Enroll-HD

A Prospective Registry Study in a Global HD Cohort

CRF Completion Guidelines

Version 1.12

Dated 23 May 2022

Sponsored by CHDI Foundation Inc.

ENROLL-HD CRF Completion Guidelines

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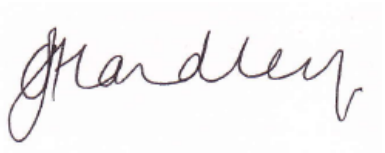
Name and Function	**Signature**	**Date**
Olivia Handley Global Project Manager		01 May 2013

Document updated	
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Olivia Handley Global Project Manager	13 December 2018
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1 GENERAL GUIDANCE

Always refer to the study protocol before completing forms. The CRF must always be completed by authorised site personnel. If you are new to the study, make sure you have completed the delegation form in the site file. Ensure data entries are consistent with the source data (usually the participant's medical record). Where data are not entered onto the EDC as source, use black ballpoint ink and write clearly ensuring that the entries are legible to others. Avoid abbreviations and acronyms, unless they are standard medical abbreviations or known to be acceptable. Ensure that you complete the 'header' information on each page consistently. Fill in EVERY field on each CRF page (unless indicated otherwise). Any discrepancies with source data should be explained and the significance noted in the CRF and/or medical records.

Missing values

Ensure data entry is as complete as possible. Do not leave blank spaces. If data are unavailable write unknown, and explain the reason why it is not available, e.g. missing date or test not done, as applicable. If a procedure was not done or not applicable, enter N for not applicable or U for unavailable where appropriate on **paper CRFs**. Do not write outside of the designated boxes. Write comments on the comments section.

All eCRFs should be completed without omitting any items. All items should be answered or commented. If information is not available and cannot be obtained, set the field state to missing, or to not applicable. To do so, click on the respective comment field in the EDC and change the field state from normal to missing or not applicable.

To facilitate the completeness of data and understanding of the assessments, training materials are available to all sites via the EDC web portal. Site staff should also be reminded to consult the "hint texts" available within the CRF. Hint texts are intended to provide clarity on how to administer a specific item and may also offer scoring guidance on how best to record a given response.

Non Applicable values

For some assessments the answer may vary according to the participant and may require additional consideration before submitting a value onto the eCRF. In cases where this happens, site staff should consult the hint texts and use the eCRF comment field whenever additional explanation is necessary. Specific instructions are given below for how to deal with these situations for Cognitive and Functional Assessments.

Corrections

To amend incorrect data on a paper CRF page, you should score through the error with a single line, without obscuring the original entry (do not use correction fluid). Write the correct data nearby and initial and date each amendment.

Dates

Do not record incomplete dates (i.e. if you know the month and year, but not the day, record-NK/04/05). Record dates in the requested format.

2 ENROLLMENT

This CRF is only filled out at baseline visit.

Field Name	Data Value	Comments
Date of informed consent	date	Enter full date when ICF was signed by participant/legal representative
Signed by	- participant - legal representative	Select one option
Participant category	- manifest/motor-manifest HD - pre-manifest/-motor-manifest HD - genotype unknown - genotype negative - family control - community control	Select one option
No history of or no concurrent major central nervous system disorder (e.g. Stroke, Parkinson's disease, Multiple Sclerosis, etc.)	- yes - no	Select one option
No choreic movement disorder	- yes - no	Select one option
Family History	- yes - no	Select one option Family Controls do not have the option to complete the Family History Optional Component. Enter “no” on the EDC and add a comment (N/A, Family Control).
Biosamples for use in research	- yes - no	Select one option
Linking clinical information from previous studies	- yes - no	Select one option
Participation in sub-studies	- yes - no	Select one option
Contact between visits	- yes - no	Select one option
Contact regarding other research studies	- yes - no	Select one option
Contact regarding post-mortem tissue collection	- yes - no	Select one option
COHORT HDID	text	Moved to Clinical trial form, read-only field
PREDICT HDID	text	Moved to Clinical trial form, read-only field

3 DEMOGRAPHICS, FIXED

This CRF is only filled out at baseline visit.

Field name	Data Value	Comments
Date of birth	date	Enter full date of birth taken from an official source (e.g. medical records for patients; driver's licence, passport for control participants).
Gender	- female - male	Select one
Ethnicity	- American Indian/Native American/Amerindian - Alaska Native/Inuit - African - North - African - South - American - Black - Asian - West - Asian - East - Caucasian - Native Hawaiian or Other Pacific Islander - Hispano or Latino Origin - Mixed - Other	Select one. If the ethnicity of the participant is not listed, mark "Other"
Handedness	- right - left - mixed	Select one. Administer the Handedness Questionnaire if there is any ambiguity based on the participant's self-report. A copy of the questionnaire should be retained for Source Data Verification

4 MEDICAL HISTORY

This CRF is only filled out at baseline visit.

Field Name	Type	Parameter
Assessment date	date	Enter full date of assessment
Has the participant had alcohol problems in the past?	- yes - no - unknown	Select one
Has the participant ever smoked?	- yes - no - unknown	Select one
Cigarettes per day	Number	Enter number
Years of smoking	Number	Enter number
Has the participant ever abused drugs?	- yes - no - unknown	Select one. If yes, answer question below.
Abuse	- yes - no	Select one. If yes, from the list of drugs, please enter abuse (yes/no), and if yes, state the frequency.
Frequency	- seldom - occasionally - frequently	Select one

5 VARIABLE, BASELINE

This CRF is only filled out at baseline visit.

Field Name	Data Value	Comments
Height	Number (cm)	Ensure you use the correct units for height. To convert inches to centimetres, multiply by 2.54
Weight	Number (kg)	Ensure you use the correct units for weight. To convert UK pounds to kilograms, multiply by 0.45
BMI	number	Calculated automatically
Date of visit	date	Enter the date of the assessment
Does the participant currently drink alcohol?	-yes -no	Select one
Units per week	number	One unit is one glass of wine (125ml) or 8 fluid oz of beer (284ml), or one measure of spirits (25-35ml)
Does the participant currently smoke?	-yes -no	Select one
Cigarettes per day	number	Enter number of cigarettes smoked per day (whole number)
Years of smoking	number	Enter number of years smoked (total)
Current caffeine use?	-yes -no	Select one
Do you drink more than 3 cups of coffee, tea and cola drinks combined per day?	-yes -no	Select one
Does the participant currently use drugs?	-yes -no	Select one. If yes, answer question below.
Drug use for mom-medical reasons? Abuse:	-yes -no	Select one. If yes, from the list of drugs, please enter abuse (yes/no), and if yes, state the frequency.
Abuse	-yes -no	Select one
Frequency	-seldom -occasionally -frequently	Select one
Marital status	-single -married -partnership -divorced -widowed -legally separated	Select one
Residence	-rural -village -town -city	Select one

ISCED education level	-ISCED 0 -ISCED 1 -ISCED 2 -ISCED 3 -ISCED 4 -ISCED 5 -ISCED 6	The highest qualification/degree obtained by attending school/university/any other formal training institution should be marked (irrespective of the length of time required/the route chosen to achieve the respective professional qualification). Note: please make sure to have the correct language selected (upper right on EDC) in order to see the ISCED localise d to your education system. A pdf download explaining the ISCED levels is provided for each country.
Years of education	number	Enter # years
Occupation	text array	Indicate as precisely as possible using the participant's self-report. Use the SNOMED look-up coding system integrated into the EDC to code the occupation. Occupation must be coded on the Variable CRF. Click the coding button, then click the coding link for the appropriate code. Occupation refers to the occupation held during most of his/her professional career.
Employment	-full-time employed -part-time employed -self employed -not employed	Select one
Status	-paid -unpaid	Select one
Have you had to stop or reduce work due to your health?	-yes -no	Select one
How many days in the last 6 months have you had off work because of HD?	number	Enter # days
How many fewer hours per week have you worked because of HD?	number	Enter # hours/week
Reason	-sick leave -retirement -working in the home (e.g. caring for children) -unemployed -training/college	Select one. If retired, please enter the item below "Retired due to:"
Retired due to	-ill health -age	Select one
Do you receive incapacity benefit/social security or disability benefit?	-yes -no	Select one
Do you intend to return to work?	-yes	Select one

	-no	
Since when have you been unemployed/retired?	4-digit year	Enter year (yyyy)

6 VARIABLE, FOLLOW-UP

This new variable follow-up CRF is completed at each follow-up study visit.

Field Name	Data Value	Comments
Date of visit	date	Enter the date of the assessment
Height	Number (cm)	Ensure you use the correct units for height. To convert inches to centimetres, multiply by 2.54
Weight	Number (kg)	Ensure you use the correct units for weight. To convert UK pounds to kilograms, multiply by 0.45
BMI	number	Calculated automatically
Does the participant currently drink alcohol?	-yes -no	Select one
Units per week	number	One unit is one glass of wine (125ml) or 8 fluid oz of beer (284ml), or one measure of spirits (25-35ml)
Does the participant currently smoke?	-yes -no	Select one
Cigarettes per day	number	Enter number of cigarettes smoked per day (whole number)
Years of smoking	number	Enter number of years smoked (total)
Current caffeine use?	-yes -no	Select one
Do you drink more than 3 cups of coffee, tea and cola drinks combined per day?	-yes -no	Select one
Does the participant currently use drugs?	-yes -no	Select one. If yes, answer question below.
Abuse	-yes -no	Select one. If yes, from the list of drugs, please enter abuse (yes/no), and if yes, state the frequency.
Frequency	-seldom -occasionally -frequently	Select one
Any changes to the rarely changing General Variable Items above	-yes -no	Select one
Participant category	-manifest/motor-manifest HD -pre-manifest/-motor-manifest HD -genotype unknown -genotype negative -family control community control	Select one

