

# **ENROLL-DOC-2006-EN-1.12**

# **Enroll-HD Annotated CRF**

**Documentation** 

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#### 1 Preamble

The purpose of this document is to provide the annotated view of the Enroll-HD eCRF (*electronic Case Report Form*). The annotated view shows all forms, variables and its variable names used within the study. The forms and variables are described in detail in detail within the data management requirements [1] and data dictionary [2] of the study.

## 2 Visit Form Schedule

The visit form schedule defines the assignment of forms to visit types:

eCRF Form	General	Family History	Baseline	Follow Up	Phone Contact	Unscheduled	Premature End
Demographic Data (Demog)	✓						
HD Clinical Characteristics (HD CC)	✓						
CAG Report (CAG)	(✓)						
Pharmacotherapy (PharmacoTx)	✓						
Nutritional Supplements (NutSuppl)	<b>✓</b>						
Non-Pharmacologic Therapies (Non-PharmacoTx)	✓						
Comorbid Conditions (Comorbid)	✓						
Clinical Trials Form (Clinical Trials)	✓						
Reportable Event (Event)	✓						
Mortality	✓						
Family History (FHx)		✓					
Enrollment into Enroll-HD (Enrollment)			<b>✓</b>				
Medical History (MHx)			✓				

eCRF Form	General	Family History	Baseline	Follow Up	Phone Contact	Unscheduled	Premature End
Variable Items Baseline (Variable)			✓				
Variable Items Follow Up (Variable)				<b>√</b>		✓	
UHDRS® Motor/Diagnostic Confidence (Motor)			✓	✓		✓	
UHDRS® Total Functional Capacity (TFC)			✓	✓		✓	
UHDRS® Functional Assessment (Function)			<b>✓</b>	<b>✓</b>		✓	
Problem Behaviours Assessment – Short (PBA-s)			✓	<b>✓</b>		✓	
Core and Extended Cognitive Assessment (Cognitive)			✓	✓		✓	
Bio Specimens for Bio Banking (Samples)			(✓)	(✓)			
Hospital Anxiety and Depression Scale - Snaith Irritability Scale (HADS-SIS)			<b>✓</b>	<b>✓</b>		<b>✓</b>	
Columbia-Suicide Severity Rating Scale (C-SSRS) – Baseline			<b>(√)</b>	(✓)		<b>✓</b>	
Columbia-Suicide Severity Rating Scale (C-SSRS) – Follow Up			(✓)	(✓)		<b>✓</b>	
Mini Mental State Examination (MMSE)			✓	✓		✓	
Physiotherapy Outcome Measures (Physio)			✓	<b>✓</b>		✓	

eCRF Form	General	Family History	Baseline	Follow Up	Phone Contact	Unscheduled	Premature End
Short Form Health Survey – 12v2 (SF12)			✓	✓		✓	
Caregivers Quality of Life Questionnaire (CareQoL)			✓	✓		✓	
Client Service Receipt Inventory (CSRI)			✓	✓		✓	
Work Productivity and Activity Impairment-Specific Health Problem (WPAI-SH)			<b>✓</b>	<b>√</b>		<b>√</b>	
Follow-up on Missed Visit (Missed Visit)					✓		
Premature End of Study (End)					✓		✓
Monitoring Baseline Visit (Monitoring BL)			✓				
Monitoring Follow Up Visit (Monitoring FUP)				✓			
Monitoring General Visit (Monitoring Gen)	<b>✓</b>						
Monitoring General Family History (Monitoring FHx)		✓					
Monitoring Event Form (Monitoring Event)	✓	✓	✓	✓	✓	✓	✓

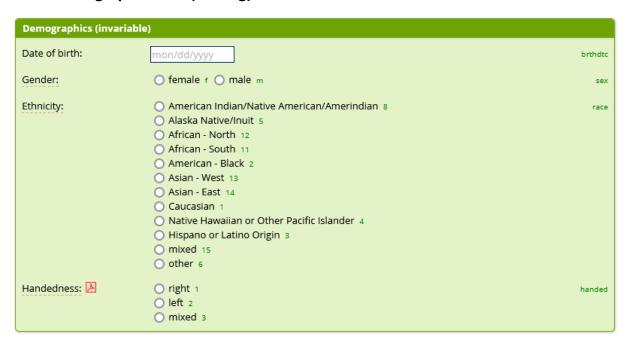
Table 1: Visit Assessment Schedule

## 3 eCRF Forms

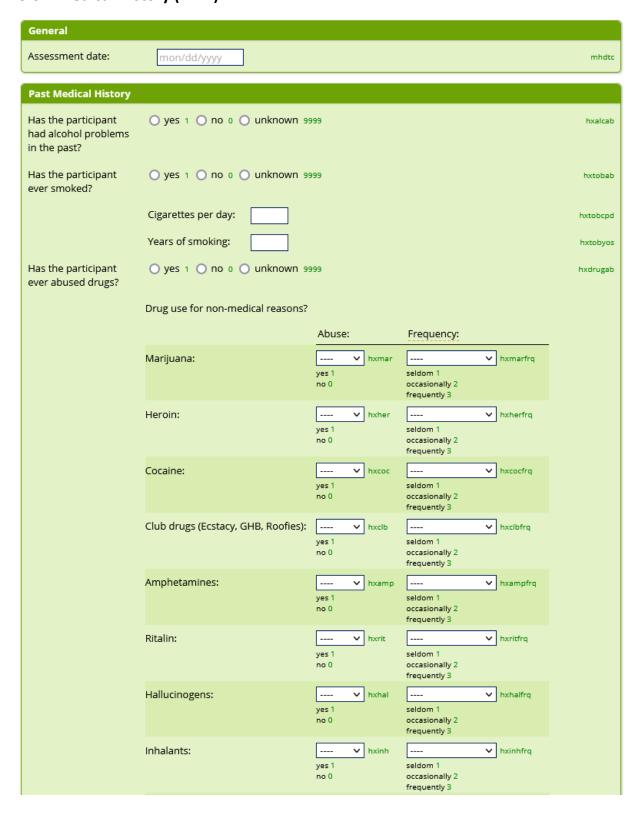
## 3.1 Enrollment into Enroll-HD (Enrollment)

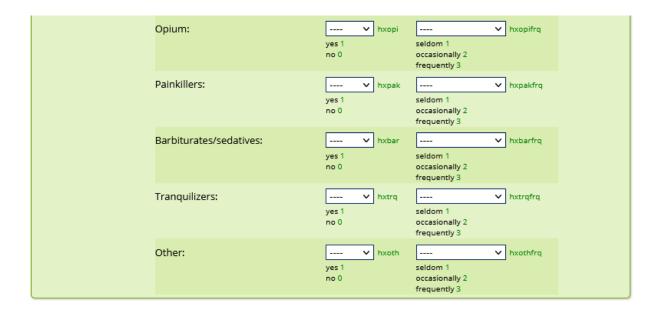
Enrollment			
Date of informed consent:	mon/dd/yyyy		rfstdtc
Signed by:	O participant 1 O	legal representative 2	sgntr
Participant category:	manifest/motor-n genotype negative family control s community control	motor-manifest HD 2 nanifest HD 3 e 4	hdcat
	No history of or no concurrent major central nervous system disorder (e.g. Stroke, Parkinson's disease, Multiple Sclerosis, etc.):	munity control):  O yes 1 O no 0	ic1
Optional Components:	Family History:	○ yes 1 ○ no 0	fhx
	Biosamples for use in research:	○ yes 1 ○ no 0	bsp
	Linking clinical information from previous studies:	○ yes 1 ○ no 0	rtrspctv
	Participation in sub-studies:	○ yes 1 ○ no 0	nvi
	Contact between visits:	○ yes 1 ○ no 0	cntct
	Contact regarding other research studies:	O yes 1 O no 0	cntctst
	Contact regarding post-mortem tissue collection:	○ yes 1 ○ no 0	cntctpmt
IDs in other Studies (alees	o ontor on the Clinical 3	Frials CDE)	
IDs in other Studies (pleas	e enter on the Clinical	Hals CRF)	
COHORT HDID:			ch_id
PREDICT HDID:			pd_id

## 3.2 Demographic Data (Demog)



### 3.3 Medical History (MHx)

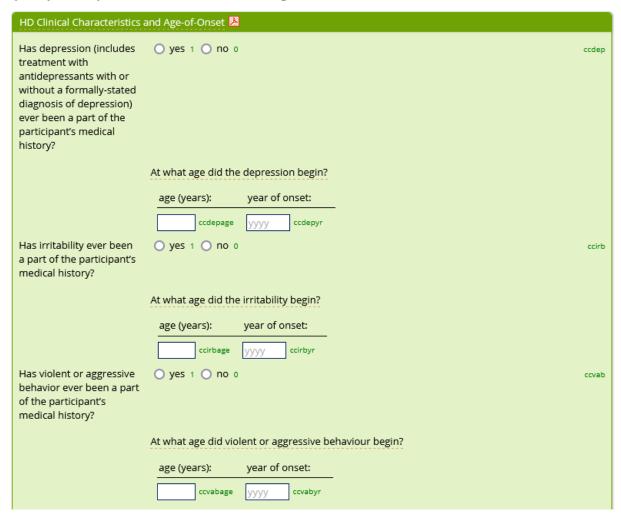




### 3.4 HD Clinical Characteristics (HD CC)

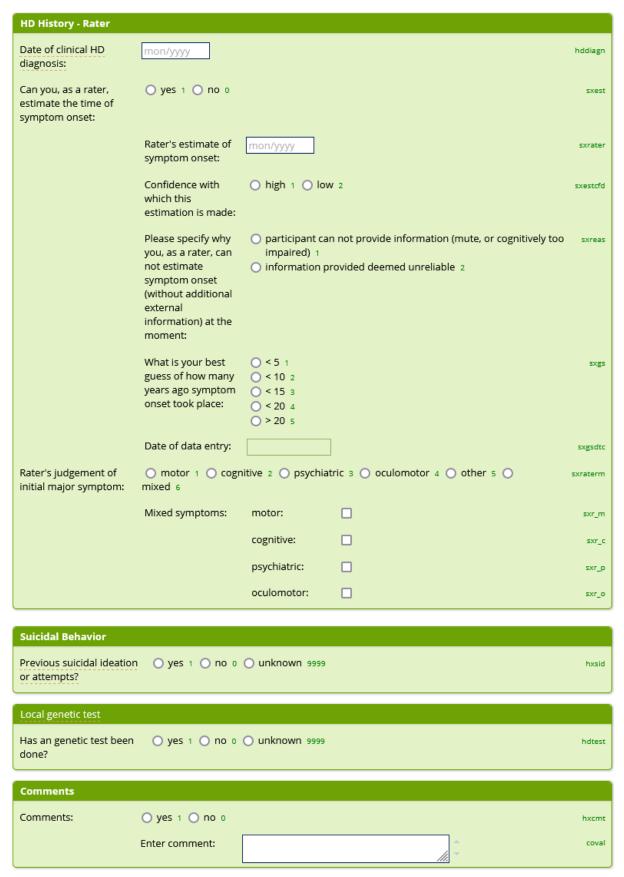


Each estimate of symptom onset should be based on ALL available sources of information including reports of participant, companions, case notes and clinical rating scales.



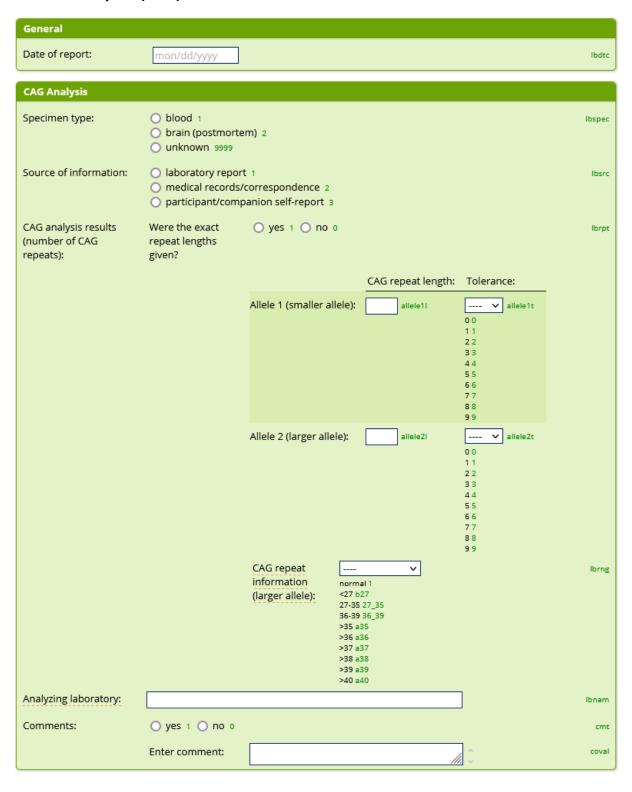
Has apathy ever been a part of the participant's medical history:	O yes 1 O no 0	ccapt
	At what age did apathy begin?	
	age (years): year of onset:	
	ccaptage yyyy ccaptyr	
Has perseverative/obsessive behaviors ever been a part of the participant's medical history:	○ yes 1 ○ no o	ccpob
	At what age did perseverative/obsessive behaviour begin?	
	age (years): year of onset:	
	ссроваде ууууу ссровуг	
Has psychosis (hallucinations or delusions) ever been a part of the participant's medical history:	○ yes 1 ○ no 0	ccpsy
	At what age did psychosis (hallucinations or delusions) begin?	
	age (years): year of onset:	
	ccpsyage yyyyy ccpsyyr	
	Does the Oyes 1 Ono 0 participant have a family history of a psychotic illness in a first degree relative:	ccpsyfh
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 1 ○ no 0	cccog
	At what age did cognitive impairment first start to have an impact on daily life?	
	age (years): year of onset:	
	cccogage yyyyy cccogyr	
History of HD Motor Sym	pptoms	,
Have motor symptoms compatible with HD ever been a part of the participant's medical history?	○ yes 1 ○ no 0	ccmtr
	At what age did the participant's motor symptoms begin?	
	age (years): year of onset:	
	comtrage	

HD History - Participar	nt and Family			
Symptoms first noted by participant:	mon/yyyy			sxsubj
Initial major symptom noted by participant:	O motor 1 O cogr mixed 6	nitive 2 🔾 psych	niatric 3 O oculomotor 4 O other 5 O	sxsubjm
	Mixed symptoms:	motor:		sxs_m
		cognitive:		sxs_c
		psychiatric:		sxs_p
		oculomotor:		sxs_o
Symptoms first noted by family:	mon/yyyy			sxfam
Initial major symptom noted by family:	O motor 1 O cogr mixed 6	nitive 2 🔾 psych	niatric 3 O oculomotor 4 O other 5 O	sxfamm
	Mixed symptoms:	motor:		sxf_m
		cognitive:		sxf_c
		psychiatric:		sxf_p
		oculomotor:		sxf_o



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### 3.5 CAG Report (CAG)



## 3.6 Pharmacotherapy (PharmacoTx)



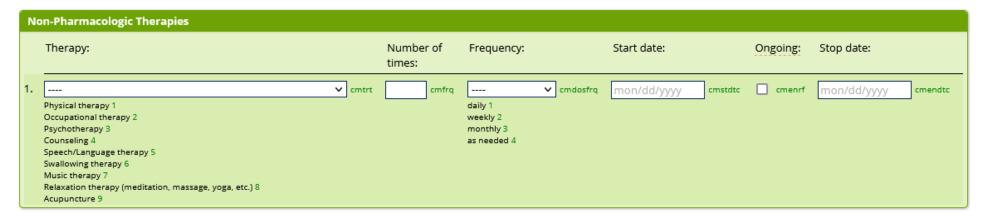
## 3.7 Nutritional Supplements (NutSuppl)



