

**NORTHERN ILLINOIS UNIVERSITY
INSTITUTIONAL REVIEW BOARD**

**POLICY ON RESEARCH PARTICIPATION OF INDIVIDUALS WITH IMPAIRED
CONSENT CAPACITY**

August 2017

The Institutional Review Board (IRB) and researchers must operate in accordance with the Belmont principles of beneficence, justice, and respect for persons to include individuals with impaired consent capacity in research studies, and must employ additional safeguards as appropriate to the study and the participant population in order to protect their rights and welfare. The need to provide special safeguards for persons with impaired consent capacity should not be used to arbitrarily exclude such persons from research if there may be a direct benefit to the individual or the development of generalizable knowledge regarding the disease or condition causing the impairment.

This policy is applicable only to persons aged 18 or over. Persons under the age of 18 are covered under the IRB policy ‘Policies and Procedures for Human Subjects Research Involving children.

Definitions

Assent

An individual’s affirmative agreement to participate in research. This should be sought in addition to the consent of a legally authorized representative or surrogate when the individual is cognitively capable of understanding the nature of his or her participation in a research study. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Impaired consent capacity

A compromised capacity to understand information related to the research and to make a reasoned decision about initial or continuing participation in research that may prevent the individual from providing legally effective consent. Such impairment or compromised capacity may be temporary, permanent, or may fluctuate. Examples of individuals who may have impaired consent capacity include individuals who have suffered a stroke or other acute and severe illness, individuals under the influence of drugs or alcohol, individuals experiencing considerable pain, individuals under extreme emotional distress, and individuals suffering from cognitive or mental disorders.

Legal Incompetence

A designation of status that has been adjudicated in a court proceeding, and often referring to an inability to manage one or more significant areas of life such as business or monetary affairs. Although an individual may be designated as legally incompetent, he or she does not automatically have impaired consent capacity in terms of consenting to research. Similarly, an individual may be legally competent, but still have impaired consent capacity in terms of providing consent to participate in a research study.

Legally Authorized Representative or Surrogate

A legally authorized representative (LAR) is an individual, judicial, or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedures involved in the research.

Absent a participant-designated or state-specified LAR for research decision making, investigators may engage and the IRB may approve as surrogates individuals who are specified in state statutes as LARs for medical decision making, or, in the absence of such statutes, individuals who would normally provide consent for medical care under prevailing, commonly accepted clinical practices.

The State of Illinois does not have specific guidance on legally authorized representatives for research purposes. For research conducted in Illinois, the IRB will use the requirements of the Health Care Surrogate Act (755 ICLS 40/) for guidance in determining who may serve as the surrogate for research consent. The following persons, in order of priority, may serve as the surrogate for research consent:

1. The subject's guardian of the person
2. The subject's spouse
3. Any adult son or daughter of the subject
4. Either parent of the subject
5. Any adult brother or sister of the subject
6. Any adult grandchild of the subject
7. A close friend of the subject
8. The subject's guardian of the estate

The researcher has the right to rely on any of the above persons to provide surrogate permission if the researcher believes, after reasonable inquiry, that a surrogate of higher priority is not available.

For research conducted outside of Illinois, a determination of who is a legally authorized representative must be made with consultation from the Office of Research Compliance, Integrity, and Safety.

Appropriateness of inclusion of persons with impaired consent capacity

Whenever possible, research should be designed to include only those individuals who are capable of consenting for themselves. However, in some studies where benefit to the participants is likely, it is more ethical and in line with the Belmont principles to include individuals with impaired consent capacity. In other studies, even those without likely benefit to participants, the only way to answer the scientific aim may be to include such individuals in the research.

A research study specifically designed to target the inclusion of individuals with impaired consent capacity must have as its goal either to study a treatment or intervention designed to directly benefit the individual, or the development of important generalizable knowledge regarding the disease or condition of the targeted population. The IRB will consider the nature and degree of anticipated impairment of the targeted study populations, the risk level of the proposed study, and the potential for direct benefit to the study participants.

