THE TEMPLE UNIVERSITY COLLABORATIVE ON
COMMUNITY INCLUSION
of Individuals with Psychiatric Disabilities

Inclusion in Research

Documenting Capacity to Consent

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The TU Collaborative on Community Inclusion has a mission of developing cutting edge knowledge to promote community living and participation of individuals with psychiatric disabilities. This includes basic research as well as intervention research. It is essential that individuals with psychiatric disabilities be included in all aspects of the research process. Institutional Review Boards (IRB) may have mistaken beliefs about the ability of people with psychiatric disabilities that can slow down or even prevent research. This document was developed to aid researchers in the development of consent protocols that 1) ensure participant understanding of study procedures and 2) demonstrate capacity to consent to institutional review boards. While there may be many instances in which researchers recruit individuals with psychiatric disabilities, this document provides guidance for studies conducted with individuals living in the community. There may be other consent requirements for individuals with psychiatric disabilities who are hospitalized, incarcerated, or under another individual's power of attorney.

Institutional Review Boards (IRB) play an important role in protecting the rights and welfare of research participants. In particular, they ensure research is ethical, there is sufficient information for informed consent, and appropriate safeguards are identified. However, because IRB are responsible for the review of a diversity of studies and the continued public stigmatization of individuals with psychiatric disabilities, IRB members often identify additional concerns when reviewing studies that include this population.

Common IRB Concerns

- Individuals with psychiatric disabilities do not have the capacity to understand the elements of the study
- Individuals with schizophrenia are too paranoid to participate in this type of study
- Individuals with psychiatric disabilities are too confused to understand this study

Addressing Concerns

- People with psychiatric disabilities are entitled to participate in research conducted in areas related to their treatment and care (Pesiah, 2012). *Benefits from the research include increased knowledge of diagnoses and symptoms, improvements in treatment, reduction in health care costs and other public health gains*
- If a person has a diagnosis, that does not imply they cannot provide consent. In fact, individuals with psychiatric disabilities demonstrate a diversity within their decision-making capacity, particularly among individuals with schizophrenia. This warrants individualized consideration of capacity (Jeste et al., 2006; Palmer & Jeste, 2006)

Preparing Consent Documents & Procedures

- Prepare consent forms using simple language to enhance comprehension
- Repetition of information within the consent form may increase understanding (Jeste et al., 2006)
- Ask targeted questions throughout the consent form and allow for open dialogue about study procedures during the consent protocol (Jeste et al., 2006)
- Utilize tools to confirm an individual's understanding of the study procedures. The University of California, San Diego Brief Assessment of Capacity to Consent (UBACC) is one easy to use tool (described below)

University of California, San Diego Brief Assessment of Capacity to Consent (UBACC)

Time to complete: 5 minutes
Purpose: Ensure understanding of study procedures, appreciation of the study risks and expectations, and reasons why someone may want to participate.

The UBACC is a 10-item scale that assesses decision-making capacity by confirming an individual's comprehension of study procedures. Research indicates this tool is both reliable and valid. Specific areas assessed include: understanding, appreciation, and reasoning. Questions are standardized, however, the research team develops acceptable responses for each question. An IRB may wish to approve the acceptable responses. Responses to questions are scored as 0, 1, or 2. A 2 indicates an acceptable response. For responses that are not scored as 2, the researcher may review those sections of the consent form and re-ask those specific questions. The UBACC guidelines indicate this may be done three times. Detailed guidelines for the UBACC are included in the Jeste et al. (2007) referenced article.

References

Jeste, D. V., Depp, C. A., & Palmer, B. W. (2006). Magnitude of impairment in decisional capacity in people with schizophrenia compared to normal subjects: an overview. *Schizophrenia bulletin*, *32*(1), 121-128.

Jeste, D. V., Palmer, B. W., Appelbaum, P. S., Golshan, S., Glorioso, D., Dunn, L. B.,… & Kraemer, H. C. (2007). A new brief instrument for assessing decisional capacity for clinical research. *Archives of general psychiatry*, *64*(8), 966-974.

Palmer, B. W., & Jeste, D. V. (2006). Relationship of individual cognitive abilities to specific components of decisional capacity among middle-aged and older patients with schizophrenia. *Schizophrenia bulletin*, *32*(1), 98-106.

Peisah, C., Vollmer-Conna, U., & Kim, S. Y. (2012). Capacity to consent to research: The evolution and current concepts. *Asia-Pacific Psychiatry*, *4*(4), 219-227.

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