Criteria for IRB Approval (HRPP 2.5)

Description:

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

Before a non-exempt study can be approved, it must meet **all** of the following requirements, ensuring the research is ethical and safe for participants.

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
- Institutional policies
- Basic ethical principles