

Parkinson's Disease CDE Revision History Document

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January 2020 Revisions

- General Core CRF updated to replace 'Gender' question with 'Sex assigned at birth' and 'Gender identity'.
- Two new CDEs added to CRF: C58676 (Sex assigned at birth) and C58677 (Gender identity). C00035 has been removed
- Start-Up document updated to reflect these changes.

March 2017 Revisions

The Cognitive Subgroup made updates to the Cognitive Guidelines document

The following changes were made to the CDE Working Group – Cognitive Table (Each of the above scales are being given a score of 1, 2, 3 for suitability (1= highest or best, 3= lowest or worst):

Addenbrooke's Cognitive Examination - Revised (ACE-R): The instrument is now called ACE – III. Cognitive Guidelines table were updated along with the instruments Notice of Copyright (NOC) with explanation for the change

Clinician Global Impression of Change (CGIC): Longitudinal rating scale usage was change from 2 to 1.5.

Montreal Cognitive Assessment (MoCA): Longitudinal rating scale usage was change from N/A to 1.

SCOPA-COG: Longitudinal rating scale usage was change from N/A to 2.

The following Notice of Copyrights (NOCs) were updated:

- Lille Apathy Rating Scale (LARS)
- The Parkinson Anxiety Scale (PAS)
- Scale for the Assessment of Positive Symptoms Parkinson's Disease (SAPS-PD)
- Questionnaire for Impulsive Compulsive Disorders in Parkinson's Disease-Rating Scale (QUIP-RS)

July 2016 Revisions

The following NOCs were updated and added to the website:

- Pathological Gambling Adaptation of the Yale-Brown Obsessive Compulsive Scale, (PG-YBOCS)
- Drooling Rating Scale(DRS)
- Parkinson's Disease-Cognitive Rating Scale (PD-CRS)

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- Movement Disorder Society Unified Parkinson's Disease Scale

Classification revisions were made to the following instruments:

Subgroup	Recommendations	Previous Classification	Updated Classification / Removal
Quality of Life	Parkinson's Disease Quality of Life Scale (PDQUALIF)	Core	Supplemental-Highly Recommended

May 2016 Revision

- Revisions to Hamilton Anxiety Depression Scale NOC. The NOC was revised to reflect the correct name of the instrument, Hamilton Anxiety Rating Scale and Hamilton Depression Rating Scale.

April 2015 Revisions

No updates.

March 2015 Revisions

- Corrections made to PD Acknowledgment section.

February 2015 Revisions

- Start-Up Resource Listing was updated with a link to the Data Standards page for PD.

January 2015 Revisions

- Revised 508 Compliant Start-Up and Highlight summaries were posted to PD.

November 2014 Revisions

- CDEs in use page was updated with new studies in PD.

September 2014 Revisions

- Page numbering in PD CRF Neuropathology was corrected.

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- Revisions made to PD Roster.

August 2014 Revisions

- PD Start-up and Highlight documents changed to reflect instrument classification changes requested by the committee.
- General Core CRF posted on PD webpage.
- Links to NeuroQOL, NIH Toolbox, and PROMIS added to PD webpage.
- Core suicidal ideation instrument, with link, added to PD Highlight document.

July 2014 Revisions

- 508-compliant versions of CDEs, NOCs and Recommendation spreadsheets uploaded.
- Addition of "NIH Resources" domain, listing the NIH Toolbox, PROMIS, and Neuro-QOL as first domain on PD webpage.

June 2014 Revisions

No updates.

May 2014 Revisions

- Start-Up Resource and Highlight documents converted to 508-compliant PDFs.

April 2014 Revisions

No updates.

March 2014 Revisions

No updates.

February 2014 Revisions

No updates.

January 2014 Revisions

- Links to Start-Up Resource Listings added to Highlight Summary documents.

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- Revision History document updated for PD.

December 2013 Revisions

- Highlight summary and start-up documents for PD updated.
- New NOCs added to PD website.

