



**OCR Clinical Trial Contracts & Strategic Relations (CTC&SR)  
Document 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	NCTE: 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>	
	<b>EMAIL ALL DOCUMENTS TO: <a href="mailto:clinicaltrials@mednet.ucla.edu">clinicaltrials@mednet.ucla.edu</a> (unless otherwise instructed)</b>						
<b>MINIMUM DOCUMENTS</b>	1) IRB NUMBER (~ Document tracking will not begin until this step is completed.): • Email Notification confirming IRB # & Application • Application must include protocol, draft consent, & if applicable, IB/device manual ***Pre-IRB number is acceptable <i>only</i> when the response to Section 2.4, Question 2.0 of the IRB application is "Yes".	<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: • 700U <b>MUST</b> be fully completed. • Electronic, fully completed <i>draft</i> acceptable as Minimum Document; however, DOCUSIGNED 700U <b>MUST</b> be submitted to CTC&SR (see FINAL DOCUMENTS section below). • For any positive disclosure - complete Industry CT Specific Supplement (see #7) <a href="#">click here for the form</a>	<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 <b>MUST</b> be submitted to CTC&SR (see FINAL DOCUMENTS section below). • For any positive disclosure - complete Industry CT Specific Supplement (see #7) <a href="#">click here for the form</a>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
	5) IF APPLICABLE - UCLA Form 700U for CRO that signs the CTA: • 700U <b>MUST</b> be fully completed. • Electronic, fully completed <i>draft</i> acceptable as Minimum Document; however, DOCUSIGNED 700U <b>MUST</b> be submitted to CTC&SR (see FINAL DOCUMENTS section below). • For any positive disclosure - complete Industry CT Specific Supplement (see #7) <a href="#">click here for the form</a>	<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 <b>MUST</b> be submitted to CTC&SR (see FINAL DOCUMENTS section below). • For any positive disclosure - complete Industry CT Specific Supplement (see #7) <a href="#">click here for the form</a>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
	7) IF APPLICABLE - Industry CT Specific Supplement • For positive financial disclosure <a href="#">click here for the form</a>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
	8a) Draft Contract ~ including payment schedule/exhibit (Word document)	<input type="checkbox"/>					
8b) Draft Contract Amendment ~ including payment schedule/exhibit, if applic (Word document)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>FINAL DOCUMENTS</b>	9) UCLA Form 700U for all Sponsors: • DOCUSIGNED 700U <b>MUST</b> be fully completed, signed, and submitted to CTC&SR.	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
	10) UCLA Form 700U Addendum for all Sponsors: • <b>MUST</b> be fully completed, signed, and submitted to CTC&SR.	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
	11) IF APPLICABLE - UCLA Form 700U for CRO that signs the CTA: • DOCUSIGNED 700U <b>MUST</b> be fully completed, signed, and submitted to CTC&SR.	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
	12) IF APPLICABLE - UCLA Form 700U Addendum for CRO that signs the CTA: • <b>MUST</b> be fully completed, signed, and submitted to CTC&SR.	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
	13) EPASS - Fully completed and signed. <a href="#">click here for EPASS</a>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
	14) 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"/>
	15) Conflict of Interest Review Committee (CIRC) Recommendation Letter - <i>If item #7 required</i>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
<b>APPROVALS</b>	16) IRB Approval (To be verified in WebIRB/OnCore by CTC&SR Team)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	17) Final Budget Signoff Email Notification (Issued by OCR Research Quality (RQ))	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	18) PI and CTC&SR Sign Final Agreement/Amendment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	