Severe: I could barely do this **or** I could not do it at all.

Document the interviewer's answers to cognitive test questions 1 and 2 while the study participant(s) is/are reading/responding to the FuRST 2.0 item.

0.0 Please write in the study participant(s) self-rating here _____

H HC

1.0 What issues with the FuRST 2.0 item did you observe while the study participant(s) was/were reading or interpreting the question?

2.0 What issues with the FuRST 2.0 response options did you observe while the study participant(s) was/were reading or interpreting the response options?

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Test Questions to be used with the *study participant(s)* after they have read and responded to the FuRST 2.0 item:

3.0 Which parts of the question, if any, seemed difficult to understand?
(Interviewer circles above the difficult parts of the question and documents verbal reports in response to the questions below)

H HC

3.1 Please tell me what made them difficult.

H HC

3.2 In your own words, what might be a better way to ask this question?

H HC

4.0 Overall, how easy or difficult was this question for you to understand?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

5.0 What, if anything, made it difficult for you to select an appropriate response option?

H HC

5.1 How might you revise the response options to make selecting a response easier?
H HC

6.0 Overall, how easy or difficult was it for you to select a response option for that question?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

						-				
--	--	--	--	--	--	---	--	--	--	--

12. Over the past two weeks did you have difficulty using your hands? Some examples are difficulty picking things up, carrying a full cup, or turning a key.

- a. No: I had no difficulty doing this.
- b. Mild: I had difficulty doing this but could still do it well.
- c. Moderate: I had difficulty doing this well.
- d. Severe: I could barely do this **or** I could not do it at all.

Document the interviewer's answers to cognitive test questions 1 and 2 while the study participant(s) is/are reading/responding to the FuRST 2.0 item.

0.0 Please write in the study participant(s) self-rating here _____

H HC

1.0 What issues with the FuRST 2.0 item did you observe while the study participant(s) was/were reading or interpreting the question?

2.0 What issues with the FuRST 2.0 response options did you observe while the study participant(s) was/were reading or interpreting the response options?

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Test Questions to be used with the *study participant(s)* after they have read and responded to the FuRST 2.0 item:

3.0 Which parts of the question, if any, seemed difficult to understand?
(Interviewer circles above the difficult parts of the question and documents verbal reports in response to the questions below)

H HC

3.1 Please tell me what made them difficult.

H HC

3.2 In your own words, what might be a better way to ask this question?

H HC

4.0 Overall, how easy or difficult was this question for you to understand?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

5.0 What, if anything, made it difficult for you to select an appropriate response option?

H HC

5.1 How might you revise the response options to make selecting a response easier?
H HC

6.0 Overall, how easy or difficult was it for you to select a response option for that question?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

						-				
--	--	--	--	--	--	---	--	--	--	--

13. Over the past two weeks did you have difficulty with your speech? Some examples are difficulty saying what you meant to say or having others understand what you said.

- a. No: I had no difficulty doing this.
- b. Mild: I had difficulty doing this but could still do it well.
- c. Moderate: I had difficulty doing this well.
- d. Severe: I could barely do this **or** I could not do it at all.

Document the interviewer's answers to cognitive test questions 1 and 2 while the study participant(s) is/are reading/responding to the FuRST 2.0 item.

0.0 Please write in the study participant(s) self-rating here _____

H HC

1.0 What issues with the FuRST 2.0 item did you observe while the study participant(s) was/were reading or interpreting the question?

2.0 What issues with the FuRST 2.0 response options did you observe while the study participant(s) was/were reading or interpreting the response options?

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Test Questions to be used with the *study participant(s)* after they have read and responded to the FuRST 2.0 item:

3.0 Which parts of the question, if any, seemed difficult to understand?
(Interviewer circles above the difficult parts of the question and documents verbal reports in response to the questions below)

H HC

3.1 Please tell me what made them difficult.

H HC

3.2 In your own words, what might be a better way to ask this question?

H HC

4.0 Overall, how easy or difficult was this question for you to understand?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

5.0 What, if anything, made it difficult for you to select an appropriate response option?

H HC

5.1 How might you revise the response options to make selecting a response easier?

H HC

6.0 Overall, how easy or difficult was it for you to select a response option for that question?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

						-				
--	--	--	--	--	--	---	--	--	--	--

14. Over the past two weeks did you have difficulty grooming yourself? Some examples are difficulty bathing, combing your hair, or brushing your teeth.

