Parkinson’s Disease CDE Revision History Document

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August 2022 Revisions

Overview

The Parkinson's Disease (PD) Version 2.0 CDE Working Group comprehensively reviewed and updated the PD Version 1.0 CDEs. There have been significant changes to the content of the PD CDE materials in Version 2.0 compared to Version 1.0.

Subgroup Summaries were posted for PD Version 2.0 CDE Subgroups.

New Subdomains: Daily Cognitive Function and Digital Technology were added to the Outcomes and End Points Domain.

The following guidance documents were updated or newly added to the PD Version 2.0 recommendations.

Updated Guidance Documents (3)
1. Imaging Guidance for CDE Use
2. Other Non-Motor Guidance for CDE Use
   a. Question text was added for corresponding data dictionary.
   b. C10181 Thermoregulatory sweat test sweat chemical text was removed.
3. Summary of Diagnostic Criteria and Assessments for Psychosis in Parkinson's Disease

New Guidance Documents (3)
1. PhenX Social Determinants of Health Guidance
2. Best Practices for Digital Health Outcomes
3. Guidance for Digital Data Sharing

The following case report forms (CRFs) were updated, removed or newly added to the PD Version 2.0 recommendations. The corresponding data dictionaries (i.e., CDE Detail Reports) have been modified in accordance with the form changes. Population for all CDEs was corrected to Adult, as needed. Notably, there were 9 CDEs added to the list of Core CDEs for all PD studies: C00314 Medical history taken date and time; C08006 Symptoms first appear date and time; C08007 Diagnosis first given date and time; C08008 Diagnostic feature criterion type; C08009 Diagnostic feature criterion presence status; C59020 Diagnosis certainty category; C08012 Motor symptom parkinsonian initial type; C02411 Laterality type; C00023 Hand preference type. C18679 Family history medical condition relative other text was reclassified from Core to Supplemental for v2.0. C08004 Relative type other neurological disorder member number was Core in v1.0 but removed from the v2.0 recommendations.

Updated CRFs (10)
1. Demographics F2944
   a. CDEs Added
       i. C58676 Birth sex assigned type
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ii. C58780 Birth sex assigned type other text
iii. C58677 Gender identity type
iv. C58781 Gender identity type other text
v. C00030 Race USA category

b. CDEs Removed
i. C00035 Gender type
ii. C00031 Race expanded category

c. Classification Changes
i. None

d. Permissible Value Modifications
i. C00020 Ethnicity USA category
   1. Removed: Unknown
   ii. C00012 Education level USA type
       1. Added: 7th Grade or less; 8th to 12th Grade; High school graduate; 2-year college; 4-year college; Postgraduate
       2. Removed: Never attended/Kindergarten only; 1st Grade; 2nd Grade; 3rd Grade; 4th Grade; 5th Grade; 6th Grade; 7th Grade; 8th Grade; 9th Grade; 10th Grade; 11th Grade; 12th Grade, no diploma; High school graduate; GED or equivalent; Some college, no degree; Associate degree: occupational/technical/vocational program; Associate degree: academic program; Bachelor’s degree (e.g., BA, AB, BS, BBA); Master's degree (e.g., MA, MS, MEng, MEd, MBA); Professional school degree (e.g., MD, DDS, DVM, JD); Doctoral degree (e.g., PhD, EdD)

2. History of Early Exposure F2945
   a. CDEs Added
      i. C59062 Birth weight known indicator
      ii. C00311 Birth weight report value
      iii. C01581 Weight unit of measure
      iv. C59063 Birth weight source
      v. C59064 Breastfed duration range
      vi. C59073 Full biological sibling indicator
     vii. C59065 Older full biological sibling count
     viii. C59066 Twin sibling birth sex assigned type
         ix. C59067 Twin pea pod look indicator
         x. C59068 Twin difficult tell apart indicator
         xi. C16170 Menstrual period occurrence indicator
        xii. C52710 Menarche begin age value
        xiii. C59069 Menarche begin age category
        xiv. C59070 Shave facial hair regular begin age value
          xv. C59071 Shave facial hair regular begin age category
         xvi. C59072 Height in twenties measurement
        xvii. C01582 Height unit of measure
   b. CDEs Removed
      i. C08077 Full biological sibling indicator
      ii. C08082 Sibling rank type
      iii. C08083 Sibling name
      iv. C08084 Sibling gender type
      v. C08085 Sibling alive indicator
vi. C08086 Sibling current age value
vii. C08087 Sibling death age value
viii. C08088 Age value unit of measure
c. Classification Changes
   i. None
d. Permissible Value Modifications
   i. C08112 Birth weight category
      1. Added: Below average weight
   ii. C08081 Twin sibling type
      1. Removed: Unknown
3. Non-prescribed Drug Use Questionnaire F2947
   a. CDEs Added
      i. C17683 Non-prescribed controlled psychoactive drug substance marijuana text
      ii. C17684 Non-prescribed controlled psychoactive drug substance stimulant cocaine text
      iii. C17685 Non-prescribed controlled psychoactive drug substance stimulant amphetamine text
      iv. C17686 Non-prescribed controlled psychoactive drug substance sedative tranquilizer text
      v. C17688 Non-prescribed controlled psychoactive drug substance opioid text
     vi. C17687 Non-prescribed controlled psychoactive drug substance sedative barbiturate text
     vii. C59021 Non-prescribed controlled psychoactive drug substance heroin text
     viii. C17689 Non-prescribed controlled psychoactive drug substance inhalant text
     ix. C17690 Non-prescribed controlled psychoactive drug substance hallucinogen text
    x. C59022 Non-prescribed controlled psychoactive drug substance L-Dopa supplement text
     xi. C59023 Non-prescribed controlled psychoactive drug substance anti-psychotic text
     xii. C59024 Subscribed drug or substance illicitly used specify other text
   b. CDEs Removed
      i. None
c. Classification Changes
   i. None
d. Permissible Value Modifications
   i. C00712 Subscribed drug or substance illicitly used category
      1. Added: Anti-psychotics (Thorazine or Haldol); CBD (Cannabidiol); L-Dopa supplements
      2. Revised: Tranquilizers or anti-anxiety drugs (e.g., Valium, Librium, muscle relaxants, or Xanax) to Anti-anxiety drugs (Valium, Librium, muscle relaxants, or Xanax); Painkillers (e.g., Codeine, Darvon, Percodan, Dilaudid, or Demerol) to Opioids (Codeine, Fentanyl, Oxycontin, Darvon, Percodan, Dilaudid, or Demerol); Stimulants (e.g., Preludin, Benzedrine, Methadrine, uppers, or speed) to Stimulants (Crystal Meth, uppers, or speed); Other, specify (e.g., Methadone, Elavil, steroids, Thorazine, or Haldol) to Other, specify (e.g., anabolic steroids)
4. Family History F2948
   a. CDEs Added
      i. C59027 Family history relative type healthy member count
      ii. C59028 Family history relative type neurological disorder not parkinsonian code
      iii. C59029 Family history relative type neurological disorder not parkinsonian code other text
      iv. C59030 Family history relative type psychiatric disorder member count
   b. CDEs Removed
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i. C08004 Relative type other neurological disorder member number

