

SUNY Upstate Medical University Clinical Trials Standard Operating Procedures

Table of Contents

Clinical Trials Process Overview

- Pre Award
- Post Award

Appendices

- I. Research Resources
 - Pharmacy-Based Investigational Drug Service
 - Clinical Research Unit
 - Center for Outcomes Research and Evaluation
 - Core and Shared Research Facilities
- II. Guidance to Developing a Study Budget
- III. Billing Procedures
- IV. Placing Your Study on the CTO Web Site
- V. Closeout Procedures
- VI. Contact List

Clinical Trials Process Overview:

The SUNY Upstate Clinical Trials Office (CTO) serves as a central liaison for clinical research at Upstate Medical University. **All study agreements must be routed through the CTO for institutional review and signature.** The CTO also reviews study budgets and can help negotiate, when requested.

Investigators are reminded to never sign documents with sponsors without approval from the CTO.

Pre-Award:

1. Study Opportunities

- The CTO subscribes to several clinical research venues to alert sponsors of our research expertise and facilities.
- When the CTO receives sponsor requests to conduct studies at Upstate, the CTO will direct request to appropriate researchers/departments.

2. Site Questionnaire

- Sponsors often use a site questionnaire to determine if a site is appropriate for their study. The site questionnaire is designed to determine if the PI has access to adequate resources, such as staff, space, and equipment.
- Questions related to budget should not be addressed in an initial Site Questionnaire.

3. Confidentiality Agreements

- The sponsor will require that a Confidentiality Agreement (CDA) be completed, before sending the study Protocol. The purpose of the CDA is to insure that the information the PI receives from the sponsor will be kept strictly confidential.

- If the CDA is sent directly to the PI, the PI should forward the CDA to the CTO. The CTO must forward the CDA to the Research Foundation of SUNY (RF) for review and approval. Once approved by the RF, the CTO will alert PI to sign the CDA or to forward this document to CTO to sign.
- For investigator-initiated studies (seeking commercial support), the CTO will initiate the CDA and forward it to the sponsor, to protect the PI's intellectual property. The CTO retains copies of all CDAs.
- 4. Protocol Review**
- Once a CDA has been executed, the sponsor will forward a copy of the full study protocol to the PI and study team for review (or, in the case of an investigator-initiated study, the PI will forward the protocol to the sponsor).
 - The PI is encouraged to include the study team in the review to deal with issues of time, scheduling and data requirements.
 - Once the PI and study team have determined that a study is appropriate to conduct, they may either contact sponsor directly or request that the CTO to contact the sponsor.
 - Notify the CTO once the PI/study team has agreed to conduct a study and the sponsor has approved the site so that the CTO can track the status of the agreement and budget.
- 5. Draft Agreement**
- The initial agreement and budget received from the sponsor is automatically considered a "draft." If this document is sent directly to the PI, please forward it to the CTO, noting "DRAFT" on the front page and including a copy of the budget and sponsor contact information.
 - The CTO will forward the Draft Agreement to RF for institutional review. The RF will correspond directly with the sponsor to finalize the draft.
 - PI, study team and CTO should jointly review the study agreement and budget to determine the appropriate payment schedule and identify additional items necessary to conduct the study.
 - Once approved by both parties, the final agreement will be forwarded to RF, PI or CTO for signing. Sponsors typically forward 2-3 original sets to be signed so that RF and the sponsor can each retain an original agreement.
 - Again, PIs are reminded to never sign documents with sponsors without approval from the CTO to do so.
- 6. Budget**
- When developing the budget, make sure current fees and rates are used.
 - Note services that are required to conduct study, and affirm their approval, availability, and current pricing (i.e., Radiology for x-rays, Cardiology for EKGs, Pharmacy for medication, Health Connections for recruitment, etc.).
 - If the Clinical Research Unit (CRU) will be used for the study, contact the CRU to assure availability, appropriateness, and costs.
 - If requested, the CTO will review budget and make recommendations and negotiate budget revisions with the sponsor. The CTO will assure that Upstate's current indirect cost rate and fees are reflected in the budget.
 - It is the responsibility of the PI and study team to verify costs and approve the study budget. If a sponsor will not provide adequate funds to cover the direct and indirect costs of the study, including the time and effort of the study team members, the study should be declined.

7. College Face Sheet

- The College Face Sheet is an internal form that is utilized by the CTO and the Sponsored Programs Office to set up the RF Study Account and to verify that Department Chair has approved of the study.
- For industry-sponsored studies, the funding may not be fixed but is dependent upon subject enrollment and timelines. Therefore, the total funding noted on the College Face Sheet may be noted as “per subject payment” and expectation of the number of subjects to be enrolled (such as \$5,000 per patient/5 patients).
- If any funds will be expended from the study account, that are not standard care, the billing portion of the College Face Sheet must be completed.
- The College Face Sheet must be received by the CTO before the account can be set up by the RF because the CTO uses this form to complete a New Award Checklist that determines parameters the RF requires in setting up the account.

8. Account Set Up

- When the Clinical Trial Agreement and Budget have been reviewed and approved by the PI, study team, sponsor, RF and CTO, the agreement is signed by the sponsor and the PI, CTO and RF signing on behalf of the institution.
- The RF establishes a study account after the agreement has been fully executed and forwards the account information to the CTO. The CTO sends the account information to the PI and study team.

Post-Award:

1. Payments & Accounting

- Sponsor payments are to be sent directly to the RF (Upstate payee). If a payment is sent directly to the PI, it should be brought to the Research Accounting Office, 300 CAB.
- Questions regarding study accounts should be directed to the Research Accounting Office, x5146.
- The PI Award Interface available at <http://www.sunyrf.org> enables PIs and their designees to review study accounts on-line. The Research Accounting Office can provide access to this online database.

2. Study Close Out

- The following offices should be notified when a study is completed: the IRB, the CTO, and the Research Accounting Office.