CTA | Clinical Trial Agreements

CLINICAL TRIAL AGREEMENT SUBMITTAL PROCESS

A clinical trial agreement is the contract between an industry sponsor and University outlining the obligations of each party for the conduct of a sponsor-authored protocol that involves human subjects and the testing of a drug or medical device.

The following steps outline the most efficient process for initiating a private industry supported clinical trial for testing biomedical drugs or devices in accordance with FDA regulations. This process enables OCTA to negotiate a clinical trial agreement while the Principal Investigator secures other campus and compliance committee approvals.

While submitting an industry sponsored clinical trial for review, EPD must be used by all departments. The following paperwork must also be uploaded to EPD before a contract can be signed:

- ***Draft Contract from Sponsor (if available);***
- ***Draft Budget;***
- ***Protocol***
- ***Complete Proposal Application (contract, budget and protocol combined as a PDF)***

IRB number is required prior to OCTA's approval in EPD.

All paperwork must be submitted in order for the OCTA Contract Officer to begin contract negotiations.

Last updated: 6 Mar 2018

CONTACT INFORMATION

In addition to the Principal Investigator's contact information, it is important to provide complete contact information of the sponsor or CRO, if applicable, representative, especially a phone number and/or email address. The more information the OCTA Contract Officer has, the faster and more efficiently the sponsor or CRO may be contacted in order to begin the contract negotiations.

LOCATION OF THE STUDY

If the study will be conducted at more than one location, each location must be listed. If the locations change after the contract negotiation begins, inform the contracts negotiator as soon as possible. If this information is not accurate, it will delay the execution of the contract and may subject the University to unknown risks and liability.

SIGNATURES

The Clinical Trial Agreement Request form or EPD system must be signed by the Principal Investigator, Department Chair, and Department Business Officer **before ?**the informed consent may be released by OCTA to HRPP. Incomplete forms will delay the start of the study.

700-U FORM (PI'S STATEMENT OF ECONOMIC INTEREST)

Instructions on how to complete this form and to download it from the web, can be found at http://coi.ucsd.edu. California law requires University faculty members to disclose whether or not they have a financial interest in outside entities that sponsor research. This disclosure is made using the 700-U form. If there is a positive disclosure, i.e. the faculty member has an economic interest in the sponsor, the conflict of interest must be reviewed and approved by the UCSD Conflict of Interest (COI) Committee. This approval process is monitored by your contracts negotiator and no action on your part is required. Keep in mind that the COI only meets once a month. No agreement can be signed until the COI approval is obtained.

BUDGET

- A budget must be submitted showing all anticipated costs of the clinical trial and the overhead rate of 30%.
- Costs that should be included are: Total Direct costs, (i.e. patient care costs, special procedures, supplies and expenses, pharmacy fees, IRB review fees, etc.,) as well as indirect costs.
- There is a separate mandatory IRB fees for the IRB review and ongoing monitoring of the project. There fees are invoiced to the sponsor with the initial review, with the annual review and the four-year renewal.
- For more information about budget preparation submit a service request.

IRB APPROVAL LETTER

A contract cannot be finalized and a study cannot begin until there is IRB approval. The application process for IRB approval should be submitted simultaneously with the OCTA submittal process. IRB approval and final contracts will not be released until both are approved for signature.

For more information on the Institutional Review Board (IRB) and the submission process, visit the Human Research Protections Program Website.

Last updated: 20 Mar 2019

ACTIONS | OCTA

PRE-AWARD PROCESS

The OCTA Contract Officer will:

- Contact the sponsor to initiate contract negotiations;
- Provide the sponsor with the standard UCSD agreement if a sponsor agreement is not provided;
- Obtain a copy of previous agreement (if applicable);
- Review and propose revisions to the contract;
- Negotiate final revisions to the contract;

- Forward the final agreement to the Principal Investigator for signature (the PI will then send the signed contract back to the OCTA contract Officer);
- Sign the Agreement on the behalf of The Regents;
- Forward the signed contract to the Sponsor (the Sponsor will then sign the signed contract back to the contract negotiator).

Once the appropriate paperwork has been submitted, please check the OCTA Dashboard for the in-process status and notes about the study.

CONTRACT NEGOTIATIONS

Negotiations involving a contract can sometimes be quite complex and lengthy, depending upon the sponsoring organization and the nature of the work to be performed.

Contracts with clinical trial sponsors (e.g., pharmaceuticals or medical device companies, clinical research organizations) cover human testing activities related to an investigational drug, compound or device leading to approval by the Food and Drug Administration for commercial distribution.

As a public, nonprofit educational institution, the University is bound by certain policies and regulations regarding what it can and cannot accept in a clinical trial contract. These policies are designed to protect the welfare of individuals participating as research subjects; foster the University's basic mission of teaching, research and public service; and minimize the various forms of liability associated with human subject research.

For-profit private sponsors, such as pharmaceutical companies, are motivated by different forces than the University. As a result, they sometimes do not understand the ideals and principals behind our policies. Consequently, additional time may be required for contract negotiations while the contracts negotiator works with the sponsor to arrive at a mutually acceptable agreement.

When negotiating clinical trial contracts, the University primarily focuses on securing acceptable contract clauses regarding high-risk issues such as subject injury, indemnification, confidentiality, ownership of data, patent rights and publication rights.

The University's standard clinical trial agreement and the clauses proposed by the University during contract negotiations are based on the following assumptions:

- That the clinical investigation is conducted under a protocol that is a FDA Phase I, II, III, or IV drug study or a FDA regulated medical device study.
- That the Sponsor provides its proprietary product and study protocol to the University for the purpose of conducting a clinical trial; and
- That the sponsor will fully fund the cost of the trial (i.e., no work will be supported in whole or in part with other fund, including Federal funds).

POST-AWARD PROCESS

- The index number will be assigned within 1 business day
- Distribution of a copy of the executed agreement to the Principal Investigator and study team will be included with the index number

CONTRACT AMENDMENTS

Amendments, modifications, and Addenda should be entered into the OCTA Application: http://som.ucsd.edu/OCTAApplication

Last updated: 15 Mar 2019

ACTIONS | PRINCIPAL INVESTIGATOR

CLOSING A CLINICAL TRIAL

Upon the closure or termination of a clinical trial, there are certain steps that must be taken in order to complete the closing process. The following departments need to be notified of the study closure:

- HRPP should be notified in a written format that the trial is being closed, the date and the reason for the closure. Include the number of participants enrolled (if any), the number of withdrawals and the number of adverse events. HRPP will then update their records accordingly.
- OCTA must be copied on one of the above notifications so that the OCTA can update the contract records at octa@ucsd.edu.
- Conflict of Interest should be notified by completing the 700-U and marking in section 2 that this is a complete statement. The updated 700-U should be sent to Conflict of Interest at mail code 0992.

Staying abreast of the financial status of the clinical trial is always important but it is even more important when it's time to close the study. This includes ensuring the sponsor has provided payment for all the work performed, reconciliation of institutional accounts, etc.

Last updated: 15 Mar 2019

Last updated: 20 Mar 2019

Source URL: https://compass.ucsd.edu/cta-clinical-trial-agreements?qt-view__vertical_tab_section__block_28=2

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