IRB Submission Requirements (IRBNet) - (New, First Time Submissions) (Please Note – Residents, Fellows and Students are not permitted to be PI's. The PI must be a Faculty Member or Physician on Erlanger Medical Staff) All Investigators, Staff and Department Chair must sign the packet on their own behalf.

DO NOT SUBMIT THE PACKET UNTIL ALL DOCUMENTS ARE COMPLETE AND UPLOADED AND ALL SIGNATURES ARE OBTAINED and CV's and CITI TRAINING UPLOADED FOR EACH INVESTIGATOR. THE PACKAGE WILL BE CONSIDERED INCOMPLETE AND WILL NOT BE REVIEWED UNTIL COMPLETED

	Exempt Review	Expedited Review	Full Review	Outside IRB used acknowledgement	Hospital QA/QI/Not Human Subject Research **(QA/QI and NHSR projects are submitted in IRBNet)**
Initial Study Application (SmartForm Wizard tab)	x	x	x	x	
Protocol For QI, use the QI Protocol Template for Possible Research For Research or the Research Protocol Template	X	X	X	x	X
Consent Forms in **Word doc format** * (A separate HIPAA Consent is required for NCI CIRB approved projects)	X	X	X	x	
Fee Authorization form **(Industry or Grant-Funded Studies only)** *		X	X	x	
Surveys, questionnaires, evaluation instruments	X	X	X	x	x
Recruitment Materials (e.g. email/call scripts, announcements, advertisements, etc)	X	X	X	x	
Data collection sheets (spreadsheets, key sheet templates, case report forms, etc)	X	X	X	x	x
Investigator Brochures for Investigational Drugs/Devices **(if applicable)**		X	X		
Data Use Agreement if data will be shared outside of the institution and verification that all research contracts are complete.	x	x	x	x	
Central IRB approval Letter				x	
UT Medical Student HIPAA and Compliance Training Certificates from UT (if applicable)	x	x	x		x
Biostatistical Request Form * (must be completed for all investigator initiated studies)	x	x	x	x	
CITI Training and CVS for all Research Personnel. (CITI must be linked through IRBNet UserProfile and CV's added as additional training	X	X	X	x	X(only if project is determined to meet the definition of research)
Request for Human Subjects Research Determination QA/AI Activity *					x
PI, Co-PI, Key Research Staff and Department Chair Approval/signoff (via Ancillary Review) and any other applicable ancillary reviews (Use the Share button to send to research team and outside reviewers. **Each must sign on their own behalf**	X	X	X	x	x

* Templates for these documents are available in the IRBNet "For Investigators" library

IRB Submission Requirements (IRBNet)

Modifications

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	Minor Amendment	Major Amendment
Revision/Change Form (see "For Investigators" library for form)	X	X
CITI Training and CVS for all Research Personnel. (CITI can be linked through IRBNet UserProfile and CV's added as additional training	X	X
Revised documents with changes tracked/noted in Revision/Change Form Clean PDF copy of the revised documents. This includes a Final Closure if the research has ended	X	X
PI, Co-PI, research staff and **new staff** (if applicable) and any other applicable ancillary reviews (Use the Share button to send to research team and outside reviewers. **Each must sign off on their own behalf**	x	X

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IRB Submission Requirements (IRB NET version) Continuing Review Submissions

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	Expedited Review	Acknowledged Review for Commercial/NCI CIRBs	Full Review
IRB Form D – Continuing Review Request **	X	x	X
Copy of current stamped consent and Clean, most currently approved, Consent Forms/Permission Forms/Assent Forms **with previous IRB stamp removed** in **PDF format** *	X	x	X
Central IRB Approval Letter		x	
Data Safety Monitoring Board Reports	x		X
HDE Annual Reports is applicable			
Government or sponsor audit/monitoring reports	x	x	X
List of subjects enrolled and in follow-up when consent is required using only subject initials.	X	x	X
List of local SAE's that have occurred **Note**: an adverse event is classified reportable if it meets three criteria: 1) serious, 2) unexpected, and 3) possibly, probably, or clearly caused by the research intervention.	x	x	x
PI, Coodinator	X	X	X

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