

Huntington's Disease CDE Revision History

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October 2024 Revisions

- Outcomes and Endpoints; Quality of Life/Patient Reported Outcomes Domain/Subdomain
 - The Notice of Copyright, Huntington Disease Patient Report of Problems (HD-PROP), was added to Outcomes and End Points; Quality of Life/Patient Reported Outcomes domain; subdomain section as Exploratory.
- The Huntington's Disease CDE Highlight Summary Document was updated to include the additions of the following instruments:
 - The Notice of Copyright, Huntington Disease Patient Report of Problems (HD-PROP), was added to the Outcomes and End Points; Quality of Life/Patient Reported Outcomes domain; subdomain section as Exploratory.
 - The Notice of Copyright, Huntington Quality of Life Instrument (H-QoL-I), was added to the Outcomes and End Points; Quality of Life/Patient Reported Outcomes domain; subdomain section as Supplemental.
 - The Notice of Copyright, Brief Psychiatric Rating Scale (BPRS), was added to the Outcomes and End Points; Emotional/Behavioral domain; subdomain section as Exploratory.
 - The Notice of Copyright, Hamilton Depression Rating Scale (HDRS), was added to the Outcomes and End Points; Emotional/Behavioral domain; subdomain section as Supplemental.
 - The Notice of Copyright, California Verbal Learning Test - Second Edition (CVLT-II), was added to the Outcomes and End Points; Cognitive domain; subdomain section as Supplemental.
 - The Notice of Copyright, Mini-Mental State Examination (MMSE), was added to the Outcomes and End Points; Cognitive domain; subdomain section as Supplemental.
 - The Notice of Copyright, National Adult Reading Test – 2nd Edition (NART-2), was added to the Outcomes and End Points; Cognitive domain; subdomain section as Supplemental.
 - The Notice of Copyright, Edinburgh Handedness Inventory, was added to the Outcomes and End Points; Motor Function domain; subdomain section as Exploratory.

July 2024 Revisions

- Outcomes and Endpoints; Quality of Life/Patient Reported Outcomes Domain/Subdomain
 - The Notice of Copyright, Huntington Quality of Life Instrument (H-QoL-I) was added to the Outcomes and End Points; Quality of Life/Patient Reported Outcomes domain; subdomain section as Supplemental.
- Outcomes and Endpoints; Emotional/Behavioral Domain/Subdomain

- The Notice of Copyright, Brief Psychiatric Rating Scale (BPRS), was added to the Outcomes and End Points; Emotional/Behavioral domain; subdomain section as Exploratory.
- The Notice of Copyright, Hamilton Depression Rating Scale (HDRS), was added to the Outcomes and End Points; Emotional/Behavioral domain; subdomain section as Supplemental.
- Outcomes and Endpoints; Cognitive Domain/Subdomain
 - The Notice of Copyright, California Verbal Learning Test - Second Edition (CVLT-II), was added to the Outcomes and End Points; Cognitive domain; subdomain section as Supplemental.
 - The Notice of Copyright, Mini-Mental State Examination (MMSE), was added to the Outcomes and End Points; Cognitive domain; subdomain section as Supplemental.
 - The Notice of Copyright, National Adult Reading Test – 2nd Edition (NART-2), was added to the Outcomes and End Points; Cognitive domain; subdomain section as Supplemental.
- Outcomes and Endpoints; Motor Function Domain/Subdomain
 - The Notice of Copyright, Edinburgh Handedness Inventory, was added to the Outcomes and End Points; Motor Function domain; subdomain section as Exploratory.

