ANSWERS TO FREQUENTLY ASKED QUESTIONS

What is a clinical trial? (Definition used for those studies that require contracting by the FACTS office. These requirements must also be met to collect the Clinical Trial Indirect Cost Rate)

A research study where the objective is either

a) testing of drugs, devices, diagnostics, treatments, interventions, or preventive measures including testing for an unapproved indication or

b) data collection to increase knowledge that would lead to enhanced safety and efficacy of a drug or device.

The study must involve contact with humans, inclusive of medical record reviews.

The study must be industry sponsored or funded.

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

What is another name for the CTA?
It may be called a Study Agreement, a Clinical Study Agreement or any one of several other similar names.

Can another name be used other than Icahn School of Medicine at Mount Sinai on CTA’s?
No! All CTA’s must be with ISMMS not Mount Sinai Medical Center or Mount Sinai Hospital.

Who can negotiate Contracts?
The FACTS office negotiates all of the industry clinical trial agreements (CTA’s) between the Icahn School of Medicine at Mount Sinai and industry sponsors.
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.

What is 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.
What is the Institutional Review Board (IRB)?
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.

When are Consent Documents released?
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 FACTS staff.

Who prepares the CTA?
The Sponsor shall provide a template of the CTA to the principal investigator who then submits the CTA to the FACTS office for negotiation.

When is the CTA submitted?
The CTA should be submitted at the time of the InfoEd and IRB submission.

Who negotiates the budget?
Budgetary negotiations are between the Principal Investigator and the Sponsor. Be sure to include a 35% overhead charge on all line items except IRB fees. (See Sponsored Projects website for the institutional overhead policy)

Most non-financial terms of the CTA will be negotiated by a Senior Contracts Specialist in the FACTS Office. You are instructed, however, to carefully read all documents you endorse which are intended to legally outline your obligations as a participant in the 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.

Who should checks be made out to for reimbursements?
Checks should be made out to the Icahn School of Medicine at Mount Sinai.

Who are the Signatories?
The designated Institutional Officer shall endorse all CTAs. The Principal Investigator’s Signature may also be required.

What is Mount Sinai’s TAX ID?
Mount Sinai’s Tax Identification number is ID 13-6171197.