

Parkinson's Disease (PD) 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](#)).

Subgroup	Recommendations
Parkinson's disease	<p>These instruments and elements are recommended for use in all Parkinson's disease studies:</p> <p>Core instruments: Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS), Unified Parkinson's Disease Rating Scale (UPDRS): Parts 1-4 (<i>General and Motor</i>) and Parkinson's Disease Quality of Life Scale (PDQUALIF), Guidance for Industry: Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials</p> <p>Core elements: See Start-Up Resource Listing document (PD Start-Up Resource Listing)</p>
NIH Resources	<p>Core: None</p> <p>Supplemental: National Institutes of Health (NIH) Toolbox; Patient-Reported Outcomes Measurement Information System (PROMIS); Quality of Life in Neurological Disorders (Neuro-QOL)</p>
Motor Function	<p>Core: Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS) <u>OR</u> Unified Parkinson's Disease Rating Scale (UPDRS): Parts 1-4</p> <p>Supplemental: PD Medical History, PD Medication log, PD Non-medication log, Diagnostic Criteria for Parkinson's Disease, UK PD Brain Bank Criteria, PROMIS, NIH Toolbox</p>
Cognitive	<p>Core: None.</p> <p>Supplemental: Global cognitive instruments (severity, longitudinal, diagnostic): Mattis Dementia Rating</p>

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	<p>Scale (MDRS), Alzheimer's Disease Assessment Scale (ADAS-Cog), Cambridge Cognitive Assessment – Revised (CAMCOG-R), Alzheimer's Disease Cooperative Study – Clinical Global Impression of Change (ADCS-CGIC), Mini-Mental State Examination (MMSE), Parkinson's Disease – Cognitive Rating Scale (PDCRS), Scales for Outcomes in Parkinson's disease – Cognition (SCOPA-Cog)</p> <p>Screening instruments: Addenbrooke's Cognitive Examination – Revised (ACE-R), Mini-Mental State Examination (MMSE), Montreal Cognitive Assessment (MoCA), Parkinson Neuropsychometric Dementia Assessment (PANDA), Parkinson's Disease – Cognitive Rating Scale (PDCRS), Scales for Outcomes in Parkinson's disease - Cognition (SCOPA-Cog), Short Portable Mental Status Questionnaire (SPMSQ)</p>								
Quality of life	<p>Core: None.</p> <p>Highly recommended (select from one of the following): EuroQol 5-D (EQ-5D), Parkinson's disease questionnaire-39 item version (PDQ-39), Parkinson's Disease Quality of Life Scale (PDQUALIF), Parkinson's disease Quality of Life Questionnaire (PDQL), SF-36 Health Survey</p> <p>Recommended: Belastungsfragebogen für Parkinson – Patienten Kurzversion (BELA-p-k), Quality of Life in Neurological Disorders (Neuro-QOL), Nottingham Health Profile (NHP), Parkinson's Impact Scale (PIMS), Questions on Life Satisfaction – Movement Disorder and Deep Brain Stimulation Modules (QLS-MD and QLS-DBS), Scales for Outcomes in Parkinson's Disease – Psychosocial Questionnaire (SCOPA-PS), Schedule for the Evaluation of Individual Quality of Life (SEIQoL), Schedule for the Evaluation of Individual Quality of Life – Direct Weighting (SEIQoL-DW), Sickness Impact Profile (SIP), Brief version of the World Health Organization Quality of Life Assessment – 100 (WHOQOL-BREF)</p>								
