

REVIEW & NEGOTIATION PROCESS FOR SPONSOR & INVESTIGATOR INITIATED CLINICAL TRIAL AGREEMENTS



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Agenda

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- Submitting a Workflow
- Tracking the Process in MediTract
- Navigating MediTract
- The Review & Negotiation Procedure
- Investigator Initiated Trials
- Why is the CTA unsigned?
- Post-signature Process

Background

- The Financial Administration of Clinical Trial Services office (FACTS), under the auspices of the Department of Finance, is tasked with review and negotiation of Sponsor and Investigator Initiated Trial Agreements
- Agreements are assigned to Sr. Contract Specialists (SCS) based on departments
- Meditract is FACTS' contract management system which provides online and real-time access to a database of contracts and amendments

Accessing MediTract

- To initiate the review of a CTA, a submission in MediTract is required
- To access MediTract, a user logs-in with a username and password
- To request a username, email FACTS at facts@mssm.edu

Submitting a WorkFlow in MediTract

- Log into MediTract
 - Select the “Take Action” tab
 - Select “New” or “Amend”
 - Select “Clinical Trial Agreement/CDA/Site Agreement”
 - Select the “Site,” “Department”
 - Click on “Start”
 - Complete the Start Process
 - Select the Sponsor from drop down menu or add Sponsor if not listed
 - If applicable, select or add a Secondary Sponsor
 - Fill in remain in requested information
 - User may select Submit/Save Draft and Continue/Save Draft and Close/ Cancel
 - Click “OK”
 - Add attachments as necessary (i.e. Protocol, Budget, etc.)
 - Submit the “Work Flow”

MediTract Tips



- Provide any relevant information, such as the IRB submission status, PRMC Status, for IIT provide approximate amount of funding if Budget is not available), etc.
- Please insert the Sponsor's, Company's or other Third Party's name in the "Sponsor" field in MediTract
 - Do not use the CRO's name
- Please do not fill in the "Contract No" field in Start Process
- Regarding Amendments, please provide contact information for Sponsor or Company

Tracking the Process in MediTract

Access MediTract regularly for status



- Initiation Phase: Acceptance of Workflow is pending by SCS
- Document Source Phase: Review of Workflow is underway by SCS
- Document Review Phase: Redline has been exchange with Sponsor
- Signatory Phase: CTA language is finalized, but ISMMS signature pending
- Activation Phase: ISMMS has signed the CTA and the CTA has been sent to the Contract Library

Benefits of MediTract



- User may identify the SCS managing the review of the CTA
- User may communicate with SCS by sending a comment to the “Phase Owner”
- User may view any comments SCS has recorded in MediTract
- User may access the Communication tab to view communications between SCS and Sponsor
- Also, User may access the External Party Communication tab to determine whether a redline or a response to a redline has been exchanged

The Review & Negotiation Procedure



- Our goal is to send a redline to the Sponsor within 7 business days of receiving the Workflow
 - Caveat: If information is missing from the submission, it will delay the review
 - Note: We will redline a First In Human CTA (Cancer study) within 1 day
- The average length of negotiation is 4-6 weeks
 - Caveat: Duration of the negotiations may be affected by
 - i) Phase of the Study
 - ii) Sponsor's response time
 - iii) Involvement by third-party negotiator (CRO, outside counsel)
 - iv) Escalating the CTA to an internal stakeholder such as legal, risk management, press office, MSIP (in case of an Investigator Initiated Trial)

Investigator Initiated Trials

- When an agreement is submitted for review, the SCS will submit to MSIP for intellectual property review
- The redline sent to the Company will be subject to MSIP's comments if SCS's review is completed before receipt of MSIP's comments
- SCS will send MSIP any comments from Company and schedule any necessary conference calls
- If negotiations become protracted, MSIP may contact the Investigator and/or Company directly

Why is the CTA Unsigned?

- ISMMS will not necessarily sign a CTA simply because the agreement language has been finalized.
- Several factors will delay the signature of the CTA:
 - InfoEd record does not exist or is in PD form
 - Pending IRB approval
 - Pending Budget approval
 - Pending receipt of partially-executed LOI from Sponsor

Post-signature Process

- SCS will provide partially-executed to:
 - GCO
 - PPHS/IRB
 - Department
- PPHS/IRB will then release the IRB Approval Letter
- Department is to return the CTA with the PI's signature
- SCS will provide the CTA to the Sponsor or Company

Thank You!



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