

OCR Clinical Trial Contracts & Strategic Relations (CTCSR) Document Checklist for Contract Review and Execution		NEW AGREEMENT	CONTRACT AMENDMENTS				
		A	B	C	D	E	F
		New Agreement	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 (only if CRO is a party to/signs the Agreement)	NCTE: Amendment required if there is a firm fixed end date in the Agreement	Miscellaneous Amendments that do not fall under categories B-E (Documents/approvals TBD case-by-case)
EMAIL ALL DOCUMENTS TO: <a href="mailto:clinicaltrials@mednet.ucla.edu">clinicaltrials@mednet.ucla.edu</a> (unless otherwise instructed)							
For more information about CTCSR, please visit <a href="https://www.researchgo.ucla.edu/industry-clinical-trials-contracting">https://www.researchgo.ucla.edu/industry-clinical-trials-contracting</a>							
MINIMUM DOCUMENTS	1) ONCORE #50 Notification is issued ("OnCore submission requires CTCSR 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) California Form 700U for all Sponsors - DocuSigned: • DOCUSIGNED 700U MUST be fully completed, signed, and submitted to CTCSR (no watermarks). • If "yes" is selected to any question on the 700U, complete Industry CT Specific Supplement (see #5). <a href="#">Click here for the Form 700U</a>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
	4) IF APPLICABLE - California Form 700U for CRO that signs the Agreement/Amendment - DocuSigned: • DOCUSIGNED 700U MUST be fully completed, signed, and submitted to CTCSR (no watermarks). • If "yes" is selected to any question on the 700U, complete Industry CT Specific Supplement (see #5). <a href="#">Click here for the Form 700U</a>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
	5) IF APPLICABLE - Industry CT Specific Supplement • To be completed by each individual who selects "yes" to any question on the 700U/700U Addendum. <a href="#">Click here for the Industry CT Specific Supplement</a>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
	6a) Draft Contract ~ including payment terms (Word document)	<input type="checkbox"/>					
6b) 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"/>	<input type="checkbox"/>	
FINAL DOCUMENTS	7) UCLA Form 700U Addendum for all Sponsors: • MUST be fully completed, signed, and submitted to CTCSR. • If "yes" is selected to any question on the 700U Addendum, complete Industry CT Specific Supplement (see #5). <a href="#">Click here for the Form 700U Addendum</a>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
	8) IF APPLICABLE - UCLA Form 700U Addendum for CRO that signs the Agreement/Amendment: • MUST be fully completed, signed, and submitted to CTCSR. • If "yes" is selected to any question on the 700U Addendum, complete Industry CT Specific Supplement (see #5). <a href="#">Click here for the Form 700U Addendum</a>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
	9) EPASS - Fully completed and signed. <a href="#">Click here for EPASS</a>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
	10) PI Exception Letter • If applicable, contact your department for letter <a href="#">Click here for PI look up</a>	<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>
APPROVALS	11) Conflict of Interest Review Committee (CIRC) Recommendation Letter - If item #5 required	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
	12) IRB Approval (To be verified in BruinIRB/ OnCore by CTCSR Team)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	13) 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"/>
	14) PI and CTCSR Sign Final Agreement/Amendment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>