November 2013 Revisions

Overview

There have been changes to the content and structure of the Parkinson's Disease (PD) CDE materials in Version 1.2 compared to Version 1.1, including the following:

Form Status Changes

New Forms:

Nurses' Health Study Questionnaire (NHQ)

Ohio State University TBI Identification Method Short Form

Alzheimer's Disease Assessment Scale–Cognition (ADAS-cog)

Alzheimer's Disease Cooperative Study–Clinical Global Impression of Change (ADCS-CGIC)

Cambridge Cognitive Assessment –Revised (CAMCOG-R)

Mattis Dementia Rating Scale (MDRS)

Mini-Mental State Examination (MMSE)

Montreal Cognitive Assessment (MoCA)

UK Parkinson's Disease Society Brain Bank Criteria for the Diagnosis of Parkinson's Disease

Brief Index of Sexual Functioning for Women (BISF-W)

Brief Smell Identification Test (Brief-SIT)

Composite Autonomic Scoring Scale (CASS)

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Composite Autonomic Symptom Scale (COMPASS-8) (COMPASS-31)

Epworth Sleepiness Scale (ESS)

Haraldsson's Questionnaire

Instrument for the Assessment of Restless Legs Syndrome Severity (IRLSSG- Rating Scale)

International Consultation on Incontinence Modular Questionnaire-Overactive Bladder (ICIQ-OAB)

International Index of Erectile Function (IIEF-5)

International Prostate Symptom Scale (IPSS)

Karolinska Sleepiness Scale (KSS)

Numerical Rating Scale (NRS) - BOX 21 Scale

Parkinson's Neuropsychometric Dementia Assessment (PANDA)

Pelli-Robson Chart

Pittsburgh Sleep Quality Index (PSQI)

Quantitative Sudomotor Axon Reflex Test (QSART)

The American Academy of Sleep Medicine (AASM): International Classification of Sleep Disorders (ICSD) Criteria

The International Association for the Study of Pain (IASP) Definition of Pain

The International Restless Leg Syndrome Study Group Diagnostic Criteria

The REM Sleep Behavior Disorder (RBD) Screening Questionnaire (RBDSQ)

University of Pennsylvania Smell Identification Test (UPSIT)

Beck Depression Inventory – II (BDI-II)

Diagnostic and Statistical Manual of Mental Disorders (DSM-5)

Hospital Anxiety and Depression Scale (HADS)

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McElroy Diagnostic Criteria for Compulsive Buying

Montgomery-Asberg Depression Rating Scale (MADRS)

Neuropsychiatric (NPI) Inventory

Structured Clinical Interview for DSM-IV Axis Disorders-Patient Version (SCID-I/P)

Belastungsfragebogen Parkinson kurzversion (BELA-P-k)

EuroQol 5-Dimension Questionnaire (EQ-5D)

Nottingham Health Profile (NHP)

Parkinson's disease questionnaire (PDQ-39)

Quality of Life in Neurological Disorders (Neuro-QOL)

Questions on Life Satisfaction– Movement Disorder (QLS-MD) and Deep Brain Stimulation (QLS-DBS)
Modules

Schedule for the Evaluation of Individual Quality of Life - Direct Weighting (SEIQoL-DW)

Schedule for the Evaluation of Individual Quality of Life (SEIQoL)

Sickness Impact Profile (SIP)

Updated Forms:

Notice of Copyright Created (NOC) (Will replace previously existing forms)

Food Frequency Questionnaire

PD DOC Mini Environmental Risk Questionnaire for Parkinson's Disease Patients Baseline (PD DOC
MERQ-PD-B

Risk Factor Questionnaire (RFQ) – All

Risk Factor Questionnaire - NSAIDS and Calcium Channel Blockers (RFQ)

Risk Factor Questionnaire - Occupation and Employment Status (RFQ)

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Risk Factor Questionnaire - Physical Activity and Sleep (RFQ)

Risk Factor Questionnaire - Residential History (RFQ)

Risk Factor Questionnaire – Toxicants (RFQ)

Risk Factor Questionnaire - Height and Weight (RFQ-U)

Risk Factor Questionnaire – Pesticides (Home) (RFQ-U)

Risk Factor Questionnaire – Pesticides (Work) (RFQ-U)

Risk Factor Questionnaire - Smoking and Tobacco (RFQ-U)

Addenbrooke's Cognitive Examination-Revised (ACE-R)

Scales for Outcomes in Parkinson's Disease-Cognitive (SCOPA-COG)