Marital status	-single -married -partnership -divorced -widowed -legally separated	Select one
Residence	-rural -village -town -city	Select one
ISCED education level	-ISCED 0 -ISCED 1 -ISCED 2 -ISCED 3 -ISCED 4 -ISCED 5 -ISCED 6	The highest qualification/degree obtained by attending school/university/any other formal training institution should be marked (irrespective of the length of time required/the route chosen to achieve the respective professional qualification). Make sure the correct language is selected (upper right on EDC) in order to see the ISCED localised to your education system. A pdf download explaining the ISCED levels is provided for each country.
Years of education	number	Enter # years based on the answers given by the participant
Occupation	text	Please indicate as precisely as possible using the participant's self-report. Use the SNOMED look-up coding system integrated into the EDC to code the occupation Occupation refers to the occupation held during most of his/her professional career
Employment	-full-time employed -part-time employed -self employed -not employed	Select one
Status	-paid -unpaid	Select one
Reason	-sick leave -retirement -working in the home (e.g. caring for children) -unemployed -training/college	Select one.
Retired due to	-ill health -age	If retired, please select one
Do you receive incapacity benefit/social security or disability benefit?	-yes -no	Select one
Do you intend to return to work?	-yes -no	Select one
Since when have you been unemployed/retired?	4-digit year	Enter year (yyyy)

Have you had to stop or reduce work due to your health?	-yes -no	Select one
How many days in the last 6 months have you had off work because of HD?	number	Enter #days
How many fewer hours per week have you worked because of HD?	number	hours/week
Any changes to participant's medication	-yes -no	Select one
Any changes to participant's comorbid conditions	-yes -no	Select one
Any updates to family history?	-yes -no	Select one
Any updates to the clinical characteristics and/or onset of HD?	-yes -no	Select one
Has the participant had a brain MRI	-yes -no	Select one
Date of MRI	date	Enter full date of MRI

7 HD CLINICAL CHARACTERISTICS

This CRF is completed at baseline and updated at every Enroll-HD visit. Raters should use the HDCC instructions for guidance on how to administer this assessment. There is also a HDCC training video available on the Enroll-HD web portal under "Training". HDCC is completed for participants in the following categories: manifest, premanifest, genotype unknown, genotype negative. The questions about symptom onset estimated by the rater and the date of the clinical diagnosis are only completed for manifest participants.

How to obtain the information

The HDCC is a semi-structured interview however patients and families often find it difficult to pin down dates when signs/symptoms first started. Following the interview, revisit the medical records. If for example in the interview the family says behavioural difficulties started in 2001, but in the file there is a letter dated 1997 with documented behavioural issues occurring that year, then the file information supersedes the interview as it was contemporary and more likely to be accurate. The rater should estimate the earliest age at onset of the symptoms below, independent of whether they are considered to be related or unrelated to HD. For all age-related questions, please provide the examiner's best appraisal of onset age (to the nearest whole number), assimilating information from the participant, caregiver, family member and other sources.

When is a symptom a symptom?

Behavioural difficulties are common in HD. Often depressive symptoms will be on-going for decades before the patient is near prodromal. We are interested in if during the patient's medical history, has there ever been an episode of depression and when.

Field name	Data Value	Comments
Participant category	- manifest/motor-manifest HD - pre-manifest/-motor-manifest HD - genotype unknown - genotype negative - family control - community control	At baseline, this value is populated from the Enrolment CRF value submitted to the EDC. For follow-up visits, it will be populated from the Variable CRF.
Mother affected	- yes - no - unknown	If the information is not known because the parent died without showing any signs, left the family, or is currently alive without symptoms and has not undergone genetic testing, or is an adoptive parent, set the value to "missing" and add a comment.
Age at onset of symptoms in mother	Number	Enter age of onset for mother
Father affected	- yes - no - unknown	If the information is not known because the parent died without showing any signs, left the family, or is currently alive without symptoms and has not undergone genetic testing, or is an adoptive parent, set the value to "missing" and add a comment
Age at onset of symptoms in father	Number	Enter age of onset for father

Has depression (includes treatment with antidepressants with or without a formally-stated diagnosis of depression) ever been a part of the participant's medical history?	- yes - no	Depression here should refer to a history of suffering from depression for a period of 4 weeks or more. See the HDCC Guidelines for additional prompts on questions to ask during the HDCC interview.
age (years)	number	Enter age. If entered, the EDC system will automatically calculate the year of onset (based on DOB)
year of onset	number	Enter 4-digit year. If entered, the EDC system will automatically calculate age (based on DOB)
Has irritability ever been a part of the participant's medical history?	- yes - no	See the HDCC Guidelines for additional prompts on questions to ask during the HDCC interview.
age (years)	number	Enter age. If entered, the EDC system will automatically calculate the year of onset (based on DOB)
year of onset	number	Enter 4-digit year. If entered, the EDC system will automatically calculate age (based on DOB)
Has violent or aggressive behavior ever been a part of the participant's medical history?	- yes - no	See the HDCC Guidelines for additional prompts on questions to ask during the HDCC interview.
age (years)	number	Enter age. If entered, the EDC system will automatically calculate the year of onset (based on DOB)
year of onset	number	Enter 4-digit year. If entered, the EDC system will automatically calculate age (based on DOB)
Has apathy ever been a part of the participant's medical history	- yes - no	See the HDCC Guidelines for additional prompts on questions to ask during the HDCC interview.
age (years)	number	Enter age. If entered, the EDC system will automatically calculate the year of onset (based on DOB)
year of onset	number	Enter 4-digit year. If entered, the EDC system will automatically calculate age (based on DOB)
Has perseverative/obsessive behaviors ever been a part of the participant's medical history	- yes - no	See the HDCC Guidelines for additional prompts on questions to ask during the HDCC interview.

age (years)	Number	Enter age. If entered, the EDC system will automatically calculate the year of onset (based on DOB)
year of onset	Number	Enter 4-digit year. If entered, the EDC system will automatically calculate age (based on DOB)
Has psychosis (hallucinations or delusions) ever been a part of the participant's medical history	- yes - no	See the HDCC Guidelines for additional prompts on questions to ask during the HDCC interview.
age (years)	Number	Enter age. If entered, the EDC system will automatically calculate the year of onset (based on DOB)
year of onset	Number	Enter 4-digit year. If entered, the EDC system will automatically calculate age (based on DOB)
Does the participant have a family history of a psychotic illness in a first degree relative?	- yes - no	Select one
Has significant cognitive impairment (severe enough to impact on work or activities of daily living) or dementia ever been a part of the participant's medical history?	- yes - no	Select one
age (years)	Number	Enter age
year of onset	Number	Enter 4-digit year
Have motor symptoms compatible with HD ever been a part of the participant's medical history?	- yes - no	Select one option
age (years)	Number	Enter age. If entered, the EDC system will automatically calculate the year of onset (based on DOB)
year of onset	Number	Enter 4-digit year. If entered, the EDC system will automatically calculate age (based on DOB)
Symptoms first noted by participant	Date	Enter date (as complete as possible and at least including year)
Initial major symptom noted by participant	- motor - cognitive - psychiatric - oculomotor - other - mixed	Select one

If mixed symptoms	- motor - cognitive - psychiatric - oculomotor	Select multiple
Symptoms first noted by family	Date	Enter date (as complete as possible and at least including year)
Initial major symptom noted by family	- motor - cognitive - psychiatric - oculomotor - other (e.g. weight loss, insomnia) - mixed	Select one
If mixed symptoms	- motor - cognitive - psychiatric - oculomotor	Select multiple
Date of clinical HD diagnosis	Date	Enter date (as complete as possible and at least including year). Enter the date at which the participant was told for the first time by a medical professional that he/she suffers from HD. Note: For the clinical diagnosis of HD, symptoms and signs are required, not only a genetic test result.
Can you, as a rater, estimate the time of symptom onset	- yes - no	Select one
Rater's estimate of symptom onset	Date	Enter date (as complete as possible and at least including year). This should be a combination of clinical judgement and patient/caregiver information. For example, if a patient reports changes in memory in 2001, but they made redundant in 1998 due to multiple errors in the workplace, it would be reasonable to estimate onset earlier than 2001, e.g. 1998 or even 1997 or 1996.
Confidence with which this estimation is made	- high - low	Select one
Please specify why you, as a rater, cannot estimate symptom onset (without additional external information) at the moment	- participant cannot provide information (mute, or cognitively too impaired) information provided deemed unreliable	Select one
What is your best guess of how many years ago symptom onset took place	- < 5 - < 10 - < 15 - < 20 - > 20	Select one
Date of data entry	date	Enter full date each time the HDCC is updated
Rater's judgement of	- motor	This question sometimes causes concerns as

initial major symptom	- cognitive - psychiatric - oculomotor - other (e.g. weight loss, insomnia) - mixed	people are unsure whether to pick the first symptom on the date it arose (i.e. depression 1978) or what they feel was the first major symptom as the patient became prodromal. It should be what you feel is the first significant change.
If mixed symptoms	- motor - cognitive - psychiatric - oculomotor	Select multiple
Previous suicidal ideation or attempts?	- yes - no - unknown	If yes, complete the CSSRS-S Baseline form (first administration) or CSSRS-Follow-up form at subsequent Enroll-HD visits.
Has an HD genetic test been done?	- yes - no - unknown	Select one.
Comments	- yes - no	Select one
Enter comment	text	Enter any additional comments to the form, e.g. subject unaccompanied by relative or caregiver.

8 CAG

This CRF is only filled out at baseline visit for Manifest, Premanifest participants and confirmed non-mutation carriers. It can be activated at a later study visit if the gene status of an at risk participant becomes known to the study site team. This CRF is not available for Family and Community Control participants.

Locally obtained CAG repeat length data should be entered for Premanifest, Manifest, and Genotype Negative Participants. These data are important for the Enroll-HD Data Safety Monitoring Committee who will compare local CAG repeat values with the research genotype and inform the Site PI of any discrepancies that have implications for diagnosis.

Since the Enroll-HD study Operations Team is completely blind to the research genotype values, it will become important to be able to search the database for participants potentially eligible for clinical trials where CAG repeat values are part of the inclusion/exclusion criteria. To this end, locally obtained CAG repeat lengths will be used to screen for potential eligibility.

It is further important to be able to identify rare population subgroups (e.g. reduced penetrance carriers, very high repeat carriers) made possible by the availability of locally obtained CAG repeat lengths.

Data should be taken from the original laboratory report, or if not available, official medical correspondence. They will be reviewed as part of the medical monitoring for the study.

If the CAG repeat length data are derived from the COHORT study, these can be entered if no other local information is available (a comment should be added to the CRF). The CRA is permitted to check the COHORT binders during the Monitoring Visit to site.

If there is no CAG report available at site and it is not possible to obtain a copy, the CAG report form should be deactivated by the site. Do not activate the form and set all values to missing.