April 2024 Revisions

- The Huntington's Disease CDE Highlight Summary Document was updated to include the additions of the following instruments:
 - The Beck Depression Inventory II (BDI II) Notice of Copyright (NOC) was added to the Outcomes and End Points; Emotional/Behavioral domain; subdomain section as Supplemental.
 - The Berg Balance Scale (BBS) NOC was added to the Outcomes and End Points; Motor Function domain; subdomain as Supplemental – Highly Recommended.
 - The HD-PRO-TRIAD NOC was added to the Outcomes and End Points; Quality of Life/ Patient Reported Outcome domain; subdomain section as Supplemental.
- Huntington's Disease CDE Start-Up Resource Listing Document was updated to include:
 - The Berg Balance Scale (BBS) NOC and link to the BBS NOC on the website was added to the Supplemental – Highly Recommended Motor Function Instruments.
 - The following CDEs were added in the Outcome and End Points; Motor Function Domain/Subdomain:
 - C14693 Berg Balance Scale (BBS) - sit stand scale
 - C14694 Berg Balance Scale (BBS) - unsupport stand scale
 - C14695 Berg Balance Scale (BBS) - unsupport sit scale
 - C14696 Berg Balance Scale (BBS) - stand sit scale
 - C14697 Berg Balance Scale (BBS) - transfer scale

- C14698 Berg Balance Scale (BBS) - unsupport stand closed eyes scale
- C14699 Berg Balance Scale (BBS) - unsupport feet together scale
- C14700 Berg Balance Scale (BBS) - reach forward scale
- C14701 Berg Balance Scale (BBS) - retrieve floor object scale
- C14702 Berg Balance Scale (BBS) - turn head scale
- C14703 Berg Balance Scale (BBS) - turn around scale
- C14704 Berg Balance Scale (BBS) - alternate foot step up scale
- C14705 Berg Balance Scale (BBS) - unsupport stand front foot scale
- C17394 Berg Balance Scale (BBS) - stand one leg scale
- C14706 Berg Balance Scale (BBS) - scale total score

January 2024 Revisions

- Question 1 under the Birthweight section on CRF F1211 History of Early Exposure to Huntington's Disease CRF was revised from: "Were you told by a doctor or one of your parents that you were born premature?" to: "Were you told by a doctor or one of your family (e.g., parents, siblings, uncles, aunts) that you were born premature?"
- The Beck Depression Inventory II (BDI II) Notice of Copyright (NOC) was added to the Huntington's Disease (HD) data standards webpage in the Outcomes and End Points; Emotional/Behavioral domain; subdomain. The HD Oversight Committee recommended this NOC as Supplemental.
- The Berg Balance Scale (BBS) NOC was added to the Huntington's Disease (HD) data standards webpage in the Outcomes and End Points; Motor Function domain; subdomain. The HD Oversight Committee recommended this NOC as Supplemental – Highly Recommended.

September 2023 Revisions

- The HD-PRO-TRIAD Notice of Copyright (NOC) was added to the Huntington's Disease (HD) data standards webpage in the Outcomes and End Points; Quality of Life/Patient Reported Outcomes domain; subdomain. The HD Oversight Committee recommended this NOC as Supplemental.

June 2021 Revisions

- The following instrument classifications were updated:
 - Quality of Life in Neurological Disorders (Neuro-QOL): Supplemental to Supplemental-Highly Recommended
 - HDQLIFE: Supplemental to Supplemental-Highly Recommended
 - EuroQoL-5 Dimension Questionnaire (EQ-5D): Exploratory to Supplemental
 - Unified Huntington's Disease Rating Scale (UHDRS): Functional Assessment Checklist and Independence Scale both changed from Supplemental to Core

- Hospital Anxiety and Depression Scale (HADS): Supplemental to Supplemental-Highly Recommended
- Montreal Cognitive Assessment (MoCA): Supplemental to Supplemental-Highly Recommended
- The title of the Trail Making A and B Test was revised to Trail Making Test
- The Timed Up and Go instrument was moved from the Outcomes and Endpoint;Cognitive Domain;Subdomain to the Outcomes and Endpoints; Motor Function Domain;Subdomain

January 2020 Revisions

- General Core CRF updated to replace 'Gender' question with 'Sex assigned at birth' and 'Gender identity'.
- Two new CDEs added to CRF: C58676 (Sex assigned at birth) and C58677 (Gender identity). C00035 has been removed
- Start-Up document updated to reflect these changes.