Short Portable Mental Status Questionnaire (SPMSQ)

Movement Disorder Society - Unified Parkinson's Disease Rating Scale (MDS-UPDRS)

Unified Parkinson's Disease Rating Scale (UPDRS)

Berlin Questionnaire

Brief Pain Inventory (Short Form)

Cambridge-Hopkins Restless Legs Syndrome Diagnostic Questionnaire (CH-RLSQ)

Drooling Severity and Frequency Scale (DSFS)

Fatigue Severity Scale (FSS) of Sleep Disorders

Insomnia Severity Index (ISI)

Mini Nutritional Assessment (MNA)

Multiple Sleep Latency Test and Guidelines (MSLT)

Non-Motor Symptom assessment scale for Parkinson's Disease (NMSS)

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Non-Motor Symptom Questionnaire (NMS-Quest)

Parkinson's Disease Sleep Scale (PDSS)

Quality of Life in Swallowing Disorders (SWAL-QOL)

Rome III Constipation Module

Scales for Outcomes in Parkinson's Disease-Autonomic (SCOPA-Aut)

Scales for Outcomes in Parkinson's Disease-Sleep (SCOPA-Sleep)

Sialorrhea Clinical Scale for PD (SCS-PD)

Sleep Apnea Scale of Sleep Disorders Questionnaire (SA-SDQ)

Stanford Sleepiness Scale (SSS)

STOP Questionnaire

Survey Screen for Sleep Apnea (SSSA)

Swallowing Disturbance Questionnaire (SwDQ)

Apathy Scale (AS)

Brief Psychiatric Rating Scale (BPRS)

Gambling Symptom Assessment Scale (G-SAS)

Geriatric Depression Scale (GDS)

Hamilton Anxiety Rating Scale (HAM-A)

Hamilton Depression Rating Scale (HDRS)

Proposed Criteria for Diagnosis of the Syndrome of Apathy

Questionnaire about Buying Behavior (QABB)

Questionnaire for Impulsive-Compulsive Behaviors in Parkinson's Disease (QUIP) (Short form)

Questionnaire for Impulsive-Compulsive Behaviors in Parkinson's Disease (QUIP) (Long form)

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Scale for the Assessment of Positive Symptoms (SAPS)

Sexual Compulsivity Scale (SCS)

South Oaks Gambling Screen (SOGS)

Structured Clinical Interview for Pathological Gambling (SCI-PG)

36-Item Short Form Health Survey (SF-36)

Parkinson's Disease Quality of Life Scale (PDQUALIF)

Parkinson's Impact Scale (PIMS)

Scales for Outcomes in Parkinson's Disease-Psychosocial (SCOPA-PS)

World Health Organization Quality of Life Assessment (WHOQOL-BREF)

Removed Forms:

None

Detailed Form Revisions:

Additional specific changes to the CRF modules are detailed in the table included on the subsequent page.