- a. No: I had no difficulty doing this.
- b. Mild: I had difficulty doing this but could still do it well.
- c. Moderate: I had difficulty doing this well.
- d. Severe: I could barely do this **or** I could not do it at all.

Document the interviewer's answers to cognitive test questions 1 and 2 while the study participant(s) is/are reading/responding to the FuRST 2.0 item.

0.0 Please write in the study participant(s) self-rating here _____

H HC

1.0 What issues with the FuRST 2.0 item did you observe while the study participant(s) was/were reading or interpreting the question?

2.0 What issues with the FuRST 2.0 response options did you observe while the study participant(s) was/were reading or interpreting the response options?

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Test Questions to be used with the *study participant(s)* after they have read and responded to the FuRST 2.0 item:

3.0 Which parts of the question, if any, seemed difficult to understand?
(Interviewer circles above the difficult parts of the question and documents verbal reports in response to the questions below)

H HC

3.1 Please tell me what made them difficult.

H HC

3.2 In your own words, what might be a better way to ask this question?

H HC

4.0 Overall, how easy or difficult was this question for you to understand?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

5.0 What, if anything, made it difficult for you to select an appropriate response option?

H HC

5.1 How might you revise the response options to make selecting a response easier?
H HC

6.0 Overall, how easy or difficult was it for you to select a response option for that question?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

						-				
--	--	--	--	--	--	---	--	--	--	--

15. Over the past two weeks did you have difficulty dressing yourself? Some examples are difficulty using buttons and zippers, putting on jewelry or tying your shoe laces.

- a. No: I had no difficulty doing this.
- b. Mild: I had difficulty doing this but could still do it well.
- c. Moderate: I had difficulty doing this well.
- d. Severe: I could barely do this or I could not do it at all.

Document the interviewer's answers to cognitive test questions 1 and 2 while the study participant(s) is/are reading/responding to the FuRST 2.0 item.

0.0 Please write in the study participant(s) self-rating here _____

H HC

1.0 What issues with the FuRST 2.0 item did you observe while the study participant(s) was/were reading or interpreting the question?

2.0 What issues with the FuRST 2.0 response options did you observe while the study participant(s) was/were reading or interpreting the response options?

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Test Questions to be used with the *study participant(s)* after they have read and responded to the FuRST 2.0 item:

3.0 Which parts of the question, if any, seemed difficult to understand?
(Interviewer circles above the difficult parts of the question and documents verbal reports in response to the questions below)

H HC

3.1 Please tell me what made them difficult.

H HC

3.2 In your own words, what might be a better way to ask this question?

H HC

4.0 Overall, how easy or difficult was this question for you to understand?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

5.0 What, if anything, made it difficult for you to select an appropriate response option?

H HC

5.1 How might you revise the response options to make selecting a response easier?
H HC

6.0 Overall, how easy or difficult was it for you to select a response option for that question?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

						-				
--	--	--	--	--	--	---	--	--	--	--

16. Over the past two weeks did you have difficulty keeping to your day-to-day routine without assistance? Some examples are difficulty getting up, going to bed or eating meals at your usual times.

- a. No: I had no difficulty doing this.
- b. Mild: I had difficulty doing this but could still do it well.
- c. Moderate: I had difficulty doing this well.
- d. Severe: I could barely do this **or** I could not do it at all.

Document the interviewer's answers to cognitive test questions 1 and 2 while the study participant(s) is/are reading/responding to the FuRST 2.0 item.

0.0 Please write in the study participant(s) self-rating here _____

H HC

1.0 What issues with the FuRST 2.0 item did you observe while the study participant(s) was/were reading or interpreting the question?

2.0 What issues with the FuRST 2.0 response options did you observe while the study participant(s) was/were reading or interpreting the response options?

