

## 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](#)).

Disease/Domain; Subdomain	Recommendations and List of Forms
<p><b>Parkinson’s Disease</b></p>	<p><b>Core Instruments:</b> Hoehn and Yahr Scale; Montreal Cognitive Assessment (MoCA); Movement Disorder Society - Unified Parkinson's Disease Rating Scale (MDS-UPDRS); Unified Parkinson's Disease Rating Scale (UPDRS)</p> <p>Select either MDS-UPDRS (for studies focused on all severities and especially on mild/moderate participants) or UPDRS (for studies focused preferentially on advanced PD participants).</p> <p><a href="#">Guidance for Industry: Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials</a></p> <p>Surgical Complications – In order to prevent duplication of data collection, the General <a href="#">Adverse Events</a> form will be considered Core for clinical trials. If the information on that form does not completely capture what is needed, the surgical complications section on the Functional Neurosurgery: Deep Brain Stimulation CRF can be Supplemental.</p> <p><b>Supplemental – Highly Recommended Instruments– for indicated study types:</b> 15 - Item Geriatric Depression Scale (GDS-15); Apathy Scale (AS); Clinical Global Impression Scale-Improvement (CGI-I); Columbia - Suicide Severity Rating Scale (C-SSRS); Columbia - Suicide Severity Rating Scale (C-SSRS) Screener Version; Composite Autonomic Symptom Scale (COMPASS-31); Core Assessment Program for Surgical Interventional Therapies in PD (CAPSIT-PD); Dimensional Apathy Scale (DAS); Dimensional Apathy Scale (DAS) Informant/Carer-Rated Version; Enhanced Scale for the Assessment of Positive Symptoms in Parkinson’s Disease (eSAPS-PD); Epworth Sleepiness Scale (ESS) - Adult Version; EuroQoL-5 Dimension Questionnaire (EQ-5D); Hauser Motor Fluctuation Diary;</p>

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	<p>International Restless Legs Syndrome Study Group Severity Rating Scale (IRLS); Lille Apathy Rating Scale (LARS); Movement Disorder Society Clinical Diagnostic Criteria for Parkinson's Disease; Multiple Sleep Latency Test (MSLT) and Guidelines; Orthostatic Hypotension Questionnaire (OHQ); Parkinson Anxiety Scale (PAS); Parkinson's Disease Questionnaire (PDQ-39); Parkinson's Disease Sleep Scale 2nd Version (PDSS-2); Polysomnography (PSG) and Guidelines; Quality of Life in Neurological Disorders (Neuro-QOL); Questionnaire for Impulsive-Compulsive Behaviors in Parkinson's Disease (QUIP) (Long Form); Questionnaire for Impulsive-Compulsive Behaviors in Parkinson's Disease (QUIP) (Short Form); Questionnaire Impulsive-Compulsive Disorders Parkinson's Disease-Rating Scale (QUIP-RS); Risk Factor Questionnaire (RFQ) - Occupation and Employment Status; Scale for Outcomes in Parkinson's Disease-Sleep (SCOPA-Sleep); Scale for the Assessment of Positive Symptoms-Parkinson's Disease (SAPS-PD); Schwab and England Activities of Daily Living Scale; Short Form 36-Item Health Survey (SF-36); The American Academy of Sleep Medicine (AASM): International Classification of Sleep Disorders (ICSD) Criteria; The International Parkinson and Movement Disorder Society Non-Motor Rating Scale (MDS-NMS); The International Restless Legs Syndrome Study Group Diagnostic Criteria; Unified Dyskinesia Scale (UDysRS); Wearing Off Questionnaire (WOQ)</p> <p><b>Core and Supplemental – Highly Recommended CDEs:</b> See Start-Up Resource Listing document: <a href="#">Parkinson's Disease Start-Up Resource Listing</a></p>
<p><b>Participant Characteristics/ Demographics</b></p>	<p><b>Core:</b> General Core; Demographics</p> <p><b>Supplemental – Highly Recommended:</b> General Core</p> <p><b>Supplemental:</b> Demographics</p> <p><b>Exploratory:</b> None</p>
<p><b>Participant History and Family History/ Epidemiology/Environmental History</b></p>	<p><b>Core:</b> None</p> <p><b>Supplemental – Highly Recommended:</b> Risk Factor Questionnaire (RFQ) - Occupation and Employment Status</p> <p><b>Supplemental:</b> Food Frequency Questionnaire (FFQ); History of Early Exposure; Infection History; Non-prescribed Drug Use Questionnaire; Nurses' Health Study Questionnaire (NHQ); Ohio State University TBI Identification Method Short Form; Risk Factor Questionnaire (RFQ) - NSAIDS and Calcium Channel Blockers (CCB); Risk Factor Questionnaire (RFQ) - Physical Activity and Sleep; Risk Factor Questionnaire (RFQ) - Residential History; Risk Factor Questionnaire (RFQ) – Toxicants; Risk Factor Questionnaire (RFQ-U)</p>