1 Parkinson's Disease Revision History Table

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Nurses' Health Study Questionnaire (NHQ)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Ohio State University TBI Identification Method Short Form	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Alzheimer's Disease Assessment Scale– Cognition (ADAS- cog)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Alzheimer's Disease Cooperative Study- Clinical Global Impression of Change (ADCS-CGIC)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Cambridge Cognitive Assessment – Revised (CAMCOG- R)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Mattis Dementia Rating Scale (MDRS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Mini-Mental State Examination (MMSE)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Montreal Cognitive Assessment (MoCA)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
UK Parkinson's Disease Society Brain Bank Criteria for the Diagnosis of Parkinson's Disease	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Brief Index of Sexual Functioning for Women (BISF-W)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Brief Smell Identification Test (Brief-SIT)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Composite Autonomic Scoring Scale (CASS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Composite Autonomic Symptom Scale (COMPASS-8) (COMPASS-31)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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Epworth Sleepiness Scale (ESS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Haraldsson's Questionnaire	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Instrument for the Assessment of Restless Legs Syndrome Severity (IRLSSG- Rating Scale)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
International Consultation on Incontinence Modular Questionnaire- Overactive Bladder (ICIQ-OAB)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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International Index of Erectile Function (IIEF-5)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
International Prostate Symptom Scale (IPSS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Karolinska Sleepiness Scale (KSS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Numerical Rating Scale (NRS) - BOX 21 Scale	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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Parkinson's Neuropsychometric Dementia Assessment (PANDA)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Pelli-Robson Chart	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Pittsburgh Sleep Quality Index (PSQI)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Quantitative Sudomotor Axon Reflex Test (QSART)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
The American Academy of Sleep Medicine (AASM): International Classification of Sleep Disorders (ICSD) Criteria	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
The International Association for the Study of Pain (IASP) Definition of Pain	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
The International Restless Leg Syndrome Study Group Diagnostic Criteria	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
The REM Sleep Behavior Disorder (RBD) Screening Questionnaire (RBDSQ)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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University of Pennsylvania Smell Identification Test (UPSIT)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Beck Depression Inventory – II (BDI-II)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Diagnostic and Statistical Manual of Mental Disorders (DSM-5)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Hospital Anxiety and Depression Scale (HADS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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McElroy Diagnostic Criteria for Compulsive Buying	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Montgomery-Asberg Depression Rating Scale (MADRS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Neuropsychiatric (NPI) Inventory	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Structured Clinical Interview for DSM- IV Axis Disorders- Patient Version (SCID-I/P)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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Belastungsfragebogen Parkinson kurzversion (BELA-P- k)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
EuroQol 5- Dimension Questionnaire (EQ- 5D)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Nottingham Health Profile (NHP)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Parkinson's disease questionnaire (PDQ- 39)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Quality of Life in Neurological Disorders (Neuro-QOL)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Questions on Life Satisfaction– Movement Disorder (QLS-MD) and Deep Brain Stimulation (QLS-DBS) Modules	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Schedule for the Evaluation of Individual Quality of Life - Direct Weighting (SEIQoL-DW)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Schedule for the Evaluation of Individual Quality of Life (SEIQoL)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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Sickness Impact Profile (SIP)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Food Frequency Questionnaire	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
PD DOC Mini Environmental Risk Questionnaire for Parkinson's Disease Patients Baseline (PD DOC MERQ-PD- B	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire (RFQ) – All	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Risk Factor Questionnaire - NSAIDS and Calcium Channel Blockers (RFQ)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire - Occupation and Employment Status (RFQ)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire - Physical Activity and Sleep (RFQ)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire - Residential History (RFQ)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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Risk Factor Questionnaire – Toxicants (RFQ)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire - Height and Weight (RFQ-U)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire – Pesticides (Home) (RFQ-U)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire – Pesticides (Work) (RFQ-U)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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Risk Factor Questionnaire - Smoking and Tobacco (RFQ-U)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Addenbrooke's Cognitive Examination-Revised (ACE-R)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Scales for Outcomes in Parkinson's Disease-Cognitive (SCOPA-COG)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Short Portable Mental Status Questionnaire (SPMSQ)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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Movement Disorder Society - Unified Parkinson's Disease Rating Scale (MDS- UPDRS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Unified Parkinson's Disease Rating Scale (UPDRS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Berlin Questionnaire	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Brief Pain Inventory (Short Form)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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Cambridge-Hopkins Restless Legs Syndrome Diagnostic Questionnaire (CH- RLSQ)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Drooling Severity and Frequency Scale (DSFS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Fatigue Severity Scale (FSS) of Sleep Disorders	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Insomnia Severity Index (ISI)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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Mini Nutritional Assessment (MNA)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Multiple Sleep Latency Test and Guidelines (MSLT)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Non-Motor Symptom assessment scale for Parkinson's Disease (NMSS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Non-Motor Symptom Questionnaire (NMS-Quest)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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Parkinson's Disease Sleep Scale (PDSS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Quality of Life in Swallowing Disorders (SWAL- QOL)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Rome III Constipation Module	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Scales for Outcomes in Parkinson's Disease-Autonomic (SCOPA-Aut)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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Scales for Outcomes in Parkinson's Disease-Sleep (SCOPA-Sleep)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Sialorrhea Clinical Scale for PD (SCS- PD)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Sleep Apnea Scale of Sleep Disorders Questionnaire (SA- SDQ)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Stanford Sleepiness Scale (SSS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
STOP Questionnaire	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Survey Screen for Sleep Apnea (SSSA)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Swallowing Disturbance Questionnaire (SwDQ)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Apathy Scale (AS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Brief Psychiatric Rating Scale (BPRS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Gambling Symptom Assessment Scale (G-SAS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Geriatric Depression Scale (GDS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Hamilton Anxiety Rating Scale (HAM- A)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Hamilton Depression Rating Scale (HDRS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Proposed Criteria for Diagnosis of the Syndrome of Apathy	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Questionnaire about Buying Behavior (QABB)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Questionnaire for Impulsive- Compulsive Behaviors in Parkinson's Disease (QUIP) (Short form)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Questionnaire for Impulsive-Compulsive Behaviors in Parkinson's Disease (QUIP) (Long form)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Scale for the Assessment of Positive Symptoms (SAPS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Sexual Compulsivity Scale (SCS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
South Oaks Gambling Screen (SOGS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Structured Clinical Interview for Pathological Gambling (SCI-PG)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
36-Item Short Form Health Survey (SF-36)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Parkinson's Disease Quality of Life Scale (PDQUALIF)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Parkinson's Impact Scale (PIMS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Scales for Outcomes in Parkinson's Disease- Psychosocial (SCOPA-PS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
World Health Organization Quality of Life Assessment (WHOQOL-BREF)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

