

## [Contract & Grant Setup and Management](#)

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- [Investigator Initiated Trial \(IIT\) Toolkit](#)

Responsibility for handling agreements related to sponsored research and other sponsored project activities is distributed across various UCLA administrative offices based on the sponsor and the nature of the transaction. In some cases, multiple offices may share responsibility for different aspects of the negotiation and administration of the transaction/agreement.

There are 3 offices on campus that support investigators with their clinical research awards.

1. [The Clinical Trials Contracts and Strategic Relations \(CTC and SR\)](#) team works with for-profit pharmaceutical, biomedical and medical device manufactures as well as contract research organizations (“CRO”) to negotiate agreements such as confidentiality agreements related to clinical trials (“CDA”) and clinical trial agreements (“CTA”) for industry supported drug, biological and medical device trials, and is the authorized institutional signatory for these agreements. In addition, CTC&SR negotiates CDAs and CTAs with non-profits that flow through Industry funding. For questions or assistance, please contact [Clinical Trials Contracts & Strategic Relations](#). For more information, please see the [Clinical Trial Contract Checklist](#).
2. The [Office of Contracts and Grants Administration](#) facilitates government and non-profit funding awards. For questions or assistance, please contact Patti Manheim, Director, Office of Contract and Grant Administration at (310) 794-2644.
3. [UCLA Technology Development Group \(TDG\)](#) assists with industry supported basic and applied research, including material transfer agreements (MTAs). For questions or assistance, please contact Brian Roe, Director, Industry Research & Material Transfer at (310) 983-3408.

New from UC Braid - [UC Guidance on Avoiding Investigator Initiated Trial Contracting Delays](#)

Last updated: 23 Sep 2019

**Minimum Documents** are required to initiate an agreement negotiation. Receipt of complete Minimum Documents begins the review process. The type of submission (e.g. new vs amendment) will determine which Minimum Documents are necessary.

**Submit all documents to the CTC&SR Intake Team at [clinicaltrials@mednet.ucla.edu](mailto:clinicaltrials@mednet.ucla.edu)**

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## A. Original Contract Formation

The following Minimum Documents are required for all new contracts:

- EPASS
- UCLA Form 700U
- UCLA Form 700U Addendum
- If applicable, UCLA Form 700U for the CRO that signs the CTA
- If applicable, UCLA Form 700U Addend for the CRO that signs the CTA
- If applicable, Industry Clinical Trial Specific Disclosure Supplement Form
- UCLA IRB#/Informed Consent Form (ICF)/Protocol
- Draft Agreement (Word Format)

## B. Contract Amendments

Amendments to the Clinical Trial Agreements (CTA) may be required for various reasons including budget changes, a change in PI/Sponsor/CRO, or protocol changes that do not affect the budget. Please refer to the [Clinical Trial Contract Checklist](#) to see which Minimum Documents are required for your CTA Amendment.

**Submit all documents to the CTC&SR Intake Team at [clinicaltrials@mednet.ucla.edu](mailto:clinicaltrials@mednet.ucla.edu)**

## C. No Cost Time Extensions (NCTE)

A NCTE can be processed without having to amend the contract if: 1) there is no hard End Date written into the contract and, 2) there are no changes to the protocol, IRB, budget, or PI.

Submit the following Minimum Documents to the CTC&SR Intake Team at [clinicaltrials@mednet.ucla.edu](mailto:clinicaltrials@mednet.ucla.edu)

- Current IRB Approval Notice
- Email or Memo stating need for NCTE

Note: If a Contract Amendment is under review when NCTE request is received, the NCTE will be processed with the amendment once Amendment Minimum Documents have been received.

- Forms required to initiate contract review are available below. Please refer to instructions for each form.
  - [EPASS](#) and [EPASS Instructions](#)
  - [Form 700U](#)
  - [Form 700U Addendum](#)
  - [Industry Clinical Trial Specific Disclosure Supplement](#)

## CONTACT US

For any submission related questions, please email us at [clinicaltrials@mednet.ucla.edu](mailto:clinicaltrials@mednet.ucla.edu)

Last updated: 13 Nov 2019

## 1-Q. How do I know if my submission was received by CTC&SR?

1. When email submissions are received via [clinicaltrials@mednet.ucla.edu](mailto:clinicaltrials@mednet.ucla.edu), the PI department/unit administrator will receive an acknowledgement via email within two business days. The acknowledgment email is customized to your study and is created and sent as part of the CTC&SR initiation process.

**2-Q. Do I need to obtain IRB Approval before submitting a new contract submission to CTC&SR?**

1. No. IRB Approval is not required in order for our contract review to begin. We do require the study team to begin an IRB application and send us an email notification confirming the IRB#. The IRB application must include protocol and informed consent form (ICF).

