Department Actions and Responsibilities

Have a positive disclosure on your 700-U or Form 800? You may want to submit these online forms to COI prior to submitting the IPF in order to avoid delays in contract execution[2]; we can't sign a contract until positive disclosures are approved by COI.

Please contact the Cayuse team if you have any problems or questions regarding use of Cayuse[3].

Want to know the status of contract negotiations? The dept admin listed in Cayuse will be cc'd on all CTCO emails to the sponsor or CRO. Feel free to reach out to the sponsor directly for updates on their review of the contract.

Review the contract, the payment terms, budget, and any other exhibits. Are the correct budget and payment terms attached to the contract? Has the sponsor made edits you haven't reviewed?

If COI has not been completed, a positive disclosure has not been approved by COI, or if the PI hasn't completed or updated the COIR training, the contract will not be signed.

Not sure which indirect cost rate applies to your study? Send the protocol to the CTCO to determine whether the study qualifies as a clinical trial[1].

Want to know if we've received your IPF? Check the status in Cayuse.

If IRB has not been approved, the contract will not be awarded.

Negotiate the **budget and all payment terms** directly with the Sponsor/CRO.

Once the budget and payment terms have been negotiated, create an IPF (proposal) in Cayuse. Collect your chair's signature on the UBT, then upload the protocol, draft agreement, final sponsor budget, negotiated payment terms, signed UBT, and Exception to Policy for Clinical Study Agreements.

Complete your IPF and route for approval through Cayuse. Please see the Handbook for instructions[4].

You may be asked to confirm acceptance of specific contract language that could affect your department's obligations or payment rights.

Once the CTA is negotiated, you will be asked to review the agreement (including the budget and payment terms) and confirm that all departmental and PI obligations are acceptable.

Your contract analyst will email you the final version of the CTA for your approval and completion of outstanding compliance items. After approval, CTA (and IRB cert, if applicable) will be sent to PI for signature through DocuSign.

All final award documents will be available to download in Cayuse.

CTCO will send an email informing the department of which contract administrator has been assigned to the study and what required items are missing from the Cayuse submission.

After reviewing the protocol and contract, the CTCO will reach out to the sponsor/CRO to request any necessary revisions.

After the CTA is finalized, the CTCO will send the final agreement to the department for the PI's signature.

The CTA is executed and then awarded (forwarded to CGA).

CT Contracts Office (CTCO) Actions and Responsibilities

1. Definition of a Clinical Trial: http://research.ucdavis.edu/proposals-grants-contracts/helpful-links/costs/
2. Online COI submission: https://or-forms.ucdavis.edu/
3. Cayuse help: ORCayuseHelp@ucdavis.edu
4. Failure to submit a complete and correct IPF in accordance with the *Handbook for Department Industry-Funded Clinical Trial Staff, Principal Investigators and Approvers* (https://health.ucdavis.edu/media-resources/supply-chain/documents/pdfs/ct-amendment-chart-for-department-administrators.pdf) will result in delayed review. Don't forget to upload all required attachments:
   Clinical Trial: UBT, final sponsor budget and negotiated payment terms (if separate from the CTA), editable draft CTA (in Word format), protocol, and the Exception to Policy for Clinical Study Contracts
   Clinical Service: internal budget, final sponsor budget and negotiated payment terms, editable draft service agreement, and protocol