c. Classification Changes
   i. C18679 Family history medical condition relative type other text: Core (v1.0) to Supplemental (v2.0)

d. Permissible Value Modifications
   i. C00722 Family history medical condition relative type
      1. Added: Biological daughter; Biological son; Dizygotic twin; Monozygotic twin
      2. Removed: Child; Grandchild; Great-grandchild; Maternal cousin; Maternal niece/nephew; Paternal cousin; Paternal niece/nephew

5. Medical History of Parkinson’s Disease F2949
   a. CDEs Added
      i. C59020 Diagnosis certainty category
      ii. C00023 Hand preference type
   b. CDEs Removed
      i. C18029 Other abnormality posture text
      ii. C08010 Diagnosis certainty percentage range
      iii. C08011 Diagnostic alternative reason
      iv. C08015 Motor symptom parkinsonian develop type
      v. C05404 Symptom onset date and time
   c. Classification Changes
      i. C00314 Medical history taken date and time: Supplemental (v1.0) to Core (v2.0)
      ii. C08006 Symptoms first appear date and time: Supplemental (v1.0) to Core (v2.0)
      iii. C08007 Diagnosis first given date and time: Supplemental (v1.0) to Core (v2.0)
      iv. C08008 Diagnostic feature criterion type: Supplemental (v1.0) to Core (v2.0)
      v. C08009 Diagnostic feature criterion presence status: Supplemental (v1.0) to Core (v2.0)
      vi. C08012 Motor symptom parkinsonian initial type: Supplemental (v1.0) to Core (v2.0)
      vii. C02411 Laterality type: Supplemental (v1.0) to Core (v2.0)
   d. Permissible Value Modifications
      i. C08012 Motor symptom parkinsonian initial type
         1. Revised: added specify to the PV text for Dystonia (specify symptoms) and Ambulatory/Axial Difficulties-Other abnormality of posture or gait (other, specify)

6. MRI and Spectroscopy F2950
   a. CDEs Added
      i. C20247 Imaging scanner model name text
      ii. C02498 Imaging scanner software version number
      iii. C59025 Imaging radio frequency coil manufacturer name
      iv. C59026 Imaging radio frequency coil manufacturer name other text
      v. C10568 Imaging radio frequency coil channel count
      vi. C18714 Imaging radio frequency coil channel count other text
      vii. C10685 Imaging slice orientation type
      viii. C18719 Imaging slice orientation type other text
      ix. C10927 Imaging inversion time
      x. C10591 Imaging phase encode direction text
      xi. C59031 Imaging slice order text
      xii. C59582 Imaging blood oxygenation level dependent collect minute value
      xiii. C59032 Imaging eye status
      xiv. C57934 Imaging multiband use indicator
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v. C59033 Imaging band count
vi. C59034 Imaging multiecho indicator
vii. C59035 Imaging echo count
viii. C59036 Imaging scan initiation time
ix. C59037 Medication Parkinson disease indicator
x. C59038 Medication Parkinson disease last dose date time

b. CDEs Removed
i. C18613 Imaging medication pre-treatment withheld name
ii. C02497 Imaging scanner model name
iii. C18717 Imaging scanner model other text
iv. C08246 Imaging pre-scan procedure type
v. C18707 Imaging pre-scan procedure other text
vi. C08247 Imaging medication pre-treatment status
vii. C08248 Imaging medication pre-treatment withheld duration
viii. C08249 Imaging medication pre-treatment withheld duration unit of measure
ix. C08250 Imaging head position text
x. C18721 Imaging visual analysis other text
xi. C08253 Imaging visual analysis status
xii. C18720 Imaging visual analysis location performed other text
xiii. C08254 Imaging visual analysis location performed type
xiv. C08255 Imaging visual analysis blinded indicator
xv. C08252 Imaging parameter quantified type
xvi. C18704 Imaging parameter quantified other text
xvii. C18753 Spectroscopy software other text
xviii. C08256 Spectroscopy software type
xix. C08257 Spectroscopy metabolite type
xx. C18752 Spectroscopy metabolite other text
c. Classification Changes
i. All CDEs: Supplemental (v1.0) to S-HR (v2.0)
d. Permissible Value Modifications
i. C02496 Imaging scanner manufacturer name
   1. Removed: Agfa; Hitachi; Carestream; Toshiba; Hologic; Konica Minolta
ii. C02495 Imaging scanner strength value
   1. Removed: 4.0T
iii. C02499 Imaging pulse sequence type
   1. Added: PROTON; MRS
   2. Removed: T1; T2; FLAIR; DWI; MRSI; PWI; Gradient-echo; Pulsed-ASL; Continuous-ASL; Pseudocontinuous-ASL; Post-contrast FLAIR; Post-contrast T1-weighted; COW MRA; TOF Neck MRA; CE MRA; SPACE/VISTA; TSE/FSE; Dual echo PD/T2W SE; PD SE; T2W SE; T1W SE; T1W 3D gradient-echo; T1-weighted spin echo with contrast; T1-weighted spin echo without contrast; PD/T2W FSE; DIR; PSIR; fMRI; Spectroscopic imaging 2D; Spectroscopic imaging 3D; Spin echo; Pulsed-ASL; Continuous-ASL; Pseudocontinuous-ASL; Unlocalized spectroscopy; ISIS; DWI/ADC; rFOV
iv. C08243 Imaging matrix size value
   1. Removed: 256 x 256

