CTCSR FAQs

1-Q. How do I know if my submission was received by CTCSR?

1. When email submissions are received via 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 CTCSR initiation process.

2-Q. Do I need to obtain IRB Approval before submitting a new contract submission to CTCSR?

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 to 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

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:

- 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

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, 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 CTCSR 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 CTCSR

For any submission related questions, please email CTCSR at clinicaltrials@mednet.ucla.edu.

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Source URL:https://www.researchgo.ucla.edu/ctcsr-faqs

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