**3-Q. The CTA has been executed. When can I expect the fund number? Where can I go online to find it?**

1. The Office of Research Data Management will notify the study team via email when a fund number is established. You can view your Clinical Trial snapshot, budget, and CTA terms via the ORA Research Portal (<http://portal.research.ucla.edu>). This process takes approximately 2-3 business days from CTA execution.

**4-Q. How can I obtain access to the ORA Research Portal?**

1. To obtain access to the portal, please visit <http://portal.research.ucla.edu/>. Instructions on gaining access can be found on the top right corner, under 'Get Help' menu option.

**5-Q. How can I get an extension to the contract (No Cost Time Extension "NCTE")?**

1. If the CTA has a hard end date written into the contract, an amendment to the contract is required. Please submit the necessary Minimum Documents to [clinicaltrials@mednet.ucla.edu](mailto:clinicaltrials@mednet.ucla.edu)

Please consult the Clinical Trials Contract Checklist to review necessary Minimum Documents

2. If: 1) there is no hard End Date written into the contract and 2) there are no changes to the protocol, IRB, budget, or PI; then a NCTE can be processed without having to amend the contract.

Submit the following Minimum Documents to [clinicaltrials@mednet.ucla.edu](mailto:clinicaltrials@mednet.ucla.edu):

- Current IRB Approval Notice
- Email of memo indicating need for NCTE

**6-Q. The study will be closing prior to the end date listed on the snapshot in PATS. Can the end date be changed to an earlier date?**

1. Yes. An award can be prospectively closed when there is a significant difference between the actual and listed end date. If the study has terminated, IRB closure is completed, and there are no outstanding payments, we may change the end date.

Please contact our Contract Analyst for inquiries regarding this matter via [clinicaltrials@mednet.ucla.edu](mailto:clinicaltrials@mednet.ucla.edu)

**7-Q. I have a PI that is leaving UCLA. Can I transfer the CTA to another PI?**

1. Yes. With Sponsor approval, an amendment to the contract would be required for a PI change. In addition, you will need to submit new minimum documents with the new PI to [clinicaltrials@mednet.ucla.edu](mailto:clinicaltrials@mednet.ucla.edu), notify the IRB and update OnCore and the ICF. For more information, click here.

**8-Q. Why do I need to submit Forms 700U & 700U Addendum for a Contract Amendment? I submitted originals with the initial contract.**

1. Every amendment is treated as its own transaction thus requiring its own Minimum Documents, which may include 700Us & 700U Addendums. Per UCLA Policy, original 700U Forms must be sent to our office.

Please consult the Clinical Trials Contract Checklist to see if financials are required for your amendment submission.

**9-Q. Why is completion of the Industry Clinical Trial Specific Disclosure Supplement Form for Conflict of Interest Review Committee (CIRC) required for an Amendment if CIRC review was complete with the original contract?**

1. As with Form 700U (see Question 8), Industry Clinical Trial Specific Disclosure Supplement form for Positive Form 700U and/or Form 700U Addendums are required for every contract transaction, whether it is a new CTA or an amendment.

To expedite this process, if you have a Positive 700U, please complete and submit the online Industry Clinical Trial Specific Disclosure Supplement Form along with the original 700U as soon as possible.

**10-Q. When submitting an Amendment, are new Minimum Documents required?**

1. Yes. Please consult the Clinical Trials Contract Checklist to learn more.

**11-Q. Why do I need to submit the IRB # for Contract Review?**

The IRB # helps CTC&SR Database link with IRB Database and OnCore Database for study start up activities. It also allows our office to download the Protocol and ICF and view if Medicare or hospital services will be required for the study. Our office must have the Protocol and ICF in order to begin review of a study.

**CONTACT US**

For any submission related questions, please email us at [clinicaltrials@mednet.ucla.edu](mailto:clinicaltrials@mednet.ucla.edu).

Last updated: 14 Aug 2019

**Investigator Initiated Trial (IIT) Toolkit – guidance on efficient contracting to move a trial forward**

The [IIT Toolkit](#) is intended to provide guidance on the information needed when starting an IIT to facilitate efficient contracting and move the trial forward as quickly as possible. Each page below highlights information about elements of the study, questions that the contracting office will need answered, or checklist items for the PI to accomplish.

1. [IIT Toolkit Homepage](#)
2. [Study Plan](#)
3. [Protocol](#)
4. [Budget](#)
5. [Funding](#)

- [Multiple Funding Sources](#)

## 6. [Modifications and Changes](#)

### 7. **Other Situations:**

- [Correlative Studies](#)
- [Subcontracts](#)
- [Consortium Agreements](#)

This Toolkit was created by the [BRAID Contracting Work Group](#).

Last updated: 27 Nov 2018

Last updated: 14 Aug 2019

- Group 1
  - [Clinical Research Information Systems](#)
  - [Clinical Research Business Partners](#)
- Group 2
  - [Office of Research Administration](#)
  - [Jonsson Comprehensive Cancer Center](#)
- Group 3
  - [Office of Human Subjects Protection](#)
  - [CareConnect Website](#)

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