Required Documents for the KUMC eIRB Submission	
eIRB Screen	**Documents to Prepare and Upload**
Basic Information	*Proposed study protocol (or Protocol Application form for Secondary Research studies only)
Funding Sources	Grant applications (if applicable)
Study Team Members	N/A
Study Scope	N/A
Local Research Locations	Letters of support for external locations (if applicable) Communications with relying sites (if applicable)
Drugs (if checked in Study Scope)	• For investigational drugs: Investigator's brochure • FDA correspondence (if applicable) • Drug package insert, when an FDA-approved drug is being studied for an unapproved use
Devices (if checked in Study Scope)	Device Manual
Local Site Documents	*Project Description for Full Committee Review, Exempt, Expedited, or Flex Review Studies • Clean versions of proposed consent forms in Word only with no footer. • Proposed recruitment materials • PI Supplement (Full-Committee only) • IRB Checklist (Full-Committee only) • Lead Investigator Supplement (for Multi-site studies where KUMC is the Reviewing IRB) • Scientific merit review • Surveys, instruments • Data collection sheets • DSMB or DMC Charter • Subject instructions, diaries, etc. • Ancillary approval letter (e.g., RSC, Biosafety, PRMC) • Sponsor correspondence • HIPAA waiver request
Internal Reporting	N/A
	***Required on all new studies**