**Institutional Review Board**

**Investigator Guidance Series**

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**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:**
  o 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.
  o 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:**
  o 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
  o The investigator will have an opportunity to appear before the Board, however, the IRB has final authority and their decision cannot be overturned.

• **SUSPENSION:**
  o The IRB requires all research activities be halted immediately in accordance with HRPP Policy 8.6.
  o 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:**
  o The IRB requires the study to be terminated in accordance with HRPP Policy 8.6.
  o 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.