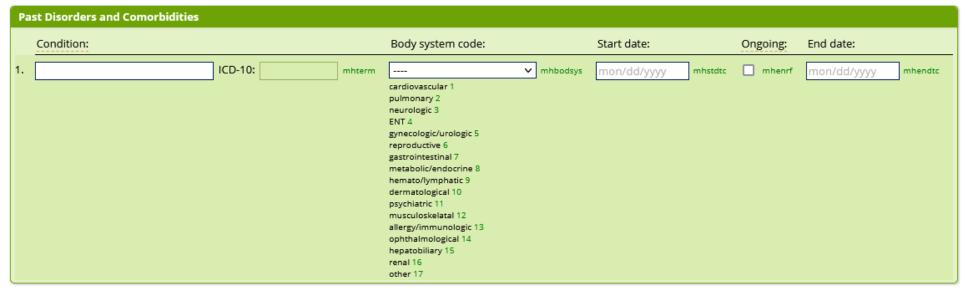
## 3.8 Clinical Trials Form (Clinical Trials)



## 3.9 Non-Pharmacologic Therapies (Non-PharmacoTx)

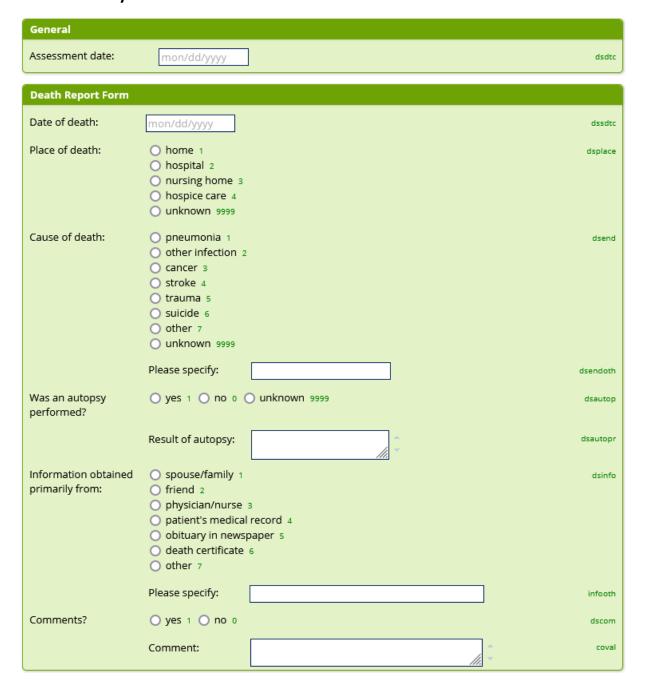


## 3.10 Comorbid Conditions (Comorbid)

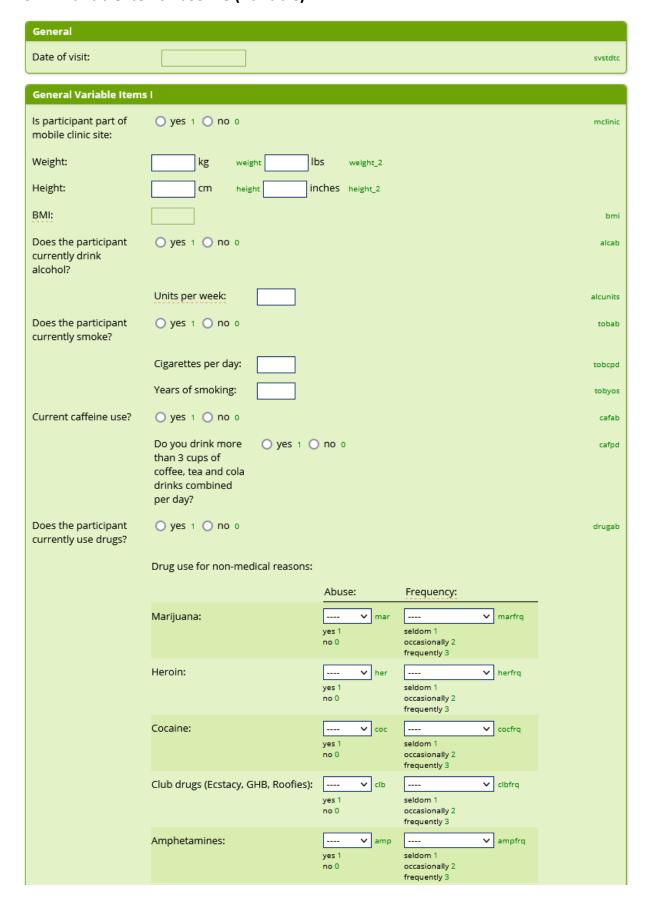


ICD-10 codes, terms and text ©World Health Organization 2011

### 3.11 Mortality



### 3.12 Variable Items Baseline (Variable)

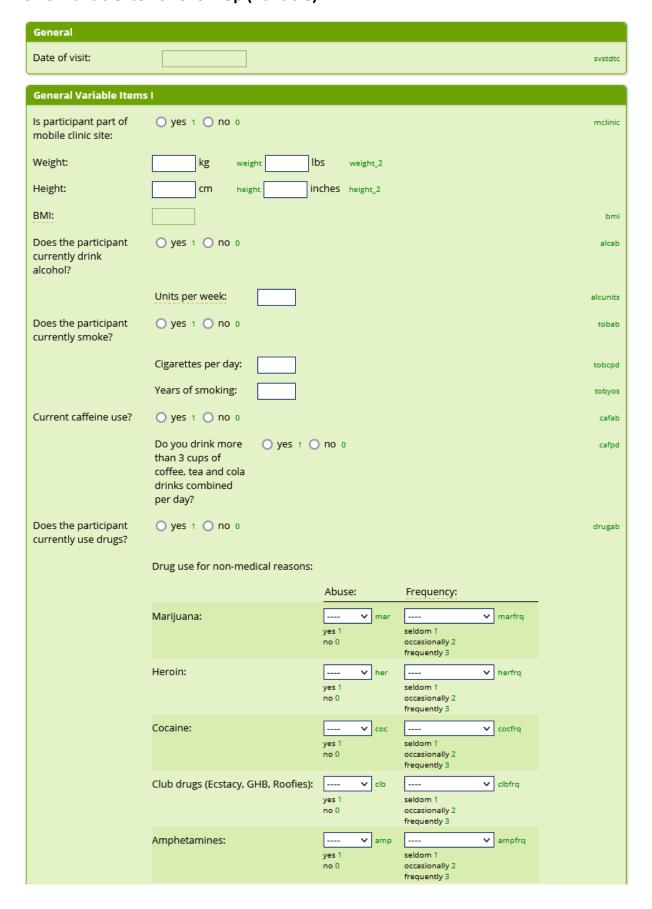






Reason:	sick leave 1 retirement 2 working in the home (e.g. caring for children) 3 unemployed 4 training/college 5	empinrsn
	Retired due to: O ill health 1 O age 2	emplnrd
Do you receive incapacity benefit/social security or disability benefit?	○ yes 1 ○ no 0	ssdb
Do you intend to return to work?	○ yes 1 ○ no 0	rtrnwk
Since when have you been unemployed/retired?		rtrddur
Additional Employmen	nt Section:	
Have you had to stop or reduce work due to your health?	○ yes 1 ○ no 0	rdcwk
	How many days in the last 6 months have you had off work because of HD?	rdcwkd
	How many hours/week fewer hours per week have you worked because of HD?	rdcwkhw

### 3.13 Variable Items Follow Up (Variable)





General Variable Item	ns II			
Any changes to the rarely changing General Variable Items above:	O yes 1 O no 0			updsc
	Participant category:	genotype unkn pre-manifest/p manifest/moto genotype nega family control community con	ore-motor-manifest HD 2 or-manifest HD 3 tive 4 5	hdcat
	Marital status:	single 1 married 3 partnership 2 divorced 4 widowed 5 legally separate	ed 6	maristat
	Residence:	rural 1 village 2 town 3 city 4		res
	ISCED education level:	ISCED 0 0 ISCED 1 1 ISCED 2 2 ISCED 3 3 ISCED 4 4 ISCED 5 5 ISCED 6 6		isced
	Years of education:	years		eduyrs
	Occupation: Employment:	full-time emplo part-time emplo self employed not employed	loyed 2	jobclas
		Status:	O paid 1 O unpaid 2	jobpaid
		Reason:	o sick leave 1 retirement 2 working in the home (e.g. caring for children): unemployed 4 training/college 5	
			Retired due to: O ill health 1 O age 2	empinrd
		Do you receive incapacity benefit/social security or disabili benefit?	O yes 1 ○ no 0	ssdb
		Do you intend to return to work?	O yes 1 O no 0	rtrnwk
		Since when have y been unemployed/retire	2222	rtrddur

Additional Employment	Section		
Have you had to stop or reduce work due to your health?	○ yes 1 ○ no 0		rdcwk
	How many days in the last 6 months have you had off work because of HD?	days	rdcwkd
	How many fewer hours per week have you worked because of HD?	hours/week	rdcwkhw
Since the last visit have t	there been		
Any changes to participant's medication?	O yes 1 O no 0		updmed
Any changes to participant's comorbid conditions?	O yes 1 O no 0		updmh
Any updates to family history?	O yes 1 O no 0		updfh
Any updates to the clinical characteristics and/or onset of HD?	O yes 1 O no 0		updhdh
Any changes to the optional components?	O yes 1 O no 0		updopt
	Family History:	O yes 1 O no 0	fhx
	Biosamples for use in research:	O yes 1 O no o	bsp
	Linking clinical information from previous studies:	O yes 1 O no 0	rtrspctv
	Participation in sub-studies:	O yes 1 O no 0	nvl
	Contact between visits:	O yes 1 O no 0	cntct
	Contact regarding other research studies:	O yes 1 O no o	cntctst
	Contact regarding post-mortem tissue collection:	○ yes 1 ○ no 0	cntctpmt
Has the participant had a brain MRI?	O yes 1 O no 0 (	unknown 9999	updmri
	Date of MRI:	mon/dd/yyyy	mridtc

## 3.14 UHDRS® Motor/Diagnostic Confidence (Motor)

			,
General			
Assessment date:	m	on/dd/yyyy	qsdtc
Rater code:			raterid
Motor score (TMS):			motscore
Motor score (TMS)			miscore
incomplete:			
Motor Assessment	: <u>X</u>		
Ocular pursuit:	Horizontal:	Vertical:	
	0	0	
	0	0	1 = jerky movement
	0	0	2 = interrupted pursuits/full range
	0	0	3 = incomplete range
	Ocularh	Oculary	4 = cannot pursue
Saccade initiation:	Horizontal:	Vertical:	
	0	0	
	0	0	1 = increased latency only
	0	0	2 = suppressible blinks or head movements to initiate
	0	0	3 = unsuppressible head movements
	O sacinith	Sacinity	4 = cannot initiate saccades
Saccade velocity:	Horizontal:	Vertical:	
	0	0	0 = normal
	0	0	1 = mild slowing
	0	0	2 = moderate slowing
	0	0	3 = severely slow, full range
	Sacvelh	O sacvelv	4 = incomplete range
Dysarthria:	O 2 = must	ear, no need t repeat to be ly incompreh	understood 2
Tongue protrusion:	1 = cann 2 = cann 3 = cann	ot keep fully յ ot keep fully յ ot fully protru	tongue protruded for 10 sec 0 protruded for 10 sec 1 protruded for 5 sec 2 protruded tongue 3 progue beyond lips 4
Finger taps:	Right:	Left:	-
	0	0	0 = normal (≥15/5 sec.)
	0	0	1 = mild slowing, reduction in amplitude (11-14/5 sec.)
	0	0	2 = moderately impaired (7-10/5 sec.)
	0	0	3 = severely impaired (3-6/5 sec.)

O fingtapr O fingtapl 4 = can barely perform task (0-2/5 sec.)

Pronate/supinate-	Right:	Left:	_						
hands:	0	0	0 = normal						
	0	0	1 = mild slov	ving and/or ir	regular				
	0	0	2 = moderat	e slowing and	lirregular				
	0	0	3 = severe sl	owing and irr	egular				
	Oprosupr	Oprosupl	4 = cannot p	erform					
Luria:	O 1 = <4 in O 2 = ≥4 in O 3 = <4 in	10 sec, no co 10 sec, no co 10 sec with o 10 sec with o ot perform 4	ue 1 cues 2 cues 3						luria
Rigidity-arms:	Right:	Left:	_						
	0	0	0 = absent						
	0	0	1 = slight or p	resent only v	vith activatio	n			
	0	0	2 = mild to m	oderate					
	0	0	3 = severe, fu	II range of mo	otion				
	O rigarmr	O rigarmI	4 = severe wi	th limited ran	ge				
Bradykinesia-body:	2 = mildl 3 = mode	mally slow (?r ly but clearly erately slow,							brady
Maximal dystonia:	Trunk:	RUE:	LUE:	RLE:	LLE:				
	0	0	0	0	0	0 = absent			
	0	0	0	0	0	1 = slight/inter	mittent		
	0	0	0	0	0	2 = mild/comm	non or moder	ate/intermittent	
	0	0	0	0	0	3 = moderate/	common		
	O dysttrnk	O dystrue	Odystlue	O dystrie	O dystlle	4 = marked/pr	olonged		
Maximal chorea:	Face:	BOL:	Trunk:	RUE:	LUE:	RLE:	LLE:		
	0	0	0	0	0	0	0	0 = absent	
	0	0	0	0	0	0	0	1 = slight/intermittent	
	0	0	0	0	0	0	0	2 = mild/common or moderate/intermittent	
	0	0	0	0	0	0	0	3 = moderate/common	1
	O chorface	O chorbol	Chortrnk	O chorrue	Chorle	ue O chorrie	Ochorlie	4 = marked/prolonged	
Gaitt	1 = wide 2 = wide 3 = walk	nal gait, narro base and/or base and wa s only with as ot attempt 4	slow 1 lks with difficu sistance 3	ilty 2					gait
Tandem walking	1 = 1 to 3 2 = >3 de 3 = cann		rom straight li	ne 1				ti	andem
Retropulsion pull test:	O 2 = woul	vers spontand d fall if not ca s to fall spont	aught 2					n	etropis

Diagnostic Confidence		·
Diagnostic confidence level (DCL):	<ul> <li>0 = normal (no abnormalities) 0</li> <li>1 = non-specific motor abnormalities (less than 50 % confidence) 1</li> <li>2 = motor abnormalities that may be signs of HD (50 - 89 % confidence) 2</li> <li>3 = motor abnormalities that are likely signs of HD (90 - 98 % confidence) 3</li> <li>4 = motor abnormalities that are unequivocal signs of HD (≥ 99 % confidence) 4</li> </ul>	diagconf

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## 3.15 UHDRS® Total Functional Capacity (TFC)

General		
Assessment date:	mon/dd/yyyy	qsdtc
Rater code:		raterid
Functional score:		tfcscore
Functional Capacity		
Occupation:	O = unable o	occupatn
	1 = marginal work only 1 2 = reduced capacity for usual job 2	
	3 = normal 3	
	<b>0</b>	
Finances:	○ 0 = unable 0 ○ 1 = major assistance 1 ○ 2 = slight assistance 2 ○ 3 = normal 3	finances
Domestic chores:	○ 0 = unable 0 ○ 1 = impaired 1 ○ 2 = normal 2	chores
ADL:	0 = total care o	adl
	1 = gross tasks only 1	
	2 = minimal impairment 2	
	○ 3 = normal 3	
Care level:	0 = full time skilled nursing 0 0 1 = home or chronic care 1 0 2 = home 2	carelevi
Information Sources:	Was the 0 1 = participant only 1	tfcsrc
	information	
	obtained from:	