Field name	Data Value	Comments
Date of report	date	This is the date of the report, not the date data were entered onto the EDC
Specimen type	- blood - brain (postmortem) - unknown	Select one
Source of information	- laboratory report - medical records/correspondence - participant/companion self report	
Were the exact repeat lengths given in the laboratory report?	- yes - no	Select one
Allele 1 CAG repeat length (smaller allele)	number	Enter the CAG repeat length for Allele 1
Tolerance	Text	Not mandatory to enter, if value is given in the report +/- tolerance
Allele 2 CAG repeat	number	Enter the CAG repeat length for Allele 2

length (larger allele)		
Tolerance	Text	Not mandatory to enter, if value is given in the report +/- tolerance
If exact length is not given: CAG repeat information (larger allele)	- normal - <27 - 27-35 - 36-39 - >35 - >36 - >37 - >38 - >39 - >40	Select one
Analyzing laboratory	text	Enter the full laboratory name, e.g. *Genetics department/service, Hospital*, do not use abbreviations
Comments	- yes - no	If yes, enter a comment.
Enter comment	text	This section can be used to clarify why exact CAG repeat lengths are not provided (e.g. genetic linkage results; departmental policy not to report exact CAG lengths)

9 COMORBID

This CRF is completed at baseline and updated at every Enroll-HD Study Visit. Review all entries at each visit and enter end dates if the comorbid condition is no longer on-going. When entering a condition, please make sure that you describe the disorder as precisely as possible. This log should also be used to capture surgical procedures (these can also be coded). Only capture relevant comorbid conditions using your best judgment.

All comorbid conditions on the Comorbid form will be coded by the central coders using ICD-10 for illnesses and MedDRA for procedures.

Field name	Data Value	Comments
Condition	text	Enter the comorbid condition. The condition will be coded by the central coding team, using ICD-10.
Body system code	- cardiovascular - pulmonary - neurologic - ENT - gynecologic/urologic - reproductive - gastrointestinal - metabolic/endocrine - hemato/lymphatic - dermatological - psychiatric - musculoskelatal - allergy/immunologic - ophtalmological - hepatobiliary - renal - other	Select one
Start date	date	Enter the start date
On-going	check box	Select if condition is ongoing. Either on-going or stop date should be entered.
End date	date	Enter the end date. Either on-going or stop date should be entered.

10 PHARMACOTX

For Enroll-HD, Pharmacotherapies (e.g. anti-depressants), Non-Pharmacotherapies (e.g. psychotherapy, physiotherapy) and Nutritional Supplements (e.g. vitamin C supplements) are recorded in separate logs.

This CRF is completed at baseline and updated at every Enroll-HD Study Visit. Review all entries at each visit and enter end dates if the medication is no longer on-going. Enter one medication per row. If three medications are used for one indication, list all three mediations individually in separate rows. At minimum the month and year of the Start and Stop dates (if applicable) must be entered.

Field name	Data Value	Comments
Drug name	text	Take care spelling the medication name; Central Coders will use this name to code using the WHO-Drug Dictionary. You can either enter the proprietary name (=trade name) used in your respective country or the generic name.
Indication	text array	Specify the reason why medication has been prescribed and be precise, e.g. 'Choreic Movements' rather than Huntington's disease; 'Depression' rather than 'Moods'. The disorder representing the indication for use of a compound can be given in English (preferred) or in your native language. Please make sure that you describe the indication as precisely as possible. Your entries will be coded by Central Coders using the MedDRA coding system. If a medication has been prescribed for more than one reason, list the main reason only as the indication.
Dose / Unit	text	If possible enter single dose, or tablet dose For dose variations within the day, for example, full and half or quarter doses, please adjust the unit dose such that all the information can fit in a single entry. Example: A participant was prescribed 25mg of a drug to be taken as follows; 1 tablet in the morning, 2 tablets at noon, 1.5 tablets in the evening and 0.5 tablet at bedtime. Entry in one single line: Option 1: This should be entered on a single line as 25mg with daily intake 1-2-1.5-0.5. Option 2: adjusting the dose to 12.5mg and enter the daily intake as follows; 2-4-3-1.
Daily intake	number	Daily intake coding includes four digits (in the morning, at noon, in the evening, at night). Each digit also represents # of doses taken per day. For example, 4 tablets taken at equal intervals = 1111, or a single dose taken at bedtime = 0001. Each digit should be entered as a whole number (no special characters e.g.".")

		or “/”). If frequency is > 4 times per day, check which frequencies overlap the same time period, e.g. 1dose very early morning and 2 doses mid-morning = 3000.
Frequency	- daily - every 2nd day - every 3rd day - weekly - every 2nd week - monthly - every 2nd month - every 3rd month - annually - as needed	Select one
Route	- p.o. - p.r. - s.c. - i.m. - i.v. - td - sl - inh - other	Select one. Abbreviations are given in full on the EDC and paper CRF.
Start date	date	Enter the start date
On-going	- yes - no	Select if condition is on-going. Either on-going or stop date should be entered.
Stop date	date	Enter the end date. Either on-going or stop date should be entered.

11 NUTSUPPL

For Enroll-HD, Pharmacotherapies (e.g. anti-depressants), Non-Pharmacotherapies (e.g. psychotherapy, physiotherapy) and Nutritional Supplements (e.g. vitamin C supplements) are recorded in separate logs.

This eCRF is completed entered at baseline and updated at every Enroll-HD Study Visit. Review all entries at each visit and enter end dates if the medication is no longer on-going.

Field name	Data Value	Comments
Supplement	text	Enter one supplement per line
Type	- vitamin & supplements - herbs (extracts) - herbs (teas) - other natural remedies - aromatherapies - homeopathic remedies - high calorie diet	Select one
Dose	- number	For any reduced dose medications (e.g. half dose), please enter this dose as a separate entry on the medication log.
Unit	- g - mg - IU - spoons - tablets - drops - capsule - other	Select one
Daily intake	- daily - every other day - every third day - weekly - every other week - monthly - every other month - every quarter - annually - as needed	Select one
Frequency	number	Daily intake coding includes four digits (in the morning, at noon, in the evening, at night). Each digit also represents # of doses taken per day. For example, 4 tablets taken at equal intervals = 1111, or a single dose taken at bedtime = 0001. Each digit should be entered as a whole number (no special characters e.g.“.” or “/”). If frequency is > 4 times per day, check which frequencies overlap the same time period, e.g. 1dose very early morning and 2 doses mid-morning = 3000.
Start date	date	Enter the start date
On-going	-Check box	Select if condition is on-going. Either on-going

		or stop date should be entered.
Stop date	date	Enter the end date. Either on-going or stop date should be entered.

12 NONPHARMACOTX

For Enroll-HD, Pharmacotherapies (e.g. anti-depressants), Non-Pharmacotherapies (e.g. psychotherapy, physiotherapy) and Nutritional Supplements (e.g. vitamin C supplements) are recorded in separate logs.

This eCRF should be entered at baseline and at every Enroll-HD Study Visit. Review all entries at each visit and enter end dates if the medication is no longer on-going.

Field name	Data Value	Comments
Therapy	- Physical therapy - Occupational therapy - Psychotherapy - Counselling - Speech/Language therapy - Swallowing therapy - Music therapy - Relaxation therapy (meditation, massage, yoga, etc.) - Acupuncture	Select one
Number of times	number	Enter # times attended
Frequency	- daily - weekly - monthly - as needed	Select one
Start date	date	Enter the start date
On-going	check box	Select if condition is ongoing. Either on-going or stop date should be entered.
Stop date	date	Enter the end date. Either on-going or stop date should be entered.

13 CLINICAL TRIALS

For Enroll-HD other former and recent trial participation shall be recorded. If the trial the participant is participating in is not listed, contact: itsupport@enroll-hd.org with the trial name and information about the trial.

This eCRF should be entered at baseline and at every Enroll-HD Study Visit. Review all entries at each visit and enter end dates if the medication is no longer on-going.

Field name	Data Value	Comments
Clinical trial name	coding field, single choice	Click on the arrow and select respective trial or study
Participant ID in trial	text	Enter participant ID in the study
Date of enrollment	date	Enter date of study enrollment (incomplete dates are allowed)
What is ppt current clinical trial status?	single choice	- active - completed - discontinued prematurely
End date of participation	date	Enter date of study end (incomplete dates are allowed)

14 MOTOR

This CRF is completed at every Enroll-HD Study Visit. Each motor rater should complete UHDRS Motor Certification on an annual basis hdtraining.enroll-hd.org. The paper CRF and eCRF contain the UHDRS Motor Examination Guidelines for assessment.

If any sections of the UHDRS Motor Assessment cannot be completed (e.g. patient fainted during assessment; patient has had a limb amputated), then the site should set the value to "not applicable" and enter a comment to explain why the assessment could not be administered.

Field name	Data Value	Comments
Assessment date	date	Enter the date of the assessment
Rater Code	number	Enter the rater code
Motor score (TMS)	number	This is automatically calculated by the EDC
Motor score (TMS) incomplete	number	This is automatically calculated by the EDC
Horizontal	-complete (normal) -jerky movement -interrupted pursuits/full range -incomplete range -cannot pursue	Select one
Vertical	-complete (normal) -jerky movement -interrupted pursuits/full range -incomplete range -cannot pursue	Select one
Horizontal	-normal -increased latency only -suppressible blinks or head movements to initiate -unsuppressible head movements -cannot initiate saccades	Select one
Vertical	-normal -increased latency only -suppressible blinks or head movements to initiate -unsuppressible head movements -cannot initiate saccades	Select one
Horizontal	-normal -mild slowing -moderate slowing -severely slow, full	Select one

	range -incomplete range	
Vertical	-normal -mild slowing -moderate slowing -severely slow, full range -incomplete range	Select one
Dysarthria	-normal -unclear, no need to repeat -must repeat to be understood -mostly incomprehensible -anarthria	Select one
Tongue protrusion	-can hold tongue fully protruded for 10 sec -cannot keep fully protruded for 10 sec -cannot keep fully protruded for 5 sec -cannot fully protrude tongue -cannot protrude tongue beyond lips	Select one
Right	-normal (≥15/5 sec.) -mild slowing, reduction in amplitude (11-14/5 sec.) -moderately impaired (7-10/5 sec.) -severely impaired (3-6/5 sec.) -can barely perform task (0-2/5 sec.)	Select one
Left	-normal (≥15/5 sec.) -mild slowing, reduction in amplitude (11-14/5 sec.) -moderately impaired (7-10/5 sec.) -severely impaired (3-6/5 sec.) -can barely perform task (0-2/5 sec.)	Select one
Right	-normal -mild slowing and/or irregular -moderate slowing and irregular -severe slowing and	Select one

	irregular -cannot perform	
Left	-normal -mild slowing and/or irregular -moderate slowing and irregular -severe slowing and irregular -cannot perform	Select one
Luria	-≥4 in 10 sec, no cue -<4 in 10 sec, no cue -≥4 in 10 sec with cues -<4 in 10 sec with cues -cannot perform	Select one
Right	-absent -slight or present only with activation -mild to moderate -severe, full range of motion -severe with limited range	Select one
Left	-absent -slight or present only with activation -mild to moderate -severe, full range of motion -severe with limited range	Select one
Bradykinesia-body	-normal -minimally slow (?normal) -mildly but clearly slow -moderately slow, some hesitation -markedly slow, long delays in initiation	Select one
Trunk	-absent -slight/intermittent -mild/common or moderate/intermittent -moderate/common -marked/prolonged	Select one
RUE	-absent -slight/intermittent -mild/common or moderate/intermittent	Select one

