Appendix
Getting Started

- Use Mozilla Firefox for best results.
- Login to: https://ucdavis.cayuse424.com/sp/ with your Kerberos ID and Password.

Submitting to the UC Davis Health Contracts Clinical Trials Contracts Office

New Internal Processing Forms (IPFs) must be submitted to the UC Davis Health Contracts Clinical Trials Contracts Office (“Clinical Trials Contracts Office”) via Cayuse SP when approvals/authorizations are needed from the department chair(s) and/or dean's office(s). For all new agreements to be processed by the Clinical Trials Contracts Office, you will select “New – UC Davis Health” from the “Proposal Type” dropdown.

For all modifications to agreements, see the separate submission instructions included in this handbook.

Confidentiality Agreements are to be e-mailed to the Clinical Trials Contracts Office analyst with an editable agreement and e-mail chain that identifies the external contact for negotiation.

*Please note that industry funded Clinical Trials do not have a “Proposal” process that are reviewed in advance of the clinical trial award. For the purposes of industry funded clinical trials, the term “proposal” as used below and in Cayuse, means the required initial documentation and setup of the Clinical Trial contract request.

Proposals/Internal Processing Forms

A new Internal Processing Form (IPF) is required for all proposals submitted to the Clinical Trials Contracts Office. A proposal for an industry-funded clinical trial in Cayuse SP is the equivalent of what is commonly known as the Clinical Trial Packet. Follow the general instructions below when creating a new Internal Processing Form unless otherwise noted.

Quick Reference

1. Start a Proposal.
2. Complete or view the status of a Proposal you started or on which you have an interest or are key personnel.
3. View Proposals in your unit that were initiated by someone else (requires appropriate access/permissions).
Cayuse SP Auto-generated Numbers

Cayuse SP creates identification numbers for each Project, Proposal, Award and Subcontract/Subaward.

1. Project Number
   a. Created by the Clinical Trials Contracts Office. Your Clinical Trials Contracts analyst will assign each Proposal and Subcontract/Subaward (if applicable) to a Project. Awards are created from Proposals and assigned to a Project.

2. Proposal Number
   a. Created by Cayuse SP when the Proposal is created.

3. Award Number
   a. Created by Cayuse SP when the Award is added to the Project. The Award Number is the Project Number plus three digits at the end that indicate the number of Awards in that Project. The first Award is the Project Number-“001”, the second is the “Project Number-002” and so forth.

4. Subcontract/Subaward Number
   a. Created by Cayuse SP when the Subcontract/Subaward is added to the Project. The Subcontract/Subaward Number is the Project Number plus three digits at the end that indicate the number of Subcontracts/Subawards in that Project. The first Subcontract/Subaward is the Project Number-“S001”, the second is the “Project Number-S002” and so forth.

Requires Re-approval by IPF Approvers

1. Find the Internal Processing Form (IPF) from My Proposals or Proposals in My Unit.
   a. Select the Proposal Number
2. Go to the Notes tab.
   a. Enter Note in the text box that you request this proposal/IPF be returned to Unsubmitted status.
   b. Select Add Note.
   c. The added Note will display under Note.
3. Email ORCayuseHelp@ucdavis.edu and request the proposal/IPF be returned to Unsubmitted status, indicating you will need to acquire re-approval by the IPF Approvers.

4. Once the proposal/IPF has been moved back to Unsubmitted status, make necessary edits.

5. Select Submit for Routing.

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**Necessary Information and Documents**

**Necessary Information**

1. Sponsor Name *(Note: Use the code for Miscellaneous Sponsors if the Sponsor is not included in the list)*
2. Academic Department or Administrative Unit administering the project
3. Primary Administrative Contact
4. Short Project Name (Protocol Number)
5. Project period (start and end dates listed on the UBT)
6. Activity Code: Select from the following Activity Codes only when submitting an industry-funded clinical trial.