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## 3.16 UHDRS® Functional Assessment (Function)

Rater code:  Functional assessment score:  Functional score incomplete:  Independence scale in %:  Functional Assessment  Could subject engage in gainful employment in his/her accustomed work:  Could subject engage in any kind of gainful employment?  Could subject engage in any kind of yolunteer or non-gainful work?  Could subject manage his/her finances (monthly) without any help?  Could subject shop for groceries without help?  Could subject supervise children without help?  Could subject operate an automobile safely and independently?  Could subject do his/her own housework without help?  Could subject do his/her own housework without help?  Could subject do his/her own laundry (wash/dry) without help?  Could subject to perate an independently?  Could subject to perate an automobile safely and independently?  Could subject do his/her own housework without help?  Could subject to his/her own laundry (wash/dry) without help?  Could subject to his/her own meals without help?  Could subject to the telephone without help?  Could subject take his/her own medications without help?  Could subject take his/her own medications without help?  Could subject take his/her own medications without help?  Could subject feed himself/herself without help?	General			
Rater code: Functional assessment score: Functional score incomplete: Independence scale in %:  Functional Assessment  Could subject engage in gainful employment in his/her accustomed work:  Could subject engage in any kind of gainful employment?  Could subject engage in any kind of gainful employment?  Could subject engage in any kind of volunteer or non-gainful work?  Could subject shop for groceries without help?  Could subject shop for groceries without help?  Could subject supervise children without help?  Could subject operate an automobile safely and independently?  Could subject oberate an automobile safely and independently?  Could subject do his/her own housework without help?  Could subject do his/her own laundry (wash/dry) without help?  Could subject take his/her own meals without help?  Could subject take his/her own medications without help?  Could subject take his/her own medications without help?  Could subject take his/herself without help?  Could subject walk to places in his/her neighbourhood without help?  Could subject walk without falling?  Could subject walk without help?  Could subject walk wit				
Functional score incomplete:  Independence scale in %:  Functional Assessment  Functional A	Rater code:			
Independence scale in %:  Functional Assessment  Functional Assessme	Functional assessment score:			
Functional Assessment	Functional score			
Could subject engage in any kind of gainful employment?  Could subject engage in any kind of gainful employment?  Could subject engage in any kind of volunteer or non-gainful work?  Could subject engage in any kind of volunteer or non-gainful work?  Could subject manage his/her finances (monthly) without any help?  Could subject shop for groceries without help?  Could subject shop for groceries without help?  Could subject handle money as a purchaser in a simple cash (shop) transaction?  Could subject supervise children without help?  Could subject operate an automobile safely and independently?  Could subject do his/her own housework without help?  Could subject do his/her own laundry (wash/dry) without help?  Could subject do his/her own laundry (wash/dry) without help?  Could subject use the telephone without help?  Could subject take his/her own medications without help?  Could subject take his/her own medications without help?  Could subject does himself/herself without help?  Could subject take himself/herself without help?  Could subject walk to places in his/her neighbourhood without help?  Could subject walk to places in his/her neighbourhood without help?  Could subject walk without falling?  Could subject walk without help?  Could subject take him without help?  Could subject walk without help?  Could subject walk without help?  Could subject walk without help?  Could subj	Independence scale in %:			
Could subject engage in any kind of gainful employment?  Could subject engage in any kind of gainful employment?  Could subject engage in any kind of volunteer or non-gainful work?  Could subject engage in any kind of volunteer or non-gainful work?  Could subject manage his/her finances (monthly) without any help?  Could subject shop for groceries without help?  Could subject shop for groceries without help?  Could subject handle money as a purchaser in a simple cash (shop) transaction?  Could subject supervise children without help?  Could subject operate an automobile safely and independently?  Could subject do his/her own housework without help?  Could subject do his/her own laundry (wash/dry) without help?  Could subject do his/her own laundry (wash/dry) without help?  Could subject use the telephone without help?  Could subject take his/her own medications without help?  Could subject take his/her own medications without help?  Could subject does himself/herself without help?  Could subject take himself/herself without help?  Could subject walk to places in his/her neighbourhood without help?  Could subject walk to places in his/her neighbourhood without help?  Could subject walk without falling?  Could subject walk without help?  Could subject take him without help?  Could subject walk without help?  Could subject walk without help?  Could subject walk without help?  Could subj				
Could subject engage in gainful employment in his/her accustomed work:  O emplust  Could subject engage in any kind of gainful employment?  O emplany  Could subject engage in any kind of volunteer or non-gainful work?  O volunt  Could subject manage his/her finances (monthly) without any help?  Could subject shop for groceries without help?  Could subject handle money as a purchaser in a simple cash (shop) transaction?  Could subject supervise children without help?  Could subject operate an automobile safely and independently?  Could subject do his/her own housework without help?  Could subject do his/her own laundry (wash/dry) without help?  Could participant prepare his/her own meals without help?  Could subject use the telephone without help?  Could subject take his/her own medications without help?  Could subject transfer between chairs without help?  Could subject transfer between chairs without help?  Could subject transfer between chairs without help?  Could subject twalk without help?  Could subject walk without help?  Could subject twalk without help?  Could subject walk without help?  Could subject twalk without help?  Could subject transfer between chairs without help?	Functional Assessment			
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Could subject manage his/her finances (monthly) without any help?  Could subject shop for groceries without help?  Could subject supervise children without help?  Could subject supervise children without help?  Could subject operate an automobile safely and independently?  Could subject do his/her own housework without help?  Could subject do his/her own laundry (wash/dry) without help?  Could subject do his/her own meals without help?  Could subject use the telephone without help?  Could subject take his/her own medications without help?  Could subject feed himself/herself without help?  Could subject dress himself/herself without help?  Could subject take himself/herself without help?  Could subject take public transport to get to places without help?  Could subject walk to places in his/her neighbourhood without help?  Could subject walk without falling?  Could subject walk without help?  Could subject comb hair without help?  Could subject transfer between chairs w	Could subject engage in any kind of gainful employment?	0	0	emplany
Could subject shop for groceries without help?  Could subject handle money as a purchaser in a simple cash (shop) transaction?  Could subject supervise children without help?  Could subject operate an automobile safely and independently?  Could subject do his/her own housework without help?  Could subject do his/her own housework without help?  Could subject do his/her own laundry (wash/dry) without help?  Could participant prepare his/her own meals without help?  Could subject use the telephone without help?  Could subject take his/her own medications without help?  Could subject take his/her own medications without help?  Could subject feed himself/herself without help?  Could subject dress himself/herself without help?  Could subject use public transport to get to places without help?  Could subject walk to places in his/her neighbourhood without help?  Could subject walk without falling?  Could subject walk without falling?  Could subject walk without help?  Could subject comb hair without help?  Could subject comb hair without help?  Could subject transfer between chairs without help?	Could subject engage in any kind of volunteer or non-gainful work?	0	0	volunt
Could subject handle money as a purchaser in a simple cash (shop) transaction?  Could subject supervise children without help?  Could subject operate an automobile safely and independently?  Could subject do his/her own housework without help?  Could subject do his/her own laundry (wash/dry) without help?  Could participant prepare his/her own meals without help?  Could subject use the telephone without help?  Could subject take his/her own medications without help?  Could subject feed himself/herself without help?  Could subject dress himself/herself without help?  Could subject dress himself/herself without help?  Could subject use public transport to get to places without help?  Could subject walk to places in his/her neighbourhood without help?  Could subject walk without falling?  Could subject walk without help?  Could subject comb hair without help?  Could subject comb hair without help?  Could subject transfer between chairs without help?	Could subject manage his/her finances (monthly) without any help?	0	0	fafinan
Could subject supervise children without help?  Could subject operate an automobile safely and independently?  Could subject do his/her own housework without help?  Could subject do his/her own laundry (wash/dry) without help?  Could participant prepare his/her own meals without help?  Could subject use the telephone without help?  Could subject take his/her own medications without help?  Could subject take his/her own medications without help?  Could subject feed himself/herself without help?  Could subject dress himself/herself without help?  Could subject bathe himself/herself without help?  Could subject use public transport to get to places without help?  Could subject walk to places in his/her neighbourhood without help?  Could subject walk without falling?  Could subject walk without help?  Could subject take hir without help?  Could subject take hir without help?  Could subject transfer between chairs without help?	Could subject shop for groceries without help?	0	0	grocery
Could subject operate an automobile safely and independently?  Could subject do his/her own housework without help?  Could subject do his/her own laundry (wash/dry) without help?  Could participant prepare his/her own meals without help?  Could subject use the telephone without help?  Could subject take his/her own medications without help?  Could subject take his/her own medications without help?  Could subject feed himself/herself without help?  Could subject dress himself/herself without help?  Could subject bathe himself/herself without help?  Could subject use public transport to get to places without help?  Could subject walk to places in his/her neighbourhood without help?  Could subject walk without falling?  Could subject walk without help?  Could subject walk without help?  Could subject comb hair without help?  Could subject transfer between chairs without help?	Could subject handle money as a purchaser in a simple cash (shop) transaction?	0	0	cash
Could subject do his/her own housework without help?  Could subject do his/her own laundry (wash/dry) without help?  Could participant prepare his/her own meals without help?  Could subject use the telephone without help?  Could subject take his/her own medications without help?  Could subject feed himself/herself without help?  Could subject dress himself/herself without help?  Could subject dress himself/herself without help?  Could subject bathe himself/herself without help?  Could subject use public transport to get to places without help?  Could subject walk to places in his/her neighbourhood without help?  Could subject walk without falling?  Could subject walk without help?  Could subject walk without help?  Could subject walk without help?  Could subject transfer between chairs without help?	Could subject supervise children without help?	0	0	supchild
Could subject do his/her own laundry (wash/dry) without help?  Could participant prepare his/her own meals without help?  Could subject use the telephone without help?  Could subject take his/her own medications without help?  Could subject feed himself/herself without help?  Could subject dress himself/herself without help?  Could subject dress himself/herself without help?  Could subject bathe himself/herself without help?  Could subject use public transport to get to places without help?  Could subject walk to places in his/her neighbourhood without help?  Could subject walk without falling?  Could subject walk without help?  Could subject walk without help?  Could subject walk without help?  Could subject comb hair without help?  Could subject transfer between chairs without help?	Could subject operate an automobile safely and independently?	0	0	drive
Could participant prepare his/her own meals without help?  Could subject use the telephone without help?  Could subject take his/her own medications without help?  Could subject feed himself/herself without help?  Could subject dress himself/herself without help?  Could subject bathe himself/herself without help?  Could subject use public transport to get to places without help?  Could subject walk to places in his/her neighbourhood without help?  Could subject walk without falling?  Could subject walk without help?  Could subject walk without help?  Could subject comb hair without help?  Could subject transfer between chairs without help?	Could subject do his/her own housework without help?	0	0	housewrk
Could subject use the telephone without help?  Could subject take his/her own medications without help?  Could subject feed himself/herself without help?  Could subject dress himself/herself without help?  Could subject bathe himself/herself without help?  Could subject use public transport to get to places without help?  Could subject walk to places in his/her neighbourhood without help?  Could subject walk without falling?  Could subject walk without help?  Could subject walk without help?  Could subject comb hair without help?  Could subject transfer between chairs without help?	Could subject do his/her own laundry (wash/dry) without help?	0	0	laundry
Could subject take his/her own medications without help?  Could subject feed himself/herself without help?  Could subject dress himself/herself without help?  Could subject bathe himself/herself without help?  Could subject use public transport to get to places without help?  Could subject walk to places in his/her neighbourhood without help?  Could subject walk without falling?  Could subject walk without help?  Could subject walk without help?  Could subject comb hair without help?  Could subject transfer between chairs without help?	Could participant prepare his/her own meals without help?	0	0	prepmeal
Could subject feed himself/herself without help?  Could subject dress himself/herself without help?  Could subject bathe himself/herself without help?  Could subject use public transport to get to places without help?  Could subject walk to places in his/her neighbourhood without help?  Could subject walk without falling?  Could subject walk without help?  Could subject walk without help?  Could subject walk without help?  Could subject comb hair without help?  Could subject transfer between chairs without help?	Could subject use the telephone without help?	0	0	telephon
Could subject feed himself/herself without help?  Could subject dress himself/herself without help?  Could subject bathe himself/herself without help?  Could subject use public transport to get to places without help?  Could subject walk to places in his/her neighbourhood without help?  Could subject walk without falling?  Could subject walk without help?  Could subject walk without help?  Could subject comb hair without help?  Could subject transfer between chairs without help?	Could subject take his/her own medications without help?	0	0	ownmeds
Could subject dress himself/herself without help?  Could subject bathe himself/herself without help?  Could subject use public transport to get to places without help?  Could subject walk to places in his/her neighbourhood without help?  Could subject walk without falling?  Could subject walk without help?  Could subject walk without help?  Could subject comb hair without help?  Could subject transfer between chairs without help?  Could subject transfer between chairs without help?		0	0	feedself
Could subject use public transport to get to places without help?  Could subject walk to places in his/her neighbourhood without help?  Could subject walk without falling?  Could subject walk without help?  Could subject comb hair without help?  Could subject transfer between chairs without help?	Could subject dress himself/herself without help?	0	0	dress
Could subject use public transport to get to places without help?  Could subject walk to places in his/her neighbourhood without help?  Could subject walk without falling?  Could subject walk without help?  Could subject comb hair without help?  Could subject transfer between chairs without help?		0	0	bathe
Could subject walk to places in his/her neighbourhood without help?  Could subject walk without falling?  Could subject walk without help?  Could subject comb hair without help?  Could subject transfer between chairs without help?  Could subject transfer between chairs without help?		0	0	pubtrans
Could subject walk without falling?  Could subject walk without help?  Could subject comb hair without help?  Could subject transfer between chairs without help?  Could subject transfer between chairs without help?  Could subject transfer between chairs without help?		0	0	
Could subject walk without help?  Could subject comb hair without help?  Could subject transfer between chairs without help?  Could subject transfer between chairs without help?		0	0	
Could subject comb hair without help?  Could subject transfer between chairs without help?  Comb		0	0	
Could subject transfer between chairs without help?		0	0	
		0	0	
		0	0	

Could subject use toilet/commode without help?

Could subject's care still be provided at home?

