

# Annotated Case Report Form (CRF) for Ad Hoc Periodic Dataset

Version 2016-10-R1

#### **Enroll-HD**

A worldwide observational study for Huntington's disease families

A CHDI Foundation Project



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#### 1 Purpose of this Document

The purpose of this document is to provide an annotated view of the eCRF (electronic Case Report Form) of Enroll-HD's Ad Hoc Visits. It shows the source of the variable names provided in the Enroll-HD plus periodic dataset, which is available to the HD research community at large. The periodic dataset represents a data extract of the Enroll-HD Electronic Data Capture (EDC) database at a defined point in time. Information that could potentially identify a participant has been removed or de-identified within this dataset. When available, CISC SDMT naming conventions were used.

The annotated view shows all forms, variables, and variable names used within the periodic dataset. Forms and variables that are not provided in the dataset are not shown in the annotated forms. Variables that have been transformed for de-identification reasons are shown in the transformed manner in the annotated view.

The variables and data files of the dataset are described in detail within the <u>data dictionary</u> for the Enroll-HD plus periodic dataset.



#### **2** Forms and Data Files

Forms are CRF entry screens that are displayed to data entry personnel and show how data is entered in the eCRF. Data files are sets of variables that define how the data are represented. The following table defines how forms and data files are related.

Form / Data File	Profile	Partici- pation	Ad Hoc
Enrollment	✓	✓	
Variable			✓
Motor			✓
TFC			✓
Function			✓
Cognitive			✓
MMSE			✓

The data files "Profile" and "Participation" are not displayed on an entry form but consist of variables of various forms. It contains key information like subject, study and region identifers and some visit-independent subject information, e.g. the subject's latest HD classification. Please refer to the data dictionary for detailed information.

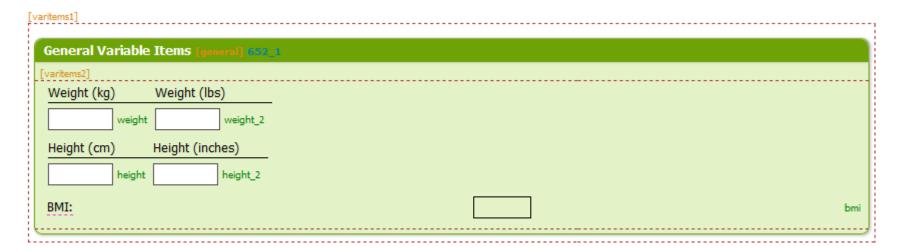


## 3 Form "Enrollment"

Enrollment [enrimmt1] 57662_1			
Day of informed consent:			rficdy
Optional Components: [enrlmnt2] 359_1	Family History:	yes 1   no 0	fhx