<table>
<thead>
<tr>
<th>Activity Code</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>06 Other Service</td>
<td>Service activity.</td>
</tr>
<tr>
<td>07 Clinical Trial – Investigator Initiated</td>
<td>Self-explanatory.</td>
</tr>
<tr>
<td>08 Clinical Trial – Sponsor Initiated</td>
<td>Self-explanatory.</td>
</tr>
<tr>
<td>14 Other</td>
<td>Anything that does not fit Activity Codes 01-13.</td>
</tr>
</tbody>
</table>

Table 2: Activity Codes

7. Type of proposal: New – UC Davis Health for all industry-funded clinical trials.
8. Instrument Type: Select from the following Instrument Types only when submitting an industry-funded clinical trial.

<table>
<thead>
<tr>
<th>Instrument Type</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contract</td>
<td>A procurement relationship that is a legally binding contract with detailed financial and legal requirements, a specific work statement, and/or a specific set of deliverables and/or reports due to the sponsor.</td>
</tr>
<tr>
<td>Non Monetary Agreement</td>
<td>An agreement that does not include money.</td>
</tr>
</tbody>
</table>

Table 3: Instrument Types – the Instrument Types above are the only type to be used for agreements processed by the Clinical Trials Contracts Office.

9. Sponsor deadline: Select the current date

10. Project Title: Replace the auto-populated short title with the entire protocol name after the protocol number in (i.e., “PROTOCOL NUMBER–COMPLETE PROTOCOL TITLE”) F&A Rate(s) (determined by activity)

11. Are animal or human subjects involved? If so, is there IACUC/IRB protocol?

12. Location (i.e.; Building, laboratory, etc.) where the activities will occur

13. If there are outgoing subawards: Contact information for the Subawardees

Necessary Documents

The following documents are needed to submit an IPF to the Clinical Trials Contracts Office:

1. Sponsor budget
2. Internal budget (UBT)
3. Protocol
4. Editable Draft Agreement (as a Word document)
5. If there are subawards: Budget, subrecipient monitoring form and subrecipient commitment form
6. Appropriate compliance forms (Form 800 and 700U), filed online (Note: The eCOI Online Disclosure System may be found at: [https://or-forms.ucdavis.edu/](https://or-forms.ucdavis.edu/))
7. Complete Principal Investigator Exception form, if applicable

NOTE: All clinical trial agreements also require that the Principal Investigator’s COIR Training is up to date, as required by the UC Office of the President.
Creating and Submitting Internal Processing Forms
(Note: All Proposal/IPF tabs must be complete, including the Budget section.)

1. Go to Start New Proposal under My Dashboard. (Note: Do not copy previous IPFs.)

2. General information: Complete the fields indicated below.
   a. Sponsor: If the sponsor is not listed, select Miscellaneous Sponsor, type the Sponsor Name in Submission Notes (last step before routing) and follow Step 4 below.
   b. Admin Unit: Unit that will administer the grant.
   c. Short Project Name: Protocol Number.
   d. Select the hyperlink to select the appropriate Activity Code (see Table 2 above).
   e. Proposal Type: New – UC Davis Health.
   f. Instrument Type: Select Contract or Non-Monetary Agreement.
   g. Select Submission Deadline: Current Date
   h. Title of Project: Protocol Number – Protocol Name.
   i. Do not Pair your Proposal/IPF.
   j. Select Save.
3. After saving the General Information page, tabs will appear to the left.
   a. Complete each section. *(Note: A green checkmark will display when each section is complete.)*
b. Investigators/Research Team: Add all Key Personnel and others that need edit access to the IPF and/or view access to the associated award. For Industry Sponsored Clinical Trial requests, add all investigators required to complete the Form 800. (Note: The IPF/Proposal will route for approval by all units with personnel on this tab unless the Other Participant – No Routing or Proposal Editor roles are selected.

i. Select the name of the Key Personnel to add. (Notes: You must enter the Lead Principal Investigator’s information first.)
   1. If the investigator is not listed and the person has a UC Davis appointment, email ORCayuseHelp@ucdavis.edu for assistance.
   2. If the investigator is not listed and does not yet, but will, have a UC Davis appointment either:
      a. Initiate, complete and process a Temporary Affiliates Form (https://itcatalog.ucdavis.edu/service/online-taf-temporary-affiliate-form) for the new appointed individual OR
      b. List the Department Chair as the Principal Investigator and update the IPF after the individual has a UC Davis appointment. This may require you to request Clinical Trials Contracts Office update the IPF record.

