

# **Office of Research Compliance (ORC) Guideline on Impaired Capacity and Consent**

## **Introduction**

This guideline details the ORC recommendations for obtaining voluntary informed consent from individuals who are invited to participate in research. Although adults are presumed to possess legal capacity to consent, some due to health or risk status, might have impaired capacity to consent to a specific research protocol. The University, its faculty, and its trainees have a common interest and a shared responsibility to ensure that volunteer participants who have, or might have, a diminished capacity to provide informed consent to a research protocol are offered opportunities to participate in research when possible, and that their consent is obtained in a way that is respectful and legally valid.

## **Scope and Requirements**

Depending on the knowledge gained from research, benefits can accrue to affected populations only if individuals representing these populations are included in research. Federal regulations governing human research require the equitable selection of participants, and foundational ethical principles such as beneficence and justice support the inclusion of participants with impaired consent capacity, provided appropriate protections are implemented.

In order to provide voluntary informed consent, participants must be able to comprehend information, deliberate on choices offered in light of personal values, understand the consequences of consent (or refusal), and communicate a decision. Some individuals may have a diminished cognitive ability to consent. Their consent capacity can be absent, impaired, fluctuating, or declining over the course of the research project. Although the underlying medical condition is likely to be relevant to whether an individual meets inclusionary criteria established on scientific grounds, the issue at the core of research consent is not medical diagnosis but rather the individual's cognitive capacity to understand the purpose of the research, the nature of the experience, the actual and potential risks, the potential personal and/or societal benefits of participation, and the right to refuse (or withdraw from) participation at any time without loss of other benefits.

When reviewing research protocols that propose to recruit individuals who may have diminished consent capacity, the IRB may consider the following concepts.

**Consent capacity assessment** – In the research context, the central question is whether the prospective volunteer is able to understand the proposed research study. Therefore, comprehension and voluntariness must be placed in the context of the nature of the experience, the level of risk, and the possibility of direct personal benefit (if any) of the particular research protocol. Investigators should assess consent capacity on an individual level, rather than judge capacity merely on the basis of an individual's status (e.g., age, disability) or medical diagnosis. Assessment might involve informal interview techniques, validated assessment tools, or other assessment strategies tailored to the specific research protocol in question. After a baseline assessment, re-assessment during the course of the study may be ethically necessary to assure that participants are protected.

**Legally Authorized Representatives (LAR)** – “Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.” (45 CFR 46.102(i)). Researchers should carefully review written authorizations or appointments presented on behalf of a participant to determine whether they are broad enough to be used for research purposes. Ohio University recognizes the authority of an individual authorized by law to make medical decisions in the nonresearch context (e.g., plenary guardian; durable power of attorney for health care; statutory surrogate for health care) to consent to the same or similar types of medical procedures involved in the research. The IRB also may impose additional safeguards in the IRB-approved research protocol to protect the rights and welfare of the participant.

**Assent and Dissent** – If the cognitive capacity assessment results suggest or affirm diminished capacity to consent to research participation, and the investigator decides to include an IRB-approved proxy decision maker in the consent process, the investigator must obtain that individual's permission

and the research volunteer's assent. The volunteer participant's dissent should always be respected.

Assent from children must be obtained and documented when they are capable of providing it. In determining whether children are capable of providing assent consider age, maturity, and psychological state of the children involved. This determination can be made for all children to be involved in the research under a particular protocol, or for each child, as appropriate. The requirement for obtaining the assent of children involved in the research may be waived if:

- The capability of some or all of the children is so limited that they cannot reasonably be consulted;
- The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research; or
- The requirements for a waiver of informed consent found in 45 CFR 46.116 are met. (45 CFR 46.408(a))

Research Advance Directives – Although uncommon, individuals can prepare an advance directive that outlines their willingness to participate in certain kinds of research before their consent capacity becomes impaired.

Stakeholder and Community Engagement – Individuals and groups from the community may also provide input during the review process through IRB membership, advisory groups, or other methods designed to elicit input.

### **Recommendations**

The ORC recommends that when a research proposal seeks to recruit individuals whose medical history or current level of functioning suggests impaired capacity to consent, the IRB may require an assessment of capacity on an individual basis to each prospective research participant, considering all of the options outlined in the Scope and Requirements section above. Additional safeguards, such as having a third party involved in the consenting process (e.g., a legally authorized representative or another person deemed by the IRB to be qualified to serve in this capacity) may be required.

Documentation from Volume 2, March 2015, Gray Matters, Topics at the Intersection of Neuroscience, Ethics, and Society, was used to help create parts of this guideline.