Psychiatric and Psychological Function	<p>Core: None.</p> <p>Supplemental:</p> <table border="0" data-bbox="440 1528 1507 1969"> <thead> <tr> <th data-bbox="440 1528 755 1560"><u>Disorder/Features</u></th> <th data-bbox="755 1528 1507 1560"><u>Data element or instrument</u></th> </tr> </thead> <tbody> <tr> <td data-bbox="440 1560 755 1717">Depression</td> <td data-bbox="755 1560 1507 1717">Hamilton Depression Rating Scale 17 item (HAM-D-17)*, Beck Depression Inventory (BDI-II), Geriatric Depression Scale (GDS) – 15 item, Montgomery-Asberg Depression Rating Scale (MADRS), Diagnostic and Statistical Manual of Mental Disorders (DSMIV-TR), Structured Clinical Interview for DSM-IV (SCID)</td> </tr> <tr> <td data-bbox="440 1717 755 1850">Anxiety</td> <td data-bbox="755 1717 1507 1850">Hamilton Anxiety Rating Scale (HARS)*, Hospital Anxiety and Depression Scale (HADS), Diagnostic and Statistical Manual of Mental Disorders (DSMIV-TR), Structured Clinical Interview for DSM-IV Axis I Disorders, Patient Edition (SCID-I/P)</td> </tr> <tr> <td data-bbox="440 1850 755 1969">Psychosis</td> <td data-bbox="755 1850 1507 1969">MDS-UPDRS Part I, Brief Psychiatric Rating Scale (BPRS), Schedule for Assessment of Positive Symptoms (SAPS)*, Diagnostic Criteria for psychosis in Parkinson's disease: report of an NINDS, NIMH work group</td> </tr> </tbody> </table>	<u>Disorder/Features</u>	<u>Data element or instrument</u>	Depression	Hamilton Depression Rating Scale 17 item (HAM-D-17)*, Beck Depression Inventory (BDI-II), Geriatric Depression Scale (GDS) – 15 item, Montgomery-Asberg Depression Rating Scale (MADRS), Diagnostic and Statistical Manual of Mental Disorders (DSMIV-TR), Structured Clinical Interview for DSM-IV (SCID)	Anxiety	Hamilton Anxiety Rating Scale (HARS)*, Hospital Anxiety and Depression Scale (HADS), Diagnostic and Statistical Manual of Mental Disorders (DSMIV-TR), Structured Clinical Interview for DSM-IV Axis I Disorders, Patient Edition (SCID-I/P)	Psychosis	MDS-UPDRS Part I, Brief Psychiatric Rating Scale (BPRS), Schedule for Assessment of Positive Symptoms (SAPS)*, Diagnostic Criteria for psychosis in Parkinson's disease: report of an NINDS, NIMH work group
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	<p>Apathy Apathy Scale (AS)*, Proposed Criteria for Diagnosis of the Syndrome of Apathy</p> <p>Impulse Control Gambling Symptom Assessment Scale (G-SAS), Pathological Gambling Adaptation of the Yale-Brown Obsessive Compulsive Scale, (PG-YBOCS), Questionnaire for Impulsive-Compulsive Behaviors in Parkinson's Disease (QUIP), South Oaks Gambling Screen (SOGS), Buying Questionnaire, Sexual Compulsivity Scale, Compulsive Eating Scale, DSM-IV-TR criteria for pathological or Problem gambling, McElroy criteria for compulsive buying, Voon criteria for compulsive sexual behavior, Modified DSM-IV-TR binge eating disorder proposed criteria, Structured Clinical Interview for Pathological Gambling</p> <p>Global Neuropsychiatric Neuropsychiatric Inventory (NPI)*, MDS-UPDRS Part I</p> <p>*These items are highly recommended for studies focused on specific disorder/psychiatric area (to allow comparison with previous studies)</p>																								
<p>Epidemiology /Environment</p>	<p>Core: None.</p> <p>Supplemental:</p> <table border="0"> <thead> <tr> <th data-bbox="472 1024 683 1052"><u>Disorder/Features</u></th> <th data-bbox="760 1024 1073 1052"><u>Data element or instrument</u></th> </tr> </thead> <tbody> <tr> <td data-bbox="472 1058 656 1085">Smoking/alcohol</td> <td data-bbox="760 1058 1198 1085">RFQ/Nurses' Health Study questionnaire</td> </tr> <tr> <td data-bbox="472 1092 688 1119">Vitals/body habitus</td> <td data-bbox="760 1092 1024 1119">RFQ (height and weight)</td> </tr> <tr> <td data-bbox="472 1125 703 1152">Occupational