June 2018 Revisions

- Start-up Resource Listing – corrected errors to reflect correct CDE classifications
 - Deleted Core CDEs for HD Studies: Race/Ethnicity expanded category (C00031) and Huntington's disease risk grade (C14939)

Domain;Subdomain	CDE Name	CDE ID
Participant Characteristics; Demographics	Race/Ethnicity expanded category	C00031
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Cytosine adenine guanine repeats information source type	C17745
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Molecular study lab name	C17746
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Cytosine Adenine Guanine repeats information source other text	C19061
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Huntington's disease risk grade	C14939
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Cytosine adenine guanine repeat results provider type	C17747

Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Cytosine adenine guanine repeat results provider other text	C19062
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- Added to Supplemental-Highly Recommended CDEs for HD Studies:
- Updated links for instruments
- Highlight Summary Document
 - Added all classification options to document. If there are not recommendations for a particular classification, "None" was stated.
 - The following corrections were made and domain;subdomain names were Quality checked:

Domain; Subdomain	Revision
Participant Characteristics; Demographics	Added General Core CRF to the Core and Supplemental-Highly Recommended Classification. Added Demographics to the Supplemental-Highly Recommended Classification.
Participant History and Family History; Epidemiology / Environmental History	Deleted Subgroup Summary listing. Listed the Risk Factor Questionnaire (RFQ) - All instrument separately from the Smoking and Tobacco subset.
Assessments and Examinations; Laboratory Tests and Biospecimens/ Biomarkers	Added DNA Elements- Information from the Laboratory, DNA Elements- Information from the Study Investigator DNA Elements- Participant/Subject Information to the Supplemental-Highly Recommended Classification. Deleted DNA Elements- Information from the Study Investigator DNA Elements- Participant/Subject Information from the Supplemental Classification.
Assessments and Examinations; Other Clinical Data	Added Neuropathology Data Form to the Core Classification. Changed "Other" to "Supplemental"
Outcomes and Endpoints; Emotional / Behavioral	Deleted Subgroup Summary listing.
Outcomes and Endpoints; Cognitive	Deleted "Speeded" before Symbol Digit Modality.
Outcomes and Endpoints; Functional Outcomes	Deleted Subgroup Summary listing.

Domain; Subdomain	Revision
	Added Sickness Impact Profile (SIP) to the Exploratory Classification.
Outcomes and Endpoints; Quality of Life	Moved EuroQoL-5 Dimension Questionnaire from the Supplemental to Exploratory Classification. Deleted Sickness Impact Profile (SIP) from the Exploratory Classification.

- Revisions were made to correct errors in CDE Classification:

CDE ID	CDE Name	CRF Module	Previous Classification	Corrected Classification
C00031	Race expanded category	Demographics (F1207)	Core	Supplemental-Highly Recommended
C14936	Cytosine adenine guanine repeats larger allele number	DNA Elements - Information from the Laboratory (F1228)	Core	Supplemental-Highly Recommended
C14937	Cytosine adenine guanine repeats smaller allele number	DNA Elements - Information from the Laboratory (F1228)	Core	Supplemental-Highly Recommended
C17745	Cytosine adenine guanine repeats information source type	DNA Elements - Information from the Study Investigator (F1229)	Core	Supplemental-Highly Recommended
C19061	Cytosine adenine guanine repeats information source other text	DNA Elements - Information from the Study Investigator (F1229)	Core	Supplemental-Highly Recommended
C17747	Cytosine adenine guanine repeat results provider type	DNA Elements - Participant/Subject Information (F1230)	Core	Supplemental-Highly Recommended
C19062	Cytosine adenine guanine repeat results provider other text	DNA Elements - Participant/Subject Information (F1230)	Core	Supplemental-Highly Recommended
All	All	Stroop Test (F1255/F2370)	Supplemental-Highly Recommended	Supplemental
All	All	Trail Making Test (F1949/F2546)	Supplemental	Supplemental-Highly Recommended
All	All	Euro-QoL (F1326/2731)	Supplemental	Exploratory

