KUMC IRB Checklist: Full Board Submission

Instructions: Please complete this form and submit with all required documents and applicable ancillary review approvals in myIRB. This tool is to serve as documentation of completion by the appropriate clinical trials staff and review by the IRB administration staff for IRB Full Board Submission.

Principal Investigator:	KUMC IRB Study #:
Protocol Title:	
The University of Kansas Health System Research Record Number (TUKHSRR) (KUMC only):	

Submission Packet Checklist

PI Check		IRB Check	
Completed & Uploaded in myIRB	**NA**	**Verified**	Please check off all the completed documents uploaded to myIRB for this study or select "NA" if that document type is not applicable. Additionally, upload the completed IRB Checklist with the title "IRB Checklist" in the "Supplemental Application" category.
			Study Documents
☐	☐	☐	Protocol, version date:_____ *Protocol submitted must be the same version reviewed at Scientific Review and must be a clean version.*
☐	☐	☐	Adult Consent Form *(clean Word version)*
☐	☐	☐	Parental Permission Form *(clean Word version)*
☐	☐	☐	Assent Form *(clean Word version)*
☐	☐	☐	Pregnancy/Pregnant Partner Consent Form *(clean Word version)*
☐	☐	☐	Surrogate Consent Form *(clean Word version)*
☐	☐	☐	Sponsor Consent Templates *(clean Word version)*
☐	☐	☐	Recruitment materials *Examples include emails, letters, flyers, posters, radio/tv ads. etc.*
☐	☐	☐	Participant facing materials, scripts, guides, surveys *Examples include diaries, questionnaires, phone scripts, interview guides etc.*
☐	☐	☐	Safety Committee Charter and Plan *Committee types include but are not limited to, DSMC, DMC, DSMB, Steering Committee or OSMB. If the study is multi-phase, a safety plan for **all** phases must be submitted.*

☐	☐	☐	Full Grant submission *NIH Grants require Certificate of Confidentiality language in the consent form*
☐	☐	☐	IND, IDE or in vitro device (IVD) Documentation *Investigational drug studies must include IND status documentation from FDA. Investigational device studies or studies involving an IVD must have non-significant risk device or exempt documentation. Alternatively, if a significant risk determination was made this documentation will need to be submitted.*
☐	☐	☐	Investigator Brochure or Package Insert, version date:_____ *Documentation submitted must be the same version reviewed at Scientific Review and must be a clean version.*
☐	☐	☐	Device manual/instructions
IRB Documents and myIRB Entry			
☐	☐	☐	KUMC IRB Checklist: Full Board Submission
☐	☐	☐	Project Description
☐	☐	☐	Signed PI Supplement
☐	☐	☐	Funding Source is entered in myIRB
☐	☐	☐	All required study personnel are entered in myIRB
☐	☐	☐	All drugs and devices used in this study are entered in the "drugs" or "device" section of myIRB
Ancillary Reviews			
☐	☐	☐	Radiation Safety Committee Submission approval date:_____
☐	☐	☐	Scientific Review *Examples include PRMC approval letter (Cancer Center only), scientific review within* myIRB *or paper scientific review form. Scientific review documentation is not required for industry sponsored multi-site trials.*
☐	☐	☐	Institutional Biosafety Committee Approval Documentation
☐	☐	☐	Submit Clinical Research Infection Control Plan Review in REDCap

_____ _____

Name of Person Completing Form *Date*