Summary of Core/Supplemental – Highly Recommended Recommendations: Parkinson's Disease CDEs

Start-up Resource – NINDS Parkinson's Disease CDE Recommendations

The National Institute of Neurological Disorders and Stroke (NINDS) and other Federal agencies and international organizations have the common mission of developing data standards for clinical research. Through the efforts of subject-specific working groups, topic-driven data elements have been created. The first set of Common Data Elements (CDEs) for Parkinson's Disease was developed in 2010. A Parkinson's Disease v2.0 CDE Working Group was convened in 2021 to perform a comprehensive review of the Parkinson's Disease CDEs. The Parkinson's Disease v2.0 CDEs were posted in August 2022. The Core data elements to be used by an investigator when beginning a research study in this disease/disorder are listed in this resource document. All other recommendations are listed on the website and should be considered based on study type.

Each CDE or instrument could be classified according to the definitions below:

General Core: A data element that is required for all NINDS funded studies.

Disease Core: A data element that collects essential information applicable to any disease-specific study, including all therapeutic areas. The NINDS and its appointed working groups assign the disease "Core" classification based on the current clinical research best practices. In each case, the disease Core CDEs are a small subset of the available CDEs, where it is anticipated that investigators will need to collect the disease Core CDEs on any type of study. These are required for all disease-specific studies.

Disease Supplemental – Highly Recommended: A data element which is essential based on certain conditions or study types in clinical research studies. In most cases, these have been used and validated in the disease area. These data elements are strongly recommended for the specified disease condition, study type or design.

Disease Supplemental: A data element which is commonly collected in clinical research studies. Use depends upon the study design, protocol or type of research involved. These are recommended, but not required, for studies.

Disease Exploratory: A data element that requires further validation but may fill current gaps in the CDEs and/or substitute for an existing CDE once validation is complete. Such data elements show great promise but require further validation before they are ready for prime-time use in clinical research studies. They are reasonable to use with the understanding that it has limited validation in the target group.

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National Institute of Health (NIH) Resources: *The NINDS also strongly encourages researchers to use these NIH developed materials for NINDS-sponsored research, when appropriate. Utilization of these resources will enable greater consistency for NINDS-sponsored research studies. These tools are free of charge.*	• **NIH Toolbox** • **Quality of Life in Neurological Disorders (Neuro-QOL)** • **Patient-Reported Outcomes Measurement Information System (PROMIS)**

Core CDEs for all NINDS Studies[1]:

Domain/Sub-Domain	CDE Name	CDE ID	Study Type
Participant Characteristics; Demographics	Birth date	C00007	All studies
Participant Characteristics; Demographics	Ethnicity USA category	C00020	All studies
Participant Characteristics; Demographics	Race USA category	C00030	All studies
Participant Characteristics; Demographics	Birth sex assigned type	C58676	All studies
Participant Characteristics; Demographics	Gender identity type	C58677	All studies
Participant Characteristics; Demographics	Medical history condition text	C00322	All studies
Participant Characteristics; Demographics	Medical history condition SNOMED CT code	C00313	All studies

[1] Note: Education year count C00015 is no longer a general Core CDE

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Core Elements for PD:

Domain; Subdomain	CDE Name	CDE ID
Participant Characteristics; Demographics	Education level USA type	C00012
Participant History and Family History; General Health History	Family history medical condition relative type	C00722
Participant History and Family History; General Health History	Family history relative type total member count	C08000
Participant History and Family History; General Health History	Family history relative type Parkinsons disease parkinsonism member count	C08003
Participant History and Family History; General Health History	Family history relative type neurological disorder not parkinsonian count	C17405
Participant History and Family History; General Health History	Family history relative type Parkinsons disease parkinsonism other neurological disorder member count	C08005
Disease/Injury Related Events; History of Disease/Injury Event	Medical history taken date and time	C00314
Disease/Injury Related Events; History of Disease/Injury Event	Symptoms first appear date and time	C08006
Disease/Injury Related Events; History of Disease/Injury Event	Diagnosis first given date and time	C08007
Disease/Injury Related Events; History of Disease/Injury Event	Diagnostic feature criterion type	C08008
Disease/Injury Related Events; History of Disease/Injury Event	Diagnostic feature criterion presence status	C08009
Disease/Injury Related Events; History of Disease/Injury Event	Diagnosis certainty category	C59020
Disease/Injury Related Events; History of Disease/Injury Event	Motor symptom parkinsonian initial type	C08012
Disease/Injury Related Events; History of Disease/Injury Event	Laterality type	C02411
Disease/Injury Related Events; History of Disease/Injury Event	Hand preference type	C00023

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General Core for all Studies:

Investigators should review the FDA's ["Guidance for Industry: Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials"](#) for the most up-to-date information about suicidal ideation and behavior. One scale that FDA suggests is the Columbia Suicide Severity Rating Scale (C-SSRS) (available at [Columbia Suicide Severity Rating Scale Website](#)).