- Revisions were made to correct errors in NOCs:

F Number	Instrument Name	Description of Change
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F1226	Unified Huntington's Disease Rating Scale (UHDRS)	Modified language in classification section to clarify that Motor and Total Functional Capacity are Core and that the Functional Assessment Checklist and Independence Scale are Supplemental.
F1255/ F2370	Stroop Test	Classification was corrected from Supplemental-Highly Recommended to Supplemental to match 2016 OC recommendations. This change was made in the classification description in the NOC and the associated CDEs.
F1278	Godin Leisure-Time Exercise Questionnaire	Added "Huntington's Disease (HD)" to the classification section.
F1508	The Medical Research Council Physical Activity Assessment	Added "Huntington's Disease (HD)" to the classification section.
F1243	Circle Tracing	Added "Huntington's Disease (HD)" to the classification section.
F1248	Mental Rotation	Added "Huntington's Disease (HD)" to the classification section.
F1322	PROMIS Pain Interference Short Form	Added "Huntington's Disease (HD)" to the classification section under Supplemental.

- CRFs - Updated the instructions on the following CRFs to reflect the correct CDE classifications.
 - Demographics (F1207)
 - revised instructions and asterisks to reflect that C00031 Race expanded category is Supplemental-Highly Recommended
 - DNA Elements - Information from the Laboratory (F1228)
 - revised instructions and add asterisks to indicate that C14936 Cytosine adenine guanine repeats larger allele number and C14937 Cytosine adenine guanine repeats smaller allele number are Supplemental-Highly Recommended
 - DNA Elements - Information from the Study Investigator (F1229)
 - revised instructions and asterisks to reflect that all CDEs are Supplemental-Highly Recommended
 - DNA Elements - Participant/Subject Information (F1230)
 - revised instructions and asterisks to reflect that all CDEs are Supplemental-Highly Recommended

December 2016 Revisions

- The Huntington's Disease Dysphasia Scale was added to the recommendations as Exploratory
- Family History CRF was updated to add the following items:

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Family History (F1209)	4.0	3.0	Major	Modified CDEs	<ul style="list-style-type: none"> - New CDE ID added: C22864 - New Permissible Values added: C14943, C14945

- The following individual CDE classification changes were made:

Individual CDE Name	Previous Classification	Current Classification
Education Year Count	Core	Supplemental–Highly Recommended
Race expanded category	Core	Supplemental–Highly Recommended
Cytosine adenine guanine repeats larger allele number	Core	Supplemental–Highly Recommended
Cytosine adenine guanine repeats smaller allele number	Core	Supplemental–Highly Recommended
Cytosine adenine guanine repeat test indicator	Core	Supplemental–Highly Recommended
Huntington’s disease risk grade	Core	Supplemental–Highly Recommended
Cytosine adenine guanine repeat known indicator	Core	Supplemental–Highly Recommended

- The following instrument classification changes were made:

Instrument Name	Previous Classification	Current Classification
Motor UHDRS	For diagnosed patients only	Core
Total Functional Capacity as part of the UHDRS	Supplemental-Highly Recommended	Core
Self-Paced Tapping	Supplemental-Highly Recommended	Supplemental
Speeded Tapping Test	Supplemental-Highly Recommended	Supplemental
Stroop Test	Supplemental-Highly Recommended	Supplemental
Problem Behaviors Assessment-Short	Core	Supplemental
UHDRS Functional Assessment Checklist	Supplemental-Highly Recommended	Supplemental
UHDRS Independence Scale	Supplemental-Highly Recommended	Supplemental

March 2015 Revisions

- Fixed spelling errors in HD Acknowledgement section.

February 2015 Revisions

No updates.

January 2015 Revisions

No updates.

