

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: 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:

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

UNMC Lead PI Responsibilities:

- Serve as the primary contact with the UNMC IRB.
- Notify relying sites of all UNMC IRB actions.
- Assure site PIs have access to UNMC's 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.
- Provide relying sites with IRB approved versions of study documents.
- Promptly report to all site PIs any unanticipated problems.
- Notify site PIs of all UNMC determinations and communications (initial review, continuing review, change requests, etc.).
- Ensure site PIs submit in a timely manner the continuing review application for their site.