August 2012 Revisions

Overview

There have been changes to the content and structure of the Parkinson's Disease (PD) CDE materials in Version 1.1 compared to Version 1.0, including the following:

- Every attempt was made to remove duplication and redundancy in the PD CDEs;
- The PD CDEs were harmonized with other large national and international standardization initiatives and efforts [e.g., International Conference on Harmonisation (ICH), Logical Observation Identifiers Names and Codes (LOINC), International Classification of Diseases (ICD), Unified Code for Units of Measure (UCUM)]
- The majority of element names and definitions were improved.
- The permissible values and references of some elements were revised; and

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- The version numbers of all forms (excluding standardized scales/instruments) were updated.
- Several guideline documents were reorganized and consolidated to make it easier to understand which standardized instruments/scales are recommended, though the recommendations themselves remained unchanged.
- Some of the forms and guideline documents were re-categorized under a different domain or subdomain to be consistent with other NINDS CDEs.

The corresponding data dictionaries (i.e., CDE Detailed Report) have been modified in accordance with the form changes.

Form Status Changes

New Forms:

- None

Updated Forms:

- Demographics
- Family History
- Functional Neurosurgery
- History of Early Exposure
- Infection History
- Medical History
- MR
- MRI and Spectroscopy
- Neuropathology
- Non-Parkinson's Disease Medication Log

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- Non-Prescribed Drug Use Questionnaire
- Parkinson's Disease Medication Log
- PET-SPECT

Removed Forms:

- None

Detailed Form Revisions:

Additional specific changes to the CRF modules are detailed in the table included on the subsequent page.

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
All	1.1	1.0	Minor	Modified CDEs	Nearly all CDE names and definitions were updated to achieve greater consistency across all NINDS CDEs and for clarity
Various	1.1	1.0	Minor	Deleted CDEs	The following types of CDEs were deleted: CDEs redundant with other CDEs; CDEs specifying unit; and CDEs specifying an "other, specify" response

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Various	1.1	1.0	Minor	Modified CDEs	For a number of CDEs, "Unknown" was added to the permissible value set and/or "Don't know" and "Missing/Unknown" were removed
Demographics	1.1	1.0	Minor	Modified CDEs	The following CDE definition and permissible values were updated: Ethnicity USA Category
Demographics	1.1	1.0	Minor	Modified CDEs	The following CDE instructions were updated: Gender type; Education level USA type
Demographics	1.1	1.0	Minor	Modified Form	The following changes were made to the form: reordering of questions; removed "or" before last permissible value choice; capitalization; changes to header
Family History	1.1	1.0	Minor	Modified Form	The following changes were made to the form: wording in column headers; changes to header; updated to reflect new number of Core elements
Family History	1.1	1.0	Minor	Modified CDEs	Permissible values were modified for CDE "Family history medical condition relative type"