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Test Questions to be used with the *study participant(s)* after they have read and responded to the FuRST 2.0 item:

3.0 Which parts of the question, if any, seemed difficult to understand?
(Interviewer circles above the difficult parts of the question and documents verbal reports in response to the questions below)

H HC

3.1 Please tell me what made them difficult.

H HC

3.2 In your own words, what might be a better way to ask this question?

H HC

4.0 Overall, how easy or difficult was this question for you to understand?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

5.0 What, if anything, made it difficult for you to select an appropriate response option?

H HC

5.1 How might you revise the response options to make selecting a response easier?
H HC

6.0 Overall, how easy or difficult was it for you to select a response option for that question?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

						-				
--	--	--	--	--	--	---	--	--	--	--

17. Over the past two weeks did you have difficulty getting to events on time without assistance? Some examples are difficulty getting to movies, family gatherings or other appointments on time.

- a. No: I had no difficulty doing this.
- b. Mild: I had difficulty doing this but could still do it well.
- c. Moderate: I had difficulty doing this well.
- d. Severe: I could barely do this **or** I could not do it at all.

Document the interviewer's answers to cognitive test questions 1 and 2 while the study participant(s) is/are reading/responding to the FuRST 2.0 item.

0.0 Please write in the study participant(s) self-rating here _____

H HC

1.0 What issues with the FuRST 2.0 item did you observe while the study participant(s) was/were reading or interpreting the question?

2.0 What issues with the FuRST 2.0 response options did you observe while the study participant(s) was/were reading or interpreting the response options?

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Test Questions to be used with the *study participant(s)* after they have read and responded to the FuRST 2.0 item:

3.0 Which parts of the question, if any, seemed difficult to understand?
(Interviewer circles above the difficult parts of the question and documents verbal reports in response to the questions below)

H HC

3.1 Please tell me what made them difficult.

H HC

3.2 In your own words, what might be a better way to ask this question?

H HC

4.0 Overall, how easy or difficult was this question for you to understand?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

5.0 What, if anything, made it difficult for you to select an appropriate response option?

H HC

5.1 How might you revise the response options to make selecting a response easier?
H HC

6.0 Overall, how easy or difficult was it for you to select a response option for that question?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

						-				
--	--	--	--	--	--	---	--	--	--	--

18. Over the past two weeks did you have difficulty keeping your surroundings clean without assistance? Some examples are difficulty cleaning your bedroom, the kitchen, or your car.

- a. No: I had no difficulty doing this.
- b. Mild: I had difficulty doing this but could still do it well.
- c. Moderate: I had difficulty doing this well.
- d. Severe: I could barely do this or I could not do it at all.

Document the interviewer's answers to cognitive test questions 1 and 2 while the study participant(s) is/are reading/responding to the FuRST 2.0 item.

0.0 Please write in the study participant(s) self-rating here _____

H HC

1.0 What issues with the FuRST 2.0 item did you observe while the study participant(s) was/were reading or interpreting the question?

2.0 What issues with the FuRST 2.0 response options did you observe while the study participant(s) was/were reading or interpreting the response options?

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Test Questions to be used with the *study participant(s)* after they have read and responded to the FuRST 2.0 item:

3.0 Which parts of the question, if any, seemed difficult to understand?
(Interviewer circles above the difficult parts of the question and documents verbal reports in response to the questions below)

H HC

3.1 Please tell me what made them difficult.

H HC

3.2 In your own words, what might be a better way to ask this question?

H HC

4.0 Overall, how easy or difficult was this question for you to understand?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

5.0 What, if anything, made it difficult for you to select an appropriate response option?

H HC

5.1 How might you revise the response options to make selecting a response easier?

H HC

6.0 Overall, how easy or difficult was it for you to select a response option for that question?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

						-				
--	--	--	--	--	--	---	--	--	--	--

19. Over the past two weeks did you have difficulty exercising? Some examples are difficulty walking for exercise, jogging, swimming, or playing a sport.

- a. No: I had no difficulty doing this **or** I have never done it.
- b. Mild: I had difficulty doing this but could still do it well.
- c. Moderate: I had difficulty doing this well.
- d. Severe: I could barely do this **or** I could not do it at all.

Document the interviewer's answers to cognitive test questions 1 and 2 while the study participant(s) is/are reading/responding to the FuRST 2.0 item.

0.0 Please write in the study participant(s) self-rating here _____

H HC

1.0 What issues with the FuRST 2.0 item did you observe while the study participant(s) was/were reading or interpreting the question?

2.0 What issues with the FuRST 2.0 response options did you observe while the study participant(s) was/were reading or interpreting the response options?

