

OCR Clinical Trial Contracts & Strategic Relations (CTC&SR) Document Submission Checklist for Contract Review and Execution	NEW CONTRACT	CONTRACT AMENDMENTS					
	A	B	C	D	E	F	
	New Contract	Budget Increase: 1) Per Subject Costs (affects all subjects on trial) 2) Invoiceables 3) Fixed Costs 4) Increase # of subjects	Budget Decrease: 1) Per Subject Cost (remove item/service from ALL subjects OR 2) Invoiceables (e.g. remove set-up fee)	Change: PI SPONSOR CRO	NGTE: Amendment required if there is a firm fixed End Date in the Agreement	Miscellaneous Amendments that do not fall under categories B-E <small>(Documents/approvals TBD case-by-case)</small>	
	EMAIL ALL DOCUMENTS TO: clinicaltrials@mednet.ucla.edu (unless otherwise instructed)						
MINIMUM DOCUMENTS	1) ONCORE #50 NOTIFICATION is issued ("OnCore submission requires CTC&SR Contract Review"): • ~ For multi-site EAP trials not tracked in OnCore, document tracking will begin upon receipt of IRB number and verification of completed IRB application.	<input type="checkbox"/>					
	2) Sponsor/ CRO Contact Information for Agreement/Amendment Negotiations: • Company name, contact name, email address, and phone number	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	3) UCLA Form 700U for all Sponsors - DocuSigned: • DOCUSIGNED 700U MUST be fully completed, signed, and submitted to CTC&SR (no watermarks). • For any positive disclosure - complete Industry CT Specific Supplement (see #7) click here for the form	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
	4) UCLA Form 700U Addendum for all Sponsors: • Electronic draft copy acceptable as Minimum Document; however, fully completed form MUST be submitted to CTC&SR (see FINAL DOCUMENTS section below). • For any positive disclosure - complete Industry CT Specific Supplement (see #7) click here for the form	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
	5) IF APPLICABLE - UCLA Form 700U for CRO that signs the CTA - DocuSigned: • DOCUSIGNED 700U MUST be fully completed, signed, and submitted to CTC&SR (no watermarks). • For any positive disclosure - complete Industry CT Specific Supplement (see #7) click here for the form	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
	6) IF APPLICABLE - UCLA Form 700U Addendum for CRO that signs the CTA: • Electronic draft copy acceptable as Minimum Document; however, fully completed form MUST be submitted to CTC&SR (see FINAL DOCUMENTS section below). • For any positive disclosure - complete Industry CT Specific Supplement (see #7) click here for the form	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
	7) IF APPLICABLE - Industry CT Specific Supplement • For positive financial disclosure (per completed 700U/700U Addendum) click here for the form	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
	8a) Draft Contract ~ including payment terms (Word document)	<input type="checkbox"/>					
8b) Draft Contract Amendment ~ including payment terms, if applicable (Word document)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
FINAL DOCUMENTS	9) UCLA Form 700U Addendum for all Sponsors: • MUST be fully completed, signed, and submitted to CTC&SR. click here for the form	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
	10) IF APPLICABLE - UCLA Form 700U Addendum for CRO that signs the CTA: • MUST be fully completed, signed, and submitted to CTC&SR. click here for the form	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
	11) EPASS - Fully completed and signed. click here for EPASS	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
12) PI Exception Letter • If applicable, contact your department for letter click here for PI look up	<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>	
APPROVALS	13) Conflict of Interest Review Committee (CIRC) Recommendation Letter - If item #7 required	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
	14) IRB Approval (To be verified in WebIRB/BruinIRB/ OnCore by CTC&SR Team)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	15) Final Budget Signoff - OnCore / Email Notification (Issued by OCR Clinical Research Finance (CRF))	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	16) PI and CTC&SR Sign Final Agreement/Amendment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>