O toilet

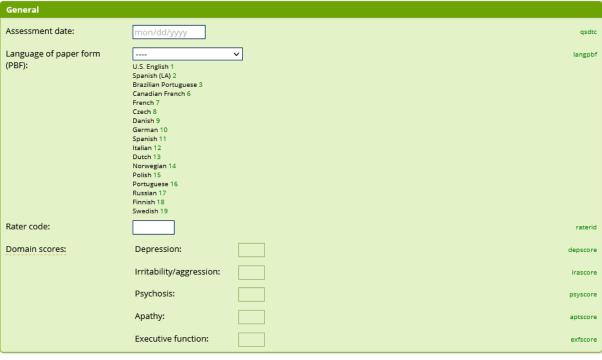
O carehome

Information sources		
Was the functional assessment information obtained from:	O subject only 1 O subject and family/companion 2	isrc

Indopendence Scale		
Independence Scale		
Subject's independence	0 100 = no special care needed 100	indepscl
in %:	95 = 95	
	90 = no physical care needed if difficult tasks are avoided 90	
	O 85 = 85	
	<ul> <li>80 = pre-disease level of employment changes or ends; cannot perform household chores to pre-disease level, may need help with finances 80</li> </ul>	
	O 75 = 75	
	<ul> <li>70 = self-care maintained for bathing, limited household duties, e.g. cooking and use of knives, driving terminates; unable to manage finances 70</li> </ul>	
	O 65 = 65	
	<ul> <li>60 = needs minor assistance in dressing, toileting, bathing; food must be cut for subject 60</li> </ul>	
	O 55 = 55	
	<ul> <li>50 = 24-hour supervision appropriate; assistance required for bathing, eating, toileting so</li> </ul>	
	O 45 = 45	
	40 = chronic care facility needed; limited self feeding, liquified diet 40	
	O 35 = 35	
	30 = subject provides minimal assistance in own feeding, bathing, toileting 30	
	O 25 = 25	
	O 20 = no speech, must be fed 20	
	O 15 = 15	
	0 10 = tube fed, total bed care 10	
	O 5 = s	

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#### 3.17 Problem Behaviours Assessment – Short (PBA-s)





	b. Frequency:	0 = never/almost never o	pbas3fr
		1 = seldom (less than once/week) 1	
		2 = sometimes (up to four times a week) 2	
		З = frequently (most days/5, 6 or 7 times a week) з	
		4 = daily/almost daily for most (or all) of day 4	
	c. Worst:	0 = absent 0	-12
	C. WOISE:		pbas3wo
		1 = slight, questionable 1 2 = mild (present, not a problem) 2	
		3 = moderate (symptom causing problem) 3	
		4 = severe (almost intolerable for carer) 4	
		4 - Severe (annost intolerable for carer) 4	
4. Irritability:	a. Severity:	0 = absent o	pbas4sv
		1 = slight, questionable 1	
		2 = mild (present, not a problem) 2	
		З = moderate (symptom causing problem) з	
		4 = severe (almost intolerable for carer) 4	
	b. Frequency:	0 = never/almost never o	pbas4fr
	b. Frequency.	1 = seldom (less than once/week) 1	puasan
		2 = sometimes (up to four times a week) 2	
		3 = frequently (most days/5, 6 or 7 times a week) 3	
		0 4 = daily/almost daily for most (or all) of day 4	
	c. Worst:	0 = absent o	pbas4wo
		1 = slight, questionable 1	
		2 = mild (present, not a problem) 2	
		○ 3 = moderate (symptom causing problem) 3	
		4 = severe (almost intolerable for carer) 4	
5. Angry or aggressive	a. Severity:	○ 0 = absent 0	pbas5sv
behaviour:	d. Severity.	1 = slight, questionable 1	poassav
		2 = mild (present, not a problem) 2	
		3 = moderate (symptom causing problem) 3	
		4 = severe (almost intolerable for carer) 4	
		O 1 Severe (annose intolerable for early) 4	
	b. Frequency:	0 = never/almost never o	pbas5fr
		1 = seldom (less than once/week) 1	
		2 = sometimes (up to four times a week) 2	
		З = frequently (most days/5, 6 or 7 times a week) з	
		4 = daily/almost daily for most (or all) of day 4	
	c. Worst:	O = absent o	pbas5wo
	C. WOLDE	1 = slight, questionable 1	poasswo
		2 = mild (present, not a problem) 2	
		3 = moderate (symptom causing problem) 3	
		4 = severe (almost intolerable for carer) 4	
<ol><li>6. Lack of initiative (apathy):</li></ol>	a. Severity:	O = absent o	pbas6sv
		1 = slight, questionable 1	
		2 = mild (present, not a problem) 2	
		○ 3 = moderate (symptom causing problem) 3	
		4 = severe (almost intolerable for carer) 4	
	b. Frequency:	0 = never/almost never o	pbas6fr
	Di i requerieji	1 = seldom (less than once/week) 1	pouson
		2 = sometimes (up to four times a week) 2	
		3 = frequently (most days/5, 6 or 7 times a week) 3	
		0 4 = daily/almost daily for most (or all) of day 4	
	c. Worst:	0 = absent o	pbas6wo
		1 = slight, questionable 1	
		2 = mild (present, not a problem) 2	
		3 = moderate (symptom causing problem) 3	
		4 = severe (almost intolerable for carer) 4	
7. Perseverative thinking or	a. Severity:	O = absent o	pbas7sv
behaviour:		1 = slight, questionable 1	
		2 = mild (present, not a problem) 2	
		○ 3 = moderate (symptom causing problem) 3	
		4 = severe (almost intolerable for carer) 4	
	b. Frequency:	0 = never/almost never o	pbas7fr
		1 = seldom (less than once/week) 1	
		2 = sometimes (up to four times a week) 2	
		3 = frequently (most days/5, 6 or 7 times a week) 3	
		( ) 4 = daily/almost daily for most for all) of day 4	

	c. Worst:		tionable 1 nt, not a problem) 2 symptom causing problem) 3	pbas7wo
8. Obsessive-Compulsive	a. Severity:	0 4 = severe (alm	ost intolerable for carer) 4	pbas8sv
Behaviours:	a. severity.	1 = slight, ques 2 = mild (prese 3 = moderate (	tionable 1 nt, not a problem) 2 symptom causing problem) 3 ost intolerable for carer) 4	ровооч
	b. Frequency:	2 = sometimes 3 = frequently	st never 0 s than once/week) 1 (up to four times a week) 2 most days/5, 6 or 7 times a week) 3 t daily for most (or all) of day 4	pbas8fr
	c. Worst:	O 3 = moderate (	tionable 1 nt, not a problem) 2 symptom causing problem) 3 ost intolerable for carer) 4	pbas8wo
9. Delusions / paranoid thinking:	a. Severity:	O 3 = moderate (	tionable 1 nt, not a problem) 2 symptom causing problem) 3 ost intolerable for carer) 4	pbas9sv
	b. Frequency:	2 = sometimes 3 = frequently	st never 0 s than once/week) 1 (up to four times a week) 2 most days/5, 6 or 7 times a week) 3 t daily for most (or all) of day 4	pbas9fr
	c. Worst:	O 3 = moderate (	tionable 1 nt, not a problem) 2 symptom causing problem) 3 ost intolerable for carer) 4	pbas9wo
10. Hallucinations:	a. Severity:	O 3 = moderate (s	nt, not a problem) 2 symptom causing problem) 3 ost intolerable for carer) 4	pbas10sv
		Please specify:		
		Modality of hallucinations:	auditory	pbas10sm_1
			visual	pbas10sm_2
			☐ tactile	pbas10sm_3
			olfactory	pbas10sm_4
			gustatory	pbas10sm_5
	b. Frequency:	2 = sometimes 3 = frequently (	st never 0 s than once/week) 1 (up to four times a week) 2 most days/5, 6 or 7 times a week) 3 t daily for most (or all) of day 4	pbas10fr
	c. Worst:	O 3 = moderate (s	rionable 1 nt, not a problem) 2 symptom causing problem) 3 ost intolerable for carer) 4	pbas10wo
		Please specify:		
		Modality of	auditory	pbas10wm_1
		hallucinations:	visual	pbas10wm_2
			tactile	pbas10wm_3
			olfactory	pbas10wm_4
			gustatory	pbas10wm_5

11. Disoriented Behaviour:	a. Severity:	<ul> <li>0 = absent 0</li> <li>1 = slight, questionable 1</li> <li>2 = mild (present, not a problem) 2</li> <li>3 = moderate (symptom causing problem) 3</li> <li>4 = severe (almost intolerable for carer) 4</li> </ul>	pbas11sv
	b. Frequency:	<ul> <li>0 = never/almost never o</li> <li>1 = seldom (less than once/week) 1</li> <li>2 = sometimes (up to four times a week) 2</li> <li>3 = frequently (most days/5, 6 or 7 times a week) 3</li> <li>4 = daily/almost daily for most (or all) of day 4</li> </ul>	pbas11fr
	c. Worst:	<ul> <li>0 = absent 0</li> <li>1 = slight, questionable 1</li> <li>2 = mild (present, not a problem) 2</li> <li>3 = moderate (symptom causing problem) 3</li> <li>4 = severe (almost intolerable for carer) 4</li> </ul>	pbas11wo
Information			
i) Is informant a relative?	spouse or partner 1 parent 2 sibling 3 child 4 other relative 5 friend or neighbor 6 professional care wo other 8 no informant - partic	orker 7	pbainfo
	parent 2 sibling 3 child 4 other relative 5 friend or neighbor 6 professional care wo	orker 7	pbainfo

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#### 3.18 Core and Extended Cognitive Assessment (Cognitive)







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Scaring guidelines were developed by the University of Ulm, Faculty of Medicine, EHDN Cognitive Phenotype Working Group.

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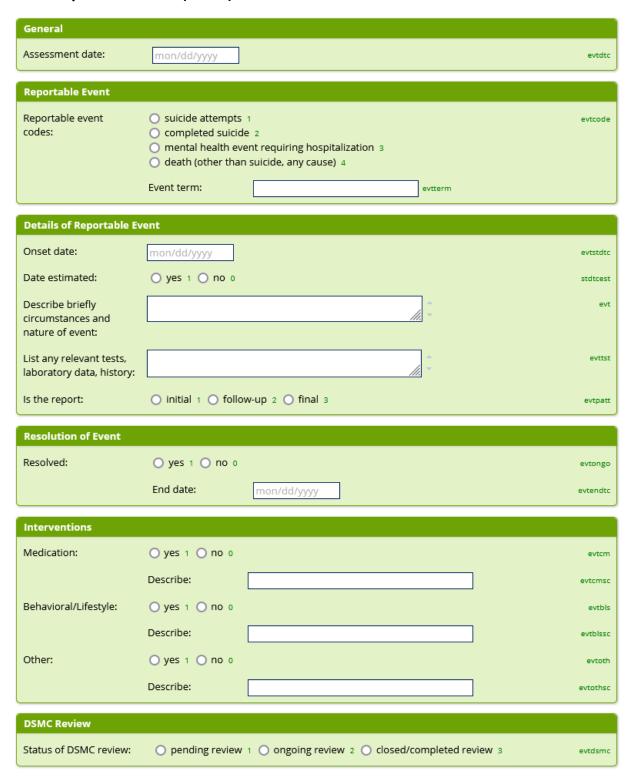
special permission agreement for research purposes only.

Verbal Fluency Test (Category): Instructions/scoring guidelines were developed by the University of Ulm, Faculty of Medicine, EHDN Cognitive Phenotype Working Group. The Categorical Fluency Test is available in the public domain and is referenced in Lezak, MD. Howieson, D.B., & Loring, D.W.(2004). Neuropsychological Assessment (4th ed.). New York: Oxford University Press

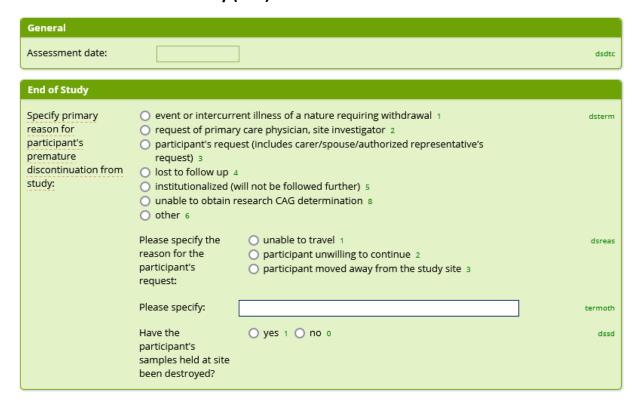
Trail Making Test: Instructions were adapted from PREDICT-HD and scoring guidelines developed by the University of Ulm, Faculty of Medicine, EHDN Cognitive Phenotype Working Group.

Verbal Fluency Test (Letters): © 1999 Huntington Study Group. All Rights Reserved. Note: The Letter Verbal Fluency Test is available in the public domain and is referenced in Lezak, MD, Howieson, D.B., & Loring, D.W. (2004). Neuropsychological Assessment (4th ed.). New York: Oxford University Press, instructions/scoring guidelines were adapted by the EHDN Cognitive Phenotype Working Group, Cognitive raters are advised to refer to the regionally adapted version of this manual where they can find the regional variations for letters to be used.

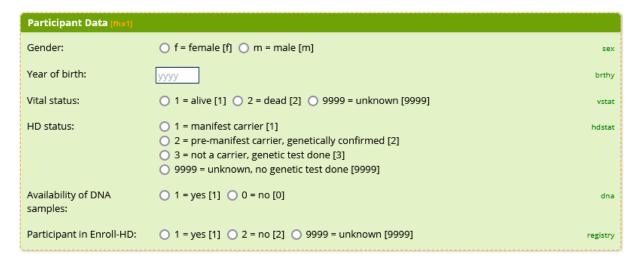
#### 3.19 Reportable Event (Event)



