

Single IRB (sIRB) Research (HRPP 1.3)

Description:

This policy describes UNMC's requirements when the UNMC IRB is serving as the sIRB for multi-site research.

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:

A reliance agreement is required for all non-exempt multi-site research.

UNMC Lead PI Responsibilities:

The lead PI acts as the main person in charge of the entire study across all sites. They are responsible for:

- Being the main contact for the UNMC IRB and for sharing all IRB decisions with the other sites
- Making sure other site investigators have access to required policies (*i.e. HRPP policies*)
- Ensure all site consent forms/information sheets follow UNMC IRB template guidelines and provide site-specific required language provided by each relying institution
- Sending IRB-approved study documents to the other sites
- Promptly reporting any unanticipated problems to all participating sites

- Notifying all participating sites of UNMC determinations and communications (e.g. *initial review, continuing review, change requests, etc.*)
- Making sure each site submits their Continuing Review application on time
- Informing sites if their IRB approval lapses and what to do about it
- Giving auditors access to all study records when needed

Procedures for Using UNMC as the Single IRB:

1. Submit a Request

- a. Fill out the **sIRB request form** which includes:
 - i. Which research network and sites are involved (if any),
 - ii. Why UNMC should act as the single IRB,
 - iii. Any important deadlines or requirements from funders

2. UNMC Must Approve

- a. The Institutional Official (IO) at UNMC must give permission for the UNMC IRB to act as the single IRB

3. Sign a Reliance Agreement

- a. This formal agreement must be signed by all participating institutions and spells out who is responsible for what
- b. UNMC prefers using the Smart IRB platform, but a different form of agreement may be used if needed

4. Each Site Must Agree

- a. Each relying site must officially agree to let UNMC review their part of the study. This includes completing the reliance agreement and implementation checklist
- b. **NOTE:** *each site must finish their own internal requirements before they can start enrolling subjects*

5. Lead PI Submits the IRB Application

- a. Once UNMC agrees to be the single IRB, the Lead PI fills out the main IRB application in RSS, listing all participating sites

6. IRB Reviews the Study

- a. UNMC's IRB reviews the research either through a full board review or expedited review, depending on study type (*NOTE: the type of review is determined by the assigned IRB analyst*)

7. Follow the Right Policies

- a. All sites must follow UNMC's rules for reporting:

- i. Adverse events
- ii. Protocol deviations
- iii. Noncompliance

b. For other things like compensation or recruitment advertisements, each site will follow their own local policies.

- i. *NOTE: if a site does not have its own rule on something, they follow UNMC's policy*

8. Consent Forms

- a. The lead PI creates a UNMC template consent form in RSS. Each participating site then:
 - i. Adds their own local information (e.g. *contact details, compensation details, etc.*)
 - ii. Submits it to the IRB for final approval