



Huntington's Disease (HD) CDE Highlight Summary Document

NIH Resources

The NINDS also strongly encourages researchers to use these NIH developed materials for NINDS-sponsored research, when appropriate. Utilization of these resources will enable greater consistency for NINDS-sponsored research studies. These tools are free of charge.

- National Institutes of Health (NIH) Toolbox
- Quality of Life in Neurological Disorders (Neuro-QOL)
- Patient-Reported Outcomes Measurement Information System (PROMIS)

Suicidal Ideation

Investigators should review the FDA's ["Guidance for Industry: Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials"](#) for the most up-to-date information about suicidal ideation and behavior. One scale that FDA suggests is the Columbia Suicide Severity Rating Scale (C-SSRS) (available at [Columbia Suicide Severity Rating Scale Website](#)).

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Domain; Subdomain	Recommendations
Huntington’s Disease	<p>These instruments and elements are recommended for use in all Huntington Disease studies:</p> <p>Core instruments: Unified Huntington’s Disease Rating Scale (UHDRS) Motor and Total Functional Capacity</p> <p>Supplemental – Highly Recommended Cognitive Instruments: Choose one of the following: Symbol Digit Modality Test and Trail Making A and B</p> <p>Supplemental – Highly Recommended Motor Function Instruments: None</p> <p>Core and Supplemental-Highly Recommended elements: See Start-Up Resource Listing document (Huntington's Disease Start-Up Resource Listing)</p>
Participant Characteristics; Demographics	<p>Core: General Core, Demographics</p> <p>Supplemental-Highly Recommended: General Core, Demographics</p> <p>Supplemental: Demographics</p> <p>Exploratory: None</p>

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Domain; Subdomain	Recommendations
Participant Characteristics; Social Status	<p>Core: None</p> <p>Supplemental-Highly Recommended: None</p> <p>Supplemental: Social Status</p> <p>Exploratory: None</p>
Participant History and Family History; General Health History	<p>Core: None</p> <p>Supplemental-Highly Recommended: None</p> <p>Supplemental: Family History</p> <p>Exploratory: None</p>
Participant History and Family History; Epidemiology / Environmental History	<p>Core: None</p> <p>Supplemental-Highly Recommended: None</p> <p>Supplemental: Food Frequency Questionnaire (FFQ), Godlin Leisure- Time Exercise Questionnaire, History of Early Exposure to Huntington’s disease, Infection History, Non-prescribed Drug Use Questionnaire, PD DOC Mini Environmental Risk Questionnaire for Parkinson’s Disease Patients Baseline (PD DOC MERQ-PD-B), Risk Factor Questionnaire (RFQ)- All, RFQ- Epidemiology of Dystonia, RFQ- NSAIDS and Calcium Channel Blockers (CCB), RFQ- Occupation and Employment Status, RFQ- Female Health History, RFQ- Residential History, RFQ- Toxicants, RFQ-U Height and Weight, RFQ- U Pesticides (Home), RFQ-U Pesticides (Work), RFQ-U Smoking and Tobacco, The Medical Research Council Physical Activity Assessment, National Institutes of Health Diet History Questionnaire (DHQ), World Health Organization Disability Assessment Schedule (WHODAS)</p> <p>Exploratory: None</p>
Disease / Injury Related Event; History of Disease / Injury Event	<p>Core: None</p> <p>Supplemental-Highly Recommended: None</p> <p>Supplemental: Medical History of Huntington’s Disease, Ohio State University TBI Identification Method Short Form</p> <p>Exploratory: None</p>

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Domain; Subdomain	Recommendations
Assessments and Examinations; Laboratory Tests and Biospecimens/ Biomarkers	<p>Core: None</p> <p>Supplemental-Highly Recommended: DNA Elements- Information from the Laboratory, DNA Elements- Information from the Study Investigator, DNA Elements- Participant/Subject Information</p> <p>Supplemental: Blood Collection and Processing Guidelines, CSF Collection and Processing Guidelines, DNA Elements- Information from the Laboratory, NINDS Repository Huntington’s Disease Data Elements, Other Biological Specimens Collection Guidelines, Solid Tissue Collection Guidelines, Urine Collection and Processing Guidelines</p> <p>Exploratory: None</p>
Assessments and Examinations; Imaging Diagnostics	<p>Core: None</p> <p>Supplemental-Highly Recommended: None</p> <p>Supplemental: Magnetic Resonance (MR) Localization Imaging</p> <p>Exploratory: None</p>
Assessments and Examinations; Other Clinical Data	<p>Core: Neuropathology Data Form</p> <p>Supplemental-Highly Recommended: None</p> <p>Supplemental: HD Brain Processing Guidelines, Neuropathology Data Form, Preparation of Brains for Stereological Evaluation Guidelines</p> <p>Exploratory: None</p>
Outcomes and Endpoints; Summary of All Outcome Recommendations	<p>Core: None</p> <p>Supplemental-Highly Recommended: None</p> <p>Supplemental: HD CDE Instrument Recommendations by Domain and Classification</p> <p>Exploratory: None</p>

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Domain; Subdomain	Recommendations
Outcomes and Endpoints; Emotional / Behavioral	<p>Core: None</p> <p>Supplemental-Highly Recommended: None</p> <p>Supplemental: Apathy Evaluation Scale, 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)</p> <p>Exploratory: None</p>
Outcomes and Endpoints; Cognitive	<p>Core: None</p> <p>Supplemental-Highly Recommended (one of the following): Symbol Digit Modality Test, Trail Making A and B</p> <p>Supplemental: Written Verbal Fluency Test, Circle Tracing, Delis Kaplan Executive Functioning System (DKEFS)- Trail Making Tests, Cognitive Summary Table and Guidelines for CDE Use, Hopkins Verbal Learning Test- Revised (HVLt-R), Cued Movement Sequencing, Emotional Recognition, Montreal Cognitive Assessment (MoCA), Map Search Task, Mental Rotation, Phonemic Verbal Fluency (PVF), Self Paced Tapping, Speeded Tapping Test Simple and Two- Choice Reaction Time, Spot the Change, Stroop Test, Timed Up and Go</p> <p>Exploratory: None</p>
Outcomes and Endpoints; Functional Outcomes	<p>Core: None</p> <p>Supplemental-Highly Recommended: None</p> <p>Supplemental: PROMIS Pain Interference Short Form, NIH Toolbox</p> <p>Exploratory: Sickness Impact Profile (SIP)</p>
Outcomes and Endpoints; Motor Function	<p>Core: Unified Huntington’s Disease Rating Scale (UHDRS) Motor and Total Functional Capacity</p> <p>Supplemental-Highly Recommended: None</p> <p>Supplemental: UHDRS (Huntington Study Group, 1996) Independence Scales and Functional Assessment Scale</p> <p>Exploratory: The Huntington's Disease Dysphagia Scale</p>

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Domain; Subdomain	Recommendations
Outcomes and Endpoints; Quality of Life	<p>Core: None</p> <p>Supplemental-Highly Recommended: None</p> <p>Supplemental: 36-Item Short Form Health Survey (SF-36), National Institutes of Health (NIH) Toolbox, Huntington’s Disease Health Related Quality of Life (HDQoL), HDQLife, Quality of Life in Neurological Disorders (Neuro-QOL)</p> <p>Exploratory: EuroQoL-5 Dimension Questionnaire</p>