Surgical Complications: In order to prevent duplication of data collection, the General [Adverse Events](#) form will be considered Core for clinical trials. If the information on that form does not completely capture what is needed, the surgical complications section on the Functional Neurosurgery: Deep Brain Stimulation CRF can be Supplemental.

Core Instruments for PD:

1. Hoehn and Yahr Scale
2. Montreal Cognitive Assessment (MoCA)
3. Movement Disorder Society - Unified Parkinson's Disease Rating Scale (MDS-UPDRS)
4. Unified Parkinson's Disease Rating Scale (UPDRS)

   Select either MDS-UPDRS (for studies focused on all severities and especially on mild/moderate participants) or UPDRS (for studies focused preferentially on advanced PD participants).

Supplemental – Highly Recommended Elements for PD:

Domain; Subdomain	CDE Name	CDE ID
Assessments and Examinations; Imaging Diagnostics	Imaging scanner manufacturer name	C02496
Assessments and Examinations; Imaging Diagnostics	Imaging scanner model name text	C20247
Assessments and Examinations; Imaging Diagnostics	Imaging scanner manufacturer name other text	C18716
Assessments and Examinations; Imaging Diagnostics	Imaging scanner software name	C08236
Assessments and Examinations; Imaging Diagnostics	Imaging scanner software version number	C02498

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Domain; Subdomain	CDE Name	CDE ID
Assessments and Examinations; Imaging Diagnostics	Imaging radio frequency coil manufacturer name	C59025
Assessments and Examinations; Imaging Diagnostics	Imaging radio frequency coil manufacturer name other text	C59026
Assessments and Examinations; Imaging Diagnostics	Imaging radio frequency coil channel count	C10568
Assessments and Examinations; Imaging Diagnostics	Imaging scanner strength value other text	C18718
Assessments and Examinations; Imaging Diagnostics	Imaging scanner strength value	C02495
Assessments and Examinations; Imaging Diagnostics	Imaging radio frequency coil channel count other text	C18714
Assessments and Examinations; Imaging Diagnostics	Imaging slice orientation type	C10685
Assessments and Examinations; Imaging Diagnostics	Imaging slice orientation type other text	C18719
Assessments and Examinations; Imaging Diagnostics	Imaging pulse sequence type	C02499
Assessments and Examinations; Imaging Diagnostics	Imaging pulse sequence type other text	C18708
Assessments and Examinations; Imaging Diagnostics	Imaging repetition gap value	C08238
Assessments and Examinations; Imaging Diagnostics	Imaging echo duration	C08239
Assessments and Examinations; Imaging Diagnostics	Imaging flip angle measurement	C08240
Assessments and Examinations; Imaging Diagnostics	Imaging field of view axis 1 measurement	C08241
Assessments and Examinations; Imaging Diagnostics	Imaging inversion time	C10927

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Domain; Subdomain	CDE Name	CDE ID
Assessments and Examinations; Imaging Diagnostics	Imaging phase encode direction text	C10591
Assessments and Examinations; Imaging Diagnostics	Imaging acquisition duration	C08242
Assessments and Examinations; Imaging Diagnostics	Imaging matrix size value	C08243
Assessments and Examinations; Imaging Diagnostics	Imaging matrix size value other text	C18700
Assessments and Examinations; Imaging Diagnostics	Imaging slice thickness value	C08244
Assessments and Examinations; Imaging Diagnostics	Imaging slice count	C08245
Assessments and Examinations; Imaging Diagnostics	Imaging slice order text	C59031
Assessments and Examinations; Imaging Diagnostics	Imaging blood oxygenation level dependent collect minute value	C59582
Assessments and Examinations; Imaging Diagnostics	Imaging eye status	C59032
Assessments and Examinations; Imaging Diagnostics	Imaging multiband use indicator	C57934
Assessments and Examinations; Imaging Diagnostics	Imaging band count	C59033
Assessments and Examinations; Imaging Diagnostics	Imaging multiecho indicator	C59034
Assessments and Examinations; Imaging Diagnostics	Imaging echo count	C59035
Assessments and Examinations; Imaging Diagnostics	Imaging scan initiation time	C59036
Assessments and Examinations; Imaging Diagnostics	Medication Parkinsons disease indicator	C59037

