

Study Start-Up Checklist

Study Title:
PI:
Sponsor:

Study Details:	
Study type:	Investigator-Initiated
Departments:	Multidisciplinary
SOC:	Not Standard of Care

Completed	Task	Date Completed	Comments
Approval Process			
	Research Proposal: Study Request Survey		
	• Protocol & Budget Allocation Outline		
	Attend RadOnc Clinical Trials Committee Meeting		
	• Approved by Radiation Oncology		
	Attend Multidisciplinary Disease Team Meeting		
	• Approved by Multidisciplinary Disease Team		
Management Decision			
Study Design Planning			
	Cost Estimate Forms (other CUIMC departments)		
	Radiation Oncology Cost Estimate Form		
	Contract (from Sponsor)		
	Consult with BERD		
	• Protocol		
	Consult with CPDM		
	• Budget		
	Informed Consent Form		
Submission Process			
	CTO Submission		
	• CTO Approval		
	Fiscal Support Submission		
	• Fiscal Support Approval		
	PRMC Feasibility Submission		
	• PRMC Approval		
	DSMC Submission		
	• DSMC Approval		
	IRB Submission		
	• IRB Approval		
	IRB Approval Submitted to CTO		
Contract Execution			
	Contract Signature		
Study Initiation			
	PRS Account		
	ClinicalTrials.gov Registration		
	Site Initiation Visit		
	Systems Set Up (ARC, Data Collection, Payment Invoicing, Core Services)		
Recruitment			
	Columbia's RecruitMe Website Posting		
	HICCC Clinical Trials Website Posting		

Key: PI