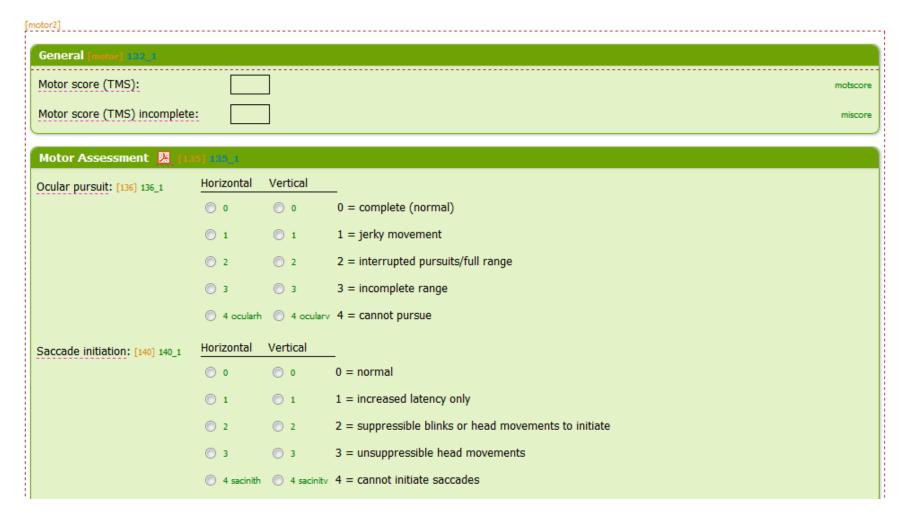


#### 4 Form "Variable Items"





### 5 Form "UHDRS Motor/Diagnostic Confidence (Motor)"





Saccade velocity: [144] 144_1	Horizontal	Vertical		
	○ 0	© 0	0 = normal	
	1	O 1	1 = mild slowing	
			2 = moderate slowing	
	⊙ 3	⊙ 3	3 = severely slow, full range	
	4 sacvelh	4 sacvely	4 = incomplete range	
Dysarthria:	⊚ 0 = norm	nal o	dys	sarth
		ear, no need t	to repeat 1	
	② 2 = must	repeat to be	understood 2	
		ly incompreh	ensible 3	
	∅ 4 = anar	thria 4		
Tongue protrusion:		_	ully protruded for 10 sec o tor	ngue
			protruded for 5 sec 2	
		ot fully protru		
			ongue beyond lips 4	
Finger taps: [150] 150_1	Right	Left	_	
	© 0	○ 0	0 = normal (≥15/5 sec.)	
	1	0 1	1 = mild slowing, reduction in amplitude (11-14/5 sec.)	
			2 = moderately impaired (7-10/5 sec.)	
	⊙ 3	3	3 = severely impaired (3-6/5 sec.)	
	4 fingtapr	0 4 fingtap	4 = can barely perform task (0-2/5 sec.)	



Pronate/supinate-hands:	Right	Left	_	******
[154] 154_1	○ 0	○ 0	0 = normal	
	1	O 1	1 = mild slowing and/or irregular	
		2	2 = moderate slowing and irregular	
			3 = severe slowing and irregular	
	4 prosup	r 🔘 4 prosupl	4 = cannot perform	
Luria:	<ul><li>1 = &lt;4 ii</li><li>2 = ≥4 ii</li><li>3 = &lt;4 ii</li></ul>	n 10 sec, no c n 10 sec, no c n 10 sec with n 10 sec with not perform 4	ue 1 cues 2	luria
Rigidity-arms: [159] 159_1	Right	Left		
	○ 0	○ 0	0 = absent	
	0 1	O 1	1 = slight or present only with activation	
			2 = mild to moderate	
	⊙ 3		3 = severe, full range of motion	
	6 4 rigarmr	4 rigarml	4 = severe with limited range	
Bradykinesia-body:	<ul><li>2 = mild</li><li>3 = mod</li></ul>	mally slow (?r ly but clearly s erately slow,		brady



	Tours	DUE	LUE	DIE			
Maximal dystonia: [164] 164_1	Trunk	RUE	LUE		LLE	-	
	0	© 0	○ 0	○ 0	○ 0	0 = absent	
	O 1	O 1	1	O 1	1	1 = slight/intermitte	ent
						2 = mild/common o	or moderate/intermittent
	3	3	3	⊙ 3		3 = moderate/com	mon
	4 dysttrnk	4 dystrue	a dystlue	0 4 dystrle	4 dystlle	4 = marked/prolon	ged
Maximal chorea: [171] 171_1	Face	BOL	Trunk	RUE	LUE	RLE LLE	<u></u>
	© 0	© 0	0	0	0	© © 0 0	0 = absent
	0 1	① 1	① 1	① 1	① 1	© © 1	1 = slight/intermittent
	© 2	© 2	© 2	© 2	© 2	© © 2	2 = mild/common or moderate/intermittent
	⊙ 3	© 3	© 3	© 3	© 3	© © 3	3 = moderate/common
	<ul><li>chorface</li></ul>	chorbol	chortrnk	chorrue	chorlu	ue  chorrle  4	chorile 4 = marked/prolonged
Gait:	0 = norma 1 = wide   2 = wide   3 = walks 4 = canno	base and/or s base and wall only with ass	slow 1 ks with difficu	lty 2			gait



		1000000
Tandem walking:	○ 0 = normal for 10 steps o	tandem
	○ 1 = 1 to 3 deviations from straight line 1	
	○ 2 = >3 deviations 2	
	⊙ 3 = cannot complete 3	
	∅ 4 = cannot attempt 4	
Retropulsion pull test:	○ 0 = normal o	retropls
	○ 1 = recovers spontaneously 1	
	2 = would fall if not caught 2	
	○ 3 = tends to fall spontaneously 3	
	○ 4 = cannot stand 4	
Diagnostic Confidence In	motor31.DCI 185-1	

Diagnostic Confidence [motor3] .DCL 185_1						
Diagnostic confidence level (DCL): © 0 = normal (no abnormalities) 0						
	○ 1 = non-specific motor abnormalities (less than 50 % confidence) 1					
2 = motor abnormalities that may be signs of HD (50 - 89 % confidence) 2						
	⊙ 3 = motor abnormalities that are likely signs of HD (90 - 98 % confidence) 3					
	4 = motor abnormalities that are unequivocal signs of HD (≥ 99 % confidence) 4					
\						



