Obtaining informed consent for research in an acute inpatient psychiatric setting

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Conducting clinical research with patients in an acute inpatient psychiatric setting raises possible ethical difficulties, in part because of concern about patients' ability to give informed consent to participate in research.

We propose the acronym CHECK (for *capacity*, *heredity*, *ethics*, *coercion-free*, and *knowledge*) to provide researchers with guidance on the process of addressing informed consent in an acute inpatient setting.

Capacity. Ensure that the patient has the decisional capacity to:

- understand disclosed information about proposed research
- appreciate the impact of participation and nonparticipation
- reason about risks and benefits of participation
- communicate a consistent choice.[1]

The standards for disclosing information to a potential participant are higher for research than in clinical practice, because patients must understand and accept randomization, placebo control, blinding, and possible exposure to non-approved treatment interventions—yet there is a balance regarding how much information is necessary for consent in a given situation.[2]

Be mindful that the severity of the patient's psychiatric illness can impair understanding and insight that might preclude giving informed consent (eg, major depression can produce a slowing of intellectual processes; mania can display distractibility; schizophrenia can compromise decisional capacity because of disorganized thinking or delusions; and neurocognitive disorders can affect the ability to process information).

The MacArthur Competence Assessment Tool for Clinical Research, designed as an aid to assessing capacity, has the most empirical support, although other instruments might be equally or better suited to some situations.[1]

Heredity. When undertaking human genetic and genomic research, create a precise, robust consent process. Genome sequencing studies can reveal information about the health of patients and their families, provoking discussion about appropriate protections for such data. Informed consent should include:

- how the data will be used now and in the future
- the extent to which patients can control future use of the data
- benefits and risks of participation, including the potential for unknown future risks
- what information, including incidental findings, will be returned to the patient
- what methods will be used to safeguard genetic testing data.[3]

Ethics. Researchers are bound by a code of ethics:

- Patients have the right to decline participation in research and to withdraw at any stage without prejudice; exclusion recognizes the need to protect those who may be incapable of exercising that right.[2] Avoid research with dissenting patients, whether or not they are considered capable.[2] Do not routinely invite treatment-refusing patients to participate in research projects, other than in extraordinary circumstances; eg, treatment-

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refusing patients who have been adjudicated as "incompetent," in which case the court-appointed surrogate decision-maker could be approached for informed consent. You should routinely seek a legal opinion in such a circumstance.

- Unless the research is examining interventions for acute and disabling psychiatric illness, consent should not be sought until patients are well enough to make an informed decision. However, clinical assessment is always needed (despite psychiatric illness category) because it cannot be assumed that psychiatric patients are unable to make such a decision (eg, in some cases, substance abuse should not automatically eliminate a participant, as long as the patient retains adequate cognitive status for informed consent).
- Capacity for consent is not "all-or-nothing," but is specific to the research paradigm. In cases of impaired decisional capacity, researchers can obtain informed consent by obtaining agreement of family, legal representative, or caregiver; therefore, research with assenting adults, who are nonetheless incapable, is unlikely to be regarded as unethical.[2]

Coercion-free. Avoid covert pressures:

- Ensure that consent is given freely without coercion or duress. This is important if the participant has a physician-patient relationship with a member of the research team. Exercise caution when research methods involve physical contact. Such contact, in incapable patients—even those who assent—could create a medico-legal conflict (eg, taking a blood sample specific for research purposes without consent could result in a charge of battery).[2] When in doubt, seek a legal opinion before enrolling decisionally incapable patients (and/or those adjudicated as incompetent) in research trials.
- Consider that participation be initiated by a third party (eg, an approach from a staff member who is not part of their care team and not involved in the research to ask if the potential participant has made a decision that he wants to have communicated to the researcher[4]).
- Require that a family member, legal representative, or caregiver be present at the time of consent with decisionally incapacitated patients.

Knowledge. The participant must be given adequate information about the project. Understand consent as an ongoing process occurring within a specific context:

- Give participants a fair explanation of the proposed project, the risks and benefits that might ensue, and, when applicable, what appropriate procedures may be offered if the participant experiences discomfort. If a study is to be blinded, patients must understand and appreciate that they could receive no benefit at all.
- Consider the importance of using appropriate language, repeating information, ensuring adequate time for questions and answers, and providing written material to the patient.[2] Avoid leaving the patient alone with an information sheet to avoid coercion, because this risks denying patients the opportunity to participate because they lack the occasion to receive information and ask questions.[4] Rather, go over the research consent document item by item with the patient in an iterative process, encouraging questions. Ensure private individual discussion between study team members and the patient to address questions related to the study.[4]
- Reapproach patients to discuss or revisit consent as needed, because their capacity to provide informed consent may vary over time. This is especially important in CNS illnesses, in which the level of cognitive function is variable. An item such as "consent status" for each encounter can be added to the checklist.

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