Department Actions and Responsibilities

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 . Submit sponsor budget, CTA, protocol, and draft UBT to Julie Calahan via email.	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 if we've received your IPF? Just check the stat us in Cayuse.	Want to know the status of contract negotiations? You can check Cayuse. Feel free to reach out to the sponsor directly for updates on the sponsor's 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?	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.
						If IRB has not been approved, the contract will not be awarded.
	Negotiate the budget and all boyment terms directly with the Sponsor/CRO. Negotiate the budget and all boyment terms, and signed UBT to Julie via email.		Complete your IPF and route for approval through Cayuse. Please see the Handbook for	asked to confirm be of acceptance of agree specific contract the language that pay could affect your con department's dep obligations or oblig	bitiated, you will lisked to review the beenent (including budget and ment terms) and irm that all artmental and Pl gations are eptable. Collect Pl's sign and foll any sign instructi provide the CTC	adure documents low will be nature available to ions download in ed by Cayuse.
Julie will provid feedback on the sponsor budget, payment terms and draft UBT.	approved and will no administra the CTCO	UBT into Cayuse stify the tive contact in that the budget s have been	CTCO will send an email informing the department of which contract administrator has been assigned to the study.	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: <u>https://or-forms.ucdavis.edu/</u>
- 3. Cayuse help: <u>ORCayuseHelp@ucdavis.edu</u>
- 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, Sponsor Budget and Payment Terms (if separate from the CTA) CTA, Protocol, and the Exception to Policy for Clinical Study Contracts Clinical Service: Internal Budget, Sponsor Budget and Payment Terms, Service Agreement, and Protocol

Sponsor Initiated Clinical Trial and Clinical Service Workflow 09/2024

If COI has not been