Assessment of capacity for consent

The investigator must ensure that the individuals who are responsible for determining whether a potential participant has the capacity to consent has the appropriate expertise necessary to determine and monitor the participant's capacity initially and on an ongoing basis. The determination may be made by an investigator or by another professional who has appropriate expertise. It may also include opinions from one or more caregivers.

Although an individual may be designated as legally incompetent, he or she does not automatically have impaired consent capacity in terms of consenting to research. Similarly, an individual may be legally competent, but still have impaired consent capacity in terms of providing consent to participate

in a research study. The determination of capacity to consent is made by individual observation and interaction with the potential participant.

The capacity to consent is protocol and situation specific. A subject may have the ability to consent to a low-risk protocol in usual circumstances, but not have the capacity to consent to a high-risk protocol in a stressful situation. Higher risk studies must have a more rigorous method of assessing capacity.

When assessing capacity to consent, it is important to know that there is no single set of standards for defining and implementing assessment of capacity to consent. In general, an assessment of an individual's capacity to consent should be based on her/his/their:

- ability to communicate a reasoned choice regarding participation
- ability to understand the nature of the research relevant to his/her/their own choice to participate or not to participate
- ability to manipulate information rationally

Assessments in a minimal risk study could be as simple as a verbal interaction between the investigator and the potential participant. More complicated assessments could include administration of a formal assessment instrument or an independent clinical (interview-type) assessment, administered after the potential participant has been fully informed of the study, which documents that the potential participant demonstrated sufficient recall and comprehension. Measures to assess the capacity to provide initial and continued consent could include the use of consent quizzes, the participation of a consent monitor, subject advocate, or independent clinician in the consent process, and the design of the consent process to include several meetings between the potential participant and the investigator.

For ongoing studies, the assessment method should also allow for repeat assessment or monitoring of the capacity to consent if the potential participant's decisional impairment changes or is expected to change. This is particularly important upon the introduction of a new or different intervention or testing along the course of the research.

An individual's cognitive abilities can be assessed by discussing the proposed study with her/him/them and then asking specific questions. It is usually more useful to ask for descriptive answers from potential participants rather than to ask questions requiring a simple yes or no answer. Such questions may include:

- Can you tell me what will happen if you agree to take part in this study?
- How might this study help you?
- How might this study not help you, or even hurt you?
- Do you have to be in this study?
- What will happen if you decide not to be in the study?
- What would you do if you wanted to stop being in the study?

If adequate consent capacity is not found upon assessment, then, in most cases, the investigator should either exclude the prospective subject from the study or seek consent from a legally authorized representative or surrogate.

Assent procedures for persons with diminished capacity to consent

When persons with diminished capacity to consent are included in research, and consent from a legally authorized representative or surrogate is used, assent must also be sought from the potential participant to the extent that the participant is capable of giving it. Where assent is required, mere failure to object

may not, absent affirmative agreement, be construed as assent. The prospective participant's objection to participation in any way, at any time, must be taken as refusal or withdrawal and be honored, even if the surrogate consentor or the investigator disagrees with the decision. However, for some studies, withdrawal may still require limited continuation of some research interventions such as tapering off of medication or other important procedures to protect participant safety and well-being. Withdrawal consequences should be made explicit in the consent and assent forms.

Individuals who are able to read and write should participate in the consent process by using an assent form written at a level suited to their cognitive abilities. Oral consent may be used for participants not able to read or write. The assent form or script should include all information that the potential participant is capable of understanding, and provide the potential participant with an opportunity to ask questions about his/her/their participation. This should include an explanation that it is okay to decide not to participate or to quit participating at any time.

Requirements for the IRB application

For research projects including participants who may have impaired capacity to consent, the IRB application should include the following information:

- The method by which prospective subjects' capacity to consent will be assessed. Less formal procedures to assess potential subjects' capacity may be acceptable where a formal assessment is not feasible or necessary.
- Who will conduct the assessment and their qualifications/training to do so.
- Whether persons deemed unable to give informed consent will be included, and if so, the procedures for obtaining the surrogate/legally authorized representative's consent and the participant's assent.
- Copies of all written consent and assent forms or oral scripts used in the study.