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Test Questions to be used with the *study participant(s)* after they have read and responded to the FuRST 2.0 item:

3.0 Which parts of the question, if any, seemed difficult to understand?
(Interviewer circles above the difficult parts of the question and documents verbal reports in response to the questions below)

H HC

3.1 Please tell me what made them difficult.

H HC

3.2 In your own words, what might be a better way to ask this question?

H HC

4.0 Overall, how easy or difficult was this question for you to understand?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

5.0 What, if anything, made it difficult for you to select an appropriate response option?

H HC

5.1 How might you revise the response options to make selecting a response easier?
H HC

6.0 Overall, how easy or difficult was it for you to select a response option for that question?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

						-				
--	--	--	--	--	--	---	--	--	--	--

20. Over the past two weeks did you have difficulty staying involved in what is going on around you? Some examples are difficulty staying up-to-date with important news or events.

- a. No: I had no difficulty doing this.
- b. Mild: I had difficulty doing this but could still do it well.
- c. Moderate: I had difficulty doing this well.
- d. Severe: I could barely do this or I could not do it at all.

Document the interviewer's answers to cognitive test questions 1 and 2 while the study participant(s) is/are reading/responding to the FuRST 2.0 item.

0.0 Please write in the study participant(s) self-rating here _____

H HC

1.0 What issues with the FuRST 2.0 item did you observe while the study participant(s) was/were reading or interpreting the question?

2.0 What issues with the FuRST 2.0 response options did you observe while the study participant(s) was/were reading or interpreting the response options?

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Test Questions to be used with the *study participant(s)* after they have read and responded to the FuRST 2.0 item:

- 3.0 Which parts of the question, if any, seemed difficult to understand?
(Interviewer circles above the difficult parts of the question and document verbal reports in response to the questions below) H HC
- 3.1 Please tell me what made them difficult. H HC
- 3.2 In your own words, what might be a better way to ask this question? H HC
- 4.0 Overall, how easy or difficult was this question for you to understand?
(Check the box on left of the applicable number)
 Very difficult 1 2 3 4 5 6 Very Easy H HC
- 5.0 What, if anything, made it difficult for you to select an appropriate response option? H HC
- 5.1 How might you revise the response options to make selecting a response easier? H HC
- 6.0 Overall, how easy or difficult was it for you to select a response option for that question?
(Check the box on left of the applicable number)
 Very difficult 1 2 3 4 5 6 Very Easy H HC

						-				
--	--	--	--	--	--	---	--	--	--	--

21. Over the past two weeks did you have difficulty controlling your temper? Some examples are getting irritated or into arguments.

- a. No: I had no difficulty doing this.
- b. Mild: I had difficulty doing this but could still do it well.
- c. Moderate: I had difficulty doing this well.
- d. Severe: I could barely do this or I could not do it at all.

Document the interviewer's answers to cognitive test questions 1 and 2 while the study participant(s) is/are reading/responding to the FuRST 2.0 item.

0.0 Please write in the study participant(s) self-rating here _____

H HC

1.0 What issues with the FuRST 2.0 item did you observe while the study participant(s) was/were reading or interpreting the question?

2.0 What issues with the FuRST 2.0 response options did you observe while the study participant(s) was/were reading or interpreting the response options?

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Test Questions to be used with the *study participant(s)* after they have read and responded to the FuRST 2.0 item:

3.0 Which parts of the question, if any, seemed difficult to understand?
(Interviewer circles above the difficult parts of the question and documents verbal reports in response to the questions below)

H HC

3.1 Please tell me what made them difficult.

H HC

3.2 In your own words, what might be a better way to ask this question?

H HC

4.0 Overall, how easy or difficult was this question for you to understand?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

5.0 What, if anything, made it difficult for you to select an appropriate response option?

H HC

5.1 How might you revise the response options to make selecting a response easier?
H HC

6.0 Overall, how easy or difficult was it for you to select a response option for that question?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

						-				
--	--	--	--	--	--	---	--	--	--	--

22. Over the past two weeks did you have difficulty with your sexual activities?

- a. No: I had no difficulty doing this.
- b. Mild: I had difficulty doing this but could still do it well.
- c. Moderate: I had difficulty doing this well.
- d. Severe: I could barely do this **or** I could not do it at all.

Document the interviewer's answers to cognitive test questions 1 and 2 while the study participant(s) is/are reading/responding to the FuRST 2.0 item.

