

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](#)).

Domain; Subdomain	Recommendations
Huntington’s Disease	<p>These instruments and elements are recommended for use in all Huntington Disease studies:</p> <p>Core instruments: Problem Behaviors Assessment-Short, Unified Huntington’s Disease Rating Scale (UHDRS)</p> <p>Supplemental – Highly Recommended Cognitive Instruments: Choose one of the following: Self-Paced Tapping, Speeded Tapping Test, Symbol Digit Modality Test, Trail Making A and B or Stroop Test</p> <p>Supplemental – Highly Recommended Motor Function Instruments (from the UHDRS; diagnosed patients only): Functional Assessment Checklist, Independence Scale, Total Functional Capacity as part of the UHDRS</p> <p>Core elements: See Start-Up Resource Listing document (Huntington's Disease Start-Up Resource Listing)</p>
Participant / Subject Characteristics; Demographics	<p>Core: Demographics</p> <p>Supplemental: Demographics</p>

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Domain; Subdomain	Recommendations
Participant / Subject Characteristics; Social Status	<p>Core: Social Status</p> <p>Supplemental: Social Status</p>
Participant / Subject History and Family History; General Health History	<p>Core: None</p> <p>Supplemental: Family History</p>
Participant / Subject History and Family History; Epidemiology / Environmental History	<p>Core: None</p> <p>Supplemental: Epi/Environment Guidelines for CDE Use, 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), 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 Risk Factor Questionnaire (RFQ)- All, The Medical Research Council Physical Activity Assessment, The National Institutes of Health Diet History Questionnaire, World Health Organization Disability Assessment Schedule (WHODAS)</p>
Disease / Injury Related Event; History of Disease / Injury Event	<p>Core: None</p> <p>Supplemental: Medical History of Huntington’s Disease, Ohio State University TBI Identification Method Short Form</p>
Assessments / Examinations / Laboratory Tests and Biospecimens; Biomarkers	<p>Core: None</p> <p>Supplemental: Blood Collection and Processing Guidelines, CSF Collection and Processing Guidelines, DNA Elements- Information from the Laboratory, DNA Elements- Information from the Study Investigator DNA Elements- Participant/Subject Information, NINDS Repository Huntington’s Disease Data Elements, Other Biological Specimens Collection Guidelines, Solid Tissue Collection Guidelines, Urine Collection and Processing Guidelines</p>

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Assessments / Examinations; Imaging Diagnostics	<p>Core: None</p> <p>Supplemental: Magnetic Resonance (MR) Localization Imaging</p>
Assessments / Examinations; Other Clinical Data	<p>Core: None</p> <p>Supplemental: HD Brain Processing Guidelines, Neuropathology Data Form, Preparation of Brains for Stereological Evaluation Guidelines</p>
Outcomes and Endpoints; Summary of All Outcome Recommendations	<p>Core: None</p> <p>Supplemental: HD CDE Instrument Recommendations by Domain and Classification</p>
Outcomes and Endpoints; Behavior / Psychiatry	<p>Core: Problem Behaviours Assessment HD- Short Version (PBA-s)</p> <p>Supplemental: Apathy Evaluation Scale, Apathy Scale (AS), Behavior/Psychiatry Guidelines for CDE Use, 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), Scale for Outcomes in PD- Sleep (SCOPA-Sleep)</p>
Outcomes and Endpoints; Cognitive Status	<p>Core: None</p> <p>Supplemental – Highly Recommended (one of the following): Speeded Tapping Test, Stroop Test, Symbol Digit Modality Test, Trail Making A and B, Self Paced Tapping</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), Simple and Two- Choice Reaction Time, Spot the Change, Timed Up and Go</p>
Outcomes and Endpoints; Functional Outcomes / Patient Reported Outcomes	<p>Core: None</p> <p>Supplemental: Functional Outcomes/Patient Reported Outcomes Guidelines for CDE Use, PROMIS Pain Interference Short Form, NIH Toolbox</p>

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Domain; Subdomain	Recommendations
Outcomes and Endpoints; Motor Function	<p>Core: Unified Huntington’s Disease Rating Scale (UHDRS)</p> <p>Supplemental – Highly Recommended: Three measures in UHDRS (Huntington Study Group, 1996), specifically: 1) Total Functional Capacity (TFC); 2) Independence Scale; and 3) Functional Assessment Scale</p> <p>Supplemental: None</p>
Outcomes and Endpoints; Quality of Life	<p>Core: None</p> <p>Supplemental: 36-Item Short Form Health Survey (SF-36), EuroQoL-5 Dimension Questionnaire, National Institutes of Health (NIH) Toolbox, Huntington’s Disease Health Related Quality of Life (HDQoL), Quality of Life in Neurological Disorders (Neuro-QOL)</p>