Cayuse SP – UC Davis

Handbook for Department