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Domain; Subdomain	CDE Name	CDE ID
Assessments and Examinations; Imaging Diagnostics	Medication prior or concomitant name	C02014
Assessments and Examinations; Imaging Diagnostics	Medication Parkinsons disease last dose date time	C59038
Assessments and Examinations; Imaging Diagnostics	Imaging radioligand type	C08258
Assessments and Examinations; Imaging Diagnostics	Imaging radioligand type dihydrotetrabenazine specify text	C59042
Assessments and Examinations; Imaging Diagnostics	Imaging radioligand type other text	C18711
Assessments and Examinations; Imaging Diagnostics	Imaging radioligand specific activity value	C08259
Assessments and Examinations; Imaging Diagnostics	Imaging radioligand specific activity value indicator	C18037
Assessments and Examinations; Imaging Diagnostics	Imaging isotope type	C08260
Assessments and Examinations; Imaging Diagnostics	Imaging isotope type other text	C18699
Assessments and Examinations; Imaging Diagnostics	Imaging camera type	C59043
Assessments and Examinations; Imaging Diagnostics	Imaging camera type other text	C59044
Assessments and Examinations; Imaging Diagnostics	Imaging radioligand dose value	C08261
Assessments and Examinations; Imaging Diagnostics	Imaging radioligand dose unit of measure	C08262
Assessments and Examinations; Imaging Diagnostics	Imaging radioligand dose other text	C18710
Assessments and Examinations; Imaging Diagnostics	Imaging radioligand injection to acquisition duration	C08263

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Domain; Subdomain	CDE Name	CDE ID
Assessments and Examinations; Imaging Diagnostics	Imaging pre-scan procedure type	C08246
Assessments and Examinations; Imaging Diagnostics	Imaging pre-scan procedure type carbidopa specify text	C59045
Assessments and Examinations; Imaging Diagnostics	Imaging pre-scan procedure type other text	C18707
Assessments and Examinations; Imaging Diagnostics	Weight measurement	C01541
Assessments and Examinations; Imaging Diagnostics	Imaging observe method status	C59046
Assessments and Examinations; Imaging Diagnostics	Imaging post injection management type	C08251
Assessments and Examinations; Imaging Diagnostics	Imaging post injection management type other text	C18705
Assessments and Examinations; Imaging Diagnostics	Imaging raw data reconstruction method type	C08264
Assessments and Examinations; Imaging Diagnostics	Imaging raw data reconstruction method other text	C18712
Assessments and Examinations; Imaging Diagnostics	Imaging attenuation correction method type	C08265
Assessments and Examinations; Imaging Diagnostics	Imaging attenuation correction method type other text	C18692
Assessments and Examinations; Imaging Diagnostics	Imaging scatter correction indicator	C59047
Assessments and Examinations; Imaging Diagnostics	Imaging deadtime correction indicator	C59048
Assessments and Examinations; Imaging Diagnostics	Imaging randoms correction indicator	C59049
Assessments and Examinations; Imaging Diagnostics	Imaging post reconstruction filter type	C08266

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Domain; Subdomain	CDE Name	CDE ID
Assessments and Examinations; Imaging Diagnostics	Imaging reconstruct image resolution full width half maximum millimeter value	C59050
Assessments and Examinations; Imaging Diagnostics	Imaging visual analysis status	C08253
Assessments and Examinations; Imaging Diagnostics	Imaging visual analysis status other text	C18721
Assessments and Examinations; Imaging Diagnostics	Imaging visual analysis location performed type	C08254
Assessments and Examinations; Imaging Diagnostics	Imaging visual analysis location performed type other text	C18720
Assessments and Examinations; Imaging Diagnostics	Imaging visual analysis blinded indicator	C08255
Assessments and Examinations; Imaging Diagnostics	Imaging visual analysis blinded other text	C18048
Assessments and Examinations; Imaging Diagnostics	Imaging outcome variable name	C08267
Assessments and Examinations; Imaging Diagnostics	Imaging outcome variable name other text	C18702
Assessments and Examinations; Imaging Diagnostics	Imaging volume of interest placement method type	C08268
Assessments and Examinations; Imaging Diagnostics	Imaging volume of interest placement method type other text	C18723
Assessments and Examinations; Imaging Diagnostics	Imaging volume of interest anatomic location type	C08269
Assessments and Examinations; Imaging Diagnostics	Imaging volume of interest anatomic location type other text	C18722
Assessments and Examinations; Imaging Diagnostics	Imaging reference region text	C08270
Assessments and Examinations; Imaging Diagnostics	Imaging MRI acquire co-registration indicator	C59051

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Domain; Subdomain	CDE Name	CDE ID
Assessments and Examinations; Imaging Diagnostics	Imaging MRI acquire co-registration date and time	C59052
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Diagnosis primary clinical parkinsonism type	C59059
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Diagnosis primary clinical parkinsonism type other text	C59060
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Diagnosis primary clinical parkinsonism status	C59061
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Symptom onset age value	C10500
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Diagnosis Parkinsons disease support sign type	C59074
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Diagnosis Parkinsons disease support sign status	C59075
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Response anti parkinsonism therapy status	C59076
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Genetic testing performed indicator	C15520
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Genetic test performed year value	C19584
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Genetic test result source type	C56033
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Genetic test result source type other text	C56035
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Genetic test result patient inform indicator	C59174
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Patient genetic test result inform source type	C59077
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	DNA known variant status	C59078

