Full Board Review (HRPP 2.2)

Description:

This policy describes UNMC's requirements for: (1) submission of items required for full IRB review; (2) IRB approval criteria, and (3) IRB actions.

Submission Requirements:

- All applications and research related forms will be submitted using the online Research Support System (RSS).
    - Continuing Reviews and certain other forms to research protocols ***approved prior to January 16, 2012*** may continue to be submitted on paper.
- The DEADLINE FOR SUBMISSION requiring review by IRB-01, IRB-02, and IRB-04 is **10 working days prior to each meeting**. IRB-05 is 6 working days prior to each meeting.

Criteria for IRB Approval:

See HRPP Policy 2.5

IRB Actions:

- **APPROVAL**
    - Initiation of research authorized (when institutional requirements are satisfied).
    - All criteria for approval are satisfied and no changes are required.
- **CONDITIONAL APPROVAL:**
    - Final approval is contingent upon IRB Executive Chair/designee review and acceptance of specified modifications and/or submission of additional documents.
    - Requirements for final approval are considered minor and not substantive in nature.

- **TABLED/RE-REVIEW REQUIRED:**
    - The IRB requires additional information in order to determine whether the criteria for approval is satisfied, and/or the IRB had concerns which warrant re-review by the full IRB.
    - If the protocol and application are revised by the investigator in response to the IRB's comments, the protocol will be returned to the full convened IRB for re-review.
- **DISAPPROVED:**
    - Applications may be disapproved if, after thoughtful deliberation, the IRB:
        - 1) Finds serious design flaws that either make obtainment of generalizable knowledge highly unlikely or places subjects at undue risk
        - 2) The risk/benefit relationship is unfavorable, or
        - 3) The protocol does not meet regulatory criteria for approval or institutional policy or requirements
        - and the investigator is unable or unwilling to make modifications to remedy these situations
    - The investigator will have an opportunity to appear before the Board, however, the IRB has final authority and their decision cannot be overturned.
- **SUSPENSION:**
    - The IRB requires all research activities be halted immediately in accordance with HRPP Policy 8.6.
    - This action may be taken in relation to continuing review, complaints, noncompliance, adverse events, and unanticipated problems involving risks to the subjects or others.
- **TERMINATION:**
    - The IRB requires the study to be terminated in accordance with HRPP Policy 8.6.
    - This action may be taken in relation to continuing review, complaints, noncompliance, adverse events, and unanticipated problems involving risks to the subjects or others.

PI Response to IRB Review Letter:

An IRB review letter will be developed and sent from the IRB Analyst.

- The PI is given 60 days from the date of the letter to respond by submitting appropriately revised documents.
- If no response is received within 60 days, or by the expiration of an extension (granted by the IRB Executive Chair/designee), the study may be withdrawn or closed.