Please use this table below to determine what documents are needed for your New Study Submission. The Regulatory Affairs Administrator will forward the appropriate documents to the TriHealth IRB once DRC and / or Administrative Approval is granted, as not all documents are required for IRB review.

ALL REQUIRED FORMS CAN BE FOUND IN THE CLINICAL RESEARCH TOOLBOX

	Sponsored (Cardiovascular, Ortho, Neuro, GI, Women's) ***(DRC)***	***Sponsored Oncology*** ***(DRC)***	***Cooperative Group Oncology*** ***(DRC)***	***Prospective PI-Initiated, Resident and Nursing Studies*** ***(DRC/ADMIN REVIEW)***	***Retrospective PI-Initiated, Resident and Nursing Studies*** ***(ADMIN REVIEW)***	***Exempt Studies*** ***(ADMIN REVIEW)***	***MFMU*** ***(DRC)***	***External (CCHMC, UCMC)*** ***(ADMIN REVIEW)***
New Study Submission Form	*X*	*X*	*X*	*X*	*X*	*X*	*X*	*X*
Key Study Personnel for New Study Submission Form (if needed)	*X**	*X**	*X**	*X**	*X**	*X*	*X**	*X**
CITI, CV and Medical Licenses in database	*X*	*X*	*X*	*X*	*X*	*X*	*X*	*X*
Protocol	*X*	*X*	*X*	*X*	*X*	*X*	*X*	*X*
Informed Consent and Authorization	*X*	*X*	*X*	*X*			*X*	*X*
Sponsor's Informed Consent and Authorization Template	*X*	*X*					*X**	*X**
Checklist for Valid Authorization if using outside IRB	*X*	*X*	*X*				*X*	*X*
Waiver or alteration of Informed Consent					*X*	*X*		
Waiver of Documentation of Informed Consent				*X1*				
Wavier or Alteration of Authorization / Partial Waiver for Recruitment Form				*X1*	*X*	*X*		*X3*
Scientific Review	*X2*			*X2*	*X2*	*X2*	*X2*	*X2*
Facility Impact Form	*X*	*X*	*X*	*X*		*X*	*X*	*X*
Pharmacy Form, if applicable	*X**	*X**	*X**	*X**			*X**	*X**
Clinical Trial Agreement	*X*	*X*	*X*				*X**	
Material Transfer Agreement	*X**	*X**	*X**	*X**			*X**	*X**
Data Use Agreement				*X**	*X**			*X**
Research Support Services Agreement				*X**	*X**			*X**
Budget	*X*	*X*	*X*	*X*			*X*	*X**
Interdepartmental Pricing Agreement	*X**	*X**	*X**	*X**			*X**	
MCA/Billing Grid	*X*	*X*	*X*	*X*				
Institution Authorization Agreement for deferral to outside IRB		*X*	*X*				*X*	*X**
CHIRB or CIRB approval Letter			*X*					
Federal Funding Sheet/Sub-recipient agreements/Capitation Schedule	*X**		*X*				*X*	*X**
EPIC New Study Setup Form	*X*	*X*	*X*	*X*	*X*		*X*	*X**
Financial Conflict of Interest Form(s)	*X*	*X*	*X*	*X*	*X*	*X*	*X*	*X*
Sub-Study Form, if applicable	*X**	*X**	*X**	*X**	*X**		*X**	*X**
HUD/HDE Checklist, if applicable	*X**	*X**	*X**				*X**	*X**
Genomics Sub-Study Form	*X**	*X**	*X**	*X**			*X**	*X**
Investigator DEA License, if study involves Controlled Substances	*X**	*X**	*X**	*X**			*X**	*X**
FDA Approval Letter for IDE, if applicable	*X*			*X**			*X**	*X**
Investigator's Brochure, Package Insert or Device Manual, if applicable	*X**	*X**	*X**	*X**			*X**	*X**
Copies of Surveys, Questionnaires or Videotapes	*X**	*X**	*X**	*X**		*X**	*X**	*X**
Recruitment materials including phone scripts	*X**	*X**	*X**	*X**			*X**	*X**
Data Collection Sheets				*X**	*X**			*X**
FDA/OHRP Audit Related Information	*X**	*X**	*X**	*X**	*X**		*X**	*X**
FDA/OHRP Relevant Documents	*X**	*X**	*X**	*X**	*X**		*X**	*X**

X if applicable, X1 if doing a questionnaire or survey study on-line, X2 Cardiovascular, Oncology PI-Initiated, Perinatal and Nursing studies only, X3 non-covered entity employees*

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