

Terminology	What it is	Where do I send it?	Email or Cayuse	What to send
Protocol Amendment	There has been a change to the Protocol (or scope of work for service agreements).	<ul style="list-style-type: none"> • If the change to the Protocol requires a change to the budget/payment terms (adding or removing procedures/visits), send to Julie. • If the change to the Protocol requires new contract language (sponsor has asked us to sign an agreement), but no change to the budget is required, send to your original contracts admin. • If the change to the Protocol doesn't require a change to the budget or to the contract language, the CTCO does not need to be notified. 	Email	<ul style="list-style-type: none"> • Updated Protocol • Editable amendment • Updated UBT/internal budget (for budget changes) • Updated sponsor budget and payment terms (for budget changes) • A new 700-U will be required prior to signature for budget changes • Updated IRB approval is required prior to award
Budget Amendment	Any changes to the previous budget or payment terms. May be initiated by either the sponsor or by the University.	Send to Julie. Once the UBT/internal budget, payment terms, and sponsor budget are finalized, Julie will forward the amendment request to the appropriate contracts admin within the CTCO for negotiation and execution.	Email	<ul style="list-style-type: none"> • Updated Protocol (if applicable) • Editable amendment • Updated UBT/internal budget • Updated sponsor budget and payment terms • A new 700-U will be required prior to signature
Contract Amendment	The sponsor or University wants to change language in the original contract or an earlier amendment.	<ul style="list-style-type: none"> • If there is also a change to the budget, follow instructions above for Budget Amendment. • If there is no change to the budget, send to your original contracts admin. 	Email	<ul style="list-style-type: none"> • Editable amendment • If there is also a change to the budget, send all items listed above for Budget Amendment
No Cost Time Extension	The sponsor or University wants to extend the end date of the contract. No additional work is being added and there is no change to the budget or contract language.	Send to your original contracts admin.	Email	<ul style="list-style-type: none"> • Editable amendment. If the original contract has a firm end date (the end date is specifically stated) then an amendment will need to be executed between the sponsor and University • If the contract does not specifically state a date on which the contract will expire, send an email with the new requested end date
PI Change	The PI for the study is being changed to a different University investigator.	<ul style="list-style-type: none"> • If there is also a change to the budget, follow instructions above for Budget Amendment, and then submit a proposal in Cayuse. • If there is no change to the budget, submit a proposal in Cayuse. 	Cayuse	<p>Follow instructions on page 37 of the Handbook for submission in Cayuse</p> <ul style="list-style-type: none"> • Protocol • Signed Clinical Trials Exception to Policy • Editable amendment • Updated UBT approved by Julie • Updated sponsor budget (if applicable) • COI disclosures will be required prior to amendment execution • Updated IRB approval will be required prior to award • Completed COIR training will be required prior to execution

Start-Up Agreement	Budget or contract negotiations have failed, but the University has incurred start up costs for the Study. Alternatively, the CTA has been executed, but no subjects were enrolled, and the criteria for being paid the negotiated start-up fee have not been met. A start-up Agreement addresses sponsor's payment to University for study-related start-up activities only.	<ul style="list-style-type: none"> • Send to Julie. Once the UBT/internal budget, payment terms, and sponsor budget are finalized, Julie will forward the start-up request to the appropriate contracts admin within the CTCO for negotiation and execution. • If a Cayuse proposal was never submitted for the anticipated study, follow instructions on page 9 of the Handbook to submit a proposal for the start-up amount only in Cayuse. 	Email or Cayuse	<ul style="list-style-type: none"> • Editable start-up agreement • UBT/internal budget for the start-up amount only • Updated sponsor budget for the start-up amount only • A 700-U will be required prior to signature
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Hint: If your amendment requires any change to the budget, your first step is to contact Julie.

If the amendment is initiated by the University, reach out to the sponsor first to inform them of your requested edits. Most sponsors prefer to use their own amendment template; however, our office is also happy to provide an amendment template.

All email requests for amendments must include:

- Sponsor name
- PI name
- Protocol number
- Cayuse Project number
- Sponsor's contact information (name and email)
- Any documents listed above under What to Send
- Updated COI disclosures may also be required prior to execution
- Updated IRB approval may be required prior to award