ii. Ensure the Unit listed is correct. If not correct, select the appropriate unit. Do not select a unit indicated as “Non Admin/Home” or that has language such as “(Use 123456)”. If this language is displayed, find and select the unit code identified in the parenthesis.

iii. Select the Role.

iv. Add the correct person months and sponsored effort. (Note: If the salary included in the IPF is not determined from effort committed, and no effort is being committed, enter 0% in the Sponsored Effort % and include the appropriate amount on your budget.)

v. Cost Shared effort should always be “0” for industry Clinical Trials.

vi. Add the appropriate Allocation of Credit. (Note: Must equal 100% total for all key personnel. Principal Investigators and departments can determine how to allocate credit. Typically, 100% of credit is given the lead Principal Investigator, even when effort is 0%).

vii. Select Save Personnel. (Note: Saved Personnel will display under List of Personnel.)

viii. Repeat for each Key Personnel and person needing edit access to the IPF and/or view access to the associated award.
c. Budget *(Note: A complete budget form is required for mandatory reporting requirements.)*
   i. Select the Summary Budget Form.
   ii. Select the total # of Budget Periods: Enter 1
   iii. Select the Current Period Start and End dates *(Note: These dates should match the UBT).*
   iv. Indicate “No” for cost sharing or cash matching.

v. F&A Rates *(Note: The F&A Rate is required.)*
   1. Select the appropriate F&A Rate(s) for the Current Period. *(Note: The Entire Project column will auto-populate if there is only one budget period.)*
   2. Leave the Use Calculated Values box checked unless you want to manually calculate the Effective Rate.
vi. Budget Categories (*The fields below are required, as applicable.*)
   1. Enter the Sponsor Direct Costs for the Current Period (*Note: This should match the UBT*).
   2. Enter each Base amount for each F&A Rate for the Current Period (*Note: Base for F&A Rate should be the same as Sponsor Direct Costs*).
   3. Leave the Use Calculated Values box checked unless you want to manually calculate the total Indirect Cost (F&A) for the Current Period.
   4. Do not enter anything in the Fee fields.
   5. Leave the Use Calculated Values box checked unless you want to manually calculate the Total Sponsor Proposed Costs.

![Budget Categories Diagram]

vii. Indicate if any Additional Resources will be used (*Note: If you selected an Affiliated Unit, include the details of what resources you will be using.*)

viii. Select Save.
d. Financial Conflicts of Interest in Research (Note: Some department contract and grant staff leave this page/tab for the Principal Investigator to complete.)
   i. Complete the applicable COI Disclosures.
   ii. Select Yes to indicate that you have filed or will file the applicable COI Disclosures.
   iii. Select Save.

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**Financial Conflicts of Interest in Research – Disclosure Process**

1. Determine What Disclosure(s) You Must File. Your funding source and type of research determines which disclosure (if any) you must submit.
   - Privately-Funded Research
   - PHS-Funded Research
   - Gov’t-Funded Research (Non-PHS)
   - Department Funded
   - Human Subject Research

2. Complete and File Your Disclosure – [Click here]

Indicates Required Fields

3. Please answer Yes or No to the items below:
   - I understand that I must complete the financial conflict of interest disclosure requirements for this project, as applicable.
   - I certify that necessary human subject, animal subject, and/or Environmental Health & Safety approvals have been obtained prior to conducting work that requires such approvals.
   - I certify that funds will be available to cover the expenditures incurred for this project in the event that the Sponsor does not provide the funds requested.

   [ ] Yes  [ ] No

[Save]  [Reset]
e. Regulatory Compliance (Note: Some department contract and grant staff leave this page/tab for the Principal Investigator to complete.)

i. Complete Human Subjects field and enter the IRB protocol numbers, if applicable. (Note: A text field will appear for protocol number entry as appropriate.)

ii. Complete the Animal Subjects field (Note: Animal clinical trials are not handled by Clinical Trials Contracts. Such IPFs should be submitted to Sponsored Programs in the Office of Research.)

iii. Complete the Hazardous Research Materials Section. If no Hazardous Materials, check None.

iv. Select Save.
f. Subrecipients
   
i. If there is/are a subrecipient(s)
      1. Enter the subrecipient(s) in the Subcontractor field. If the subrecipient is not listed, select Miscellaneous Sponsor and type the Subcontractor Name in Submission Notes (last step before routing).
      2. Select Add Subcontractor. *(Note: The required documents must be uploaded in the Proposal Attachments tab.)*

