

**IRB Submission Requirements (myResearch version)
(New, First Time Submissions)**

	Exemption Review	Expedited Review	Full Review	Not Research/Not HSR	SBU Hospital QA/QI (QA/QI projects are submitted in IRBNet)
Protocol	X	X	X	X	X
Consent Forms/Permission Forms/Assent Forms in Word doc format *	X	X	X		
Fee Authorization form (Industry-Funded Studies only) *		X	X		
HIPAA form (as applicable) *	X	X	X		
Supplemental Forms A, B, C, D, F, G (as applicable) **	X	X	X		
University Hospital Approval Form ***	X	X	X		
Surveys, questionnaires, evaluation instruments	X	X	X		
Recruitment Materials (e.g. email/call scripts, announcements, advertisements, etc)	X	X	X		
Data collection sheets (spreadsheets, key sheet templates, case report forms, etc)	X	X	X		
Package inserts for approved drugs/devices (as applicable)		X	X		
Investigator Brochures for Investigational Drugs/Devices (as applicable)		X	X		
Inclusion/Exclusion Checklist (to be completed for each subject)			X		
Request for Human Subjects Research Determination *				X	
Application for Designation of Activity as QA/QI or Research *					X
Protocol Review Monitoring Committee approval letter (if study involves cancer patient data or specimens)	X	X	X		
Department Chair Approval (via Ancillary Review) and any other applicable ancillary reviews	X	X	X		X (Chief Medical Officer approval)

* Templates for these documents are available in the myResearch “For Investigators” library

** Form A: Pregnant Women, Fetuses, and Questionably-/Non-Viable Neonates, Form B: Prisoners, Form C: International Research, Form D: Sponsor-required ICH-GCP, Form F: Minors, Form G: Consent Waivers

*** Only if your research activity involves the facilities, patients, and/or services of any of University Hospital's inpatient or outpatient locations, (with the exception of the outpatient clinics located at Riverhead, Southold, Plainview, or Medford). This includes research conducted in the Health Sciences Center.