### 3.20 Premature End of Study (End)

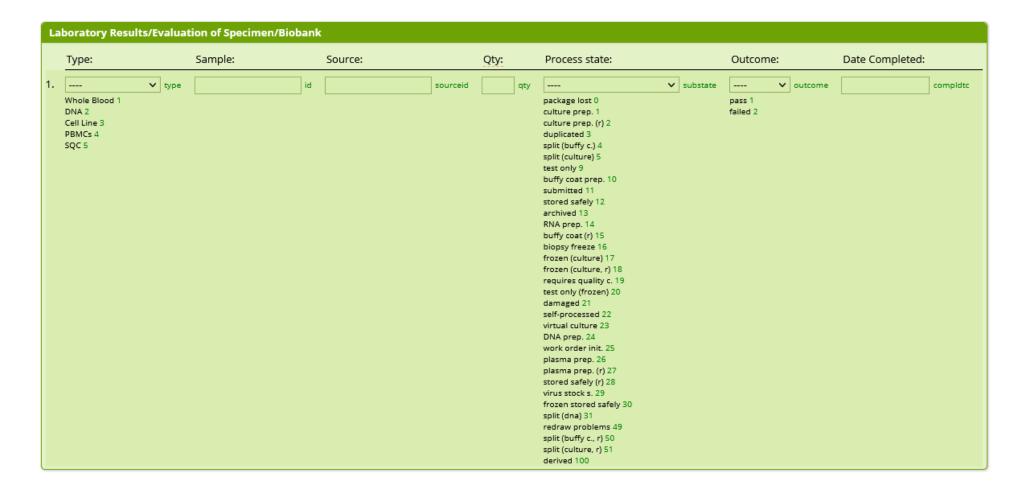


#### 3.21 Family History (FHx)

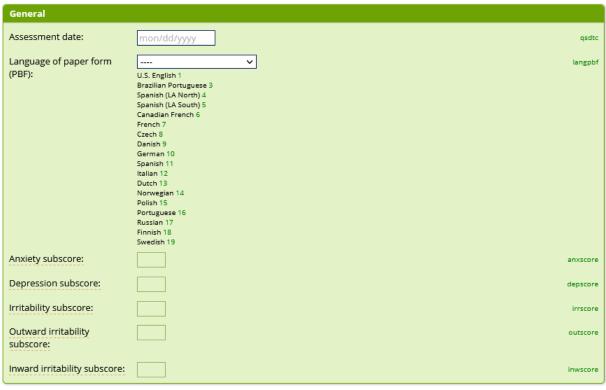


## 3.22 Bio Specimens for Bio Banking (Samples)





# 3.23 Hospital Anxiety and Depression Scale - Snaith Irritability Scale (HADS-SIS)

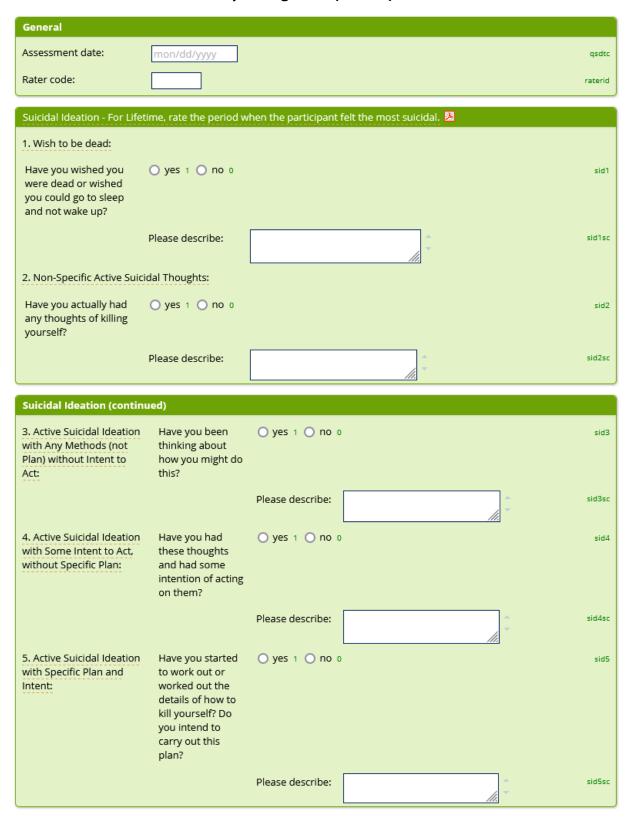


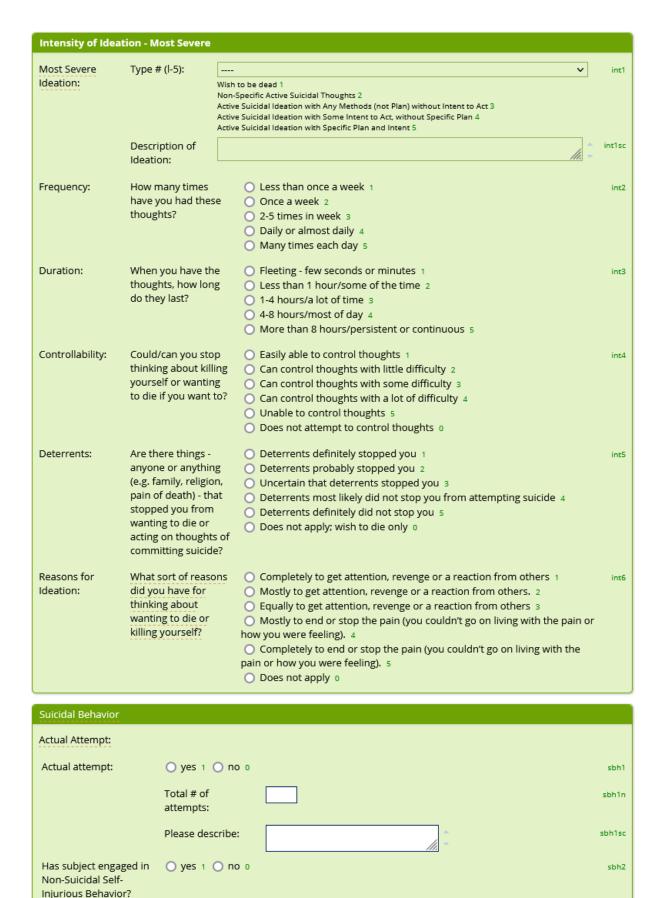
HADS - SIS 😕		
1. I feel tense or 'wound up':	most of the time 3 a lot of the time 2 from time to time, occasionally 1 not at all 0	hads1a
2. I still enjoy the things I used to enjoy:	definitely as much 0 not quite so much 1 only a little 2 hardly at all 3	hads1d
3. I get a sort of frightened feeling as if something awful is about to happen:	very definitely and quite badly 3 yes, but not too badly 2 a little, but it doesn't worry me 1 not at all 0	hads2a
4. I lose my temper and shout or snap at others:	yes, definitely 3 yes, sometimes 2 no, not much 1 no, not at all 0	sis1
5. I can laugh and see the funny side of things:	as much as I always could 0 not quite so much now 1 definitely not so much now 2 not at all 3	hads2d
6. I am patient with other people:	all of the time 0 most of the time 1 some of the time 2 hardly ever 3	sis2
7. I feel cheerful:	onever 3 on ot often 2 osometimes 1 omost of the time 0	hads3d

8. I get angry with myself and call myself names:	yes, definitely 3 sometimes 2 not often 1 no, not at all 0	sis3
9. I can sit at ease and feel relaxed:	odefinitely 0 usually 1 not often 2 not at all 3	hads3a
10. I feel as if I am slowed down:	nearly all the time 3 very often 2 sometimes 1 not at all 0	hads4d
11. I feel like harming myself:	yes, definitely 3 yes, sometimes 2 no, not much 1 no, not at all 0	sis4
12. Worrying thoughts go through my mind:	a great deal of the time 3 a lot of the time 2 not too often 1 very little 0	hads4a
13. I have lost interest in my appearance:	<ul> <li>definitely 3</li> <li>I don't take as much care as I should 2</li> <li>I may not take quite as much care 1</li> <li>I take just as much care as ever 0</li> </ul>	hads5d
14. The thought of hurting myself occurs to me:	onot very often 2 hardly ever 1 not at all 0	sis5
15. I feel restless as if I have to be on the move:	very much indeed 3 quite a lot 2 not very much 1 not at all 0	hads5a
16. I look forward with enjoyment to things:	as much as I ever did 0 rather less than I used to 1 definitely less than I used to 2 hardly at all 3	hads6d
17. I feel I might lose control and hit or hurt someone:	occasionally 2 rarely 1 never 0	sis6
18. I get a sort of frightened feeling like 'butterflies' in the stomach:	onot at all 0 occasionally 1 quite often 2 very often 3	hads6a
19. People upset me so that I feel like slamming doors or banging about:	yes, often 3 yes, sometimes 2 only occasionally 1 not at all 0	sis7
20. I get sudden feelings of panic:	very often indeed 3 quite often 2 not very often 1 not at all 0	hads7a
21. I can enjoy a good book or radio or television programme:	often 0 sometimes 1 not often 2 very seldom 3	hads7d
22. Lately I have been getting annoyed with myself:	very much so 3 rather a lot 2 not much 1 not at all 0	sis8

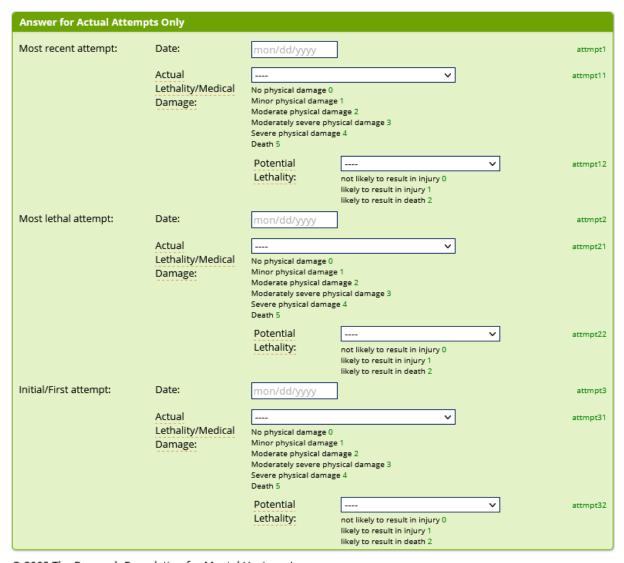
HADS copyright © R.P. Snaith and A.S. Zigmond, 1983, 1992, 1994. Record form items originally published in Acta PsychiatricaScandinavica 67, 361–70, copyright © Muniksgaard International Publishers Ltd. Copenhagen, 1983. This edition first published in 1994 by inferNelson Publishing Company Ltd. 414 Chiswick High Road, London W4 STF. GL Assessment is part of the Granada Learning Group. This form may not be reproduced by any means without first obtaining permission from the publisher. Email: permissions@glassessment.co.uk
Snaith Irritability Scale is public domain. Original Reference : Snaith, R.P. (1978), A clinical scale for the self-assessment of irritability. British journal of Psychiatry, 132, 164-171.

#### 3.24 Columbia-Suicide Severity Rating Scale (C-SSRS) – Baseline



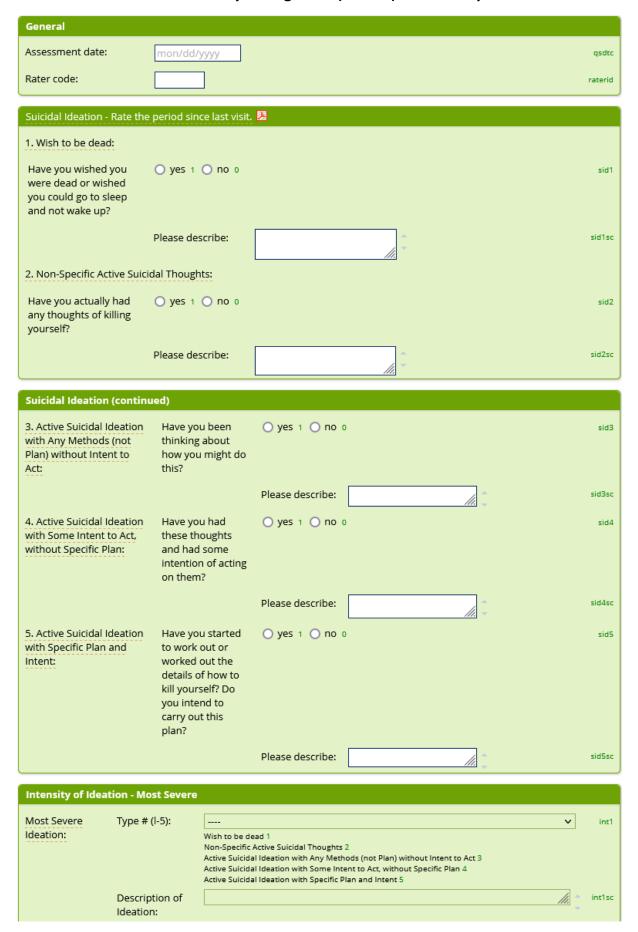


Interrupted Attempt:			
Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?	O yes 1 O no 0		sbh3
	Total # of interrupted:		sbh3n
	Please describe:		sbh3sc
Aborted Attempt:			
Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?	O yes 1 O no 0		sbh4
	Total # of aborted:		sbh4n
	Please describe:		sbh4sc
Preparatory Acts or Behav	vior:		
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)?	O yes 1 O no o		sbh5
	Please describe:		sbh5sc
Suicidal Behavior:		777	
Suicidal behaviour was present during the assessment period?	○ yes 1 ○ no 0		sbh6



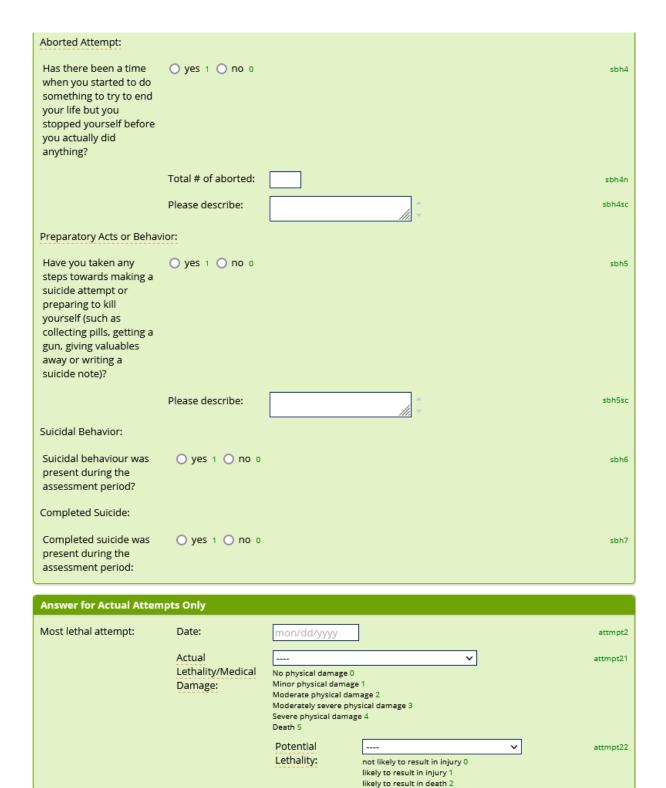
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#### 3.25 Columbia-Suicide Severity Rating Scale (C-SSRS) – Follow Up



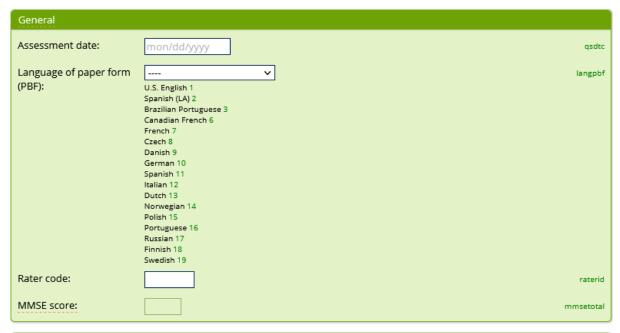
Frequency:	How many times have you had these thoughts?	<ul> <li>Less than once a week 1</li> <li>Once a week 2</li> <li>2-5 times in week 3</li> <li>Daily or almost daily 4</li> <li>Many times each day 5</li> </ul>	int2
Duration:	When you have the thoughts, how long do they last?	<ul> <li>Fleeting - few seconds or minutes 1</li> <li>Less than 1 hour/some of the time 2</li> <li>1-4 hours/a lot of time 3</li> <li>4-8 hours/most of day 4</li> <li>More than 8 hours/persistent or continuous 5</li> </ul>	int3
Controllability:	Could/can you stop thinking about killing yourself or wanting to die if you want to?	<ul> <li>Easily able to control thoughts 1</li> <li>Can control thoughts with little difficulty 2</li> <li>Can control thoughts with some difficulty 3</li> <li>Can control thoughts with a lot of difficulty 4</li> <li>Unable to control thoughts 5</li> <li>Does not attempt to control thoughts 0</li> </ul>	int4
Deterrents:	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?	<ul> <li>Deterrents definitely stopped you 1</li> <li>Deterrents probably stopped you 2</li> <li>Uncertain that deterrents stopped you 3</li> <li>Deterrents most likely did not stop you from attempting suicide 4</li> <li>Deterrents definitely did not stop you 5</li> <li>Does not apply; wish to die only 0</li> </ul>	int5
Reasons for Ideation:	What sort of reasons did you have for thinking about wanting to die or killing yourself?	<ul> <li>Completely to get attention, revenge or a reaction from others 1</li> <li>Mostly to get attention, revenge or a reaction from others. 2</li> <li>Equally to get attention, revenge or a reaction from others 3</li> <li>Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling). 4</li> <li>Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling). 5</li> <li>Does not apply 0</li> </ul>	int6

