Reliance Process from the Study Team Perspective

START HERE

Lead Study Team submits Protocol and Main Consent Documents to Reviewing IRB for Initial Review

Lead Study Team sends approval letter and model consent documents to Relying Study Team

Lead Study Team and Relying Study Team go through respective IRBs’ reliance request processes.

IRBs negotiate and fully execute reliance agreement.

Relying IRB instructs Relying Study Team on how to submit local submission for institutional requirements

Relying Study Team fills out Reviewing IRB’s Local Context Worksheet and other necessary forms and sends them to Relying IRB for review and signature

Relying Study Team completes local submission, uploading the grant/award document, approved protocol, model consent documents, and site-specific consent documents

Relying Study Team takes model consent documents from Reviewing IRB and plugs site-specific provisions for Cost, In Case of Injury, and HIPAA Authorization into the appropriate places.

Relying Study Team provides site-specific documents for site onboarding to Lead Study Team for submission to Reviewing IRB.

Once all institutional requirements completed, Relying IRB gives institutional signoff and provides signed Local Context

For future study-wide or site amendments, continuing review, or study-wide or site close-out, Relying Study Team provides any necessary information to Lead Study Team to submit to Reviewing IRB.

Relying Study Team begins study activities at the site.

Relying Study Team provides any approval letters, approved documents, or close-out letters to Relying Study Team.

Relying Study Team is responsible for providing any approval letters and approved study documents received from Lead Study Team to Relying IRB.