November 2014 Revisions

- Classification changes to NOCS in HD: Unified Huntington's Disease Rating Scale (UHDRS), Symbol Digit Modalities Test, Stroop Test, Self-Paced Tapping and Speeded Tapping Test were changed from Core to supplemental-Highly Recommended.

September 2014 Revisions

- Corrections made to footnotes of QOL Neurological disorders to include HD.

August 2014 Revisions

- General Core CRF posted to HD webpage.
- Links to NeuroQOL, NIH Toolbox, and PROMIS added to HD webpage.

July 2014 Revisions

No updates

June 2014 Revisions

No updates.

May 2014 Revisions

- HD Start-Up Resource and Highlight documents were converted to 508 Compliance PDFs.

April 2014 Revisions

No updates.

March 2014 Revisions

No updates.

February 2014 Revisions

No updates.

January 2014 Revisions

No updates.

December 2013 Revisions

Updated highlight summary and start-up resource document for HD.

November 2013 Revisions

Highlight document added for HD.

July 2013 Revisions

Overview

There have been Major changes to the content and structure of the Huntington 's disease CDE materials in Version 2.0 compared to Version 1.1, including the following:

Form Status Changes

New Forms:

Food Frequency Questionnaire (FFQ)

PD DOC Mini Environmental Risk Questionnaire (PD-DOC MERQ)

The Medical Research Council Physical Activity Assessment

NIH Diet History Questionnaire (DHQ)

World Health Organization Disability Assessment Schedule (WHODAS)

The Ohio State University TBI Identification Method Short Form (OSU TBI Form)

Timed Up and Go (TUG)

The PROMIS Pain Interference Short Form

Sickness Impact Profile (SIP)

EuroQol-5 Dimension Questionnaire (EQ-5D)

Huntington's Disease Health-related Quality of Life Questionnaire (HDQOL)

The NIH Toolbox

Quality of Life in Neurological Disorders (Neuro-QOL)

Updated Forms:

Notice of Copyright Created (NOC) (Will replace previously existing forms)

Godin Leisure-Time Exercise Questionnaire

Risk Factor Questionnaire All (RFQ)

Risk Factor Questionnaire-Epidemiology of Dystonia (RFQ)

Risk Factor Questionnaire-Female Health History (RFQ)

Risk Factor Questionnaire- NSAIDS and Calcium Channel Blockers (CCB)(RFQ)

Risk Factor Questionnaire-- Occupation and Employment Status (RFQ)

Risk Factor Questionnaire-Residential History (RFQ)

Risk Factor Questionnaire-Toxicants (RFQ)

Risk Factor Questionnaire-Height and Weight (RFQ-U)

Risk Factor Questionnaire-Pesticides (Home) (RFQ-U)

Risk Factor Questionnaire-Pesticides (Work) (RFQ-U)

Risk Factor Questionnaire-Smoking and Tobacco (RFQ-U)

Apathy Evaluation Scale (AES)

Apathy Scale (AS)

Cambridge Brain Repair Centre (BRC) HD Sleep Questionnaire

Concise Health Risk Tracking (CHRT)

Florida Obsessive Compulsive Inventory (FOCI)

Frontal Systems Behavioral Scale (FrSBe)

Hospital Anxiety and Depression Scale (HADS)

Irritability Scale

Padua Inventory - Washington State University Revision

Pittsburgh Sleep Quality Index (PSQI)

Problem Behaviours Assessment HD - Short Version (PBA-s)

Scale for Outcomes in PD-Sleep (SCOPA-Sleep)

Circle Tracing

Cued Movement Sequencing

Delis Kaplan Executive Functioning System (DKEFS) - Trail Making Tests - Parts A&B

Emotional Recognition

Hopkins Verbal Learning Test (HVLT)

Map Search Task

Mental Rotation

Montreal Cognitive Assessment (MoCA)

Phonemic Verbal Fluency Test

Self-Paced Tapping

Simple and Two-Choice Reaction Time

Speeded Tapping Test

Spot the Change

Stroop Test

Written Verbal Fluency Test

Unified Huntington's Disease Rating Scale (UHDRS)

36-Item Short Form Health Survey (SF-36)

Removed Forms:

None

Detailed Form Revisions:

Additional specific changes to the CRF modules are detailed in the table included on the subsequent page.

