

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
<i>Parkinson’s disease</i>	<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>
<i>Motor Function</i>	<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>

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	<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>
<p>Cognitive</p>	<p>Core: None.</p> <p>Supplemental: Global cognitive instruments (severity, longitudinal, diagnostic): Mattis Dementia Rating 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>
<p>Quality of life</p>	<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 fur 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>

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<p>Psychiatric and Psychological Function</p>	<p>Core: None.</p> <p>Supplemental:</p> <table border="0"> <tr> <td data-bbox="511 695 716 758"><u>Disorder/Features</u> Depression</td> <td data-bbox="776 695 1507 884"><u>Data element or instrument</u> 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="511 890 597 919">Anxiety</td> <td data-bbox="776 890 1451 1016">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="511 1022 618 1052">Psychosis</td> <td data-bbox="776 1022 1484 1148">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> <tr> <td data-bbox="511 1155 594 1184">Apathy</td> <td data-bbox="776 1155 1398 1218">Apathy Scale (AS)*, Proposed Criteria for Diagnosis of the Syndrome of Apathy</td> </tr> <tr> <td data-bbox="511 1224 691 1253">Impulse Control</td> <td data-bbox="776 1224 1495 1535">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</td> </tr> <tr> <td data-bbox="511 1541 1354 1570">Global Neuropsychiatric</td> <td data-bbox="776 1541 1354 1570">Neuropsychiatric Inventory (NPI)*, MDS-UPDRS Part I</td> </tr> </table> <p>*These items are highly recommended for studies focused on specific disorder/psychiatric area (to allow comparison with previous studies)</p>	<u>Disorder/Features</u> Depression	<u>Data element or instrument</u> 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	Apathy	Apathy Scale (AS)*, Proposed Criteria for Diagnosis of the Syndrome of Apathy	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	Global Neuropsychiatric	Neuropsychiatric Inventory (NPI)*, MDS-UPDRS Part I
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<p>Epidemiology /Environment</p>	<p>Core: None.</p> <p>Supplemental:</p> <table border="0"> <tr> <td data-bbox="488 1801 716 1988"><u>Disorder/Features</u> Smoking/alcohol Vitals/body habitus Occupational history Head injury Residential history</td> <td data-bbox="776 1801 1243 1988"><u>Data element or instrument</u> RFQ/Nurses' Health Study questionnaire RFQ (height and weight) Employment status (PhenX variable)*, RFQ Ohio State University TBI short form RFQ</td> </tr> </table>	<u>Disorder/Features</u> Smoking/alcohol Vitals/body habitus Occupational history Head injury Residential history	<u>Data element or instrument</u> RFQ/Nurses' Health Study questionnaire RFQ (height and weight) Employment status (PhenX variable)*, RFQ Ohio State University TBI short form RFQ										
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Subgroup	Recommendations		
	<p>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</p> <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>		
“Other” non-motor	<p>Core: None.</p> <p>Supplemental:</p> <table border="0"> <tr> <td style="vertical-align: top;"> <p>Disorder/Features GI (Saliva/Dysphagia/Constipation)</p> <p>Urinary</p> <p>Sexual</p> <p>Thermoregulatory</p> <p>Cardiovascular</p> </td> <td style="vertical-align: top;"> <p>Data element or instrument <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> <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> <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> <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> <p><i>Screening</i> SCOPA-AUT Item #14, 15, 16; NMS-Quest Item #20, NMSS Item #1-2; <i>Global</i> Scales for Outcomes in PD-Autonomic (SCOPA-AUT): Items #14,15,16, Non-Motor Symptoms Screening</p> </td> </tr> </table>	<p>Disorder/Features GI (Saliva/Dysphagia/Constipation)</p> <p>Urinary</p> <p>Sexual</p> <p>Thermoregulatory</p> <p>Cardiovascular</p>	<p>Data element or instrument <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> <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> <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> <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> <p><i>Screening</i> SCOPA-AUT Item #14, 15, 16; NMS-Quest Item #20, NMSS Item #1-2; <i>Global</i> Scales for Outcomes in PD-Autonomic (SCOPA-AUT): Items #14,15,16, Non-Motor Symptoms Screening</p>
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Subgroup	Recommendations
	<p>Respiratory Questionnaire (NMS-Quest): Item #20, Non-Motor Symptoms Scale (NMSS): Item #1-2, Blood Pressure, Tilt Table Testing <i>Screening:</i> Maximum Voluntary Ventilation Test or FEV1; <i>Global:</i> Maximum Voluntary Ventilation Test or FEV1, formal pulmonary function testing</p> <p>Sleep (Insomnia) <i>Screening:</i> Scales for Outcomes in Parkinson's Disease (SCOPA) Sleep nighttime subscale – used if sleep is primary outcome, else UPDRS #1.7; <i>Global:</i> Parkinson's Disease Sleep Scale (PDSS), Non-Motor Symptoms Screening Questionnaire (NMS-Quest), Insomnia Severity Index (ISI), Pittsburg Sleep Quality Index (PSQI), American Academy of Sleep Medicine Criteria, Polysomnography</p> <p>Sleep (Excessive Daytime Sleepiness) <i>Screening:</i> Epworth Sleepiness scale – used if sleep is primary outcome, else UPDRS #1.8; <i>Global:</i> Epworth Sleepiness Scale, Scales for Outcomes in Parkinson's Disease (SCOPA) Sleep, Parkinson's Disease Sleep 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; <i>Global:</i> Food</p>

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	<p>Weight Loss 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 neurosurgery	<p>Core: None.</p> <p>Supplemental: Pre-operative, intra-operative, and post-operative information</p>