CT – Application Checklist DOM Fund Manager's Manual

CLINICAL TRIALS – APPLICATION CHECKLIST Revised July 3, 2024

PI:		Division: PAT		S#:		
Sponsor:		CRO: Pro		ocol#:		
□ New	w		Date:	ate:		
Sponsor	Type	Contract Offices – Clinical	Trials			
For-Profit (Industry)	71		TDG (Dept Assignments)			
Non-Profit (Federal/State)		OCGA Submit docs via EPASS system				
Check	CTC&S	R Items (submit to ClinicalTrials@m	Date Received	Date Sent		
	sponsoi	ential Disclosure Agreement: (PI/S r CDA draft via email to <u>CDA unit,</u> contended the route the rest of the docs				
	Form 7	00-U Sponsor Docu-Sign				
	Form 7	00-U Addendum Sponsor Docu-Si				
	Form 7	00-U CRO (if applicable) Docu-Sign				
	Form 7	00-U Addendum CRO (if applicable				
	Form 7	00-U Disclosure Supplement (if ap				
	Sponsor Draft Contract (Word doc) & Sponsor Draft Budget in OnCore					
Check	TDG Ite	ems (submit to TDG Contract Officer	<u>(</u>)	Date Received	Date Sent	
	Confidential Disclosure Agreement: (PI/Study Team to submit form and sponsor CDA draft via email to TDG contact, copying Fund Mgr) After CDA is executed then route the rest of the docs.					
			amended changes			
	Form 7	40 (Federal) or Form 700-U (State)	Sponsor Docu-Sign			
	Form 7	00-U Addendum (State) Sponsor ((if applicable) Docu-Sign			

CI – Application	n Checklist		DOM	Fund N	<i>I</i> lanager's Manua		
	Form 740 (Federal) or Form 700-U (State) CRO (if applicable Sign	e) Docu-					
	Form 700-U Addendum (State) CRO (if applicable) Docu-Signature	gn					
	Form 740 Disclosure Supplement (Federal) or Form 700-U Disclosure Supplement (State) (if applicable) D						
	ISR Proposal Checklist						
	Proposal Budget						
	Health Data Oversight Committee (HDOC) (Completed by Fapplicable)						
	Sponsor Draft Contract (Word doc) & Sponsor Draft Budg						
Check	OCGA Items (submit via EPASS)	Date Received		Date Sent			
	EPASS Remarks: New – include NCT# Amendment – include brief summary of amended change:	S					
	Form 740 (Federal) or Form 700-U (State) Docu-Sign						
	Form 700-U Addendum (State) (if applicable) Docu-Sign						
	Form 740 Disclosure Supplement (Federal) or Form 700-U Disclosure Supplement (State) (if applicable) D						
	Sponsor Guidelines						
	Budget Draft Simple/ PHS398/ Center Grant and Justifica						
	Final Proposal (science, agency required signatures, biosket						
	Brief Description of Proposal Aims & Abstract						
	Subaward Required Forms & Checklist (if applicable)						
Check	Additional Required Documents for all Clinical Trials		·				
	Budget Final (available in OnCore)	Date Certified (if applicable) Date Sent to OCGA					
	IRB Approval #: (available from	Study Team)					
	NCT #: (available from Study Team/OnCore)						
	Informed Consent Form (ICF) Final (available from Study Team)						
	Protocol (available in OnCore)						
Notes: Spo	onsor Name: Contact Nan	ne:					
Coi	ntact Email: Contact Pho	ne:					