7. PET-SPECT Localization F2951
   a. CDEs Added
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i. C59042 Imaging radioligand type dihydrotetrabenazine specify text
ii. C59043 Imaging camera type
iii. C59044 Imaging camera type other text
iv. C20247 Imaging scanner model name text
v. C59045 Imaging pre-scan procedure type carbidopa specify text
vi. C59036 Imaging scan initiation time
vii. C59037 Medication Parkinsons disease indicator
viii. C59038 Medication Parkinsons disease last dose date time
ix. C59046 Imaging observe method status
x. C59047 Imaging scatter correction indicator
xi. C59048 Imaging deadtime correction indicator
xii. C59049 Imaging randoms correction indicator
xiii. C59050 Imaging reconstruct image resolution full width half maximum millimeter value
xiv. C59051 Imaging MRI acquire co-registration indicator
xv. C59052 Imaging MRI acquire co-registration date and time
xvi. C59053 Imaging quantitative outcome indicator
xvii. C59054 Imaging quantitative outcome dopamine transporter radioligand type
xviii. C59055 Imaging quantitative outcome vesicular monoamine transporter 2 radioligand type
xix. C59056 Imaging quantitative outcome tyrosine hydroxylase radioligand type
xx. C59057 Imaging amyloid centiloid anatomic site
xxi. C59058 Imaging amyloid centiloid anatomic site other text

b. CDEs Removed
   i. C18038 Isotope other text
   ii. C18717 Imaging scanner model other text
   iii. C02497 Imaging scanner model name
   iv. C18039 Scanner manufacturer other text
   v. C08247 Imaging medication pre-treatment status
   vi. C08248 Imaging medication pre-treatment withheld duration
   vii. C08249 Imaging medication pre-treatment withheld duration unit of measure
   viii. C18040 Radioligand dose other unit of measure
   ix. C18613 Imaging medication pre-treatment withheld name
   x. C18041 Imaging matrix size other scale
   xi. C18042 Post-injection management other text
   xii. C18043 Raw data reconstruction other text
   xiii. C18044 Attenuation correction other text
   xiv. C18706 Imaging post reconstruction filter other text
   xv. C18045 Post reconstruction filter other text
   xvi. C18046 Visual analysis result other text
   xvii. C18047 Visual analysis perform location other text
   xviii. C18049 Imaging outcome other name
   xix. C08273 Imaging F-dopa binding ratio value
   xx. C18053 Fdopa binding ratio other text
   xxi. C18688 Imaging amyloid standard uptake value anatomic other text
   xxii. C08274 Imaging amyloid standard uptake value anatomic site name
   xxiii. C08275 Imaging amyloid standard uptake value anatomic site value
   xxiv. C18054 Imaging amyloid standard uptake value anatomic site other name
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c. Classification Changes
   i. C08258 Imaging radioligand type: Supplemental (v1.0) to S-HR (v2.0)
   ii. C18711 Imaging radioligand type other text: Supplemental (v1.0) to S-HR (v2.0)
   iii. C08259 Imaging radioligand specific activity value: Supplemental (v1.0) to S-HR (v2.0)
   iv. C18037 Imaging radioligand specific activity value indicator: Supplemental (v1.0) to S-HR (v2.0)
   v. C08260 Imaging isotope type: Supplemental (v1.0) to S-HR (v2.0)
   vi. C18699 Imaging isotope type other text: Supplemental (v1.0) to S-HR (v2.0)
   vii. C08259 Imaging radioligand specific activity value: Supplemental (v1.0) to S-HR (v2.0)
   viii. C08261 Imaging radioligand dose value: Supplemental (v1.0) to S-HR (v2.0)
   ix. C08262 Imaging radioligand dose unit of measure: Supplemental (v1.0) to S-HR (v2.0)
   x. C18716 Imaging radioligand dose other text: Supplemental (v1.0) to S-HR (v2.0)
   xi. C08236 Imaging scanner software name: Supplemental (v1.0) to S-HR (v2.0)
   xii. C08261 Imaging scanner software name other text: Supplemental (v1.0) to S-HR (v2.0)
   xiii. C08242 Imaging acquisition duration: Supplemental (v1.0) to S-HR (v2.0)
   xiv. C08243 Imaging matrix size value: Supplemental (v1.0) to S-HR (v2.0)
   xv. C18700 Imaging matrix size value other text: Supplemental (v1.0) to S-HR (v2.0)
   xvi. C08244 Imaging slice thickness value: Supplemental (v1.0) to S-HR (v2.0)
   xvii. C08246 Imaging pre-scan procedure type: Supplemental (v1.0) to S-HR (v2.0)
   xviii. C18707 Imaging pre-scan procedure type other text: Supplemental (v1.0) to S-HR (v2.0)
   xx. C02014 Medication prior or concomitant name: Supplemental (v1.0) to S-HR (v2.0)
   xxi. C01541 Weight measurement: Supplemental (v1.0) to S-HR (v2.0)
   xxii. C08251 Imaging post injection management type: Supplemental (v1.0) to S-HR (v2.0)
   xxiii. C18705 Imaging post injection management type other text: Supplemental (v1.0) to S-HR (v2.0)
   xxiv. C08264 Imaging raw data reconstruction method type: Supplemental (v1.0) to S-HR (v2.0)
   xxv. C18712 Imaging raw data reconstruction method other text: Supplemental (v1.0) to S-HR (v2.0)
   xxvi. C08265 Imaging attenuation correction method type: Supplemental (v1.0) to S-HR (v2.0)
   xxvii. C18692 Imaging attenuation correction method type other text: Supplemental (v1.0) to S-HR (v2.0)
   xxviii. C08266 Imaging post reconstruction filter type: Supplemental (v1.0) to S-HR (v2.0)
   xxix. C08253 Imaging visual analysis status: Supplemental (v1.0) to S-HR (v2.0)
   xxx. C18721 Imaging visual analysis status other text: Supplemental (v1.0) to S-HR (v2.0)
   xxxi. C08254 Imaging visual analysis location performed type: Supplemental (v1.0) to S-HR (v2.0)
   xxxii. C18720 Imaging visual analysis location performed type other text: Supplemental (v1.0) to S-HR (v2.0)
   xxxiii. C08255 Imaging visual analysis blinded indicator: Supplemental (v1.0) to S-HR (v2.0)
   xxxiv. C18048 Imaging visual analysis blinded other text: Supplemental (v1.0) to S-HR (v2.0)
   xxxv. C08267 Imaging outcome variable name: Supplemental (v1.0) to S-HR (v2.0)
   xxxvi. C18702 Imaging outcome variable name other text: Supplemental (v1.0) to S-HR (v2.0)
   xxxvii. C08268 Imaging volume of interest placement method type: Supplemental (v1.0) to S-HR (v2.0)
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xxxviii. C18723 Imaging volume of interest placement method type other text: Supplemental (v1.0) to S-HR (v2.0)

