Research Involving Subjects with Impaired Decision-Making Capacity (HRPP 4.6)

Description:

This policy describes UNMC's requirements for IRB review of research involving subjects who have impaired decision-making capacity.

Definitions:

Decisionally Impaired Person: an adult with diminished capacity for judgment and reasoning such that they are unable to make an informed, voluntary decision to participate in research.
*This is different from competence. Competence is a legal state, not a medical one.

Legally Authorized Representative (LAR): an individual 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.
Under Nebraska law, **the following may serve as a LAR:**

- Parents/guardians having legal custody
- Court-appointed legal guardian
- Individual authorized to consent on behalf of person to a legally effective Health Care Power of Attorney

Diminished capacity may:

- Be temporary, acute
- Fluctuate
- Be more long-term or permanent
- Be a result of a psychiatric disorder, an organic impairment, a developmental disorder, or severe acute illness associated with cognitive impairment

Institutionally Authorized Surrogate (IAS): a person authorized by the Organization to provide consent for a patient who lacks capacity, and for whom there is not an LAR.

General Considerations:

- If an individual lacks capacity to consent, they can only be enrolled in research if an LAR provides consent on their behalf.
- If a prospective subject does not have an LAR, an IAS should be appointed.
- The prospective subject's capacity to choose an IAS should be assessed and if possible, their choice should be honored.
- If a person with diminished capacity regains capacity DURING RESEARCH, they must be fully informed about the research and their consent must be obtained.
- The investigator must obtain assent from decisionally-impaired persons if they're capable.
- If the research provides direct benefit or the subject cannot reasonably be consulted, assent may not be necessary (determined by the investigator or IRB).
- If a person dissents to participate, the dissent must be honored unless the research provides direct benefit.
    - If the research provides direct benefit, approval to override dissent must be obtained from the IRB Executive Chair.
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Acceptable Research Involving Decisionally Impaired Subjects:

Category 1- **minimal risk and no direct benefit**	Category 2- **greater than minimal risk and direct benefit**	Category 3- **greater than minimal risk and no direct benefit**
LAR/IAS provides consent, and subject provides assent.	LAR/IAS provides consent, and subject provides assent. • the risk-benefit relationship must be favorable • the risk-benefit relationship is at least as favorable as alternative therapies	LAR provides consent, and subject provides assent. • minor increase over minimal risk • Intervention/ procedure are commensurate with their actual situations • Intervention/ procedure likely to yield generalizable knowledge about the subject's disorder

***** Research not falling under one of these categories cannot enroll cognitively impaired persons.

*Cognitively impaired persons under a court mandated therapy for a psychiatric disorder are not eligible to participate.

Additional Protections

- Additional protections may be put in place, depending on the following:
    - Characteristics of the subject population
    - Nature of the research
    - Risk level of the research
- Protections that may be considered (but not limited to)
    - Extended consent process
    - Adult information sheet
    - Subject advocate
    - Limits placed on risk
    - Increased monitoring
    - More stringent withdrawal criteria