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	<p>- Height and Weight; Risk Factor Questionnaire (RFQ-U) - Pesticides (Home); Risk Factor Questionnaire (RFQ-U) - Pesticides (Work); Risk Factor Questionnaire (RFQ-U) - Smoking and Tobacco; Secondhand Smoke Microenvironment Questionnaire</p> <p><b>Exploratory:</b> None</p>
<p><b>Participant History and Family History/ General Health History</b></p>	<p><b>Core:</b> Family History</p> <p><b>Supplemental – Highly Recommended:</b> None</p> <p><b>Supplemental:</b> Family History</p> <p><b>Exploratory:</b> None</p>
<p><b>Disease/Injury Related Events/ History of Disease/Injury Event</b></p>	<p><b>Core:</b> Medical History of Parkinson's Disease</p> <p><b>Supplemental – Highly Recommended:</b> None</p> <p><b>Supplemental:</b> Medical History of Parkinson's Disease</p> <p><b>Exploratory:</b> None</p>
<p><b>Assessments and Examinations/ Imaging Diagnostics</b></p>	<p><b>Core:</b> None</p> <p><b>Supplemental – Highly Recommended:</b> MRI and Spectroscopy; PET-SPECT Localization</p> <p><b>Supplemental:</b> PET-SPECT Localization</p> <p><b>Exploratory:</b> None</p>
<p><b>Assessments and Examinations/ Other Clinical Data</b></p>	<p><b>Core:</b> None</p> <p><b>Supplemental – Highly Recommended:</b> None</p> <p><b>Supplemental:</b> National Alzheimer's Coordinating Center (NACC) Neuropathology Data Form</p> <p><b>Exploratory:</b> None</p>
<p><b>Assessments and Examinations/ Laboratory Tests and Biospecimens/Biomarkers</b></p>	<p><b>Core:</b> None</p> <p><b>Supplemental – Highly Recommended:</b> Parkinson's Disease Genetics</p> <p><b>Supplemental:</b> Parkinson's Disease Genetics</p> <p><b>Exploratory:</b> None</p>
<p><b>Treatment/Intervention Data/ Surgeries and Other Procedures</b></p>	<p><b>Core:</b> None</p> <p><b>Supplemental – Highly Recommended:</b> None</p> <p><b>Supplemental:</b> Functional Neurosurgery: Deep Brain Stimulation</p> <p><b>Exploratory:</b> None</p>

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<b>Treatment /Intervention Data/ Drugs</b>	<p><b>Core:</b> None</p> <p><b>Supplemental – Highly Recommended:</b> Parkinson's Disease Medication Log</p> <p><b>Supplemental:</b> Non-Parkinson's Disease Medication Log</p> <p><b>Exploratory:</b> None</p>
<b>Outcomes and End Points/ Cognitive</b>	<p><b>Core:</b> Montreal Cognitive Assessment (MoCA)</p> <p><b>Supplemental – Highly Recommended:</b> None</p> <p><b>Supplemental:</b> Addenbrooke's Cognitive Examination-III (ACE-III); Alzheimer's Disease Assessment Scale-Cognition (ADAS-cog); Cambridge Cognitive Assessment-Revised (CAMCOG-R); Cambridge Neuropsychological Test Automated Battery (CANTAB); CDR System; Mattis Dementia Rating Scale (MDRS); Mini-Mental State Examination (MMSE); Parkinson's Disease-Cognitive Rating Scale (PD-CRS); Scales for Outcomes in Parkinson's Disease-Cognitive (SCOPA-COG)</p> <p><b>Exploratory:</b> Cambridge Neuropsychological Test Automated Battery (CANTAB) Connect; Cogstate Brief Battery; Lumos Labs NeuroCognitive Performance Tests (NCPT); NeuroTrax BrainCare</p>
<b>Outcomes and End Points/ Daily Cognitive Function</b>	<p><b>Core:</b> None</p> <p><b>Supplemental – Highly Recommended:</b> None</p> <p><b>Supplemental:</b> Parkinson's Disease - Cognitive Function Rating Scale (PD-CFRS); Penn Parkinson's Daily Activities Questionnaire-15 (PDAQ-15)</p> <p><b>Exploratory:</b> None</p>
<b>Outcomes and End Points/ Motor Function</b>	<p><b>Core:</b> Hoehn and Yahr Scale; Movement Disorder Society - Unified Parkinson's Disease Rating Scale (MDS-UPDRS); Unified Parkinson's Disease Rating Scale (UPDRS)</p> <p><b>Supplemental – Highly Recommended:</b> Clinical Global Impression Scale-Improvement (CGI-I); Core Assessment Program for Surgical Interventional Therapies in PD (CAPSIT-PD); Hauser Motor Fluctuation Diary; Movement Disorder Society Clinical Diagnostic Criteria for Parkinson's Disease; Schwab and England Activities of Daily Living Scale; Unified Dyskinesia Scale (UDysRS); Wearing Off Questionnaire (WOQ)</p> <p><b>Supplemental:</b> Abnormal Involuntary Movement Scale (AIMS); Clinical Global Impression Scale-Severity (CGI-S); Rush Dyskinesia</p>