xxxix. C08269 Imaging volume of interest anatomic location type: Supplemental (v1.0) to S-HR (v2.0)

xl. C18722 Imaging volume of interest anatomic location type other text: Supplemental (v1.0) to S-HR (v2.0)

xli. C08270 Imaging reference region text: Supplemental (v1.0) to S-HR (v2.0)

d. Permissible Value Modifications

i. C08258 Imaging radioligand type
   1. Added: Ioflupane; IACFT; DTBZ, specify
   2. Removed: DaTSCAN; Altropane; Florbetamol; 2-deoxy-glucose (either C14 or H3); AMT; FCWAY; H2O15; FMZ; ECD; HMPAO

ii. C18037 Imaging radioligand specific activity value indicator
   1. Removed: Yes; No; Unknown

iii. C02496 Imaging scanner manufacturer name
   1. Removed: Agfa; Hitachi; Carestream; Toshiba; Hologic; Konica Minolta

iv. C08243 Imaging matrix size value
   1. Removed: 256 x 256

v. C08246 Imaging pre-scan procedure type
   1. Added: Carbidopa, specify
   2. Removed: Withhold medications

vi. C08266 Imaging post reconstruction filter type
   1. Removed: Gaussian; Other, specify

vii. C08254 Imaging visual analysis location performed type
   1. Removed: Central read; Local read; Local report

viii. C08271 Imaging quantitative outcome type
   1. Added: VMAT2; Tyrosine Hydroxylase; Amyloid Imaging Binding Potential; Amyloid Imaging Volume of Distribution; Amyloid Imaging Mean Cortical Binding Potential; Amyloid Imaging Centiloids
   2. Removed: Altropane; ß-CIT; Fluoro-metatyrosine (FMT)
   3. Revised: DAT Scan to DAT


a. CDEs Added

i. C59085 Parkinsons disease motor sign year duration

ii. C59583 Parkinsons disease motor sign month duration

iii. C59086 Motor fluctuation year duration

iv. C59584 Motor fluctuation month duration

v. C59087 Dyskinesia troublesome dyskinesia year duration

vi. C59585 Dyskinesia troublesome month duration

vii. C59088 Deep brain stimulation indication type

viii. C59089 Deep brain stimulation indication type medication side effect other text

ix. C59090 Deep brain stimulation indication type other text

x. C59092 Unified Parkinons Disease Rating Scale version type

xi. C59094 Unified Parkinons Disease Rating Scale part three off levodopa score

xii. C59095 L-Dopa pre-operative challenge off levodopa duration

xiii. C59096 L-Dopa pre-operative challenge off dopamine agonist duration

xiv. C59097 Dopamine agonist specify text
xv. C59099 Unified Parkinsons Disease Rating Scale part three on medication score
xvi. C59100 Functional neurosurgery target anatomic site multiple ipsilateral lead specify text
xvii. C59101 Functional neurosurgery target planning software type text
xviii. C59103 Functional neurosurgery target planning adjunct type
xix. C59105 Anesthesia type
xx. C59106 Surgery head fixation status
xxi. C59107 Surgery head fixation text
xxii. C59586 Stereotactic surgery mini-frame type other text
xxiii. C59108 Stereotactic surgery robotic guidance lead insert indicator
xxiv. C59109 Stereotactic surgery robotic guidance lead insert platform text
xxv. C59110 Surgery intra-operative target verify lead placement MRI type
xxvi. C59111 Microelectrode record microstimulation sedation type
xxvii. C59113 Microelectrode record type
xxviii. C59115 Test stimulation sedation type
xxix. C59117 Brain lead insert count
xxx. C59118 Brain lead type
xxxi. C59120 Brain lead directional type other text
xxxii. C59121 Brain lead cylindrical type other text
xxxiii. C59122 Brain lead intercontact space interval type
xxxiv. C59123 Brain lead intercontact space interval type other text
xxxv. C14517 Device manufacturer name
xxxvi. C59124 Device model name
xxxvii. C59125 Pulse generator insert count
xxxviii. C59126 Pulse generator battery type
xxxix. C59127 Pulse generator sensing function indicator
xl. C59587 Surgery procedure hour duration
xli. C54898 Surgery procedure minute duration
xlii. C59128 Imaging processing software name
xliii. C59588 Anterior commissure posterior commissure target x coordinate value
xliv. C59589 Anterior commissure posterior commissure target y coordinate value
xlv. C59590 Anterior commissure posterior commissure target z coordinate value
xlvi. C59129 Stimulation brain parameter contact configuration text
xlvii. C59130 Stimulation brain parameter negative contact text
xlviii. C59131 Stimulation brain parameter positive contact text
xlix. C59132 Stimulation brain parameter directional steering indicator
l. C59133 Stimulation brain parameter amplitude value
li. C59134 Stimulation brain parameter amplitude unit of measure
lii. C59135 Stimulation brain parameter frequency value
liii. C59136 Stimulation brain parameter pulse width value
liv. C59137 Stimulation brain paradigm type
lv. C59138 Stimulation brain paradigm type other text
lvi. C59139 Optimal programming limit stimulation adverse effect indicator
lvii. C59140 Optimal programming limit stimulation adverse effect indicator specify text
lviii. C59142 Unified Parkinsons Disease Rating Scale part three on DBS off medication score
lix. C59143 Unified Parkinsons Disease Rating Scale part three on DBS on medication score
lx. C59144 Brain lead post implant interval
lxr. C59145 Brain lead post implant interval unit of measure
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lxii. C59146 Surgical complication hemorrhage symptom status
lxiii. C59147 Adverse event treatment specify text
lxiv. C59148 Adverse event outcome status other text
lxv. C59149 Surgical complication hardware related type
lxvi. C59150 Hardware component remove type
lxvii. C59151 Brain lead remove count
lxviii. C59152 Implantable pulse generator remove count
lxix. C59153 Lead extender remove count
lxx. C59154 Brain lead replacement manipulation count
lxxi. C59155 Pulse generator replacement manipulation count
lxxii. C59156 Pulse generator replacement reason
lxxiii. C59158 Pulse generator replacement reason other text
lxxiv. C59159 Lead extender replacement manipulation count
lxxv. C59160 Lead extender replacement reason
lxxvi. C59162 Lead extender replacement reason other text

