Summary of Core/Supplemental - Highly Recommended Recommendations: Unruptured Cerebral Aneurysms and Subarachnoid Hemorrhage CDEs

Start-up Resource – NINDS Unruptured Cerebral Aneurysms and Subarachnoid Hemorrhage 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 Unruptured Cerebral Aneurysms and Subarachnoid Hemorrhage (SAH) was developed from 2015-2017. The Core and Supplemental – Highly Recommended 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.

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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.

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:[*]

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

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

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Domain/Sub-Domain	CDE Name	CDE ID	Study Type
Participant Characteristics; Demographics	Gender identity type	C58677	All studies
Participant History and Family History; General Health History	Medical history condition text	C00322	All studies
Participant History and Family History; General Health History	Medical history condition SNOMED CT code	C00313	All studies

Core CDEs for SAH Studies:

Domain; Sub-Domain	Data element	CDE ID
Assessments and Examinations/Imaging Diagnostics	Aneurysm diameter maximum measurement	C54725
Assessments and Examinations/Imaging Diagnostics	Aneurysm height measurement	C54726
Assessments and Examinations/Imaging Diagnostics	Aneurysm width measurement	C54727
Assessments and Examinations/Imaging Diagnostics	Imaging brain assessment result	C02500
Assessments and Examinations/Imaging Diagnostics	Aneurysm morphology type	C54741
Assessments and Examinations/Imaging Diagnostics	Imaging modality vessel imaging angiography type	C13879

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Domain; Sub-Domain	Data element	CDE ID
Assessments and Examinations/Imaging Diagnostics	Imaging vessel angiography arterial anatomic site	C13884
Assessments and Examinations/Laboratory Tests and Biospecimens/Biomarkers	Specimen biologic source type	C54743
Assessments and Examinations/Laboratory Tests and Biospecimens/Biomarkers	Specimen not collected reason	C54746
Assessments and Examinations/Laboratory Tests and Biospecimens/Biomarkers	Specimen acquisition anatomical site	C54747
Assessments and Examinations/Laboratory Tests and Biospecimens/Biomarkers	Specimen baseline collection indicator	C54748
Assessments and Examinations/Laboratory Tests and Biospecimens/Biomarkers	Cerebrospinal fluid collection method type	C54749
Assessments and Examinations/Laboratory Tests and Biospecimens/Biomarkers	Cerebrospinal fluid collection method other text	C54750
Assessments and Examinations/Laboratory Tests and Biospecimens/Biomarkers	Cerebrospinal fluid collection anatomic site	C54751
Assessments and Examinations/Laboratory Tests and Biospecimens/Biomarkers	Cerebrospinal fluid collection anatomic site other text	C54752

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Domain; Sub-Domain	Data element	CDE ID
Assessments and Examinations/Laboratory Tests and Biospecimens/Biomarkers	Lab specimen collection date and time	C01701
Assessments and Examinations/Laboratory Tests and Biospecimens/Biomarkers	Specimen collection tube type	C54753
Assessments and Examinations/Laboratory Tests and Biospecimens/Biomarkers	Specimen collection tube other text	C54754
Assessments and Examinations/Laboratory Tests and Biospecimens/Biomarkers	Specimen centrifugation revolutions per minute value	C55003
Assessments and Examinations/Laboratory Tests and Biospecimens/Biomarkers	Specimen centrifugation temperature value	C55004
Assessments and Examinations/Laboratory Tests and Biospecimens/Biomarkers	Specimen centrifugation duration	C55005
Assessments and Examinations/Laboratory Tests and Biospecimens/Biomarkers	Specimen time collection process interval	C55006
Assessments and Examinations/Laboratory Tests and Biospecimens/Biomarkers	Biospecimen collection type	C55008

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Domain; Sub-Domain	Data element	CDE ID
Assessments and Examinations/Laboratory Tests and Biospecimens/Biomarkers	Biospecimen collection other text	C55007
Assessments and Examinations/Laboratory Tests and Biospecimens/Biomarkers	Specimen storage temperature value	C55009
Disease/Injury Related Events/History of Disease/Injury Event	World Federation of Neurological Surgeons (WFNS) - grading system subarachnoid hemorrhage scale	C14256
Participant Characteristics/Demographics	Birth date	C00007
Participant Characteristics/Demographics	Gender Type	C00035
Participant Characteristics/Demographics	Ethnicity USA category	C00020
Participant Characteristics/Demographics	Race USA category	C00030
Participant Characteristics/Demographics	Medical history condition SNOMED CT code	C00313
Participant Characteristics/Demographics	Medical history condition text	C00322
Participant Characteristics/Demographics	Sex participant or subject genotype type	C17396
Participant Characteristics/Demographics	Age value	C00008

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Domain; Sub-Domain	Data element	CDE ID
Participant History and Family History/General Health History	Behavioral history assessment date and time	C00714
Participant History and Family History/General Health History	Tobacco current use indicator	C00710
Participant History and Family History/General Health History	Tobacco prior use indicator	C00711
Participant History and Family History/General Health History	Data collected date and time	C06005
Participant History and Family History/General Health History	Data source	C08147
Participant History and Family History/General Health History	History data not obtained reason	C11133
Participant History and Family History/General Health History	Medical history taken date and time	C00314
Participant History and Family History/General Health History	Body system category	C00312

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Domain; Sub-Domain	Data element	CDE ID
Participant History and Family History/General Health History	Hypertension indicator	C05454
Participant History and Family History/General Health History	Tobacco use started age value	C00703
Participant History and Family History/General Health History	Tobacco use stopped age value	C00701
Treatment/Intervention Data/Surgeries and Other Procedures	Intervention surgical status	C54889
Treatment/Intervention Data/Surgeries and Other Procedures	Intervention endovascular status	C54890

