# New Contract

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<td>Original Contract Formation</td>
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<td>Budget Increase to Per Patient Costs (affects all subjects on trial)</td>
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<td>Budget Increase to Invoiceables (does not affect all subjects on trial)</td>
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| Increase to:  
- Fixed Costs (i.e. IRB fee, Radiology Setup Fee, Investigational Pharmacy Fee...)  
- Per Patient Costs (increase on fees or services from all subjects on trial)  
- Invoiceables (increase a setup fee or other variable cost) | | | | | | | | | |
| Decrease to:  
- Per Patient Costs (decrease on fees or services from all subjects on trial)  
- Invoiceables (decrease a setup fee or other variable cost) | | | | | | | | | |
| Protocol Amendment that does not impact the budget in any way (e.g., Protocol Title is updated) | | | | | | | | | |
| Contract Amendment that does not impact the budget in any way (i.e. Change of Sponsor Address for notices) | | | | | | | | | |

### MINIMUM DOCUMENTS

- EPASS [Minimum Document - complete all relevant fields (including sponsor or cro contact information), except does not require Department Signature]  
- UCLA Form 700U for Sponsor(s)  
- UCLA Form700U ADDENDUM for Sponsors. For any positive disclosure - complete Industry CT Specific Supplement (see #6)  
- UCLA Form700U ADDENDUM for CRO(s) that signs the CTA. For any positive disclosure - complete Industry CT Specific Supplement (see #6)  
- IRB NUMBER - EMAIL NOTIFICATION - confirming IRB application & IRB #  
- Draft Contract (word document)  
- Draft Contract Amendment (word document) or Sponsor/CRO contact info in EPASS  
- Final Budget Signoff (PI, & as applicable CA, CRBP, CDM Office)  
- PI Signs Agreement/Amendment

### FULLY SUBMITTED DOCUMENTS

- EMailed ALL DOCUMENTS TO:  
  - clinicaltrials@mednet.ucla.edu (unless otherwise instructed)  
- Audit Trail Records

### VERSIONS

- August 21, 2017 version 4

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