b. CDEs Removed
   i. C08019 Disease duration
   ii. C18759 Surgery reason indication other text
   iii. C08020 Surgery reason indication type
   iv. C08021 Surgery indication drug or medication side effects type
   v. C08024 L-Dopa pre-operative stim-on time
   vi. C08025 L-Dopa pre-operative stim-off time
   vii. C08027 Functional neurosurgery type
   viii. C18683 Functional neurosurgery other text
   ix. C08029 Functional neurosurgery bilateral procedure type
   x. C08030 Anterior commissure posterior commissure target coordinate value
   xi. C08032 Risk Factor Questionnaire (RFQ) - significant injury surgery anesthesia administered type
   xii. C18750 Risk Factor Questionnaire (RFQ) - significant injury surgery anesthesia administered other text
   xiii. C08043 Lead implanted pulse generator model type
   xiv. C18733 Lead implanted pulse generator model other text
   xv. C08044 Operating room total time
   xvi. C08048 Medication anti-parkinsonian added after surgery indicator
   xvii. C08049 Stimulation brain parameters monopolar range
   xviii. C08050 Stimulation brain parameters bipolar range
   xix. C08052 Stimulation brain parameters amplitude range
   xx. C08053 Stimulation brain parameters frequency range
   xxi. C08054 Stimulation brain parameters pulse width range
   xxii. C08055 Stimulation brain mean value
   xxiii. C08056 Stimulation brain range value
   xxiv. C08057 L-Dopa post-operative stim - on time
   xxv. C08058 L-Dopa post-operative stim - off time
   xxvi. C08059 Surgery hardware replacement type
   xxvii. C08060 Leads replaced number
   xxviii. C08061 Implanted pulse generator replaced number
   xxix. C08062 Extenders replaced number
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xxx. C08063 Lead repositioned indicator
xxxi. C08068 Surgical complications post-operative mechanical malfunction type
xxiii. C18762 Surgical complications post-operative mechanical malfunction other text
xxxiv. C08069 Aborted procedures indicator
xxxv. C08070 Aborted procedures number
xxxvi. C18662 Aborted procedures other text
xxxvii. C08071 Aborted procedures reason
xxxviii. C08072 Surgical complication intracranial anatomic site
xxxix. C18664 Adverse event relatedness other text
xl. C08073 Adverse event relatedness source
xli. C08074 Adverse event relatedness source device type
xlii. C08075 Adverse event expected status
c. Classification Changes
   i. None
d. Permissible Value Modifications
   i. C08026 Functional neurosurgery target anatomic site
      1. Added: Ventrolateral thalamus; None; Multiple ipsilateral leads, specify
      2. Revised: Globus pallidus, pars interna (GPI) to Globus pallidus
   ii. C08031 Functional neurosurgery target planning method type
      1. Added: Indirect targeting on CT; Surgical planning software; Surgical planning adjuncts
      2. Removed: Atlas; Imaging; Ventriculography
      3. Revised: Direct to Direct targeting on MRI; Indirect to Indirect targeting on MRI;
         Other, specify to Other targeting methods, specify
   iii. C08034 Surgery head position status
      1. Revised: Elevated to Head of bed elevated; Flat to Head of bed flat
   iv. C08035 Stereotactic surgery frame type
      1. Revised: CRW to CRW headframe; Leksell to Leksell headframe; Mini-Frame to Single use mini-frame
   v. C08036 Stereotactic surgery mini-frame type
      1. Added: MRI interventions SmartFrame; Other, specify
      2. Revised: Medtronic to Medtronic Nexframe; FHC to FHC Starfix
   vi. C08038 Surgery intra-operative target verification source
      1. Added: CT or cone beam CT; MRI; Microelectrode recording and/or microstimulation;
         Test stimulation through DBS lead or other microcontact
      2. Removed: Image guidance platform; Software; Microstimulation; Macrostimulation;
         X-ray; Microelectrode recording; Serial single microelectrode recording; Multiple-electrode recording (BEN-GUN)
   vii. C08046 Medication anti-parkinsonian reduced after surgery indicator
      1. Removed: N/A; Unknown
      2. Revised: Yes, % reduction to Yes, % reduction in levodopa equivalents
   viii. C08066 Surgical complication intra-operative type
      1. Added: Procedure aborted
      2. Removed: Infarct
      3. Revised: Added event to Cardiovascular event (e.g., arrhythmia, heart attack, etc.)
   ix. C08067 Surgical complication post-operative type
      1. Added: Delirium
Parkinson’s Disease CDE Revision History Document

