CLINICAL TRIALS SUBMISSION CHECKLIST

COMPLETE FOR ALL CLINICAL TRIALS:	ASSIGNEE	DEADLINE	HELPFUL LINKS/CONTACTS
☐ Meet with RBM, SPO, and Contracts. Discuss scope of work and provide the following: • List of Site PIs, CRCs, RBMs for all sites			PROSPER Contract Preparation
• List of subs, PSA, consultant agreements			
• Draft of SOW for all agreements			
• Write checklist of deliverables with assignee and timeline for each item			
• Signed face page from all sites (at application stage) eSPA Submission			

CHOP COMPONENTS:	ASSIGNEE	DEADLINE	HELPFUL LINKS/CONTACTS
☐ Aims/Research Strategy			
☐ Budget (CTFM, CHPS, & SIFTER/OnCore Submission)			Prosper Budget Plan
☐ Human Subjects Research (HSR) Plan			
☐ DSMP/DSMB			
☐ Protocol			
☐ Investigational New Drug (IND)/Investigational Device Exemption (IDE)			INDIDE@chop.edu
☐ Data Sharing			
☐ Multi PI Plan			
☐ Consortium Agreement			
☐ Dissemination Plan			
☐ Recruitment Plan			participantrecruitme@chop.edu

NIH:	ASSIGNEE	DEADLINE	HELPFUL LINKS/CONTACTS
☐ Rigor and reproducibilty			
☐ Sex as a biological variable			

PCORI:	ASSIGNEE	DEADLINE	HELPFUL LINKS/CONTACTS
☐ Methodology Checklist			
☐ Stakeholder Engagement Plan			
☐ Milestones			
☐ Timeline			

FOR EXTERNAL SITES:	ASSIGNEE	DEADLINE	HELPFUL LINKS/CONTACTS
☐ Confirm budget (particularly if no indirects for a PSA)			
☐ Packet (Signed face page, statement of work, letter of support)			
☐ Estimated site sample size based on clinical volume/prior trials			
☐ Establish relationships with IRB, SPO, and RBMs during grant submission			

Children's Hospital of Philadelphia RESEARCH INSTITUTE

Roberts Center for Pediatric Research
2716 South Street
Philadelphia, PA 19146

Questions? Contact cpce@chop.edu
https://bit.ly/CHOPCPCE

CLINICAL TRIALS

POST-AWARD CHECKLIST

PRE-AWARD START:	ASSIGNEE	DEADLINE	HELPFUL LINKS/CONTACTS
☐ Meet with RBM, CTFM, CHPS, GCS (federal), and OCCRC (Industry). Discuss scope of work and provide the following:			
• List of Site PIs, CRCs, RBMs for all sites			
• List of subs, PSA, consultant agreements			
• Draft of SOW for all agreements			
• Determine whether IRB submissions are contingent upon constract execution a each site			
• Set up monthly meetings with RBM and SPO during study start-up			
☐ Meet with OCCRC to develop MTA, DUA, DTA as applicable			
☐ Clinicaltrials.gov Registration			Institution = CHOPphiladelphia, unique protocol ID = CHOP IRB #, will route to CHOP ORC upon submission; ORCA@chop.edu

ACTIVITY:	ASSIGNEE	DEADLINE	HELPFUL LINKS/CONTACTS
☐ For CHOP/Primary Site:			
• Creation of Manual of Operations, lab manual for sample collection/shipping, data entry instructions, etc.			
• Approval of the Umbrella IRB Submission at CHOP, ICF templates for sites to use			
• Develop fully executed subaward agreement template (experience with most sites is subcontract needs to be finalized before any IRB activities can be started)			
• Sifter submission			eSifter Link
• Database activation (creation, user testing, activating)			
• Develop template logs for sites (enrollment, training, deviation, etc.)			
• Site training (develop materials, conduct SIV, document training)			

FOR EXTERNAL COLLABORATING SITES:	ASSIGNEE	DEADLINE	HELPFUL LINKS/CONTACTS
☐ Complete PI profile and site-specific study application in the CHOP IRB Reliance Portal (CHIRP)			
☐ Signed Delegation of Authority Log			
☐ Regulatory documents received (CVs, medical license, HSP/GCP training) (at minimun for the PI)			
☐ CHOP digital identity claimed and activated in REDCap			
☐ Central IRB approval and local IRB approval at site(s)			
☐ Finalization of site subcontract/purchase service agreement/ DUA/MTA with CHOP			
☐ Subject study visit payment mechanism approved and active			

For external sites, different colors = deliverables that can be tied to invoices for start-up funds.

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