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:

Cede Review: an institution agrees to transfer IRB review and oversight authority to another institution's IRB (reviewing IRB).

Reliance Agreement: an agreement between two Organizations engaged in human subject research that documents respective authorities, roles, responsibilities, and communication between the reviewing and relying IRBs.

Relying Institution: a participating institution that cedes IRB review to the IRB of record (reviewing IRB).

Reviewing IRB (External IRB): the IRB responsible for conducting IRB review and approval.

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.