2. Removed: Infection; Mechanical malfunction
3. Revised: Infarct to Ischemic infarct
   x. C02302 Adverse event other action taken type
      1. Revised: Non-Study Treatment Required to Treatment Required, specify
   xi. C02303 Adverse event outcome status
      1. Added: Recovered/resolved without neurological deficit; Produced persistent neurological deficit; Other
      2. Removed: Recovered/Resolved; Recovered/Resolved with Sequelae; Recovering/Resolving; Not Recovered/Not Resolved; Fatal; Unknown
   xii. C08064 Lead reposition reason
      1. Added: Migration of lead from initial position; Lead fracture or electrical malfunction
      2. Removed: Mechanical breakdown; Infection
      3. Revised: Poor positioning to Poor initial positioning

9. Non-Parkinson's Disease Medication Log F2953
   a. CDEs Added
      i. C59040 Medication prior use report duration
      ii. C59041 Medication prior or concomitant as needed dose average frequency
   b. CDEs Removed
      i. C02011 Medication prior or concomitant dose frequency
      ii. C18035 Medication prior name
   c. Classification Changes
      i. None
   d. Permissible Value Modifications
      i. None

10. Parkinson’s Disease Medication Log F2954
   a. CDEs Added
      i. C02006 Medication prior or concomitant dose
      ii. C02015 Medication prior or concomitant route type
      iii. C59179 Medication prior or concomitant suppository route type
      iv. C18737 Medication prior or concomitant route type other text
      v. C59180 Medication prior or concomitant daily dose frequency
      vi. C59181 Medication prior or concomitant total daily intake text
      vii. C02016 Medication prior or concomitant start date and time
      viii. C02008 Medication prior or concomitant end date and time
   b. CDEs Removed
      i. C02002 Medication prior or concomitant use indicator
      ii. C08218 Parkinson's Disease medication class category
      iii. C02025 Medication prior or concomitant RXNorm code
      iv. C08219 Parkinson's Disease medication maximum dose
      v. C08221 Parkinson's Disease medication exposure duration
      vi. C08222 Parkinson's Disease medication exposure duration unit of measure
      vii. C02003 Medication prior or concomitant ongoing indicator
      viii. C18735 Medication prior or concomitant discontinuation other text
      ix. C08223 Medication prior or concomitant discontinuation reason
      x. C08224 Parkinson's Disease medication side effect text
   c. Classification Changes
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i. C02022 Medication prior or concomitant dose unit of measure: Supplemental (v1.0) to S-HR (v2.0)

ii. C18736 Medication prior or concomitant dose unit of measure other text: Supplemental (v1.0) to S-HR (v2.0)

iii. C02013 Medication prior or concomitant dose unit of measure UCUM code: Supplemental (v1.0) to S-HR (v2.0)

d. Permissible Value Modifications

i. C02022 Medication prior or concomitant dose unit of measure

1. Added: gr; gtt; mg/mL; tbsp; tsp; U
2. Removed: N/A

Removed CRFs (2)

1. Neuropathology: The National Alzheimer’s Coordinating Center (NACC) Neuropathology Data Form instrument was recommended in place of this CRF from v1.0.

2. MR: The MR CRF content was duplicative of the MRI and Spectroscopy CRF.

New CRFs (1)

1. Parkinson’s Disease Genetics

The following instruments were reclassified, removed, or newly added. Information in the instrument summaries was also updated as necessary. Notably, there were two instruments added to the list of Core CDEs for all PD studies: Hoehn and Yahr Scale and Montreal Cognitive Assessment (MoCA)

Updated Instrument Classifications (19)

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<th>V2.0 Classification</th>
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<tr>
<td>Composite Autonomic Symptom Scale (COMPASS-31)</td>
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<td>Hamilton Anxiety Rating Scale (HAM-A)</td>
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<tr>
<td>International Restless Legs Syndrome Study Group Severity Rating Scale (IRLS)</td>
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<tr>
<td>Lille Apathy Rating Scale (LARS)</td>
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<td>Supplemental – Highly Recommended</td>
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<tr>
<td>Montreal Cognitive Assessment (MoCA)</td>
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<td>Multiple Sleep Latency Test (MSLT) and Guidelines</td>
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<td>Parkinson's Disease Quality of Life Questionnaire (PDQL)</td>
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<td>Parkinson's Disease Quality of Life Scale (PDQUALIF)</td>
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<td>Parkinson's Disease Sleep Scale 2nd Version (PDSS-2)</td>
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<tr>
<td>Questionnaire for Impulsive-Compulsive Behaviors in Parkinson's Disease (QUIP) (Long Form)</td>
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<tr>
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<tr>
<td>Questionnaire Impulsive-Compulsive Disorders Parkinson's Disease-Rating Scale (QUIP-RS)</td>
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<td>Scale for Outcomes in Parkinson's Disease-Sleep (SCOPA-Sleep)</td>
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<tr>
<td>Schedule for the Evaluation of Individual Quality of Life (SEIQOL)</td>
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<tr>
<td>The American Academy of Sleep Medicine (AASM): International Classification of Sleep Disorders (ICSD) Criteria</td>
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<td>Supplemental – Highly Recommended</td>
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<tr>
<td>The International Restless Legs Syndrome Study Group Diagnostic Criteria</td>
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Instruments Removed (23)
1. Alzheimer’s Disease Cooperative Study-Clinical Global Impression of Change (ADCS-CGIC)
2. Belastungsfrageboge Parkinson kurzversion (BELA-P-k)
3. Brief Index of Sexual Functioning for Women (BISF-W)
4. Cambridge-Hopkins Restless Legs Syndrome Diagnostic Questionnaire (CH-RLSQ)
5. Composite Autonomic Severity Scale (CASS)
6. Geriatric Depression Scale (GDS)
7. Haraldsson’s Questionnaire
8. Neuropsychiatric Inventory Questionnaire (NPI-Q)
9. Non-Motor Symptom Assessment Scale for Parkinson’s Disease (NMSS)
10. Nottingham Health Profile (NHP)
11. Parkinson’s Neuropsychometric Dementia Assessment (PANDA)
12. PD DOC Mini Environmental Risk Questionnaire for Parkinson’s Disease Patients Baseline (PD DOC MERQ-PD-B)
13. Proposed Criteria for Diagnosis of the Syndrome of Apathy
14. Quantitative Sudomotor Axon Reflex Test (QSART)
15. Questions on Life Satisfaction - Movement Disorder (QLS-MD) and Deep Brain Stimulation (QLS-DBS) Modules
16. Risk Factor Questionnaire (RFQ) - All
17. Short Portable Mental Status Questionnaire (SPMSQ)
18. Sickness Impact Profile (SIP)
19. Sleep Apnea Scale of Sleep Disorders Questionnaire (SA-SDQ)
20. STOP Questionnaire
21. Structured Clinical Interview for DSM-IV Axis Disorders-Patient Version (SCID-I/P)
22. Structured Clinical Interview for Pathological Gambling (SCI-PG)
23. Survey Screen for Sleep Apnea (SSSA)