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	<p>Rating Scale (RDRS); UK Parkinson's Disease Society Brain Bank Criteria for the Diagnosis of Parkinson's Disease</p> <p><b>Exploratory:</b> None</p>
<p><b>Outcomes and End Points/ Other Non-Motor</b></p>	<p><b>Core:</b> None</p> <p><b>Supplemental – Highly Recommended:</b> Composite Autonomic Symptom Scale (COMPASS-31); Epworth Sleepiness Scale (ESS) - Adult Version; International Restless Legs Syndrome Study Group Severity Rating Scale (IRLS); Multiple Sleep Latency Test (MSLT) and Guidelines; Orthostatic Hypotension Questionnaire (OHQ); Parkinson's Disease Sleep Scale 2nd Version (PDSS-2); Polysomnography (PSG) and Guidelines; Scale for Outcomes in Parkinson's Disease-Sleep (SCOPA-Sleep); The American Academy of Sleep Medicine (AASM): International Classification of Sleep Disorders (ICSD) Criteria; The International Parkinson and Movement Disorder Society Non-Motor Rating Scale (MDS-NMS); The International Restless Legs Syndrome Study Group Diagnostic Criteria</p> <p><b>Supplemental:</b> Actigraphy (with Sleep Diary); Berlin Questionnaire; Brief Pain Inventory (BPI) Short Form; Brief Smell Identification Test (Brief-SIT); Constipation Severity Scale (CSS); Drooling Rating Scale (DRS); Drooling Severity and Frequency Scale (DSFS); Fatigue Severity Scale (FSS); Female Sexual Function Index (FSFI); Gastrointestinal Symptoms in Neurodegenerative Diseases Scale (GIND); Innsbruck REM Sleep Behavior Disorder Inventory (RBD-I-5); Insomnia Severity Index (ISI); International Consultation on Incontinence Modular Questionnaire-Overactive Bladder (ICIQ-OAB); International Consultation on Incontinence Questionnaire Bladder Diary (ICIQ-Bladder Diary); International Index of Erectile Function-5 (IIEF-5); International Prostate Symptom Scale (IPSS); Karolinska Sleepiness Scale (KSS); King's Parkinson's Disease Pain Scale (KPPS); Mayo Sleep Questionnaire; Mini Nutritional Assessment (MNA); Neurogenic Bladder Symptom Score (NBSS); Non-Motor Symptom Questionnaire (NMS-Quest) (PD-NMS); Numeric Rating Scale (NRS)-Box 21 Scale; Orthostatic Symptom Grading Scale; Other Non-Motor Guidance for CDE Use; Parkinson's Disease Fatigue Scale (PFS-16); Pelli Robson Test; Pittsburgh Sleep Quality Index (PSQI); Quality of Life in Swallowing Disorders (SWAL-QOL); Radboud Oral Motor Inventory for Parkinson's Disease (ROMP); Rome III/IV Constipation Module; Scale for Outcomes in Parkinson's Disease Autonomic (SCOPA-AUT); Sialorrhea Clinical Scale for Parkinson's Disease (SCS-PD); Sniffin' Sticks Test; Stanford Sleepiness Scale (SSS); STOP-BANG Questionnaire; Swallowing Disturbance Questionnaire (SDQ); The Gastrointestinal Dysfunction</p>

