

NINDS/NICHD-NCMRR NeuroRehab CDE Project Assessments and Examinations Subgroup Summary

The Assessments and Examinations subgroup reviewed existing NINDS CDEs and instruments from the assigned subdomains: Autonomic, Exercise Physiology, General and Motor, Hospital/Care Management, Non-Imaging Diagnostics, Other Clinical Data, Physical Examination, Physical/Neurological Examination, and Comorbidities (i.e., medical history). Their purview included tests and instruments that capture table one demographic information and data used to stratify, identify, or characterize participants in the first assessment. Assessments of quality of life or motor function were determined to be within the purview of those respective subgroups. This subgroup worked in collaboration with the Comorbid and Behavioral Conditions subgroup which was assigned the subdomains: Fatigue, Pain, and Sleep.

The subgroups focused on recommendations within the Core and Supplemental – Highly Recommended classifications. CDEs within the Supplemental and Exploratory classifications were not recommended in this phase of the NeuroRehab CDE project. Per project guidance, up to three Supplemental – Highly Recommended CRFs/ instruments could be recommended per subdomain.

Instruments were reviewed first. Pairs were assigned to complete an initial review of each instrument. Feedback was discussed during teleconference meetings. The subgroups deemed that the list of Supplemental instruments identified during the initial review should be revisited if usage and validity data later cross the threshold for Supplemental – Highly Recommended. In addition to identifying gap areas, these lists will inform future NeuroRehab CDE efforts.

The subgroups decided to further review instruments that were already classified as Core or Supplemental – Highly Recommended in existing NINDS CDE disorders and determine their applicability to NeuroRehab. It was not within the subgroups' purview to update the classifications for these existing disorders. They considered several additional factors when reviewing, including length of administration, applicability across diverse populations, and cost. To select the top Supplemental – Highly Recommended instruments per subdomain, reviewers considered the number of disorders that currently recommended the instrument and which are most relevant to NeuroRehab. The classifications and disorder recommendations for selected instruments align with those for the existing NINDS CDE disorders.

The Chairs selected Core and Supplemental – Highly Recommended CDEs across the subgroup's assigned subdomains based on data essential for all NeuroRehab clinical trials and specific types of trials.

The subgroup's instrument selections are recommended for general use in neurorehabilitation studies and should not differ substantially by the type of neurorehabilitation or the disorder being studied. The subgroup identified CDEs for the adult population. A separate Infant Pediatrics subgroup was responsible for making recommendations for the pediatric population.

The following instruments and CDEs were selected for inclusion in NeuroRehab v1.0.

Subdomain	Instrument/CRF Name	Classification
Autonomic	Composite Autonomic Symptom Scale	NeuroRehab Supplemental – Highly Recommended
Comorbidities	Boston Naming Test (BNT) - 30-item version	NeuroRehab Supplemental – Highly Recommended
	PROMIS Item Bank v1.0 - Alcohol: Negative Consequences	NeuroRehab Supplemental – Highly Recommended
	PROMIS Item Bank v1.0 - Dyspnea Functional Limitations	NeuroRehab Supplemental – Highly Recommended
General and Motor	Assessments and Examinations Demographic and Clinical Conditions	See CRF/CDE Details
	Fugl-Meyer Assessment	NeuroRehab Supplemental – Highly Recommended
	Functional Gait Assessment	NeuroRehab Supplemental – Highly Recommended
Other Clinical Data	Brief Symptom Inventory-18 (BSI-18)	NeuroRehab Supplemental – Highly Recommended
	Immediate Post-Concussion Assessment and Cognitive Testing (imPACT)	NeuroRehab Sport Related Concussion Core
	Patient-Reported Outcomes Measurement Information System (PROMIS)	NeuroRehab Supplemental – Highly Recommended
	Post Concussion Symptom Scale	NeuroRehab Sport Related Concussion Core
	Rivermead Post-Concussive Symptoms Questionnaire (RPQ)	NeuroRehab Supplemental – Highly Recommended
Physical/Neurological Examination	Glasgow Coma Scale (GCS)	NeuroRehab Supplemental – Highly Recommended
	NIH Stroke Scale (NIHSS)	NeuroRehab Stroke Core

Neurorehabilitation covers a broad range of interventions/evaluations for a broad range of disorders. Therefore, a neurorehabilitation CDE that is meant to apply broadly will by its nature lack specificity.

The subgroups noted that it was important to consider the time to administer an instrument. The amount of time it takes to collect all the required data can become burdensome with many instruments or long administration time. Time with patients to collect data is limited.

The subgroup discussed that input from additional subject matter experts would be needed when considering which instrument(s) to select within topics that contain multiple instrument choices like sleep or cognition, or for sub areas like constipation or bladder function where there is not expertise within the subgroup, or other another subgroup.

For this initial phase of the NeuroRehab project, new CDEs and Supplemental and Exploratory recommendations were identified as gap areas.