New Instrument Recommendations (63)

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<tr>
<th>Instrument</th>
<th>Subdomain</th>
<th>V2.0 Classification</th>
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<tr>
<td>Cambridge Neuropsychological Test Automated Battery (CANTAB) Connect</td>
<td>Cognitive</td>
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<tr>
<td>Cogstate Brief Battery</td>
<td>Cognitive</td>
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<tr>
<td>Lumos Labs NeuroCognitive Performance Tests (NCPT)</td>
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<tr>
<td>NeuroTrax BrainCare</td>
<td>Cognitive</td>
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<tr>
<td>Parkinson’s Disease - Cognitive Function Rating Scale (PD-CFRS)</td>
<td>Daily Cognitive Function</td>
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<tr>
<td>Secondhand Smoke Microenvironment Questionnaire</td>
<td>Epidemiology/Environmental History</td>
<td>Supplemental</td>
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<tr>
<td>Abnormal Involuntary Movement Scale (AIMS)</td>
<td>Motor Function</td>
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<tr>
<td>Clinical Global Impression Scale-Improvement (CGI-I)</td>
<td>Motor Function</td>
<td>Supplemental – Highly Recommended</td>
</tr>
<tr>
<td>Instrument</td>
<td>Subdomain</td>
<td>V2.0 Classification</td>
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<tr>
<td>Clinical Global Impression Scale-Severity (CGI-S)</td>
<td>Motor Function</td>
<td>Supplemental</td>
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<tr>
<td>Core Assessment Program for Surgical Interventional Therapies in PD (CAPSIT-PD)</td>
<td>Motor Function</td>
<td>Supplemental – Highly Recommended</td>
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<tr>
<td>Hauser Motor Fluctuation Diary</td>
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<tr>
<td>Hoehn and Yahr Scale</td>
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<tr>
<td>Movement Disorder Society Clinical Diagnostic Criteria for Parkinson’s Disease</td>
<td>Motor Function</td>
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<tr>
<td>Rush Dyskinesia Rating Scale (RDRS)</td>
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<tr>
<td>Schwab and England Activities of Daily Living Scale</td>
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<tr>
<td>Unified Dyskinesia Scale (UDysRS)</td>
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<td>Wearing Off Questionnaire (WOQ)</td>
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<td>National Alzheimer’s Coordinating Center (NACC) Neuropathology Data Form</td>
<td>Other Clinical Data</td>
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<td>Actigraphy (with Sleep Diary)</td>
<td>Other Non-Motor</td>
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<td>Epworth Sleepiness Scale (ESS) - Adult Version</td>
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<td>Female Sexual Function Index (FSFI)</td>
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<td>Gastrointestinal Symptoms in Neurodegenerative Diseases Scale (GIND)</td>
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<td>Hyposmia Rating Scale (HRS)</td>
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<tr>
<td>Innsbruck REM Sleep Behavior Disorder Inventory (RBD-I-5)</td>
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<tr>
<td>International Consultation on Incontinence Questionnaire Bladder Diary (ICIQ-Bladder Diary)</td>
<td>Other Non-Motor</td>
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<td>King’s Parkinson’s Disease Pain Questionnaire (KPPQ)</td>
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<td>King’s Parkinson’s Disease Pain Scale (KPPS)</td>
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<td>Mayo Sleep Questionnaire</td>
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<td>Munich Dysphagia Test - Parkinson's Disease (MDT-PD)</td>
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<td>Neurogenic Bladder Symptom Score (NBSS)</td>
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<td>Orthostatic Hypotension Questionnaire (OHQ)</td>
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<td>Orthostatic Symptom Grading Scale</td>
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<td>Parkinson’s Disease Fatigue Scale (PFS-16)</td>
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<td>Polysomnography (PSG) and Guidelines</td>
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<td>Radboud Oral Motor Inventory for Parkinson’s Disease (ROMP)</td>
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<td>Sniffin' Sticks Test</td>
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<tr>
<td>STOP-BANG Questionnaire</td>
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<tr>
<td>The Gastrointestinal Dysfunction Scale for Parkinson’s Disease</td>
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<tr>
<td>The International Parkinson and Movement Disorder Society – Non-Motor Rating Scale (MDS-NMS)</td>
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<td>The International Parkinson and Movement Disorder Society – Non-Motor Rating Scale (MDS-NMS) (GI Domain)</td>
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<td>The REM Sleep Behavior Disorder (RBD) Questionnaire – Hong Kong (RBDQ-HK)</td>
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<td>The REM Sleep Behavior Disorder Single-Question Screen (RBD1Q)</td>
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<td>The Swallowing Clinical Assessment Score in Parkinson’s Disease (SCAS-PD)</td>
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<td>Visual Impairment in Parkinson’s Disease Questionnaire (VIPD-Q)</td>
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<td>Apathy Motivation Index Caregiver Version (AMI-CG)</td>
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<td>Brief Dimensional Apathy Scale (b-DAS)</td>
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<td>Columbia - Suicide Severity Rating Scale (C-SSRS) Screener Version</td>
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<tr>
<td>Columbia - Suicide Severity Rating Scale (C-SSRS)</td>
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<td>Cornell Scale for Depression in Dementia (CSDD)</td>
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<td>Dimensional Apathy Scale (DAS)</td>
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<th>Instrument</th>
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<td>Enhanced Scale for the Assessment of Positive Symptoms in Parkinson’s Disease (eSAPS-PD)</td>
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<td>PROMIS-29 Profile</td>
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</table>

