

sIRB - UNMC process

The UNMC sIRB Process is captured in the diagram below.

Request Determination

- Lead Site submits sIRB request through RSS
- sIRB Team sets up initial consultation with Lead Site Study Team
- sIRB Request determination based on study team and HRPP resources; IRB expertise

Lead Site and Protocol Review

- Lead site submits IRB application (protocol & lead site information) through RSS
- UNMC IRB, sIRB Team reviews the submission
 - Lead Site Study Team works with sIRB Team to resolve any outstanding items
- Protocol and lead site approved

Participating Site (pSite) Review

- pSites sent invitations to complete pSite application through RSS
 - Applications reviewed by sIRB Team
 - Reliance Agreement negotiation and determination
 - Site approved as each site fulfills requirements
- Final activation contingent on meeting institutional requirements

Study Maintenance

- Activities during the course of the study include:
 - Change Requests
 - Continuing Review
 - Single Subject Deviations
 - Incident Reports
 - Adverse Events
 - Completion Reports

Contact sirb@unmc.edu with any UNMC sIRB process questions.

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