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Domain; Subdomain	CDE Name	CDE ID
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	DNA known variant description text	C59079
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Biological sample in repository indicator	C16194
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Biological sample in repository specimen type	C16195
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Biological sample in repository specimen type other text	C59080
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Biological sample in repository study initially requested name	C16196
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Biological sample in repository location name	C16197
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Biological sample in repository consent form signed indicator	C16198
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Biological sample allow share consent form indicator	C59081
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Blood sample repository name	C19516
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Brain donation register indicator	C59175
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Brain family member available indicator	C59082
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Family history relative type biological sample identifier number	C08002
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Repository contact text	C59083
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Brain tissue type repository collect text	C59176
Treatment/Intervention Data; Drugs	Medication prior or concomitant dose	C02006
Treatment/Intervention Data; Drugs	Medication prior or concomitant dose unit of measure	C02022

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Domain; Subdomain	CDE Name	CDE ID
Treatment/Intervention Data; Drugs	Medication prior or concomitant dose unit of measure other text	C18736
Treatment/Intervention Data; Drugs	Medication prior or concomitant dose unit of measure UCUM code	C02013
Treatment/Intervention Data; Drugs	Medication prior or concomitant route type	C02015
Treatment/Intervention Data; Drugs	Medication prior or concomitant suppository route type	C59179
Treatment/Intervention Data; Drugs	Medication prior or concomitant route type other text	C18737
Treatment/Intervention Data; Drugs	Medication prior or concomitant daily dose frequency	C59180
Treatment/Intervention Data; Drugs	Medication prior or concomitant total daily intake text	C59181
Treatment/Intervention Data; Drugs	Medication prior or concomitant start date and time	C02016
Treatment/Intervention Data; Drugs	Medication prior or concomitant end date and time	C02008

Supplemental – Highly Recommended Instruments for PD:

1. 15 - Item Geriatric Depression Scale (GDS-15)

2. Apathy Scale (AS)

3. Clinical Global Impression Scale-Improvement (CGI-I)

4. Columbia - Suicide Severity Rating Scale (C-SSRS)

5. Columbia - Suicide Severity Rating Scale (C-SSRS) Screener Version

6. Composite Autonomic Symptom Scale (COMPASS-31)

7. Core Assessment Program for Surgical Interventional Therapies in PD (CAPSIT-PD)

8. Dimensional Apathy Scale (DAS)

9. Dimensional Apathy Scale (DAS) Informant/Carer-Rated Version

10. Enhanced Scale for the Assessment of Positive Symptoms in Parkinson's Disease (eSAPS-PD)

11. Epworth Sleepiness Scale (ESS) - Adult Version

12. EuroQoL-5 Dimension Questionnaire (EQ-5D)

13. Hauser Motor Fluctuation Diary

14. International Restless Legs Syndrome Study Group Severity Rating Scale (IRLS)

15. Lille Apathy Rating Scale (LARS)

16. Movement Disorder Society Clinical Diagnostic Criteria for Parkinson's Disease

17. Multiple Sleep Latency Test (MSLT) and Guidelines

18. Orthostatic Hypotension Questionnaire (OHQ)

19. Parkinson Anxiety Scale (PAS)

20. Parkinson's Disease Questionnaire (PDQ-39)

21. Parkinson's Disease Sleep Scale 2nd Version (PDSS-2)

22. Polysomnography (PSG) and Guidelines

23. Quality of Life in Neurological Disorders (Neuro-QOL)

24. Questionnaire for Impulsive-Compulsive Behaviors in Parkinson's Disease (QUIP) (Long Form)

25. Questionnaire for Impulsive-Compulsive Behaviors in Parkinson's Disease (QUIP) (Short Form)

26. Questionnaire Impulsive-Compulsive Disorders Parkinson's Disease-Rating Scale (QUIP-RS)

27. Risk Factor Questionnaire (RFQ) - Occupation and Employment Status

28. Scale for Outcomes in Parkinson's Disease-Sleep (SCOPA-Sleep)

29. Scale for the Assessment of Positive Symptoms-Parkinson's Disease (SAPS-PD)

30. Schwab and England Activities of Daily Living Scale

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

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

33. The International Parkinson and Movement Disorder Society – Non-Motor Rating Scale (MDS-NMS)

34. The International Restless Legs Syndrome Study Group Diagnostic Criteria

35. Unified Dyskinesia Scale (UDysRS)

36. Wearing Off Questionnaire (WOQ)

For the complete list of NINDS CDE recommendations for PD, please see the [NINDS CDE website](#).