

Key Benchmarks

Phase 1: Request for Reliance on External IRB

a. eIRB+ Submission

- Required Documents:
- Draft reliance agreement
 - Protocol
 - sIRB Letter of Support if federally funded

b. Northwestern Reliance Review

Reliance considerations reviewed. Analyst obtains Northwestern's signature on reliance agreement.

c. Reliance Agreement Returned

Northwestern signed reliance agreement returned via eIRB+.

Phase 2: Northwestern Site Review by External IRB

Start here if using a master agreement

If site is Consenting

a. Consent Form Customization

Include relevant required Northwestern consent form and HIPAA language

b. External IRB Review

External IRB reviews Northwestern site and customized materials as applicable.

c. Northwestern Site Approval

External IRB issues approval letter for the Northwestern site.

Phase 3: Northwestern IRB Initial Acknowledgement

a. Return Site Approval to eIRB+

- Required Documents:
- Northwestern site approval letter
 - Fully signed reliance agreement
 - Study materials used at Northwestern

b. Northwestern Reliance Review

Reliance analyst reviews submission, consent form language (if applicable), COI, and CITI training.

c. Northwestern IRB Acknowledgement

Reliance analyst issues Acknowledgement letter. Local activities may begin.