	-moderate/common -marked/prolonged	
LUE	-absent -slight/intermittent -mild/common or moderate/intermittent -moderate/common -marked/prolonged	Select one
RLE	-absent -slight/intermittent -mild/common or moderate/intermittent -moderate/common -marked/prolonged	Select one
LLE	-absent -slight/intermittent -mild/common or moderate/intermittent -moderate/common -marked/prolonged	Select one
Face	-absent -slight/intermittent -mild/common or moderate/intermittent -moderate/common -marked/prolonged	Select one
BOL	-absent -slight/intermittent -mild/common or moderate/intermittent -moderate/common -marked/prolonged	Select one
Trunk	-absent -slight/intermittent -mild/common or moderate/intermittent -moderate/common -marked/prolonged	Select one
RUE	-absent -slight/intermittent -mild/common or moderate/intermittent -moderate/common -marked/prolonged	Select one
LUE	-absent -slight/intermittent -mild/common or moderate/intermittent -moderate/common -marked/prolonged	Select one

RLE	-absent -slight/intermittent -mild/common or moderate/intermittent -moderate/common -marked/prolonged	Select one
LLE	-absent -slight/intermittent -mild/common or moderate/intermittent -moderate/common -marked/prolonged	Select one
Gait	-normal gait, narrow base -wide base and/or slow -wide base and walks with difficulty -walks only with assistance -cannot attempt	Select one
Tandem walking	-normal for 10 steps -1 to 3 deviations from straight line ->3 deviations -cannot complete -cannot attempt	Select one
Retropulsion pull test	-normal -recovers spontaneously -would fall if not caught -tends to fall spontaneously -cannot stand	Select one
Diagnostic confidence level (DCL)	-normal (no abnormalities) -non-specific motor abnormalities (less than 50 % confidence) -motor abnormalities that may be signs of HD (50 - 89 % confidence) -motor abnormalities that are likely signs of HD (90 - 98 % confidence) -motor abnormalities that are unequivocal signs of HD (≥ 99 % confidence)	Select one. DCL is based on the Total Motor Score and clinician's impression of motor abnormalities being consistent with HD.

If TMS and DCL are discrepant: Reason for discrepancy between DCL/Total Motor Score	text	Explain why the values are correct as they are.

15 **TFC**

This CRF is completed at every Enroll-HD Study Visit. Each rater is encouraged to review the Functional Assessment Training Videos available under: https://studies.enroll-hd.org/training. The paper CRF and eCRF contain the UHDRS TFC Guidelines for assessment.

If any sections of the UHDRS TFC cannot be completed (e.g. patient fainted during assessment and no companion), then the site should set the value to “not applicable” and enter a comment to explain why the assessment could not be administered.

Field name	**Data Value**	**Comments**
Assessment date	date	Enter the date you completed the assessment
Rater Code	number	Enter the rater code
Functional score	number	This is automatically calculated by the EDC
Occupation	- unable - marginal work only - reduced capacity for usual job - normal	Select one. If the participant is retired, the rater should estimate his/her potential capacity to work.
Finances	- unable - major assistance - slight assistance - normal	Select one
Domestic chores	- unable - impaired - normal	Select one
ADL	- total care - gross tasks only - minimal impairment - normal	Select one
Care level	- full time skilled nursing - home or chronic care - home	Select one
Was the information obtained from	- participant only - participant and family/companion	Select one

16 FUNCTION

This CRF is completed at every Enroll-HD Study Visit. Each rater is encouraged to review the Functional Assessment Training Videos available under: https://studies.enroll-hd.org/training. The paper CRF and eCRF contain the UHDRS Functional Assessment Scale and Independence Scale Guidelines for assessment.

If any sections of the UHDRS TFC cannot be completed (e.g. patient fainted during assessment and no companion), then the site should set the value to “not applicable” and enter a comment to explain why the assessment could not be administered.

When an answer to any of the questions of the Functional Assessment form has omitted and the participant has given consent for taking contact between visits, the investigator should attempt to get this information e.g. by phone. A comment indicating that an answer has been collected this way should be entered into the comment field.

When a question does not directly apply to a participant, the rater should consult the UHDRS Functional Assessment Scale guidelines for suggested “anchors”. The score (yes or no) should be based on a *comparative task*. Some examples of comparative tasks given in the guidelines are:

“*Could subject do his/her own housework without help?* The hint text reads “Housework activities might include cooking, vacuuming, dusting, taking out the rubbish, and doing dishes. If a subject never did any housework, ask about picking up after themselves (e.g., doing light dusting or making the bed) and hanging up his/her clothes. Housework might also extend to light gardening if that was the subject's responsibility. If assistance is required the answer is “no”.

“Could subject use public transportation to get places without help?” The hint text reads “Public transportation includes bus and train. If there is no public transportation the question should be; 'If public transportation were available, could he/she use it without assistance?'”

The only **exception** where there is no comparative task would be the question about driving:

“Could subject operate an automobile safely and independently? The hint text reads “Operating an automobile safely and independently means the subject can drive without others feeling afraid to drive with the subject and showing good judgment. If the person has never learned how to drive, please file a comment indicating 'Not applicable'.

Field name	Data Value	Comments
Assessment date	date	Enter the date you completed the assessment
Rater Code	number	Enter the rater code
Functional Assessment Score	number	This is automatically calculated by the EDC
Functional score incomplete	number	This is automatically calculated by the EDC
Independence scale in %	number	This is automatically calculated by the EDC
Could subject engage in gainful employment in his/her accustomed work	- yes - no	Select one
Could subject engage in any kind of gainful employment?	- yes - no	Select one
Could subject engage in any kind of volunteer or non-gainful work?	- yes - no	Select one

Could subject manage his/her finances (monthly) without any help?	- yes - no	Select one
Could subject shop for groceries without help?	- yes - no	Select one
Could subject handle money as a purchaser in a simple cash (shop) transaction?	- yes - no	Select one
Could subject supervise children without help?	- yes - no	Select one
Could subject operate an automobile safely and independently?	- yes - no	Select one. If the participant has never learned to drive, set value to “not applicable” and enter a comment
Could subject do his/her own housework without help?	- yes - no	Select one
Could subject do his/her own laundry (wash/dry) without help?	- yes - no	Select one
Could participant prepare his/her own meals without help?	- yes - no	Select one
Could subject use the telephone without help?	- yes - no	Select one
Could subject take his/her own medications without help?	- yes - no	Select one
Could subject feed himself/herself without help?	- yes - no	Select one
Could subject dress himself/herself without help?	- yes - no	Select one
Could subject bathe himself/herself without help?	- yes - no	Select one
Could subject use public transport to get to places without help?	- yes - no	Select one
Could subject walk to places in his/her neighbourhood without help?	- yes - no	Select one
Could subject walk without falling?	- yes - no	Select one
Could subject walk without help?	- yes - no	Select one
Could subject comb hair without help?	- yes - no	Select one
Could subject transfer between chairs without	- yes - no	Select one

help?		
Could subject get in and out of bed without help?	- yes - no	Select one
Could subject use toilet/commode without help?	- yes - no	Select one
Could subject's care still be provided at home?	- yes - no	Select one
Was the functional assessment information obtained from	- subject only - subject and family/companion	Select one
Subject's independence in %	- no special care needed - no physical care needed if difficult tasks are avoided - pre-disease level of employment changes or ends; cannot perform household chores to pre-disease level, may need help with finances - self-care maintained for bathing, limited household duties, e.g. cooking and use of knives, driving terminates; unable to manage finances - needs minor assistance in dressing, toileting, bathing; food must be cut for subject - 24-hour supervision appropriate; assistance required for bathing, eating, toileting - chronic care facility needed; limited self feeding, liquified diet - subject provides minimal assistance in own feeding, bathing, toileting - no speech, must be fed - tube fed, total bed care	Select one

17 **PBA-s**

This assessment must be administered by a PBA-s trained rater. Additional training materials are available under: https://studies.enroll-hd.org/training.

This assessment should be filled out on the Paper Based Form (PBF) first and transferred onto the EDC. The PBF should be used to record down any rater observations and notes related to the assessment. Original PBFs should be retained by the site as they may be required for Source Data Verification.

If for any item, the rater was unable to assess because condition too advanced (e.g. mute and immobile), then the rater should enter an 8 on the PBF, set the value to "missing" on the EDC, and add the following comment: 8 =unable to assess because condition too advanced (e.g. mute and immobile).
For lack of initiative (apathy), perseverative thinking or behaviour, delusions/paranoid thinking, these items would usually be rated 9 (data missing) in the absence of a reliable informant.