Supplemental – Highly Recommended CDEs for SAH Studies:

Domain; Sub-Domain	Data element	CDE ID
Assessments and Examinations/Imaging Diagnostics	Imaging modality vessel imaging angiography type	C13879
Assessments and Examinations/Imaging Diagnostics	Brain aneurysm unruptured number	C52544

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Domain; Sub-Domain	Data element	CDE ID
Assessments and Examinations/Imaging Diagnostics	Laterality type	C02411
Assessments and Examinations/Imaging Diagnostics	Aneurysm neck maximum measurement	C54728
Assessments and Examinations/Imaging Diagnostics	Aneurysm aspect ratio value	C54729
Assessments and Examinations/Imaging Diagnostics	Aneurysm size ratio value	C54730
Assessments and Examinations/Imaging Diagnostics	Aneurysm bottleneck factor value	C54731
Assessments and Examinations/Imaging Diagnostics	Aneurysm shape pathology type	C54739
Assessments and Examinations/Imaging Diagnostics	Aneurysm size increase indicator	C54742
Assessments and Examinations/Imaging Diagnostics	Imaging study date and time	C02494
Assessments and Examinations/Imaging Diagnostics	Imaging acquisition reason	C13751
Assessments and Examinations/Imaging Diagnostics	Magnetic resonance angiography type	C13882
Assessments and Examinations/Imaging Diagnostics	Computer tomography (CT) angiography type	C13883
Assessments and Examinations/Imaging Diagnostics	Imaging aneurysm anatomic site	C54675

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Domain; Sub-Domain	Data element	CDE ID
Assessments and Examinations/Imaging Diagnostics	Imaging aneurysm dome size value	C54757
Assessments and Examinations/Imaging Diagnostics	Imaging aneurysm occlusion percent value	C54762
Assessments and Examinations/Imaging Diagnostics	Imaging aneurysm Raymond Roy Occlusion Classification category	C54763
Assessments and Examinations/Physical/Neurological Examination	Subarachnoid hemorrhage rebleeding indicator	C53684
Assessments and Examinations/Physical/Neurological Examination	Autosomal dominant polycystic kidney disease history current diagnosis indicator	C54106
Assessments and Examinations/Physical/Neurological Examination	Subarachnoid hemorrhage clinical deterioration infarction delayed cerebral ischemia indicator	C53687
Assessments and Examinations/Physical/Neurological Examination	Subarachnoid hemorrhage clinical deterioration delayed cerebral ischemia indicator	C53689
Assessments and Examinations/Physical/Neurological Examination	Subarachnoid hemorrhage cerebral infarction delayed cerebral ischemia indicator	C53691
Disease/Injury Related Events/History of Disease/Injury Event	Glasgow Coma Scale (GCS) - Motor response scale	C01001

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Domain; Sub-Domain	Data element	CDE ID
Disease/Injury Related Events/History of Disease/Injury Event	Glasgow Coma Scale (GCS) - Verbal response scale	C01002
Disease/Injury Related Events/History of Disease/Injury Event	Glasgow Coma Scale (GCS) - Eye response scale	C01000
Participant Characteristics/Demographics	Education year count	C00015
Participant Characteristics/Demographics	Gender Type	C00035
Participant History and Family History/General Health History	Tobacco product used type	C00719
Participant History and Family History/General Health History	Tobacco cigarettes smoked daily average number	C00709
Participant History and Family History/General Health History	Alcohol current use indicator	C00705
Participant History and Family History/General Health History	Alcohol prior use indicator	C00706
Participant History and Family History/General Health History	Alcohol use frequency	C00730

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Domain; Sub-Domain	Data element	CDE ID
Participant History and Family History/General Health History	Drug or substance current illicit use indicator	C00713
Participant History and Family History/General Health History	Regular aerobic exercise indicator	C55989
Participant History and Family History/General Health History	Family history unruptured intracranial aneurysm indicator	C52529
Participant History and Family History/General Health History	Family history subarachnoid hemorrhage unruptured intracranial aneurysm indicator	C52530
Participant History and Family History/General Health History	Family history subarachnoid hemorrhage family member type	C52531
Participant History and Family History/General Health History	History previous subarachnoid hemorrhage unruptured intracranial aneurysm indicator	C52533
Participant History and Family History/General Health History	Autosomal dominant polycystic kidney disease indicator	C52534
Participant History and Family History/General Health History	Ethnicity pertinent intracranial aneurysm type	C52535

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Domain; Sub-Domain	Data element	CDE ID
Participant History and Family History/General Health History	Blood pressure systolic measurement	C01565
Participant History and Family History/General Health History	Blood pressure diastolic measurement	C01507
Participant History and Family History/General Health History	Tobacco smoke pack-year value	C06108
Participant History and Family History/General Health History	Alcohol drinking day average drinks consumed range	C00704
Participant History and Family History/General Health History	Alcohol consume six or more drinks frequency	C00707
Participant History and Family History/General Health History	Modified Rankin Scale (mRS) Score	C13230
Treatment/Intervention Data/Surgeries and Other Procedures	Vessel repair anatomic site	C54884
Treatment/Intervention Data/Surgeries and Other Procedures	Subarachnoid hemorrhage ictus elapsed day count	C54885

General Core for all Studies:

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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).

Supplemental – Highly Recommended for SAH Studies -

The following instruments are Supplemental-Highly Recommended for SAH:

- Modified Rankin Scale (mRS)
- Montreal Cognitive Assessment (MoCA)

For the complete list of NINDS CDE recommendations for SAH, please see the NINDS CDE website.