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Food Frequency Questionnaire (FFQ)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
PD DOC Mini Environmental Risk Questionnaire (PD-DOC MERQ)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
The Medical Research Council Physical Activity Assessment	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
NIH Diet History Questionnaire (DHQ)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
World Health Organization Disability Assessment Schedule (WHODAS)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
The Ohio State University TBI Identification Method Short Form (OSU TBI Form)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Timed Up and Go (TUG)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
The PROMIS Pain Interference Short Form	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Sickness Impact Profile (SIP)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
EuroQol-5 Dimension Questionnaire (EQ-5D)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Huntington's Disease Health-related Quality of Life Questionnaire (HDQOL)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
The NIH Toolbox	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Quality of Life in Neurological Disorders (Neuro-QOL)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Godin Leisure- Time Exercise Questionnaire	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire All (RFQ)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire- Epidemiology of Dystonia (RFQ)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire- Female Health History (RFQ)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Risk Factor Questionnaire- NSAIDS and Calcium Channel Blockers (CCB)(RFQ)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire- - Occupation and Employment Status (RFQ)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire- Residential History (RFQ)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire- Toxicants (RFQ)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire- Height and Weight (RFQ- U)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Risk Factor Questionnaire- Pesticides (Home) (RFQ- U)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire- Pesticides (Work) (RFQ- U)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire- Smoking and Tobacco (RFQ- U)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Apathy Evaluation Scale (AES)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Apathy Scale (AS)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Cambridge Brain Repair Centre (BRC) HD Sleep Questionnaire	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Concise Health Risk Tracking (CHRT)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Florida Obsessive Compulsive Inventory (FOCI)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Frontal Systems Behavioral Scale (FrSBe)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Hospital Anxiety and Depression Scale (HADS)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Irritability Scale	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Padua Inventory - Washington State University Revision	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Pittsburgh Sleep Quality Index (PSQI)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Problem Behaviours Assessment HD - Short Version (PBA- s)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Scale for Outcomes in PD-Sleep (SCOPA-Sleep)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Circle Tracing	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Cued Movement Sequencing	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Delis Kaplan Executive Functioning System (DKEFS) - Trail Making Tests - Parts A&B	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Emotional Recognition	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Hopkins Verbal Learning Test (HVLTL)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Map Search Task	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Mental Rotation	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Montreal Cognitive Assessment (MoCA)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Phonemic Verbal Fluency Test	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Self-Paced Tapping	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Simple and Two-Choice Reaction Time	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Speeded Tapping Test	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Spot the Change	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Stroop Test	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Written Verbal Fluency Test	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Unified Huntington's Disease Rating Scale (UHDRS)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
36-Item Short Form Health Survey (SF-36)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

October 2012 Revisions

Overview

There have been changes to the content and structure of the Huntington's disease (HD) CDE materials in Version 1.1 compared to Version 1.0, including the following:

- Every attempt was made to remove duplication and redundancy in the HD CDEs;
- The HD CDEs were harmonized with other large national and international standardization initiatives and efforts [e.g., International Conference on Harmonization (ICH), Logical Observation Identifiers Names and Codes (LOINC), International Classification of Diseases (ICD), Unified Code for Units of Measure (UCUM)]
- The majority of element names and definitions were improved.
- The permissible values and references of some elements were revised; and
- The version numbers of all forms (excluding standardized scales/instruments) were updated.
- Several guideline documents were reorganized and consolidated to make it easier to understand which standardized instruments/scales are recommended, though the recommendations themselves remained unchanged.
- Some of the forms and guideline documents were re-categorized under a different domain or subdomain to be consistent with other NINDS CDEs.