0.0 Please write in the study participant(s) self-rating here _____

H HC

1.0 What issues with the FuRST 2.0 item did you observe while the study participant(s) was/were reading or interpreting the question?

2.0 What issues with the FuRST 2.0 response options did you observe while the study participant(s) was/were reading or interpreting the response options?

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Test Questions to be used with the *study participant(s)* after they have read and responded to the FuRST 2.0 item:

3.0 Which parts of the question, if any, seemed difficult to understand?
(Interviewer circles above the difficult parts of the question and documents verbal reports in response to the questions below)

H HC

3.1 Please tell me what made them difficult.

H HC

3.2 In your own words, what might be a better way to ask this question?

H HC

4.0 Overall, how easy or difficult was this question for you to understand?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

5.0 What, if anything, made it difficult for you to select an appropriate response option?

H HC

5.1 How might you revise the response options to make selecting a response easier?
H HC

6.0 Overall, how easy or difficult was it for you to select a response option for that question?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

						-				
--	--	--	--	--	--	---	--	--	--	--

23. Over the past two weeks did you have difficulty driving a car?

- a. No: I had no difficulty doing this **or** I have never done it.
- b. Mild: I had difficulty doing this but could still do it well.
- c. Moderate: I had difficulty doing this well.
- d. Severe: I could barely do this **or** I could not do it at all.

Document the interviewer's answers to cognitive test questions 1 and 2 while the study participant(s) is/are reading/responding to the FuRST 2.0 item.

0.0 Please write in the study participant(s) self-rating here _____

H HC

1.0 What issues with the FuRST 2.0 item did you observe while the study participant(s) was/were reading or interpreting the question?

2.0 What issues with the FuRST 2.0 response options did you observe while the study participant(s) was/were reading or interpreting the response options?

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Test Questions to be used with the *study participant(s)* after they have read and responded to the FuRST 2.0 item:

3.0 Which parts of the question, if any, seemed difficult to understand?
(Interviewer circles above the difficult parts of the question and document verbal reports in response to the questions below)

H HC

3.1 Please tell me what made them difficult.

H HC

3.2 In your own words, what might be a better way to ask this question?

H HC

4.0 Overall, how easy or difficult was this question for you to understand?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

5.0 What, if anything, made it difficult for you to select an appropriate response option?

H HC

5.1 How might you revise the response options to make selecting a response easier?

H HC

6.0 Overall, how easy or difficult was it for you to select a response option for that question?
(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

						-				
--	--	--	--	--	--	---	--	--	--	--

24. Over the past two weeks did you have difficulty sleeping? Some examples are difficulty falling asleep, difficulty sleeping through the night, or waking too early.

- a. No: I had no difficulty doing this.
- b. Mild: I had difficulty doing this but could still do it well.
- c. Moderate: I had difficulty doing this well.
- d. Severe: I could barely do this **or** I could not do it at all.

Document the interviewer's answers to cognitive test questions 1 and 2 while the study participant(s) is/are reading/responding to the FuRST 2.0 item.

0.0 Please write in the study participant(s) self-rating here _____

H HC

1.0 What issues with the FuRST 2.0 item did you observe while the study participant(s) was/were reading or interpreting the question?

2.0 What issues with the FuRST 2.0 response options did you observe while the study participant(s) was/were reading or interpreting the response options?

						-				
--	--	--	--	--	--	---	--	--	--	--

Cognitive Test Questions to be used with the *study participant(s)* after they have read and responded to the FuRST 2.0 item:

3.0 Which parts of the question, if any, seemed difficult to understand?
(Interviewer circles above the difficult parts of the question and documents verbal reports in response to the questions below)
 H HC

3.1 Please tell me what made them difficult.
 H HC

3.2 In your own words, what might be a better way to ask this question?
 H HC

4.0 Overall, how easy or difficult was this question for you to understand?
(Check the box on left of the applicable number)
 Very difficult 1 2 3 4 5 6 Very Easy
 H HC

5.0 What, if anything, made it difficult for you to select an appropriate response option?
 H HC

5.1 How might you revise the response options to make selecting a response easier?
 H HC

6.0 Overall, how easy or difficult was it for you to select a response option for that question?
(Check the box on left of the applicable number)
 Very difficult 1 2 3 4 5 6 Very Easy
 H HC

						-				
--	--	--	--	--	--	---	--	--	--	--

Disclaimer: We asked about many problems people with Huntington's disease may have. Some of these questions may apply to you and others may not, but to be complete we are asking all the questions to every person. Thank you for taking the time to complete this questionnaire.

