

Task Type	Task		Study Team [i]	Clinical Trials Office [ii]	Partner Hospital Liaison [iii]	OnCore Automatic Notification	Concurrent OnCore Status(s)
Vetting	1	Obtains protocol and draft versions of ICF, CTA, and budget from Sponsor	X				Not Applicable
	2	Submits study & relevant documents to OnCore for Admin-SRB review	X				New
	3	Conducts RBHS feasibility and intake assessment to determine study implementation plan		X			New, On Agenda
Operations	4	Issues RBHS Admin-SRB Approval (triggers CTO startup activities)		X		X	SRB Approval
	5	Builds OnCore protocol record and calendar		X			SRB Approval
	6	Submits partner hospital application (i.e., OCRA Receipt or RUG-IRC Application)	X [iv]	X [v]			SRB Approval
	7	Performs Medicare Coverage Analysis for any studies involving routine care or billable clinical procedures	O	X			SRB Approval
IRB Review	8	Submits and obtains IRB approval for study	X				IRB Initial Approval
	9	Documents Initial IRB Approval in OnCore (triggers OnCore IRB Approval notification)	X				IRB Initial Approval
	10	Notifies CTO of Initial IRB Approval				X	IRB Initial Approval
Budgeting	11	Initiates cost gathering and submits pricing request for partner hospital services and procedures	O [vi]	X			IRB Initial Approval
	12	Submits preliminary budget proposal to sponsor and negotiates fees for budgetary components	O	X			IRB Initial Approval
Contracting	13	Reviews contract terms and negotiates with Sponsor		X			IRB Initial Approval
	14	Finalizes contract and budget for execution & routes for signatures		X			IRB Initial Approval
	15	Drafts and executes facility/data use agreements with sponsor			X		SRB Approval
	16	Drafts and executes Research Plan with partner hospital		X			SRB Approval, IRB Initial Approval
Operations	17	Uploads FE CTA/budget document and builds budget into OnCore		X			IRB Initial Approval
	18	Builds FE budget into OnCore		X			IRB Initial Approval
	19	Enters final budget into Oracle for award setup	X				IRB Initial Approval
	20	Submits ClinCard study build request	X				IRB Initial Approval
	21	Builds subject reimbursement schedule in ClinCard		X			IRB Initial Approval
	22	Transmits study record, calendar, and billing grid to Epic [vii]		X			CTO Signoff
Study Activation	23	Issues partner hospital approval to begin recruitment and protocol activity			X		CTO Signoff
	24	Notifies study team of startup activity completion and documents CTO Signoff status in OnCore		X		X	CTO Signoff
	25	Conducts Site Initiation Visit & receives Site Activation Letter from sponsor	X				CTO Signoff
	26	Updates OnCore status to Open to Accrual	X				Open to Accrual
Post-Activation	27	Recruits and carries out protocol activity	X				Open to Accrual
	28	Documents source data & enters into EDC	X				Open to Accrual
	29	Documents accrual, visits, and procedures in OnCore	X				Open to Accrual
	30	Maintains Site Investigator File, regulatory documents, and OnCore IRB approval status	X				Open to Accrual
	31	Submits Change Review to OnCore in the event of major protocol amendment, budget amendment, and/or contract amendment	X				Open to Accrual
	32	Invoices sponsor for protocol-related costs and fees	O	O			Open to Accrual
	33	Reconciles sponsor milestone (EDC) payments with study budget	O	O			Open to Accrual
	34	Assists with required financial reports or analysis	O	O			Open to Accrual

[i] Includes principal investigators, research coordinators, research nurses, regulatory coordinators, budget/financial managers, other department managers  
 [ii] Includes CTO contract manager, CTO budget analyst, and other clinical research administrators  
 [iii] Partner Hospital Liaisons: Arleen Wallen (UH Newark); Sabeena/IRC (RWJBH)  
 [iv] Applies only to RWJMS  
 [v] Applies only to NJMS  
 [vi] Study team may elect to negotiate the study budget directly with the sponsor. In such cases, CTO will review final budget terms prior to execution.  
 [vii] Applies only to sites that are live with CRPC integration and studies that are deemed to have billing risk