

Checklist of Documents for KUMC IRB Application	
eIRB Screen	Documents to Prepare and Upload
Basic Information	*Proposed study protocol
Funding Sources	Grant applications (if applicable)
Study Team Members	N/A
Study Scope	N/A
External Sites (if checked in Study Scope)	IRB Reliance Letter (if available). Letter of support (if applicable)
Drugs (if checked in Study Scope)	<ul style="list-style-type: none"> • 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
Consent Form and Recruitment Materials	All proposed consent forms <u>in Word only with no footer</u> . All proposed recruitment materials
Internal Reporting	N/A
Supporting Documents	<p>*Project Description for Full Committee Review, Exempt, Expedited, or Retrospective Studies If Applicable:</p> <ul style="list-style-type: none"> • Supplemental applications • Signed Scientific Merit/Dept Chair Review • Surveys, instruments • Data collection sheet • DSMB or DMC Charter • Subject instructions, diaries, etc. • PRMC approval letter • Sponsor correspondence • HIPAA waiver request
	*Required on all new studies