3. Select Authorize Subcontractor List.
ii. If no subrecipients, select No Subcontractors.
g. Foreign Activity (Note: Some department contract and grant staff leave this page/tab for the Principal Investigator to complete.)
   i. Answer the Foreign Activity questions and complete any associated text fields and drop-down lists. (Note: A text field and/or drop-down list will appear as appropriate.)
      1. If the project will involve export control but the foreign location is unknown at the time of IPF, select To Be Determined for the foreign location. (Note: Select control and the country simultaneously to select multiple countries.)
   ii. Select Save.
i. Special Interest
   i. Answer the questions, entering protocol numbers as applicable. (*Note: A text field will appear for protocol number entry as appropriate.*)
   ii. Question 5 should be answered yes as this refers to the sponsor agreement.
   iii. Select Save.
j. **Additional Questions**
   
i. Answer all required Additional Questions (indicated by a red *).
   
ii. If this is a Limited Submission, upload the selection notification email in the Proposal Attachments tab.
   
iii. All Clinical Trial Contracts should state “Human Health” in the dropdown under “Health Relatedness”.
   
iv. Select Save.
k. Location of Sponsored Activities
   i. Indicate all locations where the work under this project will be performed and the Percent of Work at each location. Do not enter location of Subawardee(s). (Note: This list should match the 1572.)
   ii. Select Add. (Note: The location will appear under the appropriate listing. An error will display until the total Location of Sponsored Activities equals 100%.)
I. Proposal Abstract
   i. Indicate “No” under question 1.
   ii. For Abstract details, type N/A.
   iii. Under Field of Science, no selection is needed.
   iv. Select Save.
m. Proposal Attachments
   i. Upload applicable documents. See the Necessary Documents section if you are unsure of what to upload. (Note: UBT’s will need to include “internal budget” in the file name, sponsor budget’s will need to include “sponsor budget” in the file name.)
      1. Browse your computer and select the document to upload.
      2. Select the Document Type.
      3. Select Add.
      4. Repeat the Upload Process until all documents are loaded.
      5. When uploading the Exception to Policy for Clinical Study Contracts, select “Other” in the dropdown.

![Proposal Attachments](image_url)
n. Approving Units
   i. Check the Approving Units that auto-populate for accuracy. *(Note: Contact ORCayuseHelp@ucdavis.edu if a Unit name is blank. If a Non Admin unit is listed, ensure it is a rollup unit from one of the other units listed. Rollup will display under Role(s).)*
   ii. Add other Units if appropriate. *(Note: Do not add the Clinical Trials Contracts Office. The IPF will route to the Clinical Trials Office after all department/school level approvals have been obtained.)*
   iii. Re-order the Routing if needed. *(Note: If the IP is being routed to the School of Medicine, reorder it to after all School of Medicine units. If the IPF is being routed to the School of Veterinary Medicine, reorder it to after all School of Veterinary Medicine units.)*
   iv. Select Authorize Unit Listing.
Submission Notes

i. Add any notes regarding this IPF in the Notes field, such as:

1. If you selected “Miscellaneous Sponsors” for either the Sponsor or Subcontractor(s), enter the name, address and contact information (person’s name and phone number) of Sponsors or Subcontractor(s). (Note: You would have selected Miscellaneous Sponsors.)
2. Add the contact person from the Sponsor who is responsible for negotiating the agreement and their contact information, including an email address AND phone number.
3. If a CRO is involved, enter the name of the CRO, their address, the contact person from the CRO who is responsible for negotiating the agreement and their contact information, including an email address AND phone number.

ii. Select Add Note. (Note: Notes cannot be edited or deleted.)

Submit for Routing

i. Ensure green checkmarks are indicated for all tabs.

ii. Select Submit for Routing. (Note: The Principal Investigator should complete this step as the IPF can no longer be edited after it is submitted for routing.)

iii. Select Yes when asked “Are you sure you wish to submit this Proposal Record?”.