# 6 Form "UHDRS Total Funtional Capacity (TFC)"

General [He] 893_1		
Functional score:		tfcscore
Functional Capacity [functeap	] 895_1	
Occupation:	○ 0 = unable o	occupatn
	○ 1 = marginal work only 1	
	2 = reduced capacity for usual job 2	
	○ 3 = normal 3	
Finances:	○ 0 = unable o	finances
Tinances.	1 = major assistance 1	
	2 = slight assistance 2	
	3 = normal 3	
	0 5 - HOTHIAL 3	
Domestic chores:	$\bigcirc$ 0 = unable 0 $\bigcirc$ 1 = impaired 1 $\bigcirc$ 2 = normal 2	chores
ADL:	0 = total care o	adl
	○ 1 = gross tasks only 1	
	2 = minimal impairment 2	
	○ 3 = normal 3	
Complements		carelevl
Care level:	0 = full time skilled nursing o	
	1 = home or chronic care 1	
	○ 2 = home 2	



## 7 Form "UHDRS Functional Assessment/Independence Scale (Function)"

General [function] 849_1		
Functional assessment score:		fascore
Functional score incomplete:		fiscore
Independence Scale [indep1] .Indepo	indence 693_1	
Subject's independence in %:	<ul> <li>100 = no special care needed 100</li> <li>95 95</li> <li>90 = no physical care needed if difficult tasks are avoided 90</li> <li>85 95</li> <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> <li>75 75</li> <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> <li>65 65</li> <li>60 = needs minor assistance in dressing, toileting, bathing; food must be cut for subject 60</li> <li>55 55</li> <li>50 = 24-hour supervision appropriate; assistance required for bathing, eating, toileting 50</li> <li>45 45</li> <li>40 = chronic care facility needed; limited self feeding, liquified diet 40</li> <li>35 35</li> <li>30 = subject provides minimal assistance in own feeding, bathing, toileting 30</li> <li>25 25</li> <li>20 = no speech, must be fed 20</li> <li>15 15</li> <li>10 = tube fed, total bed care 10</li> <li>5 5</li> </ul>	indepscl

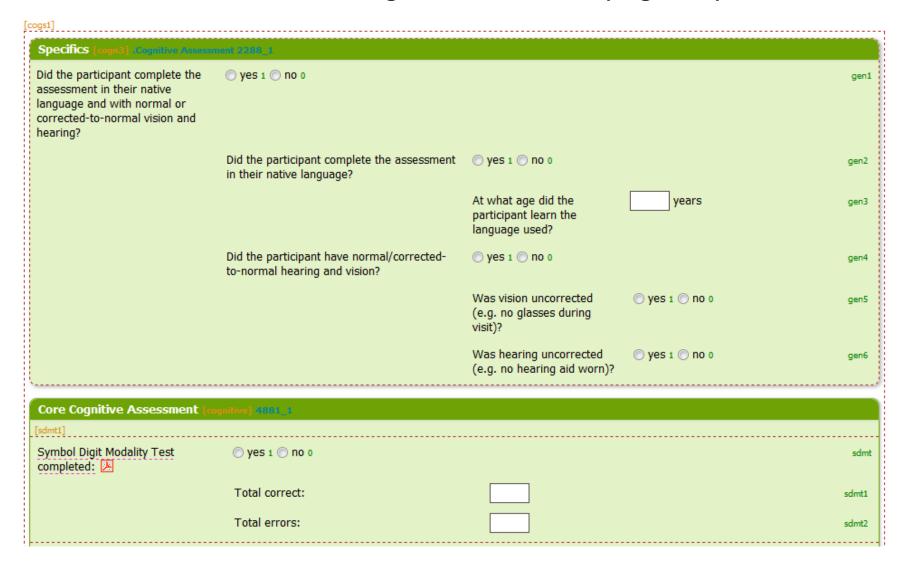


## 8 Form "Mini Mental State Examination (MMSE)"

General [mmse] 3078_1	
MMSE score:	 mmsetotal



### 9 Form "Core and Extended Cognitive Assessment (Cognitive)"



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[verfct1]			140000
Verbal Fluency Test (Category) completed: 🄼	yes 1   no 0		verfct
	Category:	animals 1	verfctd
	Total correct (1 min):		verfct5
	Total intrusion errors:		verfct6
	Total perseverative errors:		verfct7
[scnt1]			
Stroop Color Naming Test completed:	yes 1   no 0		scnt
	Total correct:		scnt1
	Total errors:		scnt2
	Total self-corrected errors:		scnt3
[swrt1]			
Stroop Word Reading Test completed: 🔼	yes 1   no 0		swrt
	Total correct:		swrt1
	Total errors:		swrt2
	Total self-corrected errors:		swrt3



E 947		44,454,44
Stroop Interference Test completed: 🔼	yes 1	 sit
	Total correct:	sit1
	Total errors:	sit2
	Total self-corrected errors:	sit3
[verflt1]		
Verbal Fluency Test (Letters) completed: 🄀	⊚ yes 1 ⊚ no 0	verfit
	Total correct (3 min):	verflt05
	Total intrusion errors:	verfit06
	Total perseverative errors:	verfit07



## **Revision History**

Version	Summary of Changes	
2016-10-R1	Initial version of annotated CRF for the Ad Hoc dataset.	