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Functional Neurosurgery	1.1	1.0	Minor	Modified Form	The following changes were made to the form: changes to header; capitalization; grammar
Functional Neurosurgery	1.1	1.0	Major	New CDE	The following CDEs were added: "Surgical or therapeutic procedure start date and time"
Functional Neurosurgery	1.1	1.0	Major	Modified CDEs	Permissible values were updated for: Surgical complications post-operative type; Aborted procedures reason; Adverse event severity scale; Adverse event other action taken type; Adverse event outcome status
Functional Neurosurgery	1.1	1.0	Minor	Modified CDEs	Instructions were updated for: Surgical Complications
History of Early Exposure to PD	1.1	1.0	Minor	Modified Form	The following changes were made to the form: header and footer modified; skip logic modified; instruction to specify units added; relabeled "sex" as "gender"
History of Early Exposure to PD	1.1	1.0	Minor	Modified CDEs	Permissible values were updated for the following CDEs: Sibling gender type; Sibling alive indicator

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Infection History	1.1	1.0	Minor	Modified Form	The following changes were made to the form: header modified; skip logic modified
Infection History	1.1	1.0	Minor	Modified CDEs	Permissible values were updated for the following CDEs: Influenza vaccine received frequency; Meningitis or encephalitis diagnosed type
Medical History of Parkinson's Disease	1.1	1.0	Minor	Modified Form	The following changes were made to the form: modified header
Medical History of Parkinson's Disease	1.1	1.0	Minor	Deleted CDEs	The following CDE was removed from the form: Form not Done
Medical History of Parkinson's Disease	1.1	1.0	Minor	New CDE	The following CDE was added to the body of the form: Medical history taken date and time
Medical History of Parkinson's Disease	1.1	1.0	Minor	Modified CDEs	Permissible values were updated for: Symptom laterality type
MR	1.1	1.0	Minor	Modified Form	The following was modified on the form: header; instructions; label of CDE "Medication prior or concomitant name"
MR	1.1	1.0	Minor	Modified CDEs	Permissible values were updated for "imaging matrix size value"

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
MRI and Spectroscopy	1.1	1.0	Minor	Modified Form	The header was modified on the form
MRI and Spectroscopy	1.1	1.0	Minor	Modified CDEs	Permissible values were updated for "imaging matrix size value"
Neuropathology	1.1	1	Minor	Modified form	The following changes were made to the form; Header updated; Codes for permissible values were removed
Neuropathology	1.1	1	Minor	Modified CDEs	Permissible values were updated for most CDEs on this form
Non-Parkinson's Disease Medication Log	1.1	1.0	Minor	Modified Form	The following was modified on the form: grammar; header; reformatted table; instructions for table
Non-Parkinson's Disease Medication Log	1.1	1.0	Major	New CDEs	The following CDEs were added: Medication prior or concomitant RXNorm code; Medication prior or concomitant dose unit of measure UCUM code
Non-prescribed Drug Use Questionnaire	1.1	1.0	Minor	Modified Form	The following changes were made to the form: capitalization; grammar
Non-prescribed Drug Use Questionnaire	1.1	1.0	Minor	Modified CDEs	Updated permissible values for "Drug or substance illicitly used category"

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Parkinson's Disease Medication Log	1.1	1.0	Minor	Modified Form	The following was modified on the form: header; removed line numbers in table; relabeled column headers; reordered permissible values in table; removed note regarding side effects chart; PD Medication name reference table
Parkinson's Disease Medication Log	1.1	1.0	Minor	Modified CDEs	Permissible values were updated for the following CDE: Medication prior or concomitant class name
Parkinson's Disease Medication Log	1.1	1.0	Minor	Modified CDEs	Instructions were updated for the following CDEs: Medication prior or concomitant name; Medication prior or concomitant side effect type
Parkinson's Disease Medication Log	1.1	1.0	Major	New CDEs	The following CDEs were added: Medication prior or concomitant RXNorm code; Medication prior or concomitant dose unit of measure UCUM code
PET-SPECT	1.1	1.0	Minor	Modified Form	The following was modified on the form: grammar; instructions; header; labeling of PVs for "Imaging radioligand type" and "Imaging quantitative outcome type"

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
PET-SPECT	1.1	1.0	Minor	Modified CDEs	Permissible values were updated for "imaging matrix size value"