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: when one institution lets another institution's IRB take over review and oversight of a specific study (reviewing IRB).

Reliance Agreement: a formal agreement between two organizations doing research that outlines who is responsible for what when one IRB reviews the research for both.

Relying Institution: an institution that agrees to use another institution's IRB (cede review) instead of doing its own review.

Reviewing IRB (External IRB): the IRB that reviews and approves the research for all participating sites in a multisite study.

General Considerations:

Research may not start until approval is issued by both 1) the UNMC ORA and 2) the external IRB of record.

Ceding IRB Review to an external IRB is 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:

The UNMC PI must:

- Submit a reliance request to UNMC ORA and apply to the external IRB
    - ***NOTE**: UNMC IRB has a master reliance agreement in place with Advarra, WCG, and NCI, therefore a separate reliance agreement is not necessary*
- Follow all:
    - External IRB determinations
    - Applicable UNMC HRPP policies
- Complete and submit a cIRB application
- Complete all submission requirements for the external IRB
- **Promptly report to the external IRB:**
    - Protocol changes
    - COI management plans
    - Noncompliance, protocol deviations, and subject complaints
    - DSMB reports
    - Adverse events and unanticipated problems involving risk to subject
    - Copies of reports to OHRP/FDA (as applicable)
- **Promptly report to UNMC IRB:**
    - New COIs or changes to COI management plans
    - Requirements imposed by the external IRB
    - Personnel changes
    - Internal Adverse Events
    - Incidents of noncompliance
    - Copies of all OHRP and/or FDA reports
- Ensure all research staff are:
    - Qualified and trained
    - Aware of consent procedures and documentation requirements
- Conduct monitoring with external IRB and ORA
- Notify the ORA when the study is complete

Procedures for Using an External IRB:

1. **Submitting the Application:**
    a. PI must submit a Central IRB (cIRB) Application in the RSS system for non-exempt human subject research
    b. <u>The application must include:</u>
        i. The full protocol
        ii. The sponsor's consent forms or information sheets
2. **IRB Analyst Review:**
    a. The IRB Analyst checks that your study meets all UNMC internal requirements, including:
        i. UNMC HRPP policies
        ii. Required ancillary reviews (e.g. COI, SRC, P&T, IDRC, etc.)
        iii. Contract reviews
        iv. Budget/Coverage Analysis
    b. The IRB Analyst confirms all applicable agreements are in place, including:
        i. IRB Reliance Agreement
        ii. Data Use/Transfer Agreements
        iii. Sponsored Contracts
3. **Conditional Acceptance:**
    a. If everything is in order, the PI will receive a ***conditional acceptance letter*** outlining any outstanding requirements
    b. The following local documents will be made available to the IRB of record:
        i. Consent template with included UNMC required language
        ii. COI management plans
        iii. Local policy and regulatory details
4. **Final Acceptance:**
    a. Once everything is complete, including the signed IRB Reliance Agreement *(as applicable),* the IRB Analyst will issue an acceptance letter. **NOTE**: the study cannot start until this is received.
    b. From this point on, all communication about IRB matters should go through the IRB of record (except for specific reporting to UNMC as noted in earlier sections). UNMC IRB staff can't answer questions about external IRB determinations.