



**Clinical Trial Contract  
Submission Checklist for Contract Review**

NEW CONTRACT	CONTRACT AMENDMENTS					
	A	B	C	D	E	F
<b>Original Contract Formation</b>		<b>Budget Increase:</b> 1) Per Patient Costs (affects all subjects on trial) 2) Invoiceables 3) Fixed Costs 4) Increase # of subjects	<b>Budget Decrease:</b> 1) Per Patient Cost (remove item/service from ALL subjects OR 2) Invoiceables (e.g. remove set-up fee)	<b>Change:</b> PI SPONSOR CRO	<b>NCTE:</b> Amendment required if there is a firm fixed End Date in the Agreement	<b>Miscellaneous</b> Amendments that do not fall under categories B-E

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

MINIMUM DOCUMENTS

FINAL DOCUMENTS

<b>1) EPASS :</b> <ul style="list-style-type: none"> <li>Complete all relevant fields including Sponsor/CRO contact information.</li> <li>Draft does not require Department Signature</li> </ul> <a href="#">click here for the form</a>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
<b>2) UCLA Form 700U for all Sponsor(s):</b> <ul style="list-style-type: none"> <li>ORIGINAL 700U <b>MUST</b> be submitted to Clinical Trial Contracts.</li> <li>To expediate process, submit electronic copy as well.</li> <li>For any positive disclosure - complete Industry CT Specific Supplement (see #6)</li> </ul> <a href="#">click here for the form</a>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
<b>3) UCLA Form 700U ADDENDUM for all Sponsors:</b> <ul style="list-style-type: none"> <li>For any positive disclosure, complete Industry CT Specific Supplement (see #6)</li> </ul> <a href="#">click here for the form</a>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
<b>4) IF APPLICABLE - UCLA Form 700U for CRO that signs the CTA(s):</b> <ul style="list-style-type: none"> <li>ORIGINAL 700U <b>MUST</b> be submitted to Clinical Trial Contracts.</li> <li>To expediate process, submit electronic copy as well.</li> <li>For any positive disclosure - complete Industry CT Specific Supplement (see #6)</li> </ul> <a href="#">click here for the form</a>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
<b>5) IF APPLICABLE - UCLA Form 700U ADDENDUM for CRO that signs the CTA:</b> <ul style="list-style-type: none"> <li>For any positive disclosure, complete Industry CT Specific Supplement (see #6)</li> </ul> <a href="#">click here for the form</a>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
<b>6) If APPLICABLE - Industry CT Specific Supplement</b> <ul style="list-style-type: none"> <li>For positive financial disclosures</li> </ul> <a href="#">click here for the form</a>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
<b>7) IRB NUMBER:</b> <ul style="list-style-type: none"> <li>Email Notification confirming IRB # &amp; Application</li> <li>Application must include Protocol, consent, &amp; IB/Device Manual</li> </ul>	<input type="checkbox"/>					
<b>8a) Draft Contract</b> (Word document)	<input type="checkbox"/>					
<b>8b) Draft Contract Amendment</b> (word document) or Sponsor/CRO contact info in EPASS		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>9) Budget</b> <ul style="list-style-type: none"> <li>Upon Clinical Trial Contracts Request Study Team to provide when "Limited Oncore Build" determined</li> </ul>						
<b>10) IRB Approval Letter</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>11) Approved ICF</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>12) Fully Signed EPASS</b>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
<b>13) Clinicaltrials.gov NCT#</b> <ul style="list-style-type: none"> <li>Enter in 'Remarks' section of EPASS or in your submission email when EPASS not required</li> </ul> <a href="#">click here for look up</a>	<input type="checkbox"/>					
<b>14) PI Exception Letter</b> <ul style="list-style-type: none"> <li>If applicable, contact your department for letter</li> </ul> <a href="#">click here for PI look up</a>	<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>
<b>15) Final Budget Signoff</b> (PI & as applicable CA, CRBP, CDM office)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>
<b>16) Conflict of Interest Review Committee (CIRC) Letter</b> - If item #6 required	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
<b>17) PI Signs Agreement/Amendment</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>