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 who lacks sufficient judgment and reasoning to make an informed, voluntary decision about participating in research.

**This is different from competence. Competence is a legal state, not a medical one.*

Legally Authorized Representative (LAR): someone authorized under the law, or by institutional policy if no law applies, to consent to research participation on behalf of another. Under Nebraska law, **the following may serve as a LAR:**

- Parents/guardians having legal custody
- Court-appointed legal guardian
- Individual with a valid Health Care Power of Attorney

Institutionally Authorized Surrogate (IAS): a person approved by the institution to consent to medical procedures for someone who lacks capacity and has no legally defined LAR. Their authority is determined by institutional policies (e.g. Nebraska Medicine MS14 or Children's Nebraska consent policies).

Appointment and Authority of LAR or IAS:

- LAR required when subject lacks capacity
- If no LAR is available, identify an IAS
- Subject's input into selecting an IAS should be respected when possible
- **Criteria for IAS:** Must be available, willing, capable, and appropriate
- **Decision-making standard:**
    - ***Substituted Judgment*** preferred (what the subject would choose if competent)
    - ***Best Interest*** used only when subject's preferences are unknown

Assent and Dissent:

- **Assent Required:** when the subject is capable of providing it
- **Assent NOT Required:** if the subject lacks capacity or research offers potential for direct benefit only available through participation
- **Dissent MUST Be Honored** unless:
    - The research offers direct subject benefit
    - IRB Executive Chair approval is obtained to override dissent
    - IRB must be notified and has authority to review or reverse the decision

Acceptable Research Categories:

Category 1: Minimal Risk, No Direct Benefit

- **Requires LAR or IAS consent and subject assent**

Category 2: Greater than Minimal Risk with Direct Benefit

Permitted if:

- Favorable risk/benefit ratio
- Equal or better than alternative therapies
- **Requires LAR or IAS consent and subject assent**

Category 3: Greater than Minimal Risk, No Direct Benefit

ONLY allowed if:

- Minor increase over minimal risk
- Procedures are commensurate with the subject's actual condition/situation
- Knowledge gained is vital to understanding or treating the subject's disorder
- **Requires LAR consent and subject assent**
- IAS cannot consent for this category

PROHIBITED RESEARCH:

- Any research not fitting Categories 1-3
- Research involving subjects under court-mandated psychiatric treatment

If a Participant Regains Capacity DURING THE STUDY:

- They must be fully informed about the research and how they were enrolled
- Their informed consent must be obtained to continue participation
- This process must comply with HRPP Policy 5.1

If a Participant Regains Capacity AFTER RESEARCH COMPLETION:

- They still must be fully informed about the research and the conditions of their enrollment

Consent Forms/Information Sheet:

- Consent from a LAR or IAS must be documented in accordance with HRPP Policy 5.1
- **If appropriate:**
    - Participants with impaired decision-making should receive an Information Sheet
    - **This sheet must:**
        - Use simple, clear language suitable for the participant's cognitive level
        - Include elements of assent, aligning with the Information Sheet Template

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