4. If you selected Miscellaneous Sponsor for a Sponsor or Subaward, email ORCayuseHelp@ucdavis.edu and request the Sponsor or Subawardee be added.
Editing an Internal Processing Form that has been Submitted for Routing

Once an IPF/Proposal has been Submitted for Routing, it may no longer be edited. If you need to make revisions, please follow the appropriate instructions below.

- Revisions that require re-approval from the IPF Approvers are:
  - Budget Cost Share, Incorrectly Applied (match/in-kind) (not applicable to Clinical Trial Contracts)
  - Effort Changed from Direct Charge to Cost-Share
  - Key-personnel added to the project after routing to Clinical Trials Contracts Office
  - Subawards added to the budget after routing to Clinical Trials Contracts Office
  - Incomplete IPF/proposal (refer to Necessary Information and Documents)
  - Other revisions representing a significant change in commitment of departmental and/or campus resources

- Minor revisions that do not require re-approval from IPF Approvers include, but are not limited to:
  - Change in project title
  - Change in project dates
  - Edits to the abstract field
  - Minor budget edits

Does Not Require Re-approval by IPF Approvers

1. Find the IPF from My Proposals or Proposals in My Unit.
   a. Select the Proposal Number.
2. Go to the Notes tab.
   a. Enter Note in the text box that you request this proposal/IPF be returned to Unsubmitted status
   b. Select Add Note.

c. The added Note will display under Note.
3. Email ORCayuseHelp@ucdavis.edu and request the proposal/IPF be returned to Unsubmitted status and state reason, indicating that this does not require re-approval by the IPF Approvers.

4. Make necessary edits in the proposal/IPF.

5. Email ORCayuseHelp@ucdavis.edu and request the IPF be returned to Admin Office in Process status, or Dept Approval In Process status (if the IPF Approval process was incomplete). (Note: Do not Submit for Routing again. If Submit for Routing is selected, all IPF Approvals already obtained will need to be re-obtained).
Certifying/Signing an Internal Processing Form


2. Select the PI Certification Inbox.

3. Select the appropriate Proposal Number.
4. Review the IPF. *(Note: You may view the electronic IPF/proposal or a PDF.)*
5. Select Certify Proposal when ready to “sign”.

6. Review the Certifications.
7. Select Submit Certification.
8. The IPF will now show as Certified within the Approvals tab.
Checking the Status of a Routed IPF
Internal Processing Form Status Definitions

<table>
<thead>
<tr>
<th>Status</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unsubmitted</td>
<td>Not submitted for routing</td>
</tr>
<tr>
<td>Dept Approval in Process</td>
<td>Pending IPF approvals; submitted for routing</td>
</tr>
<tr>
<td>Admin Office in Process</td>
<td>Received by Clinical Trials Contracts Office but not assigned</td>
</tr>
<tr>
<td>Under Award Negotiation</td>
<td>Under analyst review and/or contract negotiation</td>
</tr>
<tr>
<td>Pending Award</td>
<td>Negotiation of CTA finalized</td>
</tr>
<tr>
<td>Reopened</td>
<td>IPF reopened for department to edit</td>
</tr>
<tr>
<td>Withdrawn</td>
<td>IPF withdrawn by the Principal Investigator</td>
</tr>
<tr>
<td>Not Funded</td>
<td>IPF not funded by the sponsor</td>
</tr>
<tr>
<td>Funded</td>
<td>Awarded</td>
</tr>
</tbody>
</table>

For Internal Processing Forms You Initiated

The following instructions also apply if you are listed in the Investigators/Research Team tab in any role.

1. From the Proposal Dashboard, open the My Proposals tab.
2. Select the Submitted Proposals tab if the IPF has already been submitted to the Clinical Trials Contracts Office.
3. Search for the IPF by date created, Proposal Number, Principal Investigator’s name, Project Name, Sponsor Deadline or your role.
4. The IPF status will display in the last field (to the right).
5. To view the detailed status, open the relevant IPF by selecting the Proposal Number.
6. View the bottom of the Approvals tab.

7. View the Notes tab to see if there are any outstanding items.
For Internal Processing Form Initiated by Someone Else

If you are a Principal Investigator, key personnel or another contributing member in any role listed on the Investigators/Research Tab, you will have access to IPFs started on your behalf. However, if you are not key personnel, this will require the appropriate level of access. See the Role Manager in your department if you need access but do not have it.