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	<p>Scale for Parkinson's Disease; The International Association for the Study of Pain (IASP) Definitions for Pain; The International Parkinson and Movement Disorder Society Non-Motor Rating Scale (MDS-NMS) (GI Domain); The REM Sleep Behavior Disorder (RBD) Questionnaire – Hong Kong (RBDQ-HK); The REM Sleep Behavior Disorder (RBD) Screening Questionnaire (RBDSQ); The REM Sleep Behavior Disorder Single-Question Screen (RBD1Q); The Swallowing Clinical Assessment Score in Parkinson's Disease (SCAS-PD); University of Pennsylvania Smell Identification Test (UPSIT)</p> <p><b>Exploratory:</b> Hyposmia Rating Scale (HRS); King's Parkinson's Disease Pain Questionnaire (KPPQ); Munich Dysphagia Test - Parkinson's Disease (MDT-PD); Visual Impairment in Parkinson's Disease Questionnaire (VIPD-Q)</p>
<p><b>Outcomes and End Points/ Psychiatric and Psychological Functions</b></p>	<p><b>Core:</b> None</p> <p><b>Supplemental – Highly Recommended:</b> 15 - Item Geriatric Depression Scale (GDS-15); Apathy Scale (AS); Columbia - Suicide Severity Rating Scale (C-SSRS); Columbia - Suicide Severity Rating Scale (C-SSRS) Screener Version; Dimensional Apathy Scale (DAS); Dimensional Apathy Scale (DAS) Informant/Carer-Rated Version; Enhanced Scale for the Assessment of Positive Symptoms in Parkinson's Disease (eSAPS-PD); Lille Apathy Rating Scale (LARS); Parkinson Anxiety Scale (PAS); Questionnaire for Impulsive-Compulsive Behaviors in Parkinson's Disease (QUIP) (Long Form); Questionnaire for Impulsive-Compulsive Behaviors in Parkinson's Disease (QUIP) (Short Form); Questionnaire Impulsive-Compulsive Disorders Parkinson's Disease-Rating Scale (QUIP-RS); Scale for the Assessment of Positive Symptoms-Parkinson's Disease (SAPS-PD)</p> <p><b>Supplemental:</b> Apathy Motivation Index (AMI); Apathy Motivation Index Caregiver Version (AMI-CG); Beck Depression Inventory II (BDI-II); Brief Dimensional Apathy Scale (b-DAS); Brief Psychiatric Rating Scale (BPRS); Compulsive Eating Scale (CES); Cornell Scale for Depression in Dementia (CSDD); Diagnostic and Statistical Manual of Mental Disorders (DSM-5); Gambling Symptom Assessment Scale (G-SAS); Hamilton Anxiety Rating Scale (HAM-A); Hamilton Depression Rating Scale (HDRS); Hospital Anxiety and Depression Scale (HADS); McElroy Diagnostic Criteria for Compulsive Buying; Montgomery-Asberg Depression Scale (MADRS); Neuropsychiatric Inventory (NPI); Parkinson's Psychosis Rating Scale (PPRS); Pathological Gambling Adaptation of the Yale-Brown Obsessive Compulsive Scale (PG-YBOCS); Parkinson's Psychosis Questionnaire (PPQ); Patient Health Questionnaire-2 (PHQ-2); Patient Health Questionnaire-9 (PHQ-9) Depression Scale; Psychosis and Hallucinations Questionnaire (PsychH-Q); Questionnaire about</p>

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	<p>Buying Behavior (QABB); Scale for the Assessment of Positive Symptoms (SAPS); Sexual Compulsivity Scale (SCS); South Oaks Gambling Screen (SOGS)</p> <p><b>Exploratory:</b> None</p>
<p><b>Outcomes and End Points/ Quality of Life/Patient Reported Outcomes</b></p>	<p><b>Core:</b> None</p> <p><b>Supplemental – Highly Recommended:</b> EuroQoL-5 Dimension Questionnaire (EQ-5D); Parkinson's Disease Questionnaire (PDQ-39); Quality of Life in Neurological Disorders (Neuro-QOL); Short Form 36-Item Health Survey (SF-36)</p> <p><b>Supplemental:</b> Parkinson's Disease Quality of Life Questionnaire (PDQL); Parkinson's Disease Quality of Life Scale (PDQUALIF); Parkinson's Impact Scale (PIMS); PROMIS-29 Profile; PROMIS Item Bank v1.2 - Global Health; Scales for Outcomes in Parkinson's Disease-Psychosocial (SCOPA-PS); Schedule for the Evaluation of Individual Quality of Life - Direct Weighting (SEIQoL-DW); World Health Organization Quality of Life Assessment (WHOQOL-BREF)</p> <p><b>Exploratory:</b> Schedule for the Evaluation of Individual Quality of Life (SEIQoL)</p>