

INDUSTRY SPONSORED CLINICAL TRIALS PROCESS

SUNY UPSTATE MEDICAL UNIVERSITY

Study Initiation

Initial contact is made:

1. Investigator initiated study - PI sends study proposal to sponsor.
2. CTO contacts PIs in respective clinical research areas when opportunities become available.
3. PI has worked w/sponsor in previous study

Sponsor sends confidentiality agreement (CDA) (which CTO Officer signs and faxes immediately back to sponsor), protocol, other applicable prestudy documentation will be sent to PI/CRA.

Can we do it?

- Timeframe
- Appropriate budget?
- Patients
- Protocol
- Staff availability

PI and CRA determine feasibility of doing study. Sponsor reviews site qualifications/conducts site visit. If approved to do study, alert CTO IMMEDIATELY (x5476).

Pre-Award Process

Sponsor sends CTA + Budget to PI who advises CTO.

Contact internal services for their cooperation (i.e. Radiology Process)

CTO forwards CTA to legal in Albany. PI/CRA will review budget and negotiate with sponsor patient care costs, then forward budget to CTO for final review and approval.

These items are done simultaneously
Send College Face Sheet to CTO

Complete IRB Application/Submit Protocol to SUNY Upstate IRB for Review/Approval (Application and Guidelines available online)

Revisions Needed

No Revisions Needed

Study Protocol IRB Review completed, study approved. Approval Letter immediately forwarded to Sponsor

1. RF/Albany emails revisions directly to sponsor for final agreement.
2. Sponsor sends final agreement to RF for signature.

1. RF signs contract, forwards to CTO for PI signature.
2. CTO forwards to sponsor for signature.
3. Sponsor forwards one fully executed original to RF.

RF Account is Established (Project#/Award #/Task#) Account administered by Sponsored Program Administration and Research Accounting Department (for accounting questions: x5146)

Post Award Process

RF Account is established by RF/Albany. Account administered by Sponsored Program Administration and Research Accounting Department.

Study Process

Ongoing administrative work, completion of CRFs, amendments, etc.

1. Study initiation visit from sponsor.
2. Site receives drug and approval from sponsor to begin study

Patient enrollment begins

Site visits by sponsor's monitor

Monthly update reports to/from CTO for patient recruitment/follow-up

Patient enrollment ends

Study closeout visit by sponsor

Send final report to IRB: request termination

Final queries completed

Final payment from sponsor

Grant closeout, archiving of records

LEGEND:

CRF: Case report forms/data forms

CTA: Clinical trial agreement

CTO: Clinical trials office

CRO: Clinical research organization, company hired by sponsor to monitor, coordinate study with sites

CRA: Clinical research associate

IRB: Institutional Review Board, responsible for protection of human subjects

PI: Principal investigator, faculty member responsible for conducting study

RF: Research Foundation

SPONSOR: Company paying for study/pharmaceutical or device manufacturer