Field name	**Data Value**	**Comments**
Assessment date	date	Enter the date of the assessment
Rater Code	number	Enter the rater code
Depression	number	This is automatically calculated by the EDC
Irritability/aggression	number	This is automatically calculated by the EDC
Psychosis	number	This is automatically calculated by the EDC
Apathy	number	This is automatically calculated by the EDC
Executive function	number	This is automatically calculated by the EDC
Severity[1]	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for carer)	Select one
Frequency[1]	- never/almost never - seldom (less than once/week) - sometimes (up to four times a week) - frequently (most days/5, 6 or 7 times a week) - daily/almost daily for most (or all) of day	Select one
Worst[1]	- absent - slight, questionable - mild (present, not a	Worst scores are based on worst severity rating since last study visit. This value should not be entered for any symptoms for the Enroll-HD

[1] Severity. Frequency and Worst scores are taken for low mood, suicide, anxiety, irritability, aggressive behaviour, apathy, perseveration, obsessive compulsive behaviours, psychosis, and disorientation

	problem) - moderate (symptom causing problem) - severe (almost intolerable for carer)	Baseline Visit. The rater should set the value to “missing”.
Is informant a relative?	- spouse or partner - parent - sibling - child - other relative - friend or neighbor - professional care worker - other - no informant - participant came alone	Select one
Is informant a household member?	- 1. household member (i.e. relative or friend who lives with participant) - 2. not a household member but has frequent contact with participant (most days) - 3. not a household member and sees participant less than three or four times a week - 4. staff of residential care home or hospital	Select one. Categories 2 and 3 could apply to family, friends or professional care workers. A paid carer who stays with subject at home for three hours every weekday would be rated as 2.
General comments	text	Add general comments as needed

18 COGNITIVE

Cognitive training materials for the core and extended battery are available under: https://studies.enroll-hd.org/training.

This assessment should be filled out on the Paper Based Form (PBF) first and transferred onto the EDC. The PBF should be used to record down any rater observations and notes related to the assessment. Original PBFs should be retained by the site as they may be required for Source Data Verification.

Please read the Cognitive Manual carefully before administering and scoring each of the assessments. Site staff should exercise their judgement in completing/omitting a task if the patient is too advanced or is unable to complete a test due to specific reasons.
If the task was **not attempted** then select 'no' in the CRF field (e.g. ´Name of Cognitive Test´ completed: Yes/No). In the comment box adjacent to this question, enter one of the following reasons:

- *Participant refused*
- *Please select 'value is missing' if the task was accidentally omitted and enter a comment to that effect.*
- *Please select 'value is missing' if the patient is colour blind and enter a comment to that effect.*

If the task **was attempted** but the participant was unable to comprehend the instructions so the task was aborted or if the participant is too advanced to attempt the task, please select 'yes' in the CRF field *Name of Cognitive Test* completed yes/no, and **enter 0** for **both number correct and number of errors.** Note, for the Trail-Making Test (Parts A&B), enter 240 (maximum time allowed before test is discontinued) for 'time to complete' and 0 for the number of errors. In the comment box adjacent to the field please enter one of the following reasons.

- *Participant unable to comprehend instructions / engage with task*
- *Task not attempted as participant too advanced*

If the task **was attempted** but had to be stopped due to motor disorder please select 'yes' in the CRF field *Name of Cognitive Test* completed yes/no, and **enter 0** for **both number correct and number of errors**. Note, for the Trail-Making Test (Parts A&B), enter 240 (maximum time allowed before test is discontinued) for 'time to complete' and 0 for the number of errors. In the comment box adjacent to the field (see Figure 1), please enter the following reason:

- *Task abandoned due to motor disorder*

If the task **was attempted** and the participant seemed to understand the instructions, but was unable to positively score, enter 'yes' to was the task completed and simply enter **0 for number correct and number of errors.** Note, for the Trail-Making Test (Parts A&B), enter 240 (maximum time allowed before test is discontinued) for 'time to complete' and 0 for the number of errors.

Field name	**Data Value**	**Comments**
Assessment date	date	Enter full date of assessment
Rater Code	number	Enter the rater code
Did the participant complete the assessment	- yes - no	Select one

in their native language and with normal or corrected-to-normal vision and hearing?		
Did the participant complete the assessment in their native language?	- yes - no	Select one
At what age did the participant learn the language used?	Number of years	
Did the participant have normal/corrected-to-normal hearing and vision?	- yes - no	Select one
Was vision uncorrected (e.g. no glasses during visit)?	- yes - no	Select one
Was hearing uncorrected (e.g. no hearing aid worn)?	- yes - no	Select one
Symbol Digit Modality Test completed	- yes - no	Select one
Total correct	number	Enter number
Total errors	number	Enter number
Reason why test was not completed	- cognitive impairment - motor impairment - mental state - physical health - visual impairment - language barrier - refusal - study conflict - scheduling issue - site error	Select one
Verbal Fluency Test (Category) completed	- yes - no	Select one
Category	- animals - other	Select one
Please specify	text	If other, please specify (e.g. food items)
Total correct 0-15 seconds	number	Enter number
Total correct 16-30 seconds	number	Enter number
Total correct 31-45 seconds	number	Enter number
Total correct 46-60	number	Enter number

seconds		
Total correct (1 min)	number	This is automatically calculated by the EDC
Total intrusion errors	number	Enter number
Total perseverative errors	number	Enter number
Reason why test was not completed	- cognitive impairment - motor impairment - mental state - physical health - visual impairment - language barrier - refusal - study conflict - scheduling issue - site error	Select one
Stroop Word Reading Test completed	- yes - no	Select one
Total correct	number	Enter number
Total errors	number	Enter number
Total self-corrected errors	number	Enter number
Reason why test was not completed	- cognitive impairment - motor impairment - mental state - physical health - visual impairment - language barrier - refusal - study conflict - scheduling issue - site error	Select one
Stroop Colour Naming Test completed	-yes -no	Select one
Total correct	number	Enter number
Total errors	number	Enter number
Total self-corrected errors	number	Enter number
Reason why test was not completed	- cognitive impairment - motor impairment - mental state - physical health - visual impairment - language barrier - refusal - study conflict - scheduling issue - site error	Select one

Stroop Interference Test completed	-yes -no	Select one
Total correct	number	Enter number
Total errors	number	Enter number
Total self-corrected errors	number	Enter number
Trail making Test completed	- yes - no	Select one
Part A: time to complete	number	Enter number, maximum = 240
Part A: total correct	number	Enter number
Part A: total errors	number	Enter number
Part B: time to complete	Number (sec)	Enter number, maximum = 240
Part B: total correct	number	Enter number
Part B: total errors	number	Enter number
Verbal Fluency Test (Letters) completed	- yes - no	Select one
Total correct 0-15 seconds	number	Enter number
Total correct 16-30 seconds	number	Enter number
Total correct 31-45 seconds	number	Enter number
Total correct 46-60 seconds	number	Enter number
Total correct (3 min)	number	This is automatically calculated by the EDC
Total intrusion errors	number	Enter number
Total perseverative errors	number	Enter number

19 **MMSE**

The MMSE is part of the extended Cognitive Assessment for Enroll-HD. The paper-based form must be downloaded from the Enroll-HD website. The assessment can only be used for the Enroll-HD study.

The additional stimuli (e.g. instruction to “CLOSE YOUR EYES” and the interlocking pentagons) are appended to the paper-based form download.

The rater should check the MMSE scoring criteria embedded in the assessment before confirming whether the responses are correct or incorrect.

Field name	**Data Value**	**Comments**
Assessment date	date	Enter the date the assessment was completed
MMSE score	number	This is automatically calculated by the EDC
Year?	- incorrect - correct	Select one
Season?	- incorrect - correct	Select one
Month of the year?	- incorrect - correct	Select one
Day of the week?	- incorrect - correct	Select one
Date?	- incorrect - correct	Select one
State (province)?	- incorrect - correct	Select one
County (or city/town)?	- incorrect - correct	Select one
City/town (or part of city/neighborhood)?	- incorrect - correct	Select one
Building (name or type)?	- incorrect - correct	Select one
Floor of the building (room number or address)?	- incorrect - correct	Select one
Word 1	- incorrect - correct	Select one
Word 2	- incorrect - correct	Select one
Word 3	- incorrect - correct	Select one
[Step 1]	- incorrect - correct	Select one
[Step 2]	- incorrect - correct	Select one

[Step 3]	- incorrect - correct	Select one
[Step 4]	- incorrect - correct	Select one
[Step 5]	- incorrect - correct	Select one
Word 1	- incorrect - correct	Select one
Word 2	- incorrect - correct	Select one
Word 3	- incorrect - correct	Select one
1 [Pencil or pen]	- incorrect - correct	Select one
2 [Watch]	- incorrect - correct	Select one
No ifs, ands or buts	- incorrect - correct	Select one
Take in right hand	- incorrect - correct	Select one
Fold in half	- incorrect - correct	Select one
Put on floor (or table)	- incorrect - correct	Select one
Close your eyes	- incorrect - correct	Select one
Sentence	- incorrect - correct	Select one
Figure	- incorrect - correct	Select one

20 EVENT

Field name	Data Value	Comments
Assessment date	date	Enter the date the information was obtained.
Reportable event codes	single choice	- suicide attempts - completed suicide - mental health event requiring hospitalization - death (other than suicide, any cause)
Event term	text	Enter a description of the event, e.g. Suicide Attempt
MedDRA code	- Term - Modified Term - Code - Certainty	This item will be coded by the Central Coders.
Onset date	date	Enter the date the event started
Date estimated	- yes - no	Select yes if date is estimate
Resolved	- yes - no	Select yes if resolved
End date	date	End the date the event ended
Describe briefly circumstances and nature of event	text	Enter description
Medication	- yes - no	Select yes if any medications have been prescribed as interventions
Describe	text	Enter description
Behavioral/Lifestyle	- yes - no	Select yes if any behavioural/lifestyle have been prescribed as interventions
Describe	text	Enter description
Other	- yes - no	Select yes if any other type of treatment has been prescribed as intervention
Describe	text	Enter description
List any relevant tests, laboratory data, history	text	Enter description
Is the report	- initial - follow-up - final	Select one
Status of DSMC review	- pending review - on-going review - closed/completed review	For internal use only; not completed by the site.

21 FAMILY HISTORY

The participant must have provided consent for the Optional Component to collect Family History information.

The Family History Source Data File is a paper-based form that should be used to collect information on family members. The focus of family history information should be on the side of the family affected by HD. The information from the FH Source Data File and from medical records (if available) should be used to create the online Family History tree. Each relative is assigned a "node" and the data points listed in the table below can be entered. For further guidelines on how to create an online Family History tree, see the EDC manual listed under https://studies.enroll-hd.org/training.