1. From the Proposal Dashboard, open the Proposals in My Unit tab
2. Search for the IPF by date submitted, Proposal Number, Lead Principal Investigator, Project Name, Sponsor, Admin Unit or Status. (Note: This list may be filtered by multiple fields simultaneously.)
3. Follow Steps 4 to 7 above.
Awards

Quick Reference

1. View the status of an Award for a [IPF you initiated](#) or on which you are key personnel.
2. View the status of an Award for a [IPF initiated by a Principal Investigator or another department administrator](#) in your unit.
Submitting Award Modifications and Supplemental IPFs

For any Award modification (e.g., amendment, change in internal budget not requiring amendment, change in end date), send the e-mail request to the amendments analyst in the Clinical Trials Contracts Office with the following:

1. For Amendments – after final budget is negotiated with sponsor, e-mail the fully-editable amendment agreement and revised and approved UBT along with any e-mail chain identifying the sponsor contact for contract analyst to negotiate the amendment language (ensure the 700-U is updated in the eCOI system if there is an increase or any change to sponsor information)
2. For time extension/closeout – e-mail the new end date to the amendments analyst so that the analyst can advise if amendment is required
3. For an internal budget change only that does not require an amendment – e-mail the approved UBT to the amendments analyst (ensure the 700-U is updated in the eCOI system if there is an increase)

If an Award modification includes either of the following then a new Internal Processing Form (IPF) must be submitted for new approvals of the department chair and Dean.

1. Change in Principal Investigator
2. Change in Administrative Unit of the award (e.g., from Pediatrics to Internal Medicine)

Follow the steps above for Creating and Submitting IPFs with the following differences.

1. General Information (Note: Variation from Creating and Submitting IPFs)
   a. Short Title: Begin with [Action] instead of the submission deadline (e.g., “Change in PI” [Principal Investigator Last Name] [Sponsor])
   b. Proposal Type: New – UC Davis Health
   c. Select Save.
2. Budget
   a. Unless there is also a budget amendment, the budget should be $0.
3. Required documents
   a. Signed Clinical Trials Exception to Policy from new PI
   b. Editable amendment
   c. Signed UBT approved by Julie
   d. COI disclosures
   e. Please note, updated IRB approval will be required prior to award
Checking the Status of an Award

Award Status Definitions

<table>
<thead>
<tr>
<th>Status</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pending</td>
<td>The award is not fully executed</td>
</tr>
<tr>
<td>Active</td>
<td>The award has been fully executed and routed to Contracts and Grants Accounting</td>
</tr>
</tbody>
</table>

For Key Personnel and Others Listed on the Investigators/Research Team tab

1. From the Award Dashboard, open the My Awards tab.
2. Search for the Award by Project Number, Project Title, Lead Principal Investigator, Sponsor, etc. (Note: Filter this list by multiple fields simultaneously.)
3. The Award status is shown to the far right side of the screen.

4. Open the relevant Award by selecting the Award Number.
5. View the Notes tab to see if there are any outstanding items.
6. View the Documents tab to see the Award documents.

For Users with Award Data Access

If you are a Principal Investigator or key personnel, you will have access to IPFs started on your behalf and the associated Awards. However, if you are not a Principal Investigator this will require the appropriate level of access. See the Role Manager in your department if you need this access but do not have it.

1. From the Award Dashboard, open the Awards in My Unit tab.
2. Follow **Steps 2 to 6 above**.
Subawards/Subcontracts

Quick Reference
1. View the status of a Subaward/Subcontract for users listed on the Investigators/Research Team tab or on which you are key personnel.
2. View the status of a Subaward/Subcontract for users with Award Data Access in your unit.

Checking the Status of a Subaward/Subcontract

Subaward/Subcontract Status Definitions

<table>
<thead>
<tr>
<th>Status</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Awaiting) Admin Dept</td>
<td>Action is required by the Principal Investigator/department</td>
</tr>
<tr>
<td>(Awaiting) Award Mgr/Analyst</td>
<td>Action is required by the Award Analyst</td>
</tr>
<tr>
<td>(Awaiting) Subcontractor</td>
<td>Action is required by the Subcontractor/Subawardee</td>
</tr>
<tr>
<td>Fully Executed</td>
<td>The Subaward/Subcontract is fully executed and has been sent to CGA</td>
</tr>
</tbody>
</table>
For Key Personnel and Others Listed on the Investigators/Research Team Tab

1. From the Award Dashboard, open the My Awards tab.
2. Go to the Active Projects tab.
3. Search by Project Number, Project Title, Lead Principal Investigator, Sponsor, etc. (Note: Filter this list by multiple fields simultaneously.)

