

NINDS CDE Project Traumatic Brain Injury Version 3.0

Review Considerations for Patient Advocates and People with Lived Experience

Patient advocates and people with lived experience are asked to provide specific input on the following concepts during instrument and CRF review:

Acceptability: How well a tool, survey, or guidance fits the needs and preferences of people with TBI, their caregivers and their advocates. If something is acceptable, it feels suitable, respectful, and comfortable for the people using or experiencing it.

Burden: The amount of work, time, or stress that a tool, survey, or guidance places on people with TBI, their caregivers and their advocates. This includes things like how long it takes, how much it costs, and how tiring, inconvenient or confusing it might be.

Relevance: How meaningful or important a tool, survey, or guidance is to people with TBI, their caregivers and their advocates. Something is relevant if it directly addresses the real-life experiences, concerns, and priorities of those living with TBI and their caregivers.

Feasibility: The extent to which a tool, survey, or guidance can be realistically carried out in all the different settings where people with TBI receive care or support. It considers practical factors like time, cost, and staffing, as well as whether the process will fit easily into the routines of both individuals with TBI, their caregivers and those who help them (e.g., care navigators).

Clarity/Comprehensibility: How easy it is for people with TBI and their caregivers to understand questions, instructions, or materials. This involves using clear language, straightforward formats, and other methods that make it simpler for different individuals—including those with cognitive or communication challenges—to fully grasp what is being asked of them.

Cultural Sensitivity: The degree to which a tool, survey, or guidance respects, recognizes and is understood by different backgrounds, beliefs, and communication styles of people with TBI and their communities. It involves making sure materials and procedures are appropriate for various languages, cultures, traditions, religious and spiritual beliefs so everyone feels valued and respected as a whole person.

Emotional/Physical Safety: How well a tool, survey, or guidance protects people with TBI from additional distress, discomfort, or harm. This includes taking steps to ensure that the process does not trigger traumatic memories, cause physical strain, or place undue emotional burden on participants and their caregivers.