98. Disclaimer Item number for cognitive testing purposes

Cognitive Test Question for the Interviewer

1.0 What difficulties did you observe or hear voiced while watching the study participant(s) read the questionnaire disclaimer?

Cognitive Test Questions for the Study Participant(s) Regarding the Questionnaire Disclaimer

2.0 How easy or difficult was this disclaimer for you to understand?

(Check the box on left of the applicable number)

Very difficult 1 2 3 4 5 6 Very Easy

H HC

If your rating was less than 6, please provide additional information below

3.0 Which parts of the disclaimer were difficult to understand? What was the difficulty?

(Interviewer circles above the difficult parts of the question and documents verbal reports in response to the questions below)

H HC

3.1 Explain why the language in the disclaimer made it difficult in the space below.

H HC

						-				
--	--	--	--	--	--	---	--	--	--	--

99. STUDY PARTICIPANT(S) DEBRIEFING AFTER COMPLETING THE FuRST 2.0 QUESTIONNAIRE

For questions 1-3 below, the interviewer reads each question to the study participant(s) and summarizes the study participant(s) answers to each question below it using the study participant(s) own words whenever possible.

1.0 Overall, did you find the assessment questions in the questionnaire difficult? __ (Y/N)

H HC

1.1 If yes, what made them difficult?

H HC

2.0 Did you find any of the assessment questions in the questionnaire upsetting? __ (Y/N)

H HC

2.1 If yes, what made them upsetting?

H HC

3.0 Did you find the questions or the response options hard to read? __ (Y/N)

H HC

3.1 If yes, check all reasons that apply.

H HC

- Print was too small to read easily**
- Lines were too close together**
- Words were difficult to understand**
- Response options were not appropriate for me**

↑ **Other:** _____



						-				
--	--	--	--	--	--	---	--	--	--	--

[Note: At this point, the cognitive test is complete for the study participant(s).]

INTERVIEWER DEBRIEFING

4. Which, if any, of the questions in the FuRST 2.0 questionnaire seemed to make the study participant(s) uncomfortable? Why? Note: *if information is available, please also indicate if it was the HDGEC participant or the companion who was made uncomfortable.*

5. Other comments to help improve the FuRST 2.0 questionnaire items, disclaimer statement or instructions?

The Cognitive Test is now complete.



						-				
--	--	--	--	--	--	---	--	--	--	--

Before submitting the cognitive test copies for the study participant(s):

- ▶ Review the recorded data to ensure all data are legible, intelligible, and complete.
- ▶ Ensure the page with consent information, eligibility criteria and who is attending cognitive testing is complete and signed by the Site PI or Site PI’s designee.
- ▶ Ensure all the details on FuRST 2.0 Cognitive Test Form (Site Number, Site Name, Site Interviewer Name, HD Stage, Companion Relationship to the HDGEC Participant, Visit Date, and Study Participant(s) Demographics) are completed appropriately on the copy of the FuRST 2.0 questionnaire.
- ▶ Ensure the HDGEC Participant Research ID is entered on the header of each page of the FuRST 2.0 questionnaire.

Interviewer’s Statement:

I acknowledge that I’ve interviewed the study participant(s), completed and reviewed all data contained in this Interview Guide (which is considered as Paper CRF) per the instructions. All documented data are to my best of my knowledge, correct as of the date below

Interviewer’s Name

Please Print

Interviewer’s Signature:

Date:

____/____/_____
DD MMM YYYY

Site Principal Investigator’s statement:

By my signature below I affirm that the Interviewer is qualified to conduct the interview. I’ve reviewed and approved the Paper CRF for the study participant. I understand that questions may result from missing, unclear or incorrect entries. I understand that it will be necessary for me or my qualified staff to make the appropriate corrections to the Paper CRF. By my signature below, I authorize approved staff to make necessary corrections. I understand that I am ultimately responsible for any correction made by my staff.

Site Principal Investigator’s Name:

Please Print

Site Principal Investigator’s Signature:

Date:

____/____/_____
DD MMM YYYY