

## NINDS/NICHD-NCMRR NeuroRehab CDE Project Participation Subgroup Summary

The Participation subgroup used the WHO International Classification of Functioning, Disability and Health (ICF) definition of Participation as selection criteria: **Participation** is involvement in a life situation. The subgroup further noted that Participation occurs within a societal framework, representing roles that are valued within a particular society. Some of these roles involve direct social interaction, while some may occur without social interaction, but still fulfill a valued role in society.

The subgroup reviewed the ICF Activity and Participation domains to determine which subdomains represent participation. The decision was made to include the following subdomains:

- Domestic Life (caring for others; acquisition of necessities)
- Interpersonal Interactions
- Major Life Areas
- Community, Social, and Civic Life

The subgroup determined that majority of an instrument has to reflect participation to be recommended by the subgroup.

### Summary of Recommendations

Instrument	Subdomain	Classification
PROMIS v2.0- Satisfaction With Social Roles and Activities	Participation	NeuroRehab Supplemental – Highly Recommended
PROMIS v2.0- Ability to Participate in Social Roles and Activities	Participation	NeuroRehab Supplemental – Highly Recommended

**Supplemental – Highly Recommended Definition:** A data element or measure which is considered essential based on certain conditions or study types in NeuroRehab clinical studies. Subject matter experts will focus on selecting up to 3 CRF Modules or Instruments per subdomain within the subgroup. Following the criteria for selecting measurements, these data elements or measures are extensively validated and widely used. There are extensive psychometric properties reported (i.e., responsiveness, reliability) and evidence of use in several NeuroRehab studies. There is evidence of construct validity often using large samples and/or various supportive studies. These data elements are strongly recommended for NeuroRehab clinical studies depending on the disease area, study design, protocol or type of research involved.

The two instruments recommended by the Participation subgroup are indicated for studies requiring a measure of participation and are applicable across diagnostic groups that are able to self-respond.

The two PROMIS instruments are for use in adults (18+) only. The instruments can be used by neurorehabilitation patients who are living in the community and are not institutionalized.

Participation is concept that is applicable to all diagnoses and populations; it is not unique to neurorehabilitation. Since participation is an outcome that is measured in the community, it is not an appropriate CDE for neurorehabilitation research conducted entirely in the inpatient setting.

The gap areas recognized in this initial NeuroRehab CDE project (i.e., potential new instruments) will provide a framework for identifying a continuum of CDE development activities needing to be addressed in upcoming annual reviews.

The following instruments were recommended by the Participation subgroup as gap areas:

- Assessment of Life Habits (Life-H)\*
- Assistive Technology Device Predisposition Assessment (ATD-PA)
- Community Integration for Injured Service Members (CRIS)
- Community Participation Indicators (CPI)
- ICF Measure of Participation and Activities (IMPACT)
- ICF Measure of Participation and Activities Screener (IMPACT-S)
- Impact on Participation and Autonomy (IPA)
- Keele Assessment of Participation (KAP)
- PAR-PRO
- Participation Assessment with Recombined Tools-Objective (PART-O)
- Participation Measure – 3 Domains, 4 Dimensions (PM-3D4D)
- Participation Measure for Post-Acute Care (PM-PAC)
- Participation Objective Participation Subjective (POPS)
- Participation Survey / Mobility (P-scale)
- Rating of Perceived Participation (ROPP)
- Role Checklist: Participation and Satisfaction
- Sydney Psychosocial Reintegration Scale Version 2
- Utrecht Scale for Evaluation of Rehabilitation-Participation (USER-P)

\* The Life-H instrument was recommended as Supplemental – Highly Recommended by the Activities of Daily Living subgroup for studies requiring a measure of Activities of Daily Living and Instrumental Activities of Daily Living for all conditions that impact participation. However, the Participation subgroup does not believe the Life-H meets the Supplemental – Highly Recommended classification for Participation studies and should therefore be considered at a lower classification (e.g., Supplemental) for Participation studies during a future review.