Field name	Data Value	Comments
Gender	- female male	Select one (this is automatically populated for the HDID participant based on the Demog form)
Year of birth	number	Enter number of years
Vital status	- alive - dead - unknown	Select one
Year of death	4-digit year	Enter year of death (yyyy)
Cause of death	text	Enter cause of death
HD status	- manifest carrier - pre-manifest carrier, genetically confirmed - not a carrier, genetic test done - unknown, no genetic test done	Select one
Degree of certainty	0,1, 2, 3, 4, or 5	Select a value between 0-5 where 0 = not at all certain and 5 = completely certain
Availability of DNA samples	- yes - no	Enter 'yes' if there is locally stored DNA available on this relative.
Participant in Enroll-HD	- yes - no - unknown	Select one
Pseudonym	text	Enter HDID if known

22 SAMPLES

Samples are collected from every participant in Enroll-HD. A 10ml sample is collected for research CAG genotyping at baseline (note, this same is not required if the research CAG genotype has already been acquired from the Registry study).

A maximum of 20ml ACD blood samples are collected from research participants at every study visit if s/he has consented to the Optional Component to donate bio samples for research purposes.

Field name	Data Value	Comments
Date and time of collection	Date:time	Enter the date and time bio samples were collected from the participant
Withdrawal number	number	Automatically set by the EDC.
Specimen	- ACD - LiHep - Z (Urine) - Tissue - EDTA - PAXGene - K3-EDTA	Automatically set to ACD by the EDC.
Bar code	text	Scan this in using the barcode scanner or enter manually. If there is no barcode on the tube enter B00000000000, set the field state to "wrong" and enter a comment. If no samples are being shipped, the fields must be left blank, the field state must be set to "missing" and the comment must state that no samples are being shipped.
No.	Number	Set the number to the total number of vacutainers shipped (that contain bio samples; do not count any empty/unused and returned vacutainers).
Shipped	- yes - no	Select one
Airway bill no (DHL)	number	Scan this in using the barcode scanner or enter manually
Date of notification	date	Entered by BioRep
Date of receipt	date	Entered by BioRep
Total shipping time	number array	Entered by BioRep
Resubmit notification to BioRep	- yes - no	Select this check box if the original notification was not received by BioRep. The action means that the Samples CRF will be resubmitted to the EDC so that the information reaches the BioRep system.
Product	- Cell line - DNA - Plasma - Urine	Entered by BioRep

	- SQC - Buffy coat	
No.	number	Entered by BioRep
Date of receipt	date	Entered by BioRep
Receipt state	drop down menu	Entered by BioRep
Outcome	- pass - failed	Entered by BioRep
Date Completed	Date	Entered by BioRep
ID	number	Automatically generated by the EDC; this Lab ID should be used instead of the HDID in any communication by the site with the study team (including BioRep).

23 C-SSRS BL

The CSSRS-S Baseline version should be used the first time the participant receives this scale for a study visit.

The CSSRS-S must only be administered to participants reporting suicidal ideation/attempts, but should be administered at every visit with every participant. If the form is not completed during a visit, it needs to be deactivated.

The paper-based form of the CSSRS-S Baseline should be used when administering this assessment.

Field name	Data Value	Comments
Assessment date	date	Enter the date the assessment was performed
Have you wished you were dead or wished you could go to sleep and not wake up	- yes - no	Select one
Please describe	text	Transcribe the participant's self-report
Have you actually had any thoughts of killing yourself	- yes - no	Select one
Please describe	text	Transcribe the participant's self-report
Have you been thinking about how you might do this	- yes - no	Select one
Please describe	text	Transcribe the participant's self-report
Have you had these thoughts and had some intention of acting on them	- yes - no	Select one
Please describe	text	Transcribe the participant's self-report
Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan	- yes - no	Select one
Please describe	text	Transcribe the participant's self-report
Type	- Wish to be dead - Non-Specific Active Suicidal Thoughts - Active Suicidal Ideation with Any Methods (not Plan) without Intent to Act - Active Suicidal Ideation with Some Intent to Act, without Specific Plan	Select one

	- Active Suicidal Ideation with Specific Plan and Intent	
Description of Ideation	text	Transcribe the participant's self-report
How many times have you had these thoughts	1, 2, 3, 4, or 5	Select one
When you have the thoughts, how long do they last	1, 2, 3, 4, or 5	Select one
Could/can you stop thinking about killing yourself or wanting to die if you want to	0,1, 2, 3, 4, or 5	Select one
Are there things - anyone or anything (e.g. family, religion, pain of death) - that stopped you from wanting to die or acting on thoughts of committing suicide	0,1, 2, 3, 4, or 5	Select one
What sort of reasons did you have for thinking about wanting to die or killing yourself	0,1, 2, 3, 4, or 5	Select one
Actual attempt	- yes - no	Select one
Total # of attempts	number	Enter the # of suicide attempts
Please describe	text	Transcribe the participant's self-report
Has subject engaged in Non-Suicidal Self-Injurious Behavior?	- yes - no	Select one
Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?	- yes - no	Select one
Total # of interrupted	number	
Please describe	text	Transcribe the participant's self-report
Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?	- yes - no	Select one
Total # of aborted	- yes	Select one

	- no	
Please describe	text	Transcribe the participant's self-report
Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?	- yes - no	Select one
Please describe	text	Transcribe the participant's self-report
Suicidal behaviour was present during the assessment period?	- yes - no	Select one
Date	date	Enter the full date of the most recent attempt
Actual Lethality/Medical Damage	- No physical damage - Minor physical damage - Moderate physical damage - Moderately severe physical damage - Severe physical damage - Death	Select one
Potential Lethality	- not likely to result in injury - likely to result in injury - likely to result in death	Select one
Date	date	Enter the full date of the most lethal attempt
Actual Lethality/Medical Damage	- No physical damage - Minor physical damage - Moderate physical damage - Moderately severe physical damage - Severe physical damage - Death	Select one
Potential Lethality	- not likely to result in injury - likely to result in injury - likely to result in death	Select one
Date	date	Enter the full date of the initial/first attempt

Actual Lethality/Medical Damage	- No physical damage - Minor physical damage - Moderate physical damage - Moderately severe physical damage - Severe physical damage - Death	Select one
Potential Lethality	- not likely to result in injury - likely to result in injury - likely to result in death	Select one

24 **C-SSRS FUP**

The CSSRS-S Follow-up version should be used at every follow-up visit.

The CSSRS-S must be administered at every visit with every participant. If the form is not completed during a visit, it needs to be deactivated.

The paper-based form of the CSSRS-S Follow-up should be used when administering this assessment.

Field name	**Data Value**	**Comments**
Assessment date	date	Enter the date the assessment was performed
Have you wished you were dead or wished you could go to sleep and not wake up	- yes - no	Select one
Please describe	text	Transcribe the participant's self-report
Have you actually had any thoughts of killing yourself	- yes - no	Select one
Please describe	text	Transcribe the participant's self-report
Have you been thinking about how you might do this	- yes - no	Select one
Please describe	text	Transcribe the participant's self-report
Have you had these thoughts and had some intention of acting on them	- yes - no	Select one
Please describe	text	Transcribe the participant's self-report
Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan	- yes - no	Select one
Please describe	text	Transcribe the participant's self-report
Type	- Wish to be dead - Non-Specific Active Suicidal Thoughts - Active Suicidal Ideation with Any Methods (not Plan) without Intent to Act - Active Suicidal Ideation with Some Intent to Act, without Specific Plan - Active Suicidal Ideation with	Select one

	Specific Plan and Intent	
Description of Ideation	text	Transcribe the participant's self-report
How many times have you had these thoughts	1, 2, 3, 4, or 5	Select one
When you have the thoughts, how long do they last	1, 2, 3, 4, or 5	Select one
Could/can you stop thinking about killing yourself or wanting to die if you want to	0, 1, 2, 3, 4, or 5	Select one
Are there things - anyone or anything (e.g. family, religion, pain of death) - that stopped you from wanting to die or acting on thoughts of committing suicide	0, 1, 2, 3, 4, or 5	Select one
What sort of reasons did you have for thinking about wanting to die or killing yourself	0, 1, 2, 3, 4, or 5	Select one
Actual attempt	- yes - no	Select one
Total # of attempts	number	Enter number of attempts
Please describe	text	Transcribe the participant's self-report
Has subject engaged in Non-Suicidal Self-Injurious Behavior?	- yes - no	Select one
Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?	- yes - no	Select one
Total # of interrupted	number	Enter number of attempts interrupted
Please describe	text	Transcribe the participant's self-report
Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?	- yes - no	Select one
Total # of aborted	number	Enter the number of attempts aborted
Please describe	text	Transcribe the participant's self-report

Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?	- yes - no	Select one
Please describe	text	Transcribe the participant's self-report
Suicidal behaviour was present during the assessment period?	- yes - no	Select one
Completed suicide was present during the assessment period	- yes - no	Select one
Date	date	Enter the full date of the most lethal attempt
Actual Lethality/Medical Damage	- No physical damage - Minor physical damage - Moderate physical damage - Moderately severe physical damage - Severe physical damage - Death	Select one
Potential Lethality	- not likely to result in injury - likely to result in injury - likely to result in death	Select one

25 PHYSIO

There are two Physiotherapy outcome measures in the Enroll-HD assessment; the Timed Up and GO (TUG) and the 30 Second Chair-Stand test. Guidelines to administer and score each outcome measure are provided as pdfs within the EDC.

Field name	Data Value	Comments
Assessment date	date	Enter the date the assessments were completed.
Timed "Up and Go" performed	- yes - no	Select yes if the assessment was completed.
Total time	number	Enter the total # seconds the participant took to complete the task.
30 second chair stand test performed	- yes - no	Select yes if the assessment was completed
Number of times the participant stands in 30 seconds	number	Enter the # times the participant stands in 30s.

26 **HADS-SIS**

This self-report questionnaire records depression, anxiety and irritability. It is recommended that the PBA-s rater reviews the HAD-SIS in advance of administering the PBA-s.

The paper-based form of the HADS-SIS should be used by participants completing this questionnaire.

Check the participant has not accidentally omitted any items.

Field name	**Data Value**	**Comments**
Assessment date	date	Enter the date that the participant completed the questionnaire
Anxiety subscore	number	This is automatically calculated by the EDC
Depression subscore	number	This is automatically calculated by the EDC
Irritability subscore	number	This is automatically calculated by the EDC
Outward irritability subscore	number	This is automatically calculated by the EDC
Inward irritability subscore	number	This is automatically calculated by the EDC
I feel tense or 'wound up'	- most of the time - a lot of the time - from time to time, occasionally - not at all	Participant should select one; enter the corresponding value onto the eCRF.
I still enjoy the things I used to enjoy	- definitely as much - not quite so much - only a little - hardly at all	Participant should select one; enter the corresponding value onto the eCRF.
I get a sort of frightened feeling as if something awful is about to happen	- very definitely and quite badly - yes, but not too badly - a little, but it doesn´t worry me - not at all	Participant should select one; enter the corresponding value onto the eCRF.
I lose my temper and shout or snap at others	- yes, definitely - yes, sometimes - no, not much - no, not at all	Participant should select one; enter the corresponding value onto the eCRF.
I can laugh and see the funny side of things	- as much as I always could - not quite so much now - definitely not so much now - not at all	Participant should select one; enter the corresponding value onto the eCRF.

