

Research Consent Capacity in Individuals with and without Traumatic Brain Injury (TBI)

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Abstract

Mild traumatic brain injury (TBI) is a common injury historically associated with sports and motor vehicle accidents (1). Currently between 10-30% of Operation Enduring Freedom and Operation Iraqi Freedom (OEF/OIF) veterans return home with combat-related TBI (2-4). Most TBI is staged as mild, yet up to 20% of patients with mild TBI have persistent cognitive impairments measurable more than one year after the initial injury (5). In response to this emerging problem in the military, Congress enacted the Traumatic Brain Injury Health Enhancement and Long-Term Support Act of 2007, to fund research on TBI (6).

Current TBI research includes experimental rehabilitation techniques and clinical pharmacological trials aimed at treating TBI symptoms. Some of these research protocols are procedurally complex, risk laden and may offer limited, if any, direct individual benefit. The growth of research in TBI spotlights an unavoidable and ethically critical gap in knowledge: does cognitive vulnerability in individuals with TBI threaten their ability to consent to participation in research? While we expect research on individuals severely impaired by TBI would provoke cautious review, there is no information available to guide researchers, granting agencies, policy-makers and Institutional Review Boards (IRBs) on the extent of vulnerability in mild-moderate TBI. Although studies of research consent capacity (RCC) in other populations have exponentially increased in recent years and led to the development of structured interview tools, notably the MacArthur Treatment Competence Tool for Clinical Research (MacCAT-CR), (7) there is no research on the ability of individuals with TBI to read, comprehend, and make a reasoned, meaningful choice about participating in research. The goal of this pilot study is to determine the feasibility of a larger, federally-funded study that would examine whether individuals with mild to moderate TBI have deficits in RCC and to inform potential measures for such a study.

AIM 1: Determine feasibility of a large study of RCC in individuals with TBI

1a) Measure the prevalence and severity of impairment in RCC in subjects with and without TBI in order to determine power needed for a larger study.

AIM 2: Refine and evaluate measures in preparation for a large study of RCC in individuals with TBI

2a) In subjects with TBI who have completed neuropsychological evaluations within the previous 12 months - explore the relationship between RCC and performance on neuropsychological tests in order to inform choices about neuropsychological measures that would be used in a future study.

2b) Determine test-retest reliability of questions that further assess RCC and explore subjects' beliefs about and motivators for research participation - including altruism, financial incentives and dependence on others (family, physicians, researchers).

We will use the results as a springboard for a large, federally-funded grant proposal (VA or NIH) that will describe impairments in RCC and examine distinguishing cognitive characteristics that predict deficits in RCC in individuals with TBI. The overall goal of our research program is to develop educational interventions for both research subjects with TBI and their families, inform policy around research in this patient group, and develop guidelines for IRBs.