

## **Criteria for IRB Approval (HRPP 2.5)**

### **Description:**

This policy describes UNMC's criteria for IRB approval for human subject research.

### **CRITERIA FOR IRB APPROVAL:**

- 1) Risks are minimized.
- 2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
- 3) Selection of subjects is equitable.
- 4) Informed consent will be sought from each potential subject or their legally authorized representative (LAR).
- 5) Informed consent will be appropriately documented.
- 6) All individuals involved in the obtainment and documentation of informed consent have the necessary expertise and knowledge to properly obtain consent.
- 7) , The research plan makes adequate provisions for monitoring data to ensure safety of subjects. Some studies may need an independent data and safety monitoring board (DSMB).
- 8) There are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data.
- 9) Additional safeguards are included for studies involving subjects that are likely to be vulnerable to coercion or undue influence (i.e. children, prisoners, decision-making capacity impaired, economically or educationally disadvantaged, etc.).

### **Additional Considerations:**

- Federal, state, and local laws and regulations
- UNMC policies
- Basic ethical principles