

Study Start-Up Checklist

Study Title:

PI:

Sponsor:

Study Details:

Study type: Industry-Sponsored

Departments: Multidisciplinary

SOC: Not Standard of Care

Completed	Task	Date Completed	Comments	
Approval Process				
	Research Proposal: Study Request Survey			
	• Protocol & Budget Allocation Outline			
	Attend RadOne 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)			
	Protocol (from Sponsor)			
	Budget (from Sponsor)			
	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