



**OCR Clinical Trial Contracts & Strategic Relations (CTC&SR)
Document Checklist for Contract Review and Execution**

NEW CONTRACT	CONTRACT AMENDMENTS				
	A	B	C	D	E
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>

EMAIL ALL DOCUMENTS TO: clinicaltrials@mednet.ucla.edu (unless otherwise instructed)

	A	B	C	D	E	F
MINIMUM DOCUMENTS	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"/>
	3) UCLA Form 700U for all Sponsors: • 700U MUST be fully completed. • Electronic, fully completed <i>draft</i> acceptable as Minimum Document; however, ORIGINAL 700U 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"/>
	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: • 700U MUST be fully completed. • Electronic, fully completed <i>draft</i> acceptable as Minimum Document; however, ORIGINAL 700U 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"/>
	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 click here for the form	<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"/>	
FINAL DOCUMENTS	9) UCLA Form 700U for all Sponsors: • ORIGINAL WET-INK SIGNED 700U MUST 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: • MUST 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: • ORIGINAL 700U MUST 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: • MUST 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. click here for EPASS	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
	14) 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"/>
	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"/>
APPROVALS	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"/>