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.
- Protocols must be submitted prior to the deadline found on HERE to be considered for board review.

When Does the IRB Meet?

- **Adult Board:** 1st and 3rd Thursday of the month
    - The adult board only meets once in the months of January and July
- **Pediatric Board:** 4th Tuesday of the month
- **Single IRB:** 2nd Friday of the month

Criteria for IRB Approval:

See HRPP Policy 2.5

IRB Actions:

- **APPROVAL**
  - All criteria for approval are satisfied and no changes are required
  - The study may start (when institutional requirements are satisfied)
- **CONDITIONAL:**
  - Minor changes are required
  - Final approval contingent upon IRB review and acceptance of changes and/or submission of additional documents
- **TABLED:**
  - Major changes required or there is significant missing information
  - Re-review by the full IRB is required
- **DISAPPROVED:**
  - The study may NOT move forward
  - Applications may be disapproved if 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 PI may appeal the decision, but the IRB has final authority and their decision cannot be overturned
- **SUSPENSION (HRPP Policy 8.6):**
  - The study must immediately stop temporarily due to safety or compliance concerns
  - 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 (HRPP Policy 8.6):**
  - The study must immediately stop permanently
  - This action may be taken in relation to continuing review, complaints, noncompliance, adverse events, and unanticipated problems involving risks to the subjects or others

After the Review: What Happens Next?

- The PI receives a letter via email from the IRB that explains the decision made
- **If changes are required, the PI has 60 days from the date of the letter to submit them**
    - **<u>If no response is received within 60 days,</u>** or by the expiration of an extension (granted by the IRB Executive Chair/designee), the study may be withdrawn or closed

Review by Other Committees:

Besides the IRB, other institutional committees might need to review the study (e.g. radiation safety, Investigational Device, Biosafety, etc.). Final approval only happens after these groups have provided their approval to the IRB.

Final Approval Letter:

Once all changes are accepted and other necessary approvals are in place, the ORA sends the final letter allowing the study to start. This letter should be read carefully as it includes:

- ***Important dates*** (review, approval, **expiration**)
- ***Risk level*** (minimal or greater than minimal)
- ***Specific federal protections used*** (e.g. children, prisoners, pregnant women, fetuses, neonates)