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:

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