I am patient with other people	- all of the time - most of the time - some of the time - hardly ever	Participant should select one; enter the corresponding value onto the eCRF.
I feel cheerful	- never - not often - sometimes - most of the time	Participant should select one; enter the corresponding value onto the eCRF.
I get angry with myself and call myself names	- yes, definitely - sometimes - not often - no, not at all	Participant should select one; enter the corresponding value onto the eCRF.
I can sit at ease and feel relaxed	- definitely - usually - not often - not at all	Participant should select one; enter the corresponding value onto the eCRF.
I feel as if I am slowed down	- nearly all the time - very often - sometimes - not at all	Participant should select one; enter the corresponding value onto the eCRF.
I feel like harming myself	- yes, definitely - yes, sometimes - no, not much - no, not at all	Participant should select one; enter the corresponding value onto the eCRF.
Worrying thoughts go through my mind	- a great deal of the time - a lot of the time - not too often - very little	Participant should select one; enter the corresponding value onto the eCRF.
I have lost interest in my appearance	- definitely - I don't take as much care as I should - I may not take quite as much care - I take just as much care as ever	Participant should select one; enter the corresponding value onto the eCRF.
The thought of hurting myself occurs to me	- sometimes - not very often - hardly ever - not at all	Participant should select one; enter the corresponding value onto the eCRF.
I feel restless as if I have to be on the move	- very much indeed - quite a lot - not very much - not at all	Participant should select one; enter the corresponding value onto the eCRF.
I look forward with enjoyment to things	- as much as I ever did - rather less than I used to - definitely less than I	Participant should select one; enter the corresponding value onto the eCRF.

	used to - hardly at all	
I feel I might lose control and hit or hurt someone	- sometimes - occasionally - rarely - never	Participant should select one; enter the corresponding value onto the eCRF.
I get a sort of frightened feeling like 'butterflies' in the stomach	- not at all - occasionally - quite often - very often	Participant should select one; enter the corresponding value onto the eCRF.
People upset me so that I feel like slamming doors or banging about	- yes, often - yes, sometimes - only occasionally - not at all	Participant should select one; enter the corresponding value onto the eCRF.
I get sudden feelings of panic	- very often indeed - quite often - not very often - not at all	Participant should select one; enter the corresponding value onto the eCRF.
I can enjoy a good book or radio or television programme	- often - sometimes - not often - very seldom	Participant should select one; enter the corresponding value onto the eCRF.
Lately I have been getting annoyed with myself	- very much so - rather a lot - not much - not at all	Participant should select one; enter the corresponding value onto the eCRF.

27 **SF12**

Field name	Data Value	Comments
Assessment date	date	Enter the date that the participant completed the questionnaire
1. In general, would you say your health is?	- excellent - very good - good - fair - poor	Select one
2.a. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	- yes, limited a lot - yes, limited a little - no, not limited at all	Select one
2.b. Climbing several flights of stairs	- yes, limited a lot - yes, limited a little - no, not limited at all	Select one
3.a. Accomplished less than you would like	- all of the time - most of the time - some of the time - a little of the time - none of the time	Select one
3.b. Were limited in the kind of work or other activities	- all of the time - most of the time - some of the time - a little of the time - none of the time	Select one
4.a. Accomplished less than you would like	- all of the time - most of the time - some of the time - a little of the time - none of the time	Select one
4.b. Did work or other activities less carefully than usual	- all of the time - most of the time - some of the time - a little of the time - none of the time	Select one
5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	- not at all - a little bit - moderately - quite a bit - extremely	Select one
6.a. Have you felt calm and peaceful?	- all of the time - most of the time - some of the time - a little of the time - none of the time	Select one

6.b. Did you have a lot of energy?	- all of the time - most of the time - some of the time - a little of the time - none of the time	Select one
6.c. Have you felt downhearted and low?	- all of the time - most of the time - some of the time - a little of the time - none of the time	Select one
7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?	- all of the time - most of the time - some of the time - a little of the time - none of the time	Select one

28 CAREQOL

There must be a caregiver ICF in place for the caregiver who completes the CQoL questionnaire. A new ICF must be completed if the caregiver changes between study visits.

The Care QoL appears for unknown, pre-manifest, manifest, negative. You have to explicitly submit the Enrollment Form to enable it to appear in the visit.

A caregiver does not receive an HDID unless they are also enrolling in the study as a family control.

The CareQoL should be completed on the paper-based form available on the EDC.

Field name	Data Value	Comments
Assessment date	date	Enter the date that the caregiver completed the questionnaire
ID of caregiver	number	Assign this number. The first ID will be 001. Any change of caregiver at subsequent visits will increment by 1, e.g. 002, 003 and so on. A record of the caregiver ID is maintained by the site in the ISF.
Does the caregiver have a unique HD identifier (HDID)?	- yes - no	If yes, enter the HDID if the caregiver is also a participant in Enroll-HD (e.g. Family Control)
Caregiver's HDID	text	Enter the Caregiver's Enroll-HD Participant HDID if known.
What is your year of birth?	number	Caregiver's self-report of DOB.
What is your gender?	- female - male	Select one
Country of residence	single choice	Select one of the countries listed in the CRF
How many years of education have you had?	number	Select one
Do you have a job	- yes, full time - yes, part time - no	Select one
What is your marital status	- single - married - partnership - divorced - widowed - legally separated	Select one
How long have you known about Huntington's Disease in the family of the affected person(s)?	number	Enter number of years
How long have you been	number	Enter number of years

caring for any Huntington's Disease affected person(s)?		
Are you the main carer for the HD affected person(s)?	- yes - no	Select one
The HD affected person(s) is/are my	- sibling - spouse/partner - parent - child - other	Select one
Please specify	text	
Have you previously cared for any other person(s) with Huntington's Disease?	- yes - no	Select one
The affected person is/was my	text	
Do you have children who are at risk/carrier/symptomatic?	- yes - no	Select one
How many persons live in your household?	number	
Do you live in the same household as the HD person(s)?	- yes - no	Select one
How satisfied are you with your physical health?	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=dissatisfied, 10= satisfied)
How satisfied are you with your psychological health?	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=dissatisfied, 10= satisfied)
How satisfied are you with what you have achieved in life?	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=dissatisfied, 10= satisfied)
How satisfied are you with family relationships?	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=dissatisfied, 10= satisfied)
How satisfied are you with your relationships with your friends?	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=dissatisfied, 10= satisfied)
How satisfied are you with feeling a part of your social environment?	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=dissatisfied, 10= satisfied)
How satisfied are you with the medical treatment that your HD relative(s) receive(s)?	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=dissatisfied, 10= satisfied)

How satisfied are you with the way other people behave towards the HD person?	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=dissatisfied, 10= satisfied)
How satisfied are you with the professional support you receive?	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=dissatisfied, 10= satisfied)
I feel a sense of loss	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel a sense of grieving	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel happy	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel a sense of anguish	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel full of fear	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel safe	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel guilty	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel financially disadvantaged	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel isolated	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel there is hope for the future	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel exhausted	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel supported	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel depressed	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)

I feel sad	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel stressed	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel worried about the genetic consequences of Huntington's Disease	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel that my own needs are important to others	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel lonely	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel that Huntington's Disease brought something positive to my life	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel comforted by my beliefs (religious, philosophical or spiritual)	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel that I can cope	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel that Huntington's Disease has made me a stronger person	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel that I have had a duty of care forced on me	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel like I don't know who I am anymore	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel that my role as a carer is rewarding	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel restricted by a regimented daily routine	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel restricted by having to provide continuous care	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel resentful	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)

I feel embarrassed by the behaviour of my HD relative(s)	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel ashamed of the behaviour of my HD relative(s)	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel frustrated by the misconceptions of others towards my HD relative(s)	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel threatened	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel frustrated by the discrimination of others toward my HD	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel restricted by the need to maintain secrecy about Huntington's Disease in the family	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel I have enough time for myself	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel I get enough sleep	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel I have somebody to turn to for assistance if I am overwhelmed	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
I feel satisfied with my overall quality of life	0,1,2,3,4,5,6,7,8,9, or 10	Enter value between 0 and 10 (0=never, 10= always)
Is there anything else related to your caring role that you feel hasn't been covered in this questionnaire?	- yes - no	Select one
Could you please describe what it is?	text	Enter description
As a carer of someone with HD, is there anything that affects you most?	- yes - no	Select one
positive	text	Enter positive effects
negative	text	Enter negative effects
Can you think of anything that would most improve your quality of life as a carer?	- yes - no	Select one

Could you please describe what it is?	text	Enter description
Have you taken any action to achieve this?	- yes - no	Select one
What action have you taken?	text	Enter the action taken

29 **CSRI**

The CSRI can be completed by the participant (and/or caregiver), or if assistance is required, with the help of a member of the study team.

