

Where to upload documents for External IRB Studies: Study vs. Site Submissions in eIRB+

Study Document	STU or IRBSITE?	Page Name
Protocol	Study Submission ("STU")	Basic Information
Local Protocol Addendum	Study Submission ("STU")	Basic Information
Consent Form(s) - Northwestern specific language*	Site Submission ("IRBSITE" a.k.a. "Site")	Site-Specific Documents
Consent Form Template(s)	Study Submission ("STU")	Study-Related Documents for non-NU Research Sites
Investigator Brochure	Study Submission ("STU")	Drugs
Package Insert	Study Submission ("STU")	Drugs
Device Manual	Study Submission ("STU")	Devices
Recruitment Material - Overall Study	Study Submission ("STU")	Study-Related Documents for non-NU Research Sites
Recruitment Material - Northwestern Site	Site Submission ("IRBSITE" a.k.a. "Site")	Site-Specific Documents
Questionnaires - Overall Study	Study Submission ("STU")	Study-Related Documents for non-NU Research Sites
Questionnaires – Northwestern Site	Site Submission ("IRBSITE" a.k.a. "Site")	Site-Specific Documents
External IRB Approval Letter - Initial Site Approval	Study Submission ("STU")	External IRB
External IRB Approval Letters – Post-Initial Approval**	Site Submission ("IRBSITE" a.k.a. "Site")	Site-Specific Documents
Reliance Agreement***	Site Submission ("IRBSITE" a.k.a. "Site")	Site-Specific Documents

*E.g., Northwestern PI contact information, HIPAA, subject injury, financial disclosures, etc.

** Continuing review approvals, modification approvals, RNI determinations, closure letters

*** Institutional Authorization Agreement (IAA), Master Agreement Acknowledgement Letters (Commercial IRBs), SMART IRB Letter of Acknowledgement (LOA)