history</td> <td data-bbox="760 1125 1227 1152">Employment status (PhenX variable)*, RFQ</td> </tr> <tr> <td data-bbox="472 1159 602 1186">Head injury</td> <td data-bbox="760 1159 1154 1186">Ohio State University TBI short form</td> </tr> <tr> <td data-bbox="472 1192 678 1220">Residential history</td> <td data-bbox="760 1192 808 1220">RFQ</td> </tr> <tr> <td data-bbox="472 1226 691 1253">Dietary information</td> <td data-bbox="760 1226 1170 1253">Harvard FFQ, NHANES FFQ (alternate)</td> </tr> <tr> <td data-bbox="472 1260 647 1287">Physical activity</td> <td data-bbox="760 1260 808 1287">RFQ</td> </tr> <tr> <td data-bbox="472 1293 634 1320">Drugs of abuse</td> <td data-bbox="760 1293 1052 1320">Drug history questionnaire</td> </tr> <tr> <td data-bbox="472 1327 704 1354">Medication – all past</td> <td data-bbox="760 1327 943 1354">List and duration</td> </tr> <tr> <td data-bbox="472 1360 656 1388">Infection history</td> <td data-bbox="760 1360 1227 1388">Immunizations, pneumonia, CNS infections</td> </tr> <tr> <td data-bbox="472 1394 711 1421">NSAIDS, CCBs, Statins</td> <td data-bbox="760 1394 980 1421">PD-DOC MERQ, RFQ</td> </tr> </tbody> </table> <p>*These items highly recommended for studies where the exposure information may be used in analyses as co-variables to account for possible confounding</p>	<u>Disorder/Features</u>	<u>Data element or instrument</u>	Smoking/alcohol	RFQ/Nurses' Health Study questionnaire	Vitals/body habitus	RFQ (height and weight)	Occupational history	Employment status (PhenX variable)*, RFQ	Head injury	Ohio State University TBI short form	Residential history	RFQ	Dietary information	Harvard FFQ, NHANES FFQ (alternate)	Physical activity	RFQ	Drugs of abuse	Drug history questionnaire	Medication – all past	List and duration	Infection history	Immunizations, pneumonia, CNS infections	NSAIDS, CCBs, Statins	PD-DOC MERQ, RFQ
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<p>"Other" non-motor</p>	<p>Core: None.</p> <p>Supplemental:</p> <table border="0"> <thead> <tr> <th data-bbox="472 506 716 533"><u>Disorder/Features</u></th> <th data-bbox="764 506 1073 533"><u>Data element or instrument</u></th> </tr> </thead> <tbody> <tr> <td data-bbox="472 537 716 600">GI (Saliva/Dysphagia/Constipation)</td> <td data-bbox="764 537 1497 726"> <p><i>Screening:</i> MDS-UPDRS (2.2, 2.3, 1.11) <i>Global:</i> Drooling Severity and Frequency Scale (DSFS), Drooling Rating Scale(DRS), Silorrhea Clinical Scale for PD (SCS-PD), GI Functional Testing – Saliva/Drooling, Rome III Constipation Module, Constipation Severity Scale (CSS), GI Functional testing-Constipation</p> </td> </tr> <tr> <td data-bbox="472 730 716 758">Urinary</td> <td data-bbox="764 730 1497 825"> <p>MDS-UPDRS*, <i>Screening</i> MDS-UPDRS 1.10; <i>Global</i> International Prostate Symptom Scale (IPSS), ICIQ Overactive Bladder(ICIQ-OAB), Urodynamic Testing</p> </td> </tr> <tr> <td data-bbox="472 829 716 856">Sexual</td> <td data-bbox="764 829 1497 1213"> <p><i>Screening</i> Scales for Outcomes in PD-Autonomic (SCOPA-AUT): Items#21,22 (males), SHIM (males); Non-Motor Symptoms Screening Questionnaire (NMS-Quest) Items #18,19 (males and females); <i>Global</i> Scales for Outcomes in Parkinson's Disease-Autonomic (SCOPA-AUT): Item #22 and #21, Sexual Health Inventory for Men (SHIM) also called the International Index of Erectile Function-5 (IIEF-5), Non-Motor Symptoms Screening Questionnaire (NMS-Quest): Item #18 and #19, Non-Motor Symptoms