4. Select the Project Number associated with the Subaward/Subcontract.

5. Go the Subcontracts tab.
6. Select the Subcontract Number to view Subaward/Subcontract details.
   a. The Status is shown in the Subcontracts list.

7. View the Notes section for status updates from the Subawards team, including the name of the assigned analyst.

8. Go to the Documents tab to retrieve the fully executed Subaward document(s).
For Users with Award Data Access

If you are a Principal Investigator or key personnel, you will have access to IPFs started on your behalf and the associated Awards. However, if you are not a Principal Investigator this will require the appropriate level of access. See the Role Manager in your department if you need this access but do not have it.

1. From the Award Dashboard, open the Awards in My Unit tab.

2. Follow steps 2 to 7 above.
Resources

1. Handbook for Industry-Funded Clinical Trial Department Staff, Principal Investigators and Approvers: https://spark.ucdavis.edu/training/cayuse-end-users_ct-specific/
2. UC Davis Cayuse Landing Page: http://spark.ucdavis.edu/cayuse/
3. UC Davis Cayuse SP Training Schedule, Materials and User Guides: http://spark.ucdavis.edu/training
4. UC Davis Cayuse SP FAQs: http://spark.ucdavis.edu/spark-faq/#csp
5. UC Davis Cayuse Help Desk: ORCayuseHelp@ucdavis.edu
6. UC Davis Cayuse Listserv: https://lists.ucdavis.edu/sympa/subscribe/spark_info
7. Cayuse Support and Community: https://support.evisions.com/
Appendix

Clinical Trials Contracts Office Workflow Diagram
2. Online COI submission: [https://or-forms.ucdavis.edu/](https://or-forms.ucdavis.edu/)
3. Cayuse help: [ORCayuseHelp@ucdavis.edu](mailto: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 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
   - Service: Internal Budget, Sponsor Budget and Payment Terms, Service Agreement, and Protocol

CT Contracts Office (CTCO) 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; we can’t sign a contract until positive disclosures are approved by COI.
- **Negotiate the budget and all payment terms directly with the Sponsor/CRO.**
- **Complete your IPF and route for approval through Cayuse.** Please see the Handbook for instructions.
- **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).**
- **If IRB has not been approved, the contract will not be awarded.**
- **All final award documents will be available to download in Cayuse.**
- **If COI has not been completed, a positive disclosure has not been approved by COI, or if the PI hasn’t completed the COIR training, the contract will not be signed.**
- **Collect the PI’s signature and follow any signature instructions provided by the CTCO.**
- **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?**
- **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.**
- **Want to know if we’ve received your IPF? Just check Cayuse.**
- **Please contact the Cayuse team if you have any problems or questions regarding use of Cayuse.**
- **If you haven’t reviewed the contract, you’ll need to sign COI.** Cayuse help: ORCayuseHelp@ucdavis.edu
- **Submit sponsor budget, CTA, protocol, and draft UBT to Julie.**
- **Once the budget and payment terms have been negotiated, create an IPF in Cayuse. Collect your chair’s signature on the UBT, then submit your Cayuse proposal number, the final sponsor budget, payment terms, and signed UBT to Julie.**
- **CTCO will send the final IPF and route for approval through Cayuse. Please see the Handbook for instructions.**
- **Collect your chair’s signature on the UBT and notify the administrative contact in the CTCO that the budget documents have been approved.**
- **Julie will upload the approved UBT into Cayuse and will notify the administrative contact in the CTCO that the budget documents have been approved.**
- **Julie will provide feedback on the sponsor budget, payment terms, and draft UBT.**
- **Julie will upload the approved UBT into Cayuse and will notify the administrative contact in the CTCO that the budget documents have been approved.**

Sponsor initiated Clinical Trial and Clinical Service Workflow 02/2020