

ASKGCO

In Preparation of a Clinical Trial Submission

ANSWERS TO FREQUENTLY ASKED QUESTIONS

CLINICAL TRIAL AGREEMENT?

A Clinical Trial Agreement (CTA) is a legal document establishing contractual obligations for both Mount Sinai School of Medicine and a commercial sponsor (generally a pharmaceutical or biotech company). CTAs are issued by the Sponsor.

- **ANOTHER NAME FOR THE CTA?**

Yes, it may be called a *Study Agreement*, a *Clinical Study Agreement* or any one of several other similar names.

- **ANOTHER NAME FOR MOUNT SINAI SCHOOL OF MEDICINE?**

No! All CTA's must be with the **Mount Sinai School of Medicine (MSSM)** *not* Mount Sinai Medical Center or Mount Sinai Hospital.

CONTRACT NEGOTIATIONS?

The CTA is binding when endorsed by the Sponsor and/or a third-party organization contracted by the Sponsor.

Many pharmaceutical and biotech companies contract out some or all administrative services to Clinical Research Organizations (CROs) or other third-party entities. These organizations are authorized to contractually negotiate and obligate on the sponsor's behalf. The letter of indemnification (*see indemnification*), however, must be from the Sponsor.

INDEMNIFICATION?

An indemnification is a declaration by the Sponsor to legally hold harmless the Institution in the event of legal suit. It can be part of the CTA, or issued as a separate letter. (refer to Mt. Sinai's sample indemnification)

INSTITUTIONAL REVIEW BOARD (IRB)?

- **ROLE?** The IRB is the Institutional oversight committee to ensure compliance with DHHS Regulations and Policies regarding human subject involvement in research. The IRB does not review or endorse CTAs.

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- **CONSENT DOCUMENTS?**

A final, stamped consent document will be released when:

- 1? the CTA (including indemnification) is acceptable and endorsed *and*
- 2? all requirements for IRB review and approval have been finalized (including revisions).

These activities will be coordinated by the GCO staff.

PROPOSAL SUBMISSION?

- **WHO PREPARES?**

The Sponsor shall provide an official Protocol, CTA, including Indemnification and Investigator Brochure (optional).

The Principal Investigator shall prepare a GCO application to include 3 copies of the Sponsor's protocol.

- **WHEN?**

Ideally, the CTA should be submitted at the time of or prior to the GCO paperwork. If you have not submitted GCO paperwork on the study yet, please enclose a cover letter stating when you will be submitting it.

- **WHAT?**

The full complement of applicable GCO forms including CTA (with Indemnification) *plus* three copies of the Clinical Trial Protocol.

Please include the name and number of the person negotiating the contract on behalf of the Sponsor.

- **WHO NEGOTIATES?**

Budgetary negotiations are between the Principal Investigator and the Sponsor. Be sure to include a 35% overhead charge on all line items.

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Most non-financial terms of the CTA will be negotiated by a Grants and Contracts representative. You are instructed, however, to *carefully read all documents* you endorse which are intended to legally outline your obligations as a participant in that Trial. Violating the terms of the agreement could jeopardize your funding and/or involve you in a lawsuit.

Only one individual can be identified as the Principal Investigator on a study. All paperwork and documents should reflect this designation.

REIMBURSEMENTS OR CHECKS?

Checks should be made out to the *Mount Sinai School of Medicine*

SIGNATORIES?

The designated Institutional Officer shall endorse all CTAs. The Principal Investigator's Signature may also be required.

TAX ID?

Mount Sinai's Tax Identification number is ID 13-6171197A1.