**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 (Birth sex assigned type ) and C58677 (Gender identity type). 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)
- Movement Disorder Society Unified Parkinson’s Disease Scale

Classification revisions were made to the following instruments:

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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.
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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.
- 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.
- 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
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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)

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)

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### Detailed Form Revisions:

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

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## Risk Factor Questionnaire - Physical Activity and Sleep (RFQ)

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## Risk Factor Questionnaire - Residential History (RFQ)

- **Current Version**: 2.0
- **Previous Version**: 1.2
- **Change Classification**: Major
- **Change Type**: Notice of Copyright
- **Description of Change**: A Notice of Copyright was created for this form and will replace the existing form.

## Risk Factor Questionnaire – Toxicants (RFQ)

- **Current Version**: 2.0
- **Previous Version**: 1.2
- **Change Classification**: Major
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## Risk Factor Questionnaire - Height and Weight (RFQ-U)

- **Current Version**: 2.0
- **Previous Version**: 1.2
- **Change Classification**: Major
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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
- 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
Parkinson’s Disease CDE Revision History Document

- Family History
- Functional Neurosurgery
- History of Early Exposure
- Infection History
- Medical History
- MR
- MRI and Spectroscopy
- Neuropathology
- Non-Parkinson’s Disease Medication Log
- 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.
### Parkinson’s Disease CDE Revision History Table

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<td>Modified CDEs</td>
<td>Nearly all CDE names and definitions were updated to achieve greater consistency across all NINDS CDEs and for clarity</td>
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<td>The following types of CDEs were deleted: CDEs redundant with other CDEs; CDEs specifying unit; and CDEs specifying an &quot;other, specify&quot; response</td>
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<td>Modified CDEs</td>
<td>For a number of CDEs, &quot;Unknown&quot; was added to the permissible value set and/or &quot;Don't know&quot; and &quot;Missing/Unknown&quot; were removed</td>
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<td>1.1</td>
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<td>Minor</td>
<td>Modified Form</td>
<td>The following changes were made to the form: changes to header; capitalization; grammar</td>
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<td>Functional Neurosurgery</td>
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<td>Major</td>
<td>New CDE</td>
<td>The following CDEs were added: &quot;Surgical or therapeutic procedure start date and time&quot;</td>
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<tr>
<td>CRF Module/ Guideline</td>
<td>Current Version</td>
<td>Previous Version</td>
<td>Change Classification</td>
<td>Change Type</td>
<td>Description of Change</td>
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<td>Major</td>
<td>Modified CDEs</td>
<td>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</td>
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<td>Instructions were updated for: Surgical Complications</td>
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<td>History of Early Exposure to PD</td>
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<td>Minor</td>
<td>Modified Form</td>
<td>The following changes were made to the form: header and footer modified; skip logic modified; instruction to specify units added; relabeled &quot;sex&quot; as &quot;gender&quot;</td>
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<td>Permissible values were updated for the following CDEs: Sibling gender type; Sibling alive indicator</td>
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<td>Infection History</td>
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<td>The following changes were made to the form: header modified; skip logic modified</td>
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<td>Permissible values were updated for the following CDEs: Influenza vaccine received frequency; Meningitis or encephalitis diagnosed type</td>
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<td>CRF Module/ Guideline</td>
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<td>Medical History of Parkinson's Disease</td>
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<td>The following was modified on the form: header; instructions; label of CDE &quot;Medication prior or concomitant name&quot;</td>
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<td>Modified CDEs</td>
<td>Permissible values were updated for &quot;imaging matrix size value&quot;</td>
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<tr>
<td>MRI and Spectroscopy</td>
<td>1.1</td>
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<td>The header was modified on the form</td>
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<td>Minor</td>
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<td>The following changes were made to the form; Header updated; Codes for permissible values were removed</td>
</tr>
<tr>
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<tr>
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<td>Minor</td>
<td>Modified CDEs</td>
<td>Permissible values were updated for most CDEs on this form</td>
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<td>Non-Parkinson's Disease Medication Log</td>
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<td>Minor</td>
<td>Modified Form</td>
<td>The following was modified on the form: grammar; header; reformatted table; instructions for table</td>
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<td>Major</td>
<td>New CDEs</td>
<td>The following CDEs were added: Medication prior or concomitant RXNorm code; Medication prior or concomitant dose unit of measure UCUM code</td>
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<tr>
<td>Non-prescribed Drug Use Questionnaire</td>
<td>1.1</td>
<td>1.0</td>
<td>Minor</td>
<td>Modified Form</td>
<td>The following changes were made to the form: capitalization; grammar</td>
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<tr>
<td>Non-prescribed Drug Use Questionnaire</td>
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<td>Minor</td>
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<td>Updated permissible values for &quot;Drug or substance illicitly used category&quot;</td>
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<td>Parkinson's Disease Medication Log</td>
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<td>Minor</td>
<td>Modified Form</td>
<td>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</td>
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## Parkinson’s Disease CDE Revision History Document

<table>
<thead>
<tr>
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<td>Parkinson's Disease Medication Log</td>
<td>1.1</td>
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<td>Permissible values were updated for the following CDE: Medication prior or concomitant class name</td>
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<td>The following CDEs were added: Medication prior or concomitant RXNorm code; Medication prior or concomitant dose unit of measure UCUM code</td>
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<tr>
<td>PET-SPECT</td>
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<td>1.0</td>
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<td>The following was modified on the form: grammar; instructions; header; labeling of PVs for &quot;Imaging radioligand type&quot; and &quot;Imaging quantitative outcome type&quot;</td>
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<td>Minor</td>
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