Field name	**Data Value**	**Comments**
Assessment date	date	Enter full date of Assessment
Neurology outpatient visit	- yes - no	Select one
Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD
Use in the last 6 months for other reasons	number	If yes, enter the number of visits for other reasons
Other hospital outpatient visit	- yes - no	Select one
Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD
Use in the last 6 months for other reasons	number	If yes, enter the number of visits for other reasons
Ambulatory or same day surgery	- yes - no	Select one
Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD
Use in the last 6 months for other reasons	number	If yes, enter the number of visits for other reasons
Nursing or residential home	- yes - no	Select one
Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD
Use in the last 6 months for other reasons	number	If yes, enter the number of visits for other reasons
Inpatient hospital stay	- yes - no	Select one
Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD
Use in the last 6 months for other reasons	number	If yes, enter the number of visits for other reasons
Inpatient hospital stay - intensive care unit (ICU)	- yes - no	Select one
Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD
Use in the last 6 months for other reasons	number	If yes, enter the number of visits for other reasons
Hospital emergency room visits	- yes - no	Select one
Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD

Use in the last 6 months for other reasons	number	If yes, enter the number of visits for other reasons
Other inpatient hospital stay	- yes - no	Select one
Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD
Use in the last 6 months for other reasons	number	If yes, enter the number of visits for other reasons
General practitioner (GP) or internist/family doctor	- yes - no	Select one
Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD
Use in the last 6 months for other reasons	number	If yes, enter the number of visits for other reasons
Physical Therapist (PT)	- yes - no	Select one
Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD
Use in the last 6 months for other reasons	number	If yes, enter the number of visits for other reasons
Psychiatrist	- yes - no	Select one
Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD
Use in the last 6 months for other reasons	number	If yes, enter the number of visits for other reasons
Psychologist/psychotherapist	- yes - no	Select one
Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD
Use in the last 6 months for other reasons	number	If yes, enter the number of visits for other reasons
Counsellor	- yes - no	Select one
Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD
Use in the last 6 months for other reasons	number	If yes, enter the number of visits for other reasons
Family therapist/marriage guidance	- yes - no	Select one
Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD
Use in the last 6 months for other reasons	number	If yes, enter the number of visits for other reasons
Dietician/nutritionist	- yes - no	Select one

Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD
Use in the last 6 months for other reasons	number	If yes, enter the number of visits for other reasons
Clinical geneticist	- yes - no	Select one
Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD
Use in the last 6 months for other reasons	number	If yes, enter the number of visits for other reasons
Social worker	- yes - no	Select one
Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD
Use in the last 6 months for other reasons	number	If yes, enter the number of visits for other reasons
Practice nurse (nurse practitioner or physician assistant)	- yes - no	Select one
Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD
Use in the last 6 months for other reasons	number	If yes, enter the number of visits for other reasons
Home healthcare nurse	- yes - no	Select one
Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD
Use in the last 6 months for other reasons	number	If yes, enter the number of visits for other reasons
Speech therapist	- yes - no	Select one
Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD
Use in the last 6 months for other reasons	number	If yes, enter the number of visits for other reasons
Home help/home care worker	- yes - no	Select one
Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD
Use in the last 6 months for other reasons	number	If yes, enter the number of visits for other reasons
Acupuncturist	- yes - no	Select one
Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD
Use in the last 6 months	number	If yes, enter the number of visits for other

for other reasons		reasons
Homeopath	- yes - no	Select one
Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD
Use in the last 6 months for other reasons	number	If yes, enter the number of visits for other reasons
Herbalist	- yes - no	Select one
Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD
Use in the last 6 months for other reasons	number	If yes, enter the number of visits for other reasons
Aromatherapy	- yes - no	Select one
Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD
Use in the last 6 months for other reasons	number	If yes, enter the number of visits for other reasons
Reflexologist	- yes - no	Select one
Use in the last 6 months because of your HD	number	If yes, enter the number of visits because of HD
Use in the last 6 months for other reasons	number	If yes, enter the number of visits for other reasons
Other service	- yes - no	Select one
Genetic test	- yes - no	Select one
No. in the last 6 months	number	If yes, enter number of tests in the last 6 months
Why did you have this test/investigation?	text	Enter comment
Magnetic Resonance Image (MRI)	- yes - no	Select one
No. in the last 6 months	number	Enter number of MRI scans in the last 6 months
Why did you have this test/investigation?	text	Enter the reason(s) for having the scans
CT/CAT scan	- yes - no	Select one
No. in the last 6 months	number	Enter number of CAT scans in the last 6 months
Why did you have this test/investigation?	text	Enter the reason(s) for having the scans

Electroencephalogram (EEG)	- yes - no	Select one
No. in the last 6 months	number	Enter number of EEGs in the last 6 months
Why did you have this test/investigation?	text	Enter the reason(s) for having the scans
Blood test	- yes - no	Select one
No. in the last 6 months	number	Enter number of blood tests in the last 6 months
Why did you have this test/investigation?	text	Enter the reason(s) for having the scans
Personal care (e.g. bathing, dressing)	- yes - no	Select one
Average no. of hours per week	number	Enter the average number of hours per week
Any other information?	text	Enter comment
Help inside the home (e.g. cooking, cleaning)	- yes - no	Select one
Average no. of hours per week	number	Enter the average number of hours per week
Any other information?	text	Enter comment
Help outside the home (e.g. shopping)	- yes - no	Select one
Average no. of hours per week	number	Enter the average number of hours per week
Any other information?	text	Enter comment
Other	- yes - no	Select one
Average no. of hours per week	number	Enter the average number of hours per week
Any other information?	text	Enter comment
Stair lift	- yes - no	Select one
Was this in the last 6 months?	- yes - no	Select one
Handrails	- yes - no	Select one
Was this in the last 6 months?	- yes - no	Select one
Ramps	- yes - no	Select one
Was this in the last 6 months?	- yes - no	Select one

Shower/bath relocation	- yes - no	Select one
Was this in the last 6 months?	- yes - no	Select one
Toilet relocation	- yes - no	Select one
Was this in the last 6 months?	- yes - no	Select one
Redesign kitchen	- yes - no	Select one
Was this in the last 6 months?	- yes - no	Select one
Chair raises/special chair	- yes - no	Select one
Was this in the last six months?	- yes - no	Select one
Bed moved downstairs	- yes - no	Select one
Was this in the last 6 months?	- yes - no	Select one
Hospital bed	- yes - no	Select one
Was this in the last 6 months?	- yes - no	Select one
Other	- yes - no	Select one
Was this in the last 6 months?	- yes - no	Select one
Wheelchair	- yes - no	Select one
Did you receive it in the last 6 months?	- yes - no	Select one
Crutches/sticks	- yes - no	Select one
Did you receive it in the last 6 months?	- yes - no	Select one
Zimmer frame	- yes - no	Select one
Did you receive it in the last 6 months?	- yes - no	Select one
Commode	- yes - no	Select one
Did you receive it in the last 6 months?	- yes - no	Select one
Bath board	- yes - no	Select one

Did you receive it in the last 6 months?	- yes - no	Select one
Pressure relieving cushions/mattress	- yes - no	Select one
Did you receive it in the last 6 months?	- yes - no	Select one
Adapted eating utensils	- yes - no	Select one
Did you receive it in the last 6 months?	- yes - no	Select one
Other	- yes - no	Select one
Did you receive it in the last 6 months?	- yes - no	Select one

30 **WPAI-SHP**

The WPAI-SHP form should only be filled out by manifest or pre-manifest participants as it asks specifically how HD has impacted their work life.
The paper-based form of the WPAI-SHP should be given to the participant to complete this questionnaire.

Field name	**Data Value**	**Comments**
Assessment date	date	Enter the date that the participant completed the questionnaire
Work time missed due to HD	number	This is automatically calculated by the EDC
Impairment while working due to HD	number	This is automatically calculated by the EDC
Overall work impairment due to HD	number	This is automatically calculated by the EDC
Activity impairment due to HD	number	This is automatically calculated by the EDC
Are you currently employed (working for pay)?	- yes - no	Select one
During the past seven days, how many hours did you miss from work because of problems associated with Huntington's disease?	number	Enter the # of hours missed from work because of HD
During the past seven days, how many hours did you miss from work because of any other reason, such as vacation, holidays, time off to participate in this study?	number	Enter # of hours
During the past seven days, how many hours did you actually work?	number	Enter # of hours
During the past seven days, how much did Huntington's disease affect your productivity while you were working?	0,1,2,3,4,5,6, 7,8,9, or 10	Select from 0-10 where 0= HD had no effect on my work and 10 =HD completely prevented me from working
During the past seven days, how much did Huntington's disease affect your ability to do your regular daily activities, other than work at a job?	0,1,2,3,4,5,6, 7,8,9, or 10	Select from 0-10 where 0= HD had no effect on my daily activities and 10 =HD completely prevented me from working HD had no effect on me from doing my daily activities

31 **MISSED VISIT**

This form should be completed when a participant has not attended the annual follow-up visit (+/- 3 months since baseline visit). The form should be completed by a member of the study site team who has follow-up with the participant (and/or family) to confirm the reason for the missed visit.

Field name	Data Value	Comments
Date info obtained	date	Enter the date the site member obtained the information about the reason for missed visit.
Source of information	- participant - spouse/partner - next of kin (family or friends) - physician - nurse - other (e.g. hearsay, obituary in newspaper, death certificate)	Select one
Reason for missed follow-up visit	- participant alive, unable to attend FUP, open to future FUPs - participant alive, objects to further FUP visits, open to further phone contacts - participant alive, objects to further FUP visits and to further phone contacts - participant alive, lost to FUP - participant dead - status unclear	Select one
Level of care required	- The participant does not require any help for basic activities of daily living (un/dressing, washing/bathing, getting up/going to bed). - The participant requires some help to manage basic activities of daily living (typically < 4 h	Select one

	support per day), but no full-time supervision - The participant requires extensive help to manage basic activities of daily living (typically ≥ 4 h support per day), and full-time supervision with additional help as required.	
Date since full-time dependency	date	Enter full date since full-time dependency

32 **END**

Any participant who becomes lost to follow-up, institutionalised or unable to participate due to health reasons (or other), should have the End of Study CRF completed.

Field name	**Data Value**	**Comments**
Assessment date	date	Enter full date of Assessment
Specify primary reason for participant's premature discontinuation from study	single choice	- event or intercurrent illness of a nature requiring withdrawal - request of primary care physician, site investigator - participant's request (includes carer/spouse/authorized representative's request) - lost to follow up - institutionalized (will not be followed further) - other
Please specify the reason for the participant's request	single choice	- unable to travel - participant unwilling to continue - participant moved away from the study site
Please specify	text	Enter comment

33 MORTALITY

Death is a reportable event and this CRF should be filled out for any participant who dies during the course of the study. The Enroll-HD Data Safety Monitoring Committee will review all cases of death reported during the Enroll-HD Study.

Field name	Data Value	Comments
Assessment date	date	Enter date information was entered
Date of death	date	Enter date of death
Place of death	- home - hospital - nursing home - hospice care - unknown	Select one
Cause of death	- pneumonia - other infection - cancer - stroke - trauma - suicide - other	Select one
Please specify	text	Select one
Was an autopsy performed?	- no - yes - unknown	Select one
Result of autopsy	text	Select one
Information obtained primarily from	- spouse/family - friend - physician/nurse - patient's medical record - obituary in newspaper - death certificate - other	Select one
Please specify	text	Select one
Comments?	- yes - no	Select one
Comment	text	Enter as needed