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.
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.
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.