Overview

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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