

# sIRB - UNMC process

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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](mailto:sirb@unmc.edu) with any UNMC sIRB process questions.

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