Scale (NMSS): Item #26, International Index of Erectile Function (IIEF), Brief Index of Sexual Functioning for Women (BISF-W), First International Consultation on ED; NIH Consensus Panel on Impotence, DSM-IV</p> </td> </tr> <tr> <td data-bbox="472 1218 716 1245">Thermoregulatory</td> <td data-bbox="764 1218 1497 1407"> <p><i>Screening</i> SCOPA-AUT Item #17, NMS-Quest Item #18, NMSS Item #20; <i>Global</i> Scales for Outcomes in PD-Autonomic (SCOPA-AUT): Items#17,18,20,21, Non-Motor Symptoms Screening Questionnaire (NMS-Quest): Item #18, Non-Motor Symptoms Scale (NMSS): Item #20, Composite Autonomic Symptom Scale (COMPASS) – 8 items, Composite Autonomic Scoring Scale (CASS)</p> </td> </tr> <tr> <td data-bbox="472 1411 716 1438">Cardiovascular</td> <td data-bbox="764 1411 1497 1568"> <p><i>Screening</i> SCOPA-AUT Item #14, 15, 16; 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	<p>Scale (PDSS), Non-Motor Symptoms Screening Questionnaire (NMS-Quest), Stanford Sleepiness Scale (SSS), Karolinska Sleepiness Scale (KSS), Epworth Sleepiness Scale >10, or Standard Criteria on Multiple Sleep Latency Test (MSLT)</p> <p>Sleep (Sleep Apnea) <i>Screening:</i> Berlin Questionnaire; <i>Global:</i> STOP Questionnaire, Haraldsson's Questionnaire, Sleep Apnea Scale of the Sleep Disorders, Questionnaire (SA-SDQ), Survey Screen for Sleep Apnea (SSSA), Polysomnography</p> <p>Sleep (REM sleep) <i>Screening:</i> RBD Screening Questionnaire (Stiasny-Kolster); <i>Global:</i> RBD Screening Questionnaire (Stiasny-Kolster), Non-Motor Symptoms Screening Questionnaire (NMS-Quest), Polysomnography</p> <p>Restless Leg Syndrome <i>Screening:</i> Cambridge-Hopkins Restless Legs Syndrome Questionnaire (CH-RLSq); <i>Global:</i> Instrument for the Assessment of RLS Severity (IRLSSG rating scale), IRLSSG Diagnostic criteria</p> <p>Vision Impairment <i>Screening:</i> Pelli-Robinson Chart; <i>Global:</i> Pelli-Robinson Chart, Optical Coherence Tomography</p> <p>Olfactory Impairment <i>Screening:</i> Brief Smell Identification Test – Version B (Cross-Cultural Smell Identification Test); <i>Global:</i> Smell Identification Test (University of Pennsylvania Smell Identification Test – UPSIT – 40 item</p> <p>Pain Brief Pain Inventory*; <i>Screening:</i> Brief Pain Inventory (BPI) – 9 item short version; <i>Global:</i> Pain Definitions, Numerical Rating Scale (NRS) – BOX 21 Scale, International Association for the Study of Pain criteria</p> <p>Fatigue MDS-UPDRS*; <i>Screening:</i> MDS-UPDRS; <i>Global:</i> Fatigue Severity Scale (FSS)</p> <p>Nutritional Status/ <i>Screening:</i> Mini Nutritional Assessment (MNA), weight or BMI;</p> <p>Weight Loss <i>Global:</i> Food Frequency Questionnaire (FFQ), formal dietary assessment, weight or BMI</p> <p>* These items are highly recommended for a study that has primary focus on the specific non-motor disorder.</p>
Genetics	<p>Core: Sex, Ethnicity, Date of birth, Education level, Family history</p> <p>Supplemental: Race (expanded version)</p>
Imaging	<p>Core: None.</p> <p>Supplemental: Acquisition and outcome data (MRI, Spectroscopy, PET-SPECT)</p>
Neuropath-ology	<p>Core: None.</p> <p>Supplemental: Revised NACC neuropathology form; Elements for final clinical diagnosis, banked postmortem materials, macroscopic features</p>
Functional	<p>Core: None.</p>

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<i>neurosurgery</i>	Supplemental: Pre-operative, intra-operative, and post-operative information