

Informed Consent: Understanding Decisional Capacity-- What to Look For & Who To Call?

Human Subjects Protection Unit
Office of the Clinical Director
Intramural Research Program
National Institute of Mental Health

September 14, 2010

Capacity vs. Competence

- **Capacity** refers to a one time clinical judgment of a client's ability to give informed consent.
- **Competence** refers to the ability to understand legal rights and responsibilities and the possession of authority to make legal decisions. (National Institute on Aging)

Capacity vs. Competence

- **Capacity** refers to a one time clinical judgment of a client's ability to give informed consent.
- **Competence** refers to the ability to understand legal rights and responsibilities and the possession of authority to make legal decisions. (National Institute on Aging)

Elements of a Capacity Assessment

Capacity assessments are based on a modified MacCAT-CR.* The four domains assessed are:

- 1) *understanding* of disclosed information about the nature of the research project and its procedures;
- 2) *appreciation* of the effects of research participation (or failure to participate) on subjects' own situation;
- 3) *reasoning* about participation; and
- 4) ability to communicate a *choice*.

*Appelbaum, PS & Grisso, T (2001). MacCAT-CR MacArthur Competence Assessment
Clinical Research

Tool for

What could interfere with capacity?

- Panic
- Delirium
- Psychosis
- Medical illness
- Substance abuse
- Cognitive difficulty
- Dependency upon those who provide treatment

Cognitive impairment or a psychiatric condition does not automatically remove capacity.

(Appelbaum & Grisso, 2001)

Our Contact Numbers

Clinical Research Advocates:

Julie Brintnall-Karabelas, MSW, LCSW-C	301-402-6787
Mary Ellen Cadman, RN, MSN, MSW, LGSW	301-402-6842
Carol J. Squires, MSSW, LCSW	301-402-6845
Katherine J. Whorton, MSW, LCSW-C	301-496-8782

HSPU Pager
102-11158

Sources

- Appelbaum, PS & Grisso, T (2001). MacCAT-CR MacArthur competence assessment tool for clinical research. Worcester, MA: Professional Resource Press.
- Appelbaum P; Roth, L; Lidz C; Benson P & Winslade W (1987). False hopes and best data: Consent to research and the therapeutic misconception. Hastings Cent Rep. Apr;17(2):20-4
- Berghmans, RLP (2001). Capacity and consent. Current Opinion in Psychiatry 14(491-499).
- Bridgman, AM & Wilson, MA (2000). The treatment of adult patients with a mental disability. Part 2: Assessment of competence. British Dental Journal (189)143-146.
- Chin, LJ. (2003). Informed consent in clinical research: A review for professional practice. The Journal of Oncology Management, March/April, 25-29.
- Dennis, BP (1999). The origin and nature of informed consent: Experiences among vulnerable groups. Journal of Professional Nursing 15(5) Sept-Oct.
- Dunn, LB; Nowrangi, MA; Palmer, BW; Jeste, DV & Saks, ER (2006). Assessing decisional capacity for clinical research or treatment: A review of instruments. Am J Psychiatry 163(8), 1323-1334.
- Joffe, S; Cook, EF; Cleary, PD; Clark, JW & Weeks, JC (2001). Quality of informed consent in cancer clinical trials: a cross-sectional survey. The Lancet. V358,11/2001
- Kitamura, T. (2000). Assessment of psychiatric patients' competency to give informed consent: Legal safeguard of civil right to autonomous decision-making. Psychiatry and Clinical Neurosciences, (54), 515-522.

Sources continued

- Mukherjee, S & Shaw, A (2001). Capacity to consent: Issues and controversies. Hospital Medicine 62(6) June.
- Palmer, BW & Jeste, DV (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.
- Serretti, A & Artioli, P (2006). Ethical problems in pharmacogenetic studies of psychiatric disorders. The Pharmacogenomics Journal, 6, 289-295.
- Sturman, ED (2005). The capacity to consent to treatment and research: a review of standardized assessment tools. Clin. Psychol. Rev., 25:954-974.