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

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What is the Human Subjects Protection Unit?

Clinical Research Advocates (CRAs)

- NIMH Office of the Clinical Director
- Multidisciplinary team
- Masters prepared
- Clinically experienced
- Trained in bioethics
- Independent monitors

Missions of the HSPU:

- Support independent monitoring
- Provide protection for human subjects with a focus on potentially vulnerable populations
- Protect both researcher and subject

What is Informed Consent?

- Informed consent is the agreement of a subject to participate in a research study.
- The informed consent process starts when an individual initiates discussion with a member of the NIH staff regarding participation in a research study and continues until the individual completes study participation, withdraws consent or is withdrawn from the study.
- It is the responsibility of the principal investigator to ensure that informed consent is obtained.
- Written consent documents and research protocols must be approved by the IRB.
- Consent documents are time sensitive and must be signed and dated within the date identified on the last page of the document.

Valid Consent Requires:

- **Disclosure** of relevant information
- Subject's **comprehension** of the information
- **Voluntary agreement,** free from coercion

http://ohsr.od.nih.gov/info/sheet6.html

Elements of the Consent Form

- Voluntary Participation
- Purpose
- Study Population
- Study Procedures & Design
- Risks/Inconveniences/ Discomforts
- Potential Benefits
- Treatment Alternatives
- Confidentiality
- Compensation
- New Findings
- Conflict of Interest
- Contacts

What Is The Therapeutic Misconception?

- Occurs when subjects think the primary purpose of a clinical trial is to benefit them
- 1982 study found psychiatric subjects failed to appreciate the difference between research and treatment (Appelbaum et al, 1987)
- 2001 Joffey et al examined quality of informed consent in cancer trials & found subjects unaware that:
  - this was research and not treatment
  - there was potential for incremental risk or discomfort
  - efficacy of treatment was unproven
  - benefits were uncertain
- Ethical dilemmas occur when there is a failure to separate the goals of research from that of clinical care which may negate informed consent (Appelbaum et al, 1987)

Who Gives Consent/Assent for Research Participation?

- Informed consent is valid only with adults age 18 and above.
- Assent is always obtained with children and adults who are unable to make their own decisions regarding research participation.
  Assent is the affirmative agreement to participate in research.
- Surrogate "One appointed to act in place of another."
  Legally Authorized Representative (LAR)
  - Guardian (court-appointed)
  - Durable Power of Attorney (DPA)
- Few states allow use of a DPA for research

CAPACITY TO GIVE INFORMED CONSENT

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)

Facets of Capacity:

- A subject must have capacity in order to provide informed consent
- Diagnosis alone does not determine lack of capacity
  (Palmer & Jeste, 2006; Serretti & Artioli, 2006; Sturman 2005)
- The higher risk in research, requires a higher level of capacity (Dunn et al, 2006)
- There is no single test of capacity
  (Chin, 2003; Dunn et al, 2006; Serretti & Artioli, 2006; Sturman, 2005)
- Regulations are vague resulting in a range of Institutional Review Boards' (IRBs) interpretation of appropriate assessment and protections (Dunn et al, 2006)
- There is an array of practices of documentation tools used, domains assessed and level or training (Dunn et al, 2006)

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 Tool for Clinical Research

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 <u>does not</u> automatically remove capacity.

(Appelbaum & Grisso, 2001)

CC Policy (M87-4) "Research Involving Adults Who Are or May Be Unable to Consent"

Purpose: To set forth Clinical Center policy for non-emergency research involving adults who are or who may be unable to provide initial or ongoing informed consent.

Policy: Adults are presumed capable of giving informed consent. When questions arise regarding an adult's ability to provide initial or ongoing consent, the individual should be evaluated. Adults who are unable to provide initial or ongoing consent may participate in research only when the IRB has approved the research for adults who cannot consent and an appropriate surrogate provides permission (unless the IRB waives the requirement for informed consent). Assent (i.e., affirmative agreement) should be obtained from individuals who are capable of providing it. Individuals' objections (dissent) should be respected.

This Medical Administrative Series (MAS) Policy can be accessed via:

http://intranet.cc.nih.gov/mec/mas

A responsible capacity assessment should be able to prevent two possible mistakes:

1. Subject is capable and clinician disagrees with decision and acts against subject's wishes

2. Subject is incapable and clinician supports and acts on subject's decision.

(Berghmans, 2001)

(Bridgman & Wilson, 2000)

Culture & Capacity

- In order for an assessment to be reliable the method should be psychometrically sound.
- At the same time, in order for an assessment to be valid the structure should match the subject's psychological, cultural and social background.
- Because informed consent is a process rather than a cross-sectional event, an assessment should be performed in everyday practice.
  (Kitamura, 2000, p. 520)
- It is also important to be culturally sensitive and aware of possible effects of difference in race, religion, and social class between the patient and the assessor on the process of assessment of capacity.
  (Mukhergee & Shah, 2001)

ROLE OF THE NURSE

In the Trenches

- Qualities of primary nurse relationship
- Educator
- Advocate
- Involves ongoing interaction and assessment of subject
- Identifying resources
- Communicator and Facilitator among team

"Doing things right is just as important as doing the right thing."

(Dennis, 1999 in reference to informed consent)

Clinical Examples and Implications for Patient Care

Who to Call

As per the NIH policy Medical Administrative Policy 87-4, consultation regarding whether an individual is able to provide consent may be obtained by contacting the NIH Ability to Consent Assessment Team at either: 301-496-9675 or 301-496-2429.

Our Contact Numbers

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Sources

- Appelbaum, PS & Grisso, T (2001). MacCAT-CR MacArthur competence assessment tool for clinical research. Worster, 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.