Central IRB (cIRB) Research (HRPP 1.4)

Description:
This policy describes UNMC’s requirements for the UNMC IRB to cede review to an external IRB.

Definitions:

<table>
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<tr>
<th><strong>Cede Review:</strong></th>
<th>an institution agrees to transfer IRB review and oversight authority to another institution’s IRB (reviewing IRB).</th>
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<tr>
<td><strong>Reliance Agreement:</strong></td>
<td>an agreement between two Organizations engaged in human subject research that documents respective authorities, roles, responsibilities, and communication between the reviewing and relying IRBs.</td>
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<td><strong>Relying Institution:</strong></td>
<td>a participating institution that cedes IRB review to the IRB of record (reviewing IRB).</td>
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<td><strong>Reviewing IRB (External IRB):</strong></td>
<td>the IRB responsible for conducting IRB review and approval.</td>
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General Considerations:
Research may not commence until approval by both the 1) the UNMC ORA and 2) the external IRB of record.

External IRB NOT permitted for:
1) Clinical trials initiated by a UNMC investigator
2) Use of a Humanitarian Use Device (HUD)
3) Emergency research
4) Research involving the use of vaccines developed/manipulated at UNMC/NM
5) Research involving gene transfer
6) Emergency use of a test article
7) Research involving prisoners
8) Research involving fetal tissues or HESCs
UNMC Lead PI Responsibilities:

- Complete a cIRB application.
- Complete all submission requirements for the external IRB.
- Comply with all UNMC HRPP policies.
- Comply with the external IRB’s determinations and requirements.
- **Promptly report to the external IRB:**
  - Proposed changes to research
  - COI management plans
  - Incidents of noncompliance
  - Protocol deviations
  - Complaints from subjects or others
  - Data safety monitoring reports
  - Adverse events and unanticipated problems involving risk to subject
- **Promptly report to UNMC IRB:**
  - Any new or modified conflicts of interest
  - Any additional external IRB requirements to COI plan
  - Incidents of noncompliance
  - Copies of all OHRP and/or FDA reports
  - Internal adverse events
  - Changes in study personnel
- Ensure all research staff have appropriate qualifications and expertise and understand their responsibilities.
- Conduct monitoring.
- Notify the ORA when the study is complete.