- The corresponding data dictionaries (i.e., CDE Detailed Report) have been modified in accordance with the form changes.

Form Status Changes

New Forms:

- Social Status

Updated Forms:

- CSF Collection and Processing Guidelines (formerly "CSF Collection and Processing" CRF)
- Demographics
- Family History (formerly "Family History at Baseline" CRF)
- History of Early Exposure to HD
- Infection History
- Medical History of Huntington's disease (formerly "Medical History" CRF)
- Magnetic Resonance (MR) Localization Imaging
- Neuropathology Data Form
- Other Biological Specimen Collections Guidelines (formerly "Other Biological Specimen" CRF)
- Urine Collection and Processing Guidelines (formerly "Urine Collection and Processing" CRF)
- Solid Tissue Collection Guidelines (formerly "Solid Tissue Collection" CRF)

Removed Forms:

- None

Detailed Form Revisions:

Additional specific changes to the CRF modules are detailed in the table included on the subsequent page.

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
All	1.1	1.0	Minor	Modified CDEs	Nearly all CDE names and definitions were updated to achieve greater consistency across all NINDS CDEs and for clarity

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Various	1.1	1.0	Minor	Deleted CDEs	The following types of CDEs were deleted: CDEs redundant with other CDEs; CDEs specifying unit; and CDEs specifying an "other, specify" response
Various	1.1	1.0	Minor	Modified CDEs	For a number of CDEs, "Unknown" was added to the permissible value set and in some cases "Unknown" replaced "Unknown/Don't Know"
Various	1.1	1.0	Minor	Modified Forms	Instructions were updated to include additional details.
CSF Collection and Processing Guidelines	1.1	1.0	Minor	Modified Form	Added a note explaining that the document is a guidelines document and not associated with CDEs
Demographics	1.1	1.0	Minor	Deleted CDEs	The following CDE was removed: Education Level (CDE moved to the new Social Status form)
Demographics	1.1	1.0	Minor	Modified Form	The CDE Phenotypic sex type was renamed "Gender" Permissible values did not change.
Family History	1.1	1.0	Minor	Modified Form	The form title was changed from "Family History at Baseline" to "Family History; minor formatting changes were made.
Medical History of Huntington's disease	1.1	1.0	Minor	Modified Form	The form title was changed from "Medical History" to "Medical History of Huntington's disease"; minor formatting changes were made.
MR Localization Imaging	1.1	1.0	Minor	Modified CDEs	Permissible values were modified for the following CDE: Imaging matrix size value

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
MR Localization Imaging	1.1	1.0	Minor	Modified Form	The CDE Acquisition Matrix was renamed "In-Plane Resolution Matrix"; the CDE Matrix was renamed "Matrix Size"; PVs renamed for Sequence type
Neuropathology Data Form	1.1	1.0	Minor	Modified CDEs	Permissible values were modified for the following CDE: "Gender type"
Neuropathology Data Form	1.1	1.0	Minor	Modified CDEs	Permissible values were modified for several CDEs from "Yes" / "No" to "Present" / "Absent."
Neuropathology Data Form	1.1	1.0	Minor	Modified CDEs	Final clinicopathological diagnosis type PVs were modified.
Neuropathology Data Form	1.1	1.0	Minor	Modified Form	Minor formatting changes
Other Biological Specimens Collection Guidelines	1.1	1.0	Minor	Modified Form	Added a note explaining that the document is a guidelines document and not associated with CDEs
Urine Collection and Processing Guidelines	1.1	1.0	Minor	Modified Form	Added a note explaining that the document is a guidelines document and not associated with CDEs
Solid Tissue Collection Guidelines	1.1	1.0	Minor	Modified Form	Added a note explaining that the document is a guidelines document and not associated with CDEs
Social Status	1.0	N/A	Minor	New Form	Form created using elements (e.g., Education Level) originally included on the Demographics form