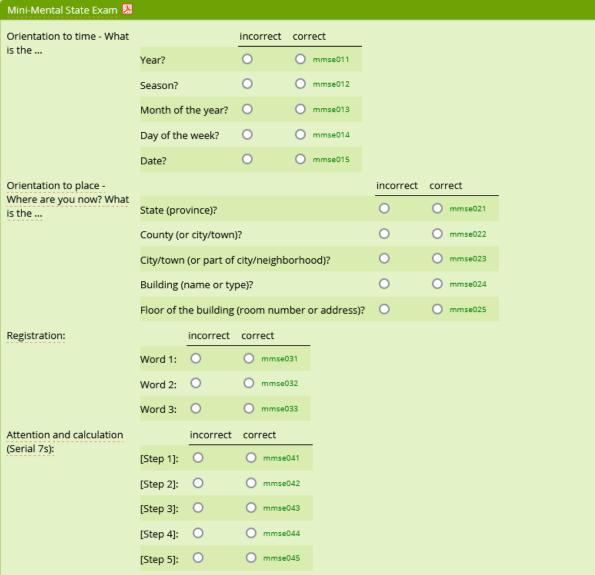
Suicidal Behavior		
Actual Attempt:		
Actual attempt:	O yes 1 O no 0	sbh1
	Total # of attempts:	sbh1n
	Please describe:	sbh1sc
Has subject engaged in Non-Suicidal Self- Injurious Behavior? Interrupted Attempt: Has there been a time when you started to do something to end your	O yes 1 O no 0	sbh2
life but someone or something stopped you before you actually did anything?		
	Total # of interrupted:	sbh3n
	Please describe:	sbh3sc



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#### 3.26 Mini Mental State Examination (MMSE)

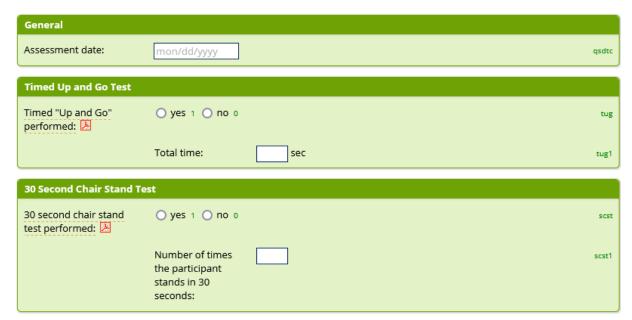




Recall:		incorrect	corre	ect	
	Word 1:	0	0	mmse051	
	Word 2:	0	0	mmse052	
	Word 3:	0	0	mmse053	
Naming - What is this?			incorre	ct corre	:t
	1 [Pencil o	or pen]:	0	O m	mse061
	2 [Watch]	:	0	O m	mse062
Repetition:			inco	rrect co	rrect
	No ifs, an	ds or buts	. 0	C	mmse07
Comprehension:			in	correct (	orrect
	Take in ri	ght hand:	C		mmse0
	Fold in ha	ılf:	C		mmse0
	Put on flo	or (or tab	le): (		mmse0
Reading:		i	ncorre	t correc	t
	Close you	ır eyes:	0	O mi	mse09
Writing:		incorre	ct co	rrect	_
	Sentence	0	0	mmse10	
Drawing:		incorrect	corre	ct	
	Figure:	0	O m	mse11	

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#### 3.27 Physiotherapy Outcome Measures (Physio)



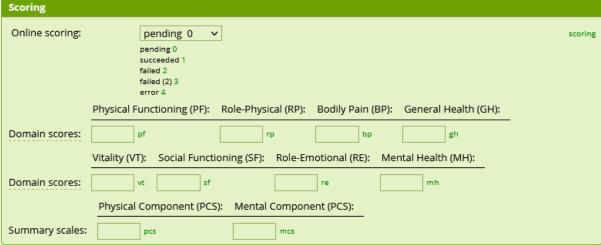
Timed "Up & Go": Podsiadlo D, Richardson S. The Timed "Up & Go": a test of basic functional mobility for frail elderly persons, J Am Geriatr Soc. 1991; 39(2):142-8.

In HD: Busse ME, Wiles CM, Rosser AE. Mobility and falls in people with Huntington's disease. J Neurol Neurosurg Psychatiry. 2009; 80(1): 88-90. 30 Second Chair Test: McCarthy EK, Horvat MA, Holtsberg PA, Wisenbaker JM. Repeated chair stands as a measure of lower limb strength in sexagenarian women, J Gerontol A Biol Sci. 2004; 59(11): 1207-12

In HD: Khalil H, van Deursen R, Quinn L, et al. F18 Clinical measurement of sit to stand performance in people with Huntington's disease: reliability and validity for 30 seconds chair sit to stand test, J Neurol Neurosurg Psychiatry 2010;81(Suppl 1):A28-A28

#### 3.28 Short Form Health Survey – 12v2 (SF12)



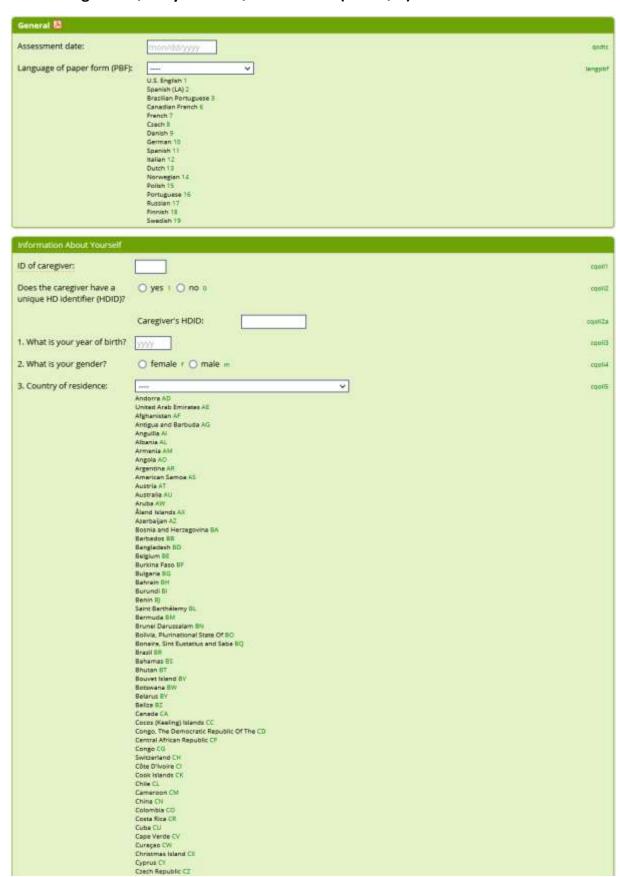


SF12 Health Survey 🤽			
1. In general, would you say your health is:	○ Excellent 1 ○ Very good 2 ○ Good 3 ○ Fair	r 4 O Poor 5	sf12_1
2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?	a) Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf:	Yes, limited a lot 1 Yes, limited a little 2 No, not limited at all 3	sf12_2
	b) Climbing several flights of stairs:	Yes, limited a lot 1 Yes, limited a little 2 No, not limited at all 3	sf12_3
3. During the past week, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?	a) Accomplished less than you would like:	<ul> <li>All of the time 1</li> <li>Most of the time 2</li> <li>Some of the time 3</li> <li>A little of the time 4</li> <li>None of the time 5</li> </ul>	sf12_4
	b) Were limited in the kind of work or other activities:	All of the time 1  Most of the time 2  Some of the time 3  A little of the time 4  None of the time 5	sf12_5
4. During the past week, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?	a) Accomplished less than you would like:	<ul> <li>All of the time 1</li> <li>Most of the time 2</li> <li>Some of the time 3</li> <li>A little of the time 4</li> <li>None of the time 5</li> </ul>	sf12_6
	b) Did work or other activities less carefully than usual:	All of the time 1  Most of the time 2  Some of the time 3  A little of the time 4  None of the time 5	sf12_7

5. During the past week, how much did pain interfere with your normal work (including both work outside the home and housework)?	O Not at all 1 O A little bit 2 O Moderately 3	Quite a bit 4 O Extremely 5	sf12_8
6. These questions are about how you feel and how things have been with you during the past week. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past week:	a) Have you felt calm and peaceful?	All of the time 1  Most of the time 2  Some of the time 3  A little of the time 4  None of the time 5	sf12_9
	b) Did you have a lot of energy?	<ul> <li>All of the time 1</li> <li>Most of the time 2</li> <li>Some of the time 3</li> <li>A little of the time 4</li> <li>None of the time 5</li> </ul>	sf12_10
	c) Have you felt downhearted and depressed?	All of the time 1  Most of the time 2  Some of the time 3  A little of the time 4  None of the time 5	sf12_11
7. During the past week, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?	O All of the time 1 O Most of the time 2 O Som	ne of the time 3 O A little of the time 4 O None of the time 5	sf12_12

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#### 3.29 Caregivers Quality of Life Questionnaire (CareQoL)



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Germany DE
Germany DE
Djabous DJ
Denmark DE
Dominica DM
Dominica DM
Dominica Republic DO
Algaria D2
Ecuador EC
Extonia EE
Egypt 10
Western Sahara EH
Eritras EE
Wastern Sehara EH
Eritros EH
Spain IS
Sthiopila ET
Finland FI
Fiji FJ
Falkiand Islands (Malvines) FK
Micronesia, Federated States Of FM
Fance Islands FD
France ER
Gabon IIA
Linked Kingdom GB
Grendos GD
Georgia GE
Grenada GD
Georgia GE
Franch Sulana GF
Guernaey GG
Ghana GH
Gibrattar GI
Grenaland GL
Gambia GM
Guinea GN
 Guadeloupe GP
Equatorial Goines GQ
Greece GP
  South Georgia and the South Sandwich Islands GS
  Guatemala G?
Guem GU
Guinea-Bizsau GW
  Guyana GIT
Hong Kong HK
Heard and McDonald Islands HM
  Honduras HN
Croatia HR
Halti HT
  Hungary HU
Indonesia IO
Ireland III
  Israel II.
Isle of Man IM
  India IN
  Iraq IQ
Iran, Islamic Republic Of III
   Iceland IS
 icerand IS
Italy IT
Jersey JE
Jamaica JM
Jordan JO
Japan JP
Kanya EE
  Kyrgyzstan KG
Cambodia KH
Kiribati Ki
  Comoras KM
Seint Kitts And Nevis KN
 Kores, Democratic People's Republic Of KP
Kores, Republic of KR
Kuwait NW
Kuwait RW
Cayman Islands KV
Kasakhtan KZ
Lao People's Democratic Republic LA
Lebanon LB
Saint Lucia LC
Liechtenstein Li
Sri Lanka LK
Jacob L
 Liberia LR
Lesotho LS
  Lithuanta LT
Luxembourg LU
Latvia LV
  Libya LY
Morocco MA
Moneco MC
Moldova, Republic of MD
  Montenegro MS
Saint Martin MF
 Madagastar MS
Marshall Islands MH
Macedonia, the Former Yugoslav Republic Of MK
Mak ML
 Mas ML
Myanmar MM
Mongola MM
Macao MG
Northern Mariana Islands MP
Martinique MQ
   Mauritania MR
 Montarrat MS
Maita MT
Mauritius MU
Maldives MV
Malawi MW
  Maxico MX
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	Malaysia MY	
	Mozembique MZ. Namibia NA	
	New Caledonia NC	
	Niger NE	
	Norfolk Island Nef	
	Nigeria NG Nicaragua NI	
	Natherlands W.	
	Norway NO	
	Nepal NP Nauru NR	
	Niue NU	
	New Zealand NZ	
	Oman OM	
	Panama PA	
	Peru PE French Folynesia PF	
	Papus New Guines PG	
	Fhilippines PH	
	Pokistan PK	
	Potend Pt. Saint Pierre And Miquelon PM	
	PRIMARY DN	
	Puerto Rico PR	
	Falestinian Territory, Occupied PS	
	Portugal PT Palau DW	
	Paraguay PV	
	Quar QA	
	Réunien RE	
	Romania RO Serbia RS	
	Russian Federation (II.)	
	Rwanda IIV	
	Saudi Arabia SA	
	Solomen Islands Sill	
	Seycheltes SC Sudan SD	
	Sweden St	
	Singapore SG	
	Swint Helene, Assemblon and Tristen De Curine SH	
	Slovenia Si Svelbard And Jan Mayen Si	
	Storakin SK	
	Sierra Leone 51	
	Sen Marine SM	
	Senegal SN Somalie SO	
	Suriname SR	
	South Sudan 18	
	See Toine and Principe ST	
	81 Selvador VV Sint Maarten (Dutch part) SX	
	Syrian Arab Republic SV	
	Sweptend SZ	
	Turks and Calcos Islands TC	
	Chad TO Togo TG	
	Thelland Til	
	Tajikistan Tj	
	Tokelay TK	
	East Timor TL	
	Turkmenistan TM Tuntila TN	
	Tongs TO	
	East Timor TP	
	Turkey TR Trinided and Tobago TT	
	Tovalu TV	
	Talwan, Province Of China TW	
	Tenzenie, United Republic of T2	
	Ukraine UA Uganda UG	
	United States US	
	Uruguay UF	
	Usbekistan UZ	
	Holy See (Vatican City State) VA Saint Vincent And The Grenedines VC	
	Venezuela, Bolharian Rapublic of VE	
	Virgin Islands, British VG	
	Virgin Intends, U.S. VI	
	Viet Nam VN Vanuatu VU	
	Walls and Future WF	
	Samoa WS	
	Verner, YE	
	Mayotta YT South Africa IA	
	Zambia ZM.	
	Zimbabwe ZW	
4. How many years of formal	years	cquiis
education have you had?		Ligano
sousaudir nave you naur		
5. Do you have a job:	○ yes, full time 2 ○ yes, part time + ○ no o	couli7
2.00 Jou nave a 100/	year and a compare and a compa	· equit
6. What is your marital	O single v	cquis
status:	married 3	- squid-
3101131		
	O partnership :	
	O divorced a	
	O widowed s	
	O legally separated 6	

