# Clinical Trial Contract Submission Checklist for Contract Review

## NEW CONTRACT

<table>
<thead>
<tr>
<th></th>
<th>Original Contract</th>
<th>Budget Increase</th>
<th>Budget Decrease</th>
<th>Change</th>
<th>NCTE</th>
<th>Miscellaneous Amendments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Formation</td>
<td>1) Per Patient Costs (affects all subjects on trial)</td>
<td>1) Per Patient Cost (remove item/service from ALL subjects or 2) Invoiceables (e.g. remove set-up fee)</td>
<td>PI SPONSOR CRO</td>
<td>Amendment</td>
<td>required if there is a firm fixed End Date in the Agreement</td>
</tr>
</tbody>
</table>

## CONTRACT AMENDMENTS

<table>
<thead>
<tr>
<th></th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EMAIL ALL DOCUMENTS TO: <a href="mailto:clinicaltrials@mednet.ucla.edu">clinicaltrials@mednet.ucla.edu</a> (unless otherwise instructed)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 1) EPASS:
- Complete all relevant fields including Sponsor/CRO contact information.
- Draft does not require Department Signature

### 2) UCLA Form 700U for all Sponsor(s):
- ORIGINAL 700U MUST be submitted to Clinical Trial Contracts.
- To expedite process, submit electronic copy as well.
- For any positive disclosure - complete Industry CT Specific Supplement (see #6)

### 3) UCLA Form 700U ADDENDUM for all Sponsors:
- For any positive disclosure, complete Industry CT Specific Supplement (see #6)

### 4) IF APPLICABLE - UCLA Form 700U for CRO that signs the CTA(s):
- ORIGINAL 700U MUST be submitted to Clinical Trial Contracts.
- To expedite process, submit electronic copy as well.
- For any positive disclosure - complete Industry CT Specific Supplement (see #6)

### 5) IF APPLICABLE - UCLA Form 700U ADDENDUM for CRO that signs the CTA:
- For any positive disclosure, complete Industry CT Specific Supplement (see #6)

### 6) IF APPLICABLE - Industry CT Specific Supplement
- For positive financial disclosures

### 7) IRB NUMBER:
- Email Notification confirming IRB # & Application
- Application must include Protocol, consent, & IB/Device Manual

#### 8a) Draft Contract (Word document)

#### 8b) Draft Contract Amendment (word document) or Sponsor/CRO contact info in EPASS

### 9) Budget
- Upon Clinical Trial Contracts Request Study Team to provide when "Limited Oncore Build" determined

### 10) IRB Approval Letter

### 11) Approved ICF

### 12) Fully Signed EPASS

### 13) Clinicaltrials.gov NCT#:
- Enter in 'Remarks' section of EPASS or in your submission email when EPASS not required

### 14) PI Exception Letter
- If applicable, contact your department for letter

### 15) Final Budget Signoff (PI & as applicable CA, CRBP, CDM office)

### 16) Conflict of Interest Review Committee (CIRC) Letter - If item #6 required

### 17) PI Signs Agreement/Amendment