Clinical Trials Office - Roles & Responsibilities (Processing of New Industry Funded Clinical Trials)	PI	Dept / Center	CTO - Administrative Asst	CTO-Coverage Analysis	CTO-Budgeting	CTO- Contracting	DCG - Award Establishment	CTO Director	VP, Research	General Counsel	USC Stevens
Initiate Trial											
Complete Clinical Trial Questionnaire in TRUE2, attaching required study documents	X	X									
Review TRUE2 submission and upon receipt of required documents, accept clinical trial			X								
Create IRIS Project Number and initiate trial in IRIS			X								
Input clinical trial into CTO Workload Spreadsheet			X								
Create Study Folders on CTO Shared Drive			X								
Assign clinical trial to CT Negotiator			X								
Assign clinical trial to CT Coverage Analysis			X								
Coverage Analysis (CA)											
Conduct Medicare Coverage Analysis (MCA)				X							
Upon completion of MCA, generate Research Order Form				X							
If no determination, review with PI and Study Team				X							
Submit completed Medicare Coverage Analysis to CTO-Budgeting and assign Budget in TRUE2				X							
Assign KC Account Number to be included in completed ROF				X							
Upload Final MCA to TRUE2				X							
Upon completion of the MCA, update TRUE2 record and CTO Workload Spreadsheet (for completion date and budget receipt date)				X							
Provide bi-weekly updates to PI and Study Team						X					
Budget development and negotiation											
Draft Budget utilizing the completed MCA					X						
Review Budget with PI and Study Team					X						
Submit Budget (Sponsor format)/Sending Counteroffer to Sponsor					X						
Negotiate Budget and Payment/Cost terms in the CTA with Sponsor					X						
Upload draft Budget and correspondence into CTO shared drive					X						
Submit Final Budget to Department Chair, or designee, for approval					X						
Approve Final Budget and upload to TRUE2	X	X									
Upon completion of the Budget, update TRUE2 record and CTO Workload Spreadsheet					X						
Provide bi-weekly updates to PI and Study Team						X					

Clinical Trial Management Process (Processing of New Industry Funded Clinical Trials)	PI	Dept / Center	CTO - Administrative Asst	CTO-Coverage Analysis	CTO-Budgeting	CTO- Contracting	DCG - Award Establishment	CTO Director	VP, Research	General Counsel	USC Stevens
Contract review and negotiation											
Review and redline CTA, incorporating rationale for any suggested changes						X					
Submit revised CTA to Sponsor						X					
Negotiate CTA terms with Sponsor (upload draft CTA and correspondence into CTO shared drive)						X					
Obtain clinicaltrials.gov number from Sponsor						X					
Submit exceptional terms for approval						X					
Consult and approve exceptional Intellectual Property (IP) terms								X			X
Consult and approve exceptional CTA business terms, including subject injury, LOL, etc.								X		X	
Consult and approve exceptional publication terms								X	X		
Prepare and submit Limitation of Liability (LOL) waiver						X					
Approve LOL waiver									X		
Perform consistency review of CTA and Budget						X					
Resolve any inconsistencies between CTA and Budget						X					
Complete ICF Consistency Checklist in iSTAR						X					
Upon obtaining any approval (including exceptional approvals) and completion of consistency review, execute CTA						X					
Upload fully executed CTA into TRUE2						X					
Review Final Documents in True 2.0 (Document Tab) to ensure consistency						X					
Provide bi-weekly updates to PI and Study Team						X					
Activation and IRIS Set-Up											
Activate clinical trial in TRUE2						X					
Complete IRIS data entry (including Review Tab)			X								