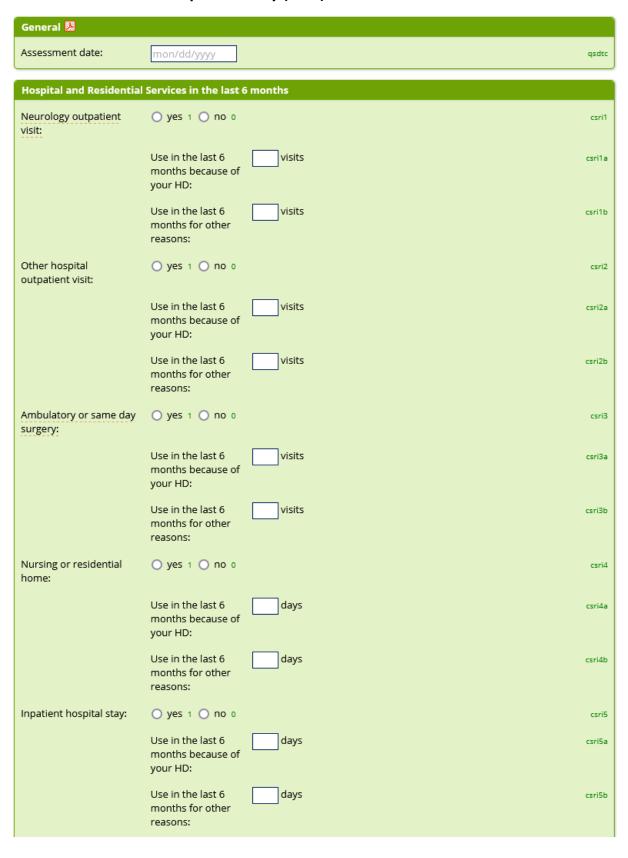
<ol> <li>How long have you known about Huntington's Disease in the family of the affected person(s)?</li> </ol>	years											Elops
8. How long have you been caring for any Huntington's Disease affected person(s)?	years											emphi 10
9. Are you the main carer for the HD affected person(s)?	O yes ( O no o											engist f
10. The HD affected	sibling											000012_1
person(s) is/are my:	spouse/partner											::qol(12_2
	parent											ceolitz_1
	child											1,571000
	other											result2.b
	Please specify:											cqol/12a
11. Have you previously cared for any other person(s) with Huntington's Disease?	○ yes 1 ○ no 0											cqc#13
	If so, what is/was their relationship to	you?										
	The affected person is/was my:											opoli13a
12. Do you have children who are at risk/carrier /symptomatic?	○ yes + ○ no o											cgoli14
13. How many persons live in your household?												capit 5
14. Do you live in the same	O yes 1 O no o											rqal18
household as the HD person(s)?												
person(s)?												
HOMELER PROPERTY CONTINUES.		0 - dissatisfied	4	2	3	4	5	6	7	8	9	10 - satisfied
person(s)?	your physical health?		1	2	3	4	5	6	7	8	9	Manager and the last
person(s)?  Quality of Life		dissatisfied		242	3 0	4 0 0	5 0 0	6 0 0	7 0 0	8 0 0		satisfied
Quality of Life  1. How satisfied are you with y 2. How satisfied are you with y		dissatisfied		242	3 0 0 0	4 0 0 0	5 0 0	6 0 0 0	7 0 0 0	8 0 0 0		Satisfied O court
Quality of Life  1. How satisfied are you with y 2. How satisfied are you with y	your psychological health? what you have achieved in life?	dissatisfied O	0	0 0	0	4 0 0 0 0	5 0 0 0 0	6 0 0 0 0	7 0 0 0 0	0 0	0	C cool2
Quality of Life  1. How satisfied are you with y 2. How satisfied are you with y 3. How satisfied are you with 4 4. How satisfied are you with 6	your psychological health? what you have achieved in life?	dissatisfied O O	0 0	0 0	0	4 0 0 0 0 0	5 0 0 0 0	6 0 0 0 0 0	7 0 0 0 0 0	0 0	0	o costs costs costs costs
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Quality of Life  1. How satisfied are you with y 2. How satisfied are you with y 3. How satisfied are you with y 4. How satisfied are you with y 5. How satisfied are you with y 6. How satisfied are you with y 6. How satisfied are you with y	your psychological health? what you have achieved in life? family relationships? your relationships with your friends?	O O O	0 0 0 0	0 0	0	4 0 0 0 0 0 0 0 0	5 0 0 0 0 0 0 0	6 0 0 0 0 0 0	0 0 0 0 0	00000	0	satisfied  C cools C cools C cools C cools C cools C cools
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Quality of Life  1. How satisfied are you with y 2. How satisfied are you with y 3. How satisfied are you with y 4. How satisfied are you with y 5. How satisfied are you with y 6. How satisfied are you with y environment? 7. How satisfied are you with y relative(s) receive(s)? 8. How satisfied are you with y the HD person? 9. How satisfied are you with y	your psychological health? what you have achieved in life? family relationships? your relationships with your friends? feeling a part of your social the medical treatment that your HD the way other people behave towards	o o o o o o o o o o o o o o o o o o o	0 0 0 0 0 0	00000000	0 0 0 0 0 0	00000000	0 0 0 0 0 0	00000000	0 0 0 0 0 0	00000000	00000000	satisfied  C coeff
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Quality of Life  1. How satisfied are you with y 2. How satisfied are you with y 3. How satisfied are you with y 4. How satisfied are you with y 5. How satisfied are you with y 6. How satisfied are you with y environment? 7. How satisfied are you with y relative(s) receive(s)? 8. How satisfied are you with y the HD person? 9. How satisfied are you with y Life stiports  1. I feel a sense of loss:	your psychological health? what you have achieved in life? family relationships? your relationships with your friends? feeling a part of your social the medical treatment that your HD the way other people behave towards	dissatisfied  O  O  O  O  O  O  O  O  O  O  O  O  O	0 0 0 0 0 0	0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0	0 0 0 0 0 0 0	0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 7	0 0 0 0 0 0 0	0 0 0 0 0 0 0	satisfied  C cools
Quality of Life  1. How satisfied are you with y 2. How satisfied are you with y 3. How satisfied are you with y 4. How satisfied are you with y 6. How satisfied are you with y environment? 7. How satisfied are you with y relative(s) receive(s)? 8. How satisfied are you with y the HD person? 9. How satisfied are you with y the HD person? 1. I feel a sense of loss: 2. I feel a sense of grieving:	your psychological health? what you have achieved in life? family relationships? your relationships with your friends? feeling a part of your social the medical treatment that your HD the way other people behave towards	O O O O O O O O O O O O O O O O O O O	0 0 0 0 0 0	0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0	0 0 0 0 0 0 0	0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 7	0 0 0 0 0 0 0	000000000000000000000000000000000000000	satisfied  C coeff

6. I feel safe:	0	0	0	0	0	0	0	0	0	0	O courts	3
7. I feel guilty:	0	0	0	0	0	0	0	0	0	0	O manié	ŝ
8. I feel financially disadvantaged:	0	0	0	0	0	0	0	0	0	0	O squit?	9
9. I feel isolated:	0	0	0	0	0	0	0	0	0	0	O coolis	ři)
10. I feel there is hope for the future:	0	0	0	0	0	0	0	0	0	0	O cqo119	3
11. I feel exhausted:	0	0	0	0	0	0	0	0	0	0	O 11(1120	18
12.1 feel supported:	0	0	0	0	0	0	0	0	0	0	O coot21	
13, I feel depressed:	0	0	0	0	0	0	0	0	0	0	O 100022	
14.1 feel sad:	0	0	0	0	0	0	0	0	0	0	O 199U3	0)
15, I feel stressed:	0	0	0	0	0	0	0	0	0	0	O tquUA	
16. I feel worried about the genetic consequences of Huntington's Disease:	0	0	0	0	0	0	0	0	0	0	O cool25	9)
17.1 feel that my own needs are important to others:	0	0	0	0	0	0	0	0	0	0	O 100176	9
18.1 feel lonely:	0	0	0	0	0	0	0	0	0	0	O :qn/27	Q.
19. I feel that Huntington's Disease brought something positive to my life:	0	0	0	0	0	0	0	0	0	0	O cqui29	16
20. I feel comforted by my beliefs (religious, philosophical or spiritual):	0	0	0	0	0	0	0	0	0	0	O equi29	0)
21. I feel that I can cope:	0	0	0	0	0	0	0	0	0	0	O squitto	i i
22. I feel that Huntington's Disease has made me a stronger person:	0	0	0	0	0	0	0	0	0	0	O squist	ī
23. I feel that I have had a duty of care forced on me:	0	0	0	0	0	0	0	0	0	0	O coolin	3
24. I feel like I don't know who I am anymore:	0	0	0	0	0	0	0	0	0	0	O matti	W
25. I feel that my role as a carer is rewarding:	0	0	0	0	0	0	0	0	0	0	O special	
26. I feel restricted by a regimented daily routine:	0	0	0	0	0	0	0	0	0	0	O equiss	il.
27.1 feel restricted by having to provide continuous care:	0	0	0	0	0	0	0	0	0	0	O cqol36	Ri.
28. I feel resentful:	0	0	0	0	0	0	0	0	0	0	O tqui37	Š.
29. I feel embarrassed by the behaviour of my HD relative(s):	0	0	0	0	0	0	0	0	0	0	O rept38	
30. I feel ashamed of the behaviour of my HD relative(s):	0	0	0	0	0	0	0	0	0	0	O 100139	20
31. I feel frustrated by the misconceptions of others towards my HD relative(s):	0	0	0	0	0	0	0	0	0	0	O squitto	0)
32.1 feel threatend:	0	0	0	0	0	0	0	0	0	0	O repiti	
33. I feel frustrated by the discrimination of others toward my HD:	0	0	0	0	0	0	0	0	0	0	O anni42	
34. I feel restricted by the need to maintain secrecy about Huntington's Disease in the family:	0	0	0	0	0	0	0	0	0	0	O cqo143	
35. I feel I have enough time for myself:	0	0	0	0	0	0	0	0	0	0	O moits	9
36. I feel I get enough sleep:	0	0	0	0	0	0	0	0	0	0	O cont45	
37.1 feel I have somebody to turn to for assistance if I am overwhelmed:	0	0	0	0	0	0	0	0	0	0	O 10846	9)
38, I feel satisfied with my overall quality of life:	0	0	0	0	0	0	0	0	0	0	O cqol47	
Improvements												
1. Is there anything else											cqo	MIT:
Could you please describe what it is?											espoli	87a
As a carer of someone						add (					cdo	618
positive:						]:					equit	18a
PARTITION .					-	-					01900	tite



The European Huntington's disease Quality of Life Working Group carer questionnaire (2006). Aubeeluck & The European Huntington's disease Quality of Life Working Group, modified from Aubeeluck (2005). © Aubeeluck & Buchanan 2005, For enquiries, please contact permissions@euro-hd.net

#### 3.30 Client Service Receipt Inventory (CSRI)



Inpatient hospital stay - intensive care unit (ICU):	O yes 1 O no 0		csri6
	Use in the last 6 months because of your HD:	days	csri6a
	Use in the last 6 months for other reasons:	days	csri6b
Hospital emergency room visits:	O yes 1 O no 0		csri61
	Use in the last 6 months because of your HD:	days	csri61a
	Use in the last 6 months for other reasons:	days	csri61b
Other inpatient hospital stay:	O yes 1 O no 0		csri7
	Use in the last 6 months because of your HD:	days	csri7a
	Use in the last 6 months for other reasons:	days	csri7b
Primary and Community	Care Services in the last (	5 months	٦
Primary and Community  General practitioner (GP) of internist/family doctor:	Care Services in the last of	5 months	csri8
General practitioner (GP)		contacts	csri8 csri8a
General practitioner (GP)	Use in the last 6 months because		
General practitioner (GP)	Use in the last 6 months because of your HD:  Use in the last 6 months for other	contacts	csri8a
General practitioner (GP) of internist/family doctor:	Use in the last 6 months because of your HD:  Use in the last 6 months for other reasons:	contacts	csri8a csri8b
General practitioner (GP) of internist/family doctor:	Use in the last 6 months because of your HD:  Use in the last 6 months for other reasons:  O yes 1 O no 0  Use in the last 6 months because	contacts	csri8a csri8b csri9
General practitioner (GP) of internist/family doctor:	Use in the last 6 months because of your HD:  Use in the last 6 months for other reasons:  O yes 1 O no 0  Use in the last 6 months because of your HD:  Use in the last 6 months for other	contacts	csri8a csri8b csri9a
General practitioner (GP) of internist/family doctor:  Physical Therapist (PT):	Use in the last 6 months because of your HD:  Use in the last 6 months for other reasons:  O yes 1 O no 0  Use in the last 6 months because of your HD:  Use in the last 6 months because of your HD:  Use in the last 6 months for other reasons:	contacts	csri8a csri8b csri9a csri9a

Psychologist/psychotherapist:	O yes 1 O no 0		csri11
	Use in the last 6 months because of your HD:	contacts	csri11a
	Use in the last 6 months for other reasons:	contacts	csri11b
Counsellor:	O yes 1 O no 0		csri12
	Use in the last 6 months because of your HD:	contacts	csri12a
	Use in the last 6 months for other reasons:	contacts	csri12b
Family therapist/marriage guidance:	O yes 1 O no 0		csri13
	Use in the last 6 months because of your HD:	contacts	csri13a
	Use in the last 6 months for other reasons:	contacts	csri13b
Dietician/nutritionist:	O yes 1 O no 0		csri14
	Use in the last 6 months because of your HD:	contacts	csri14a
	Use in the last 6 months for other reasons:	contacts	csri14b
Clinical geneticist:	O yes 1 O no 0		csri15
	Use in the last 6 months because of your HD:	contacts	csri15a
	Use in the last 6 months for other reasons:	contacts	csri15b
Social worker:	O yes 1 O no 0		csri16
	Use in the last 6 months because of your HD:	contacts	csri16a
	Use in the last 6 months for other reasons:	contacts	csri16b

Social worker:	O yes 1 O no 0		csri16
	Use in the last 6 months because of your HD:	contacts	csri16a
	Use in the last 6 months for other reasons:	contacts	csri16b
Practice nurse (nurse practitioner or physician assistant):	O yes 1 O no 0		csri17
	Use in the last 6 months because of your HD:	contacts	csri17a
	Use in the last 6 months for other reasons:	contacts	csri17b
Home healthcare nurse:	O yes 1 O no 0		csri18
	Use in the last 6 months because of your HD:	contacts	csri18a
	Use in the last 6 months for other reasons:	contacts	csri18b
Speech therapist:	O yes 1 O no 0		csri19
	Use in the last 6 months because of your HD:	contacts	csri19a
	Use in the last 6 months for other reasons:	contacts	csri19b
Home help/home care worker:	O yes 1 O no 0		csri20
	Use in the last 6 months because of your HD:	contacts	csri20a
	Use in the last 6 months for other reasons:	contacts	csri20b
Acupuncturist:	O yes 1 O no 0		csri21
	Use in the last 6 months because of your HD:	contacts	csri21a
	Use in the last 6 months for other reasons:	contacts	csri21b

Homeopath:	O yes 1 O no 0	csri22
	Use in the last 6 contacts months because of your HD:	csri22a
	Use in the last 6 contacts months for other reasons:	csri22b
Herbalist:	yes 1  ○ no 0	csri23
	Use in the last 6 contacts months because of your HD:	csri23a
	Use in the last 6 contacts months for other reasons:	csri23b
Aromatherapy:	yes 1  ○ no 0	csri24
	Use in the last 6 contacts months because of your HD:	csri24a
	Use in the last 6 contacts months for other reasons:	csri24b
Reflexologist:	○ yes 1 ○ no 0	csri25
	Use in the last 6 contacts months because of your HD:	csri25a
	Use in the last 6 contacts months for other reasons:	csri25b
Other service:	O yes 1	csri26
Investigations / Diagno	ostic Tests in the last 6 months	,
Genetic test:	○ yes 1 ○ no 0	csri27
	No. in the last 6 months:	csri27a
	Why did you have this test/investigation?	csri27sc
Magnetic Resonance Image (MRI):	O yes 1 O no 0	csri28
	No. in the last 6 months:	csri28a
	Why did you have this test/investigation?	csri28sc

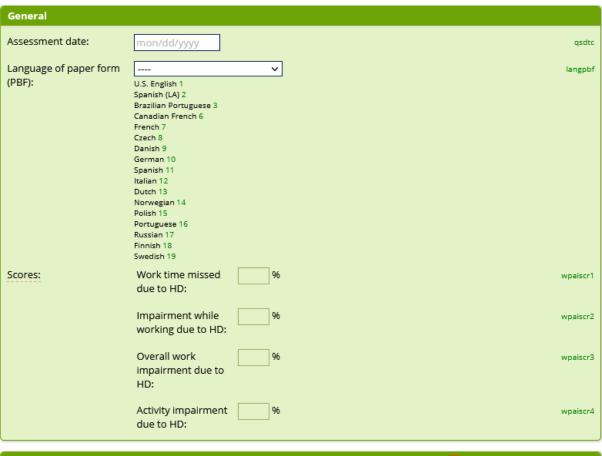
CT/CAT scan:	O yes 1 O no o		csri29
	No. in the last 6 months:		csri29a
	Why did you have this		csri29sc
	test/investigation?	?	
Electroencephalogran (EEG):	n O yes 1 O no o		csri30
	No. in the last 6 months:		csri30a
	Why did you have this		csri30sc
	test/investigation?	?	
Blood test:	O yes 1 O no 0		csri31
	No. in the last 6 months:		csri31a
	Why did you have this		csri31sc
	test/investigation?	?	
Informal Care			
Personal care (e.g. bathing, dressing):	O yes 1 O no 0		csri32
	Average no. of hours per week:	hours	csri32a
	Any other information?		csri32sc
Help inside the home (e.g. cooking, cleaning):	O yes 1 O no 0		csri33
	Average no. of hours per week:	hours	csri33a
	Any other information?		csri33sc
Help outside the home (e.g. shopping):	O yes 1 O no 0		csri34
	Average no. of hours per week:	hours	csri34a
	Any other information?		csri34sc
Other:	O yes 1 O no 0		csri35
	Average no. of hours per week:	hours	csri35a
	Any other information?		csri35sc

Adaptations to the Home			
Stairlift:	O yes 1 O no 0		csri36
	Was this in the last 6 months?	○ yes 1 ○ no 0	csri36a
Handrails:	O yes 1 O no 0		csri37
	Was this in the last 6 months?	○ yes 1 ○ no 0	csri37a
Ramps:	O yes 1 O no 0		csri38
	Was this in the last 6 months?	○ yes 1 ○ no 0	csri38a
Shower/bath relocation:	O yes 1 O no 0		csri39
	Was this in the last 6 months?	○ yes 1 ○ no 0	csri39a
Toilet relocation:	O yes 1 O no 0		csri40
	Was this in the last 6 months?	○ yes 1 ○ no 0	csri40a
Redesign kitchen:	O yes 1 O no 0		csri41
	Was this in the last 6 months?	○ yes 1 ○ no 0	csri41a
Chair raises/special chair:	O yes 1 O no 0		csri42
	Was this in the last 6 months?	O yes 1 O no 0	csri42a
Bed moved downstairs:	O yes 1 O no 0		csri43
	Was this in the last 6 months?	O yes 1 O no 0	csri43a
Hospital bed:	O yes 1 O no 0		csri44
	Was this in the last 6 months?	O yes 1 O no 0	csri44a
Other:	O yes 1 O no 0		csri45
	Was this in the last 6 months?	O yes 1 O no 0	csri45a

Aids or Devices			
Wheelchair:	O yes 1 O no 0		csri46
	Did you receive it in the last 6 months?	○ yes 1 ○ no 0	csri46a
Crutches/sticks:	O yes 1 O no 0		csri47
	Did you receive it in the last 6 months?	O yes 1 O no 0	csri47a
Zimmer frame:	O yes 1 O no 0		csri48
	Did you receive it in the last 6 months?	O yes 1 O no 0	csri48a
Commode:	O yes 1 O no 0		csri49
	Did you receive it in the last 6 months?	○ yes 1 ○ no 0	csri49a
Bath board:	O yes 1 O no 0		csri50
	Did you receive it in the last 6 months?	○ yes 1 ○ no 0	csri50a
Pressure relieving cushions/mattress:	O yes 1 O no 0		csri51
	Did you receive it in the last 6 months?	O yes 1 O no 0	csri51 a
Adapted eating utensils:	O yes 1 O no 0		csri52
	Did you receive it in the last 6 months?	○ yes 1 ○ no 0	csri52a
Other:	O yes 1 O no 0		csri53
	Did you receive it in the last 6 months?	O yes 1 O no 0	csri53a

Beecham, J. and Knapp, M. (2001) Costing psychiatric interventions. In: Measuring Mental Health Needs, 2nd edition (ed. G. Thornicroft) London: Gaskell, adapted for use in HD by The University of Ulm, Faculty of Medicine, EHDN Health Economics Working Group.

### 3.31 Work Productivity and Activity Impairment-Specific Health Problem (WPAI-SH)



Work Productivity and Ac	tivity Impairment Quest	tionnaire: Specific Health Problem (WPAI-SHP) 🤽	
Are you currently employed (working for pay)?	○ 1 = yes 1 ○ 0 =	no o	wpai01
	2. During the past seven days, how many hours did you miss from work because of	re about the past seven days, not including today.  hours	wpai02
	problems associated with Huntington's disease?  3. During the past seven days, how many hours did you miss from work because of any other reason,	hours	wpai03
	such as vacation, holidays, time off to participate in this study?  4. During the past seven days, how many hours did you actually work?	hours	wpai04

	5. During the past seven days, how much did Huntington's disease affect your productivity while you were working?	0 = HD had no effect on my work 0 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = HD completely prevented me from working 10	wpai05
6. 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 = HD had no eff 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9	fect on my daily activities o	wpai06
	0	ely prevented me from doing my daily activities 10	

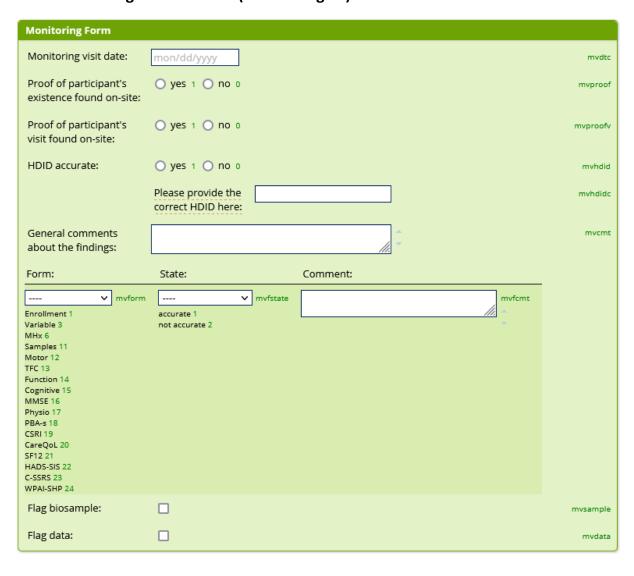
Reilly MC, Zbrozek AS, Dukes EM. The validity and reproducibility of a work productivity and activity impairment instrument. PharmacoEconomics 1993; 4(5):353-65.

# 3.32 Follow-up on Missed Visit (Missed Visit)

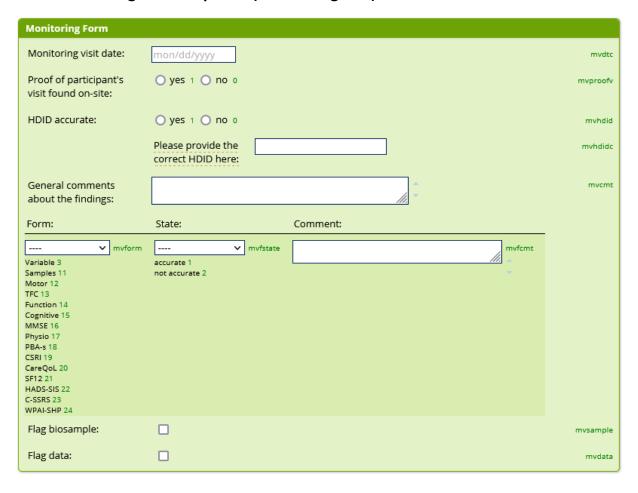
Documentation of Miss	ed Follow-Up	
Date info obtained:	mon/dd/yyyy	mvdtc
Source of information:	<ul> <li>1 = participant 1</li> <li>2 = spouse/partner 2</li> <li>3 = next of kin (family or friends) 3</li> <li>4 = physician 4</li> <li>5 = nurse s</li> <li>6 = other (e.g. hearsay, obituary in newspaper, death or</li> </ul>	mvsrc ertificate) 6
Reason for missed follow-up visit:	<ul> <li>0 = participant involved in a clinical trial, for which the suspension of Enroll-HD visits is requested 0</li> <li>1 = participant alive, unable to attend FUP, open to future FUPs 1</li> <li>2 = participant alive, objects to further FUP visits, open to further phone contacts 2</li> <li>3 = participant alive, objects to further FUP visits and to further phone contacts 3</li> <li>4 = participant alive, lost to FUP 4</li> <li>5 = participant dead 5</li> <li>6 = status unclear 6</li> </ul>	
	Level of care required:  0 = The participant does not required:  of daily living (un/dressing, wash bed). 0  1 = The participant requires som of daily living (typically < 4h sup supervision. 1  2 = The participant requires extractivities of daily living (typically time supervision with additional)	ning/bathing, getting up/going to  ne help to manage basic activities  port per day), but no full-time  ensive help to manage basic  ≥ 4h support per day), and full-
	Date since full- time dependency:	dpdtc

### 4 Monitoring Report Forms

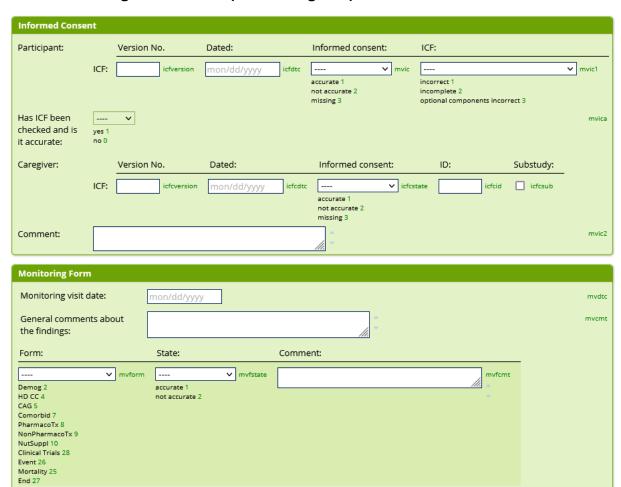
### 4.1 Monitoring Baseline Visit (Monitoring BL)



### 4.2 Monitoring Follow Up Visit (Monitoring FUP)



### 4.3 Monitoring General Visit (Monitoring Gen)



Flag data:

mvdata

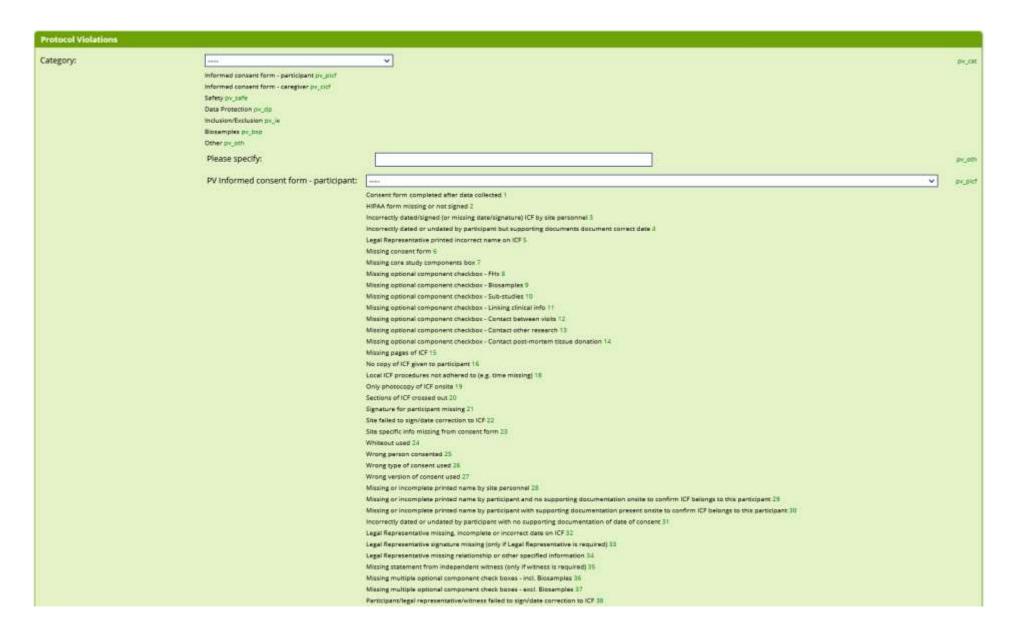
## 4.4 Monitoring General Family History (Monitoring FHx)

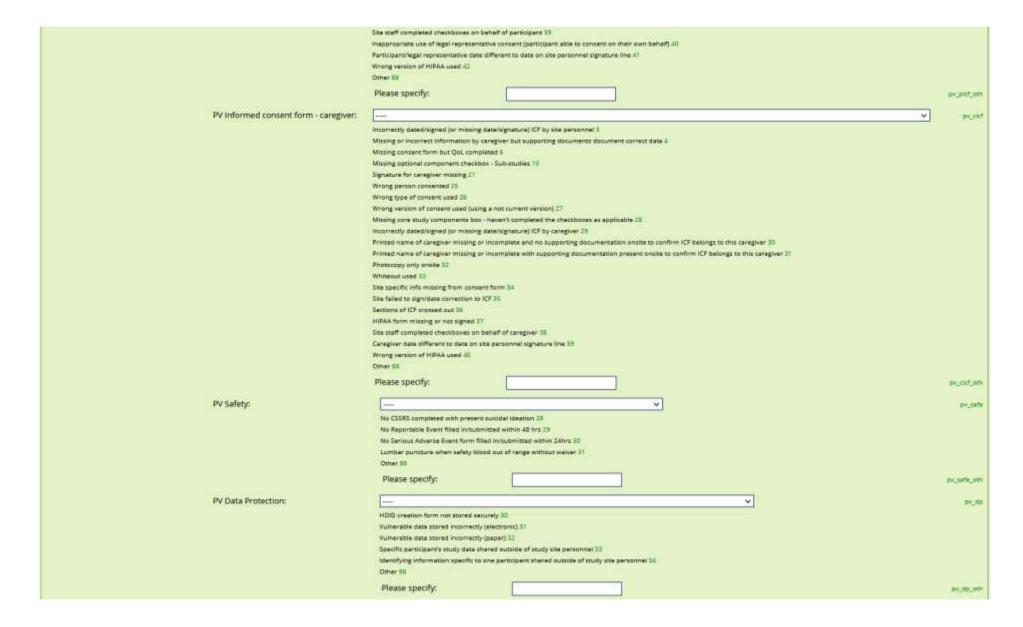


### 5 Monitoring Event Forms

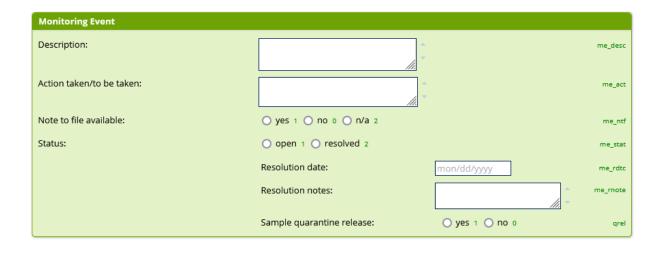
### 5.1 Monitoring Event Form (Monitoring Event)











## References

[1]	CHDI Foundation, Inc., Enroll-HD Data Management Requirements, ENROLL-REQ-2005-EN, Version 1.12, 2021
[2]	CHDI Foundation, Inc., <i>Enroll-HD Data Dictionary</i> , ENROLL-SPC-2002-EN, Version 1.12, 11-Nov-2021

# **Approval**

Document Title	Enroll-HD Annotated CRF		
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Document Type	Documentation		
Status	Final		
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Replaces Version	ENROLL-DOC-2006-EN-1.9		
Valid from	Approval		
Owner	CHDI Foundation, Inc.		

	Name	Date	Signature
Author	Gunter Antoneag	16-Nov-2021	
Review	Torsten Illmann	17-Nov-2021	
Approval	Nicole Piller	24-Jan-2022	

## **Revision Index**

Date	Version	Chapter	Summary of Change(s) and if applicable Reason for Change(s)
31-Oct-2015	1.7		Initial version of annotated CRF of Enroll-HD study, release 1.7.
06-Oct-2016	1.7.1	3.22, 3.24, 3.25, 3.29, 3.29	Slight revisions. Forms Samples, C- SSRS BL, C- SSRS FUP, CareQoL, CSRI added.
31-Dec-2017	1.9		Include update of 1.9 release
24-Jan-2022	1.12	3.21, 5.1, 3.18	Updated FHx form and Monitoring Event form. Use of new template; updated copyright information added to Core & Extended Cognitive CRF