INDIANA UNIVERSITY STUDY INFORMATION SHEET FOR

Functional Cognitive Care in Pediatric Traumatic Brain Injury

You are invited to participate in a research study exploring how occupational therapists address cognition through functional, occupation-based activities with children following a traumatic brain injury. You were selected as a possible subject because you are an occupational therapy practitioner (occupational therapists and certified occupational therapy assistants alike) serving children 21 years of age and younger following a traumatic brain injury. A traumatic brain injury includes an alteration in brain functioning following a bump, blow, jolt to the head or a penetration to the skull that occurs *after birth*. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

The study is being conducted by Dr. Martina Allen and Kristin Hull with the Indiana University Purdue University-Indianapolis Post Professional Occupational Therapy Doctorate Program. This study is not funded.

STUDY PURPOSE

The purpose of this study is to explore the use of occupational therapy in addressing functional cognition in daily living with a child following a traumatic brain injury (TBI). There are gaps with limited evidence of functional cognitive outcome measures and interventions for pediatric TBI, the appropriate services to address and educate the cognitive needs following a brain injury, and also the role and support of occupational therapy services along the continuum of care. Having a greater understanding of cognitive occupation-based activities used in pediatric TBI will allow for development of appropriate occupational therapy outcome measures to address cognition across development and provide for education in occupational therapy academia to appropriately translate knowledge to practice settings. To serve this vulnerable population not only directs client-centered cognitive and educational intervention towards the child with the TBI, but also to educate and train families, caregivers, healthcare professionals, school personnel, and the community to understand, assess, treat, direct referrals to the appropriate resources and support services, and to prevent future brain injury.

PROCEDURES FOR THE STUDY:

If you agree to be in the study, you will be asked the following things:

This mixed methods study will utilize a two-phase process.

- Within the first phase, you will be asked to complete an electronic survey with closed- and open-ended questions that will invite participants across the nation and across the care continuum to participate and provide insight and transferability of findings. The survey will be created through the Research Electronic Data Capture, also known as REDCap, a secure electronic web application for developing surveys and managing data. The electronic survey will be available for four weeks through email with one-time weekly reminders delivered electronically. The electronic survey will also be made available through websites of professional networks for a four-week timeframe. Approximate completion time is ten to fifteen minutes.
- Within the second phase, you will be asked to participate in in-depth, semi-structured, face-to-face interviews. Occupational therapy practitioners will be recruited through survey response and contact to Indiana-based organizations, as needed, for practitioners who identify interest to further collaborate with the researcher. Eight to ten interview respondents will be chosen purposefully for a variety of professional experiences, number of years working with children with TBI, and education. Interviews will plan to last approximately 60 to 90 minutes and in a location convenient to the respondent. Interview questions will be formed based upon survey results to explore more in-depth responses regarding the use of occupation-based activity to address cognitive impairments in children following TBI. Open-ended questions and open-ended probes specific to the respondents' responses will provide for opportunities to elaborate upon themes created from the survey. Upon approval of the respondent, interviews will be recorded for opportunity to transcribe and code.

RISKS AND BENEFITS

The risks of participating in this research are being uncomfortable answering the survey and/or interview questions. You have the right to decline answering any questions on survey and/or interview that may cause discomfort without penalty. You also have the right to discontinue participation within the study at any time, if you choose.

There is also a risk of loss of confidentiality. To minimize the risks of loss of confidentiality, participation will be kept confidential and anonymous. All information will be coded, transcribed and coded, and stored on a password protected computer kept secured by the researcher.

You are not expected to benefit from participating in this research. However, the benefits of participation may impact society by helping increase knowledge about the role of occupational therapy and the role of occupational therapy in pediatric traumatic brain injury care and the impact of cognition throughout the continuum of care in children following a traumatic brain injury.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published and databases in which results may be stored. All information will be stored on a password protected computer by the researcher.

During the interview phase, tape recordings will be made to record and transcribe data. The researcher will have access to these recordings. All information will be coded, transcribed and coded, and stored on a password protected computer. The tape recordings will be kept for three years (approximately year 2022) and then, destroyed.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and her research associates, the Indiana University Institutional Review Board or its designees, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) who may need to access your medical and/or research records.

PAYMENT

You will not receive payment for taking part in this study.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study, contact the researcher Kristin Hull at phone (317) 402 – 0901 or email krrbrewe@iu.edu or Dr. Martina Allen at allenmg@iu.edu.

For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact the IU Human Subjects Office at (317) 278-3458 for Indianapolis or (800) 696-2949.

VOLUNTARY NATURE OF STUDY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with Indiana University Purdue University-Indianapolis.

This research is intended for individual 18 years of age or older. If you are under age 18, do not complete the survey.