Industry Clinical Trials Contracting

- Overview
- Investigator Initiated Trial (IIT) Toolkit

Clinical Trials Contracts & Strategic Relations (CTCSR)

Agreements Under the Purview of Clinical Trials Contracts & Strategic Relations (CTCSR)

- **Confidentiality Agreements ("CDA's")/Nondisclosure Agreements ("NDA's")** covering the disclosure/exchange of a Clinical Trial protocol for the purpose of determining the feasibility of conducting a Clinical Trial.
- **Drug/Device Supply Agreements ("DSA")** directly with Industry covering the provision of drug/device at no cost for use in the conduct of a Clinical Trial.
- **Clinical Trial Agreements ("CTA")** subject to the below definition and conditions.

CTCSR Definition of a Clinical Trial

UCLA CTCSR defines a "**Clinical Trial**" consistent with the NIH definition - *a research study in which human participants are prospectively assigned to one or more interventions (which may include a placebo or other control) to assess the effects of those interventions on health-related biomedical or behavioral outcomes.*

Questions to determine if a study is a Clinical Trial:

- Does the study involve human participants?
- Are participants prospectively assigned to an intervention?
- Is the study designed to evaluate the effect of the intervention on the participants?
- Is the effect being evaluated a health-related biomedical or behavioral outcome?

  ? If the answers are all "yes," the study is a clinical trial

  ? If any answer is "no," the study is not a clinical trial.

For reference, see NIH case studies (https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/case-studies#collapseS2_top).

Clinical Trial Agreements

Pursuant to the definition above, for a Clinical Trial Agreement to be managed by CTCSR, the Clinical Trial must be fully funded/supported by, or the prime source of funding must be an industry, for-profit, or commercial entity, such as a

pharmaceutical or device company. Consortium or network (i.e., nonprofit or academic medical center consortium/network) developed/authored studies that meet the Clinical Trial definition are also managed by CTCSR.

Exception to the preceding provision: Studies which meet the definition of a Clinical Trial and are funded by SBIR/STTR through an industry, for-profit, commercial entity of the Clinical Trial are managed by CTCSR. However, these SBIR/STTR funded Clinical Trials do not satisfy criterion 3 in the Industry Clinical Trial IDC Rate section below and are therefore ineligible for the Industry Clinical Trial IDC rate. They are subject to the applicable F&A rate as noted in the Industry Clinical Trial IDC Rate section below.

Drug/Device Supply Agreement

A “Drug/Device Supply Agreement” (DSA) enables the provision of investigational or approved drug, device, and/or nutraceutical only for use in a Clinical Trial, without any accompanying funding. DSAs where the contract is directly with an industry, for-profit, commercial entity are managed by CTCSR. This agreement may also be referred to as a drug only, or device only agreement.

Industry Clinical Trial Indirect Cost (IDC)/F&A Rate

The industry clinical trial IDC/F&A rate, currently 33% (set forth here - https://ora.research.ucla.edu/wp-content/uploads/memo-roger-wakimoto-2024-08-02.pdf) applies to both industry sponsored, and PI-initiated Clinical Trials provided the requirements of ***criteria 1, 2, and 3*** below are met:

1. The clinical trial includes the prospective enrollment of human subjects and the controlled testing of a drug, device, nutraceutical, treatment, or diagnostic under an approved protocol to assess safety, efficacy, benefits, costs, or adverse reactions; ***and***
2. UCLA Health System resources are utilized **(i.e.,** services or facilities owned or operated by the UCLA Health System**)**; ***and***
3. The source of funding for the clinical trial is industry/for-profit.

Clinical Trials that do not fulfill the criteria in **1, 2, *and* 3** above are ineligible for the Industry Clinical Trial IDC rate and subject to the applicable F&A rate set forth here - https://ocga.research.ucla.edu/facilities-and-administrative/.

Non-Clinical Trial Studies/Agreements Excluded from CTCSR Management

Contracting for the following types of studies are *excluded* from CTCSR’s purview, and accordingly are not managed by CTCSR:

- Retrospective chart reviews
- Analysis of existing medical data and records
- Laboratory, basic, or applied research
- Animal studies
- Federally funded projects

For assistance related to these types of studies/projects, please contact:

- The Office of Contracts and Grants Administration (OCGA) if the study involves a contract or grant from a government or non-profit sponsor/source.
- The Technology Development Group (TDG) for a basic or applied research project supported by industry/for-profit or for material transfer agreements (MTA’s).

Submitting Documents for Contract Review

To initiate a CTA or DSA review with CTCSR, please submit the required “Minimum Documents” as detailed on the CTCSR Document Submission Checklist. Contact CTCSR Intake – clinicaltrials@mednet.ucla.edu if additional support in navigating the submission process is needed. Following CTCSR’s confirmation of receipt of Minimum Documents, the CTA/DSA will be assigned to a CTCSR team member for review and negotiation.

To initiate CDA/NDA review with CTCSR, please contact CTCSR CDA intake - clinicaltrials-cda@mednet.ucla.edu.

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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.

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