Working With CTO Contracting: How Do I Get My Clinical Trial Contract Negotiated & Why Isn’t It Signed Yet?

Jaci Brown, Manager, CTO-Contracting
Darlene Kitterman, Director, Investigator Support, OCTRI
• CTO organization
• Clinical Trial Contracting Process
• General Communication Guidelines
• CTO-Contracting Roles
• CTO-Contracting Information Needs
• What approvals are required before a contract is signed
• How to determine contract status
Clinical Trial Contracting Process Overview

- Contract negotiation begins after study is submitted to the IRB
  - CTO receives automatic notification if eCRIS box is checked in IRB
  - CTO information required for negotiation
    - Contact information for the sponsor
    - Word version of the contract
- All contract management tracked in eCRIS
- Once negotiation is complete, contract cannot be signed until all approvals for the study are obtained by the study team
• Direct communication to the appropriate person only (role, negotiator, etc.)
• Copy CTO personnel on communications only as required
• Check eCRIS or jellyfish first for status
  - If study started in eCRIS, all contracting information managed in eCRIS
  - If study not initiated in eCRIS, contracting information managed in jellyfish
• Contract Assistant *(Emily Purdin)*
  
  – CTO-Contracting’s initial external contact person
    
    • Responds to emails/questions prior to assignment to a Contract Analyst
    
    • Please only provide sponsors/CROs/universities/etc. with the Contract Assistant’s information
  
  – CTO-Contracting’s initial internal contact person
    
    • Responds to emails/questions prior to assignment to a Contract Analyst
    
    • *Please do not copy Contract Analysts on emails*
• Contract Assistant (continued)

  - Administrative duties

  • Sets up and assigns agreements to a Contract Analyst for review
    
    - Assigns Clinical Trial Agreements to a Contract Analyst after IRB/eCRIS submission
    
    - Introduces the assigned Contract Analyst to the sponsor/CRO/university/etc. and the study team
    
    * This may take a few days if sponsor/CRO name needs to be added by OPAM

  • Obtains OHSU signature after agreement is signed (if necessary) by PI, IRB/eCRIS approvals
    
    - Follows up with study teams on outstanding PI signatures
    
    - Answers non-eCRIS approval related questions regarding OHSU’s signature
    
    - Returns executed agreement to sponsor/CRO/university/etc.
    
    - Sends agreements to OPAM for OGA setup (if necessary)
• Contract Analyst
  – Negotiates legal terms in confidentiality agreements, clinical trial agreements, amendments, etc.
  – Provides negotiation status information if not available in eCRIS/Jellyfish
  – Once finalized, sends agreements to study team for PI signature (if necessary)
  – If in eCRIS, sends to person identified by study team as the Study Contact

* Check CTO-Contracting webpage for current departmental assignments
* Please direct questions to the Contract Analyst assigned in eCRIS/Jellyfish
• Study Team
  - Sends agreements and initial emails from sponsors/CROs/universities/etc. containing contact information to Contract Assistant
  - Negotiates budgets and payment terms and provides final version to Contract Analyst
  - Checks in eCRIS or jellyfish for contract status information
  - Secures eIRB/eCRIS approvals and communicates with sponsors/CROs/universities/etc. on status
  - Obtains PI signatures (if necessary)
Most information necessary for negotiation is available in eCRIS/eIRB except:
- Sponsor contact information
- WORD version of contract

Alert CTO-Contracting of any of the following:
- PI initiated
- VA involvement
- Multi-center sub-contracting requirements
- New funding/support or multiple funding/support
- Time constraints (enrollment, sponsor, fiscal)
- Any other information that might be helpful for or impact the contract negotiation

Provide the final budget/payment terms
• **My Home tabs/view all: Overview of all contracts**
  - Contracts tab
  - All CDA tab

• **Study Summary Screen: Contract status on study**

• **Contract history tab:**
  - Detailed history of contract negotiation
  - Latest version of contract
### Contracts Tab

#### eCRIS: electronic Clinical Research Information System

#### Current Research Study

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<tr>
<th>Contract #</th>
<th>CRS #</th>
<th>Contact</th>
<th>Status Date</th>
<th>Status Date</th>
<th>Contract Type</th>
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Hyperlink takes you to contract workspace.
Contract Statuses

- Agreement received (waiting for data entry): Contract uploaded, CTO data not yet entered
- Waiting for IRB submission: Haven’t started negotiation because IRB not yet submitted
- Agreement uploaded/Waiting for negotiation: Agreement can proceed but haven’t started yet
- Negotiation in process: Started reviewing agreement
- In external review: Agreement with sponsor
- In OHSU review: Agreement sent back from sponsor and CTO reviewing comments
- Waiting for approvals or final budget: Contract negotiation complete but approvals in eCRIS, IRB approval, or budget finalization is not yet done and can’t sign contract
- Waiting for Agreement from sponsor: Waiting for sponsor to send final copies to sign
- Waiting for OHSU signatures: In process of obtaining PI and OHSU signatures
- Waiting for Sponsor signature: Contract with sponsor to sign
- Pending SPA set-up: Contract has been executed and is being set-up by OPAM
- OGA Set-up complete: OGA number is available
Actions Required Prior to Contract Execution

• IRB approval
  – Institution has approved the study from a human subjects perspective
  – Liability and data use in consent match contract language

• CRBO review & approval (formerly in eIRB)
  – Costs accurately reflected in coverage analysis
  – Costs in study budget, coverage analysis, and consent language match

• Department approval (formerly PPQ)
  – PI certifies will comply with all requirements of a PI
  – Department approving the work to be conducted
    • the space and resources to conduct the work will be available
    • the personnel on the project are appropriate
    • the costs for the study are covered by the budget or, if not, the department will cover the anticipated deficit

• Clinical services approval (formerly Research Rates Request)
  – Notifies the clinical department that the study is happening
  – Verifies that the clinical department can perform the services required by the protocol
  – Verifies that the study team is budgeting for the correct service and price

• “Study Team Complete” eCRIS activity
  – Tells the system that the study team is done with the budget
  – Numbers in the budget used to generate contract set-up in OGA and manage finances
How To Determine The Status of Approvals in eCRIS

- **Study Summary Screen**: Overview of approval statuses
- **Study tabs**: Detail about each study approval process in eCRIS
- **Workflow map**: Outstanding requirements to move to the next study state
- **Dashboard tab**: Study status across all of your studies
Study Summary Screen

**Study Title:** A Multicenter, Randomized, Double-blind, Parallel Group Study of CNT0 136 (pirukumab) Administered Subcutaneously as Monotherapy Compared with Adalimumab Monotherapy, in Subjects with Active Rheumatoid Arthritis (Protocol CNT0136ARA3005)

**Principal Investigator:** Cong-Qiu Chu

**Main Study Contacts:**
- Amanda Barron
- Brenda Olmes
- Bridget Adams
- Klana Voikli-Gilani
- Mai-Lee Yap
- Margaret Sills

**Funder(s):** Janssen Research & Development LLC

**Sponsor Protocol Number:** CNT0136ARA3005

**Total Study Enrollment:** 510

**Total OHSU Approved Subjects:** 15

**PI Initiated:** no

**FDA Regulatory Information:**

**Device(s):**
- Risk Type
- IDE Category
- Number

**Drug Study:** yes  
**Drug IND:** yes

**IND Number:** 101073

**Statuses:**

**Department Review:** Submitted: No  Approved: No

**Clinical Services Review:** Yes

**GRRD Review:** Submitted: Yes  Completed: Yes  Approved: Yes

**Budgets and Contracts:**

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**IRB Number:** IRB00001042

**IRB Status:** Active
• Log into eCRIS
• Navigate to the study
• Click on “Workflow Map”
- Log into eCRIS
- Click on “My Home”
- Click on “view all”
- Click on Dashboard tab
• CTO Website:  http://www.ohsu.edu/xd/research/administration/clinical-trials-office/contracting/index.cfm

• eCRIS:  https://ecris.ohsu.edu

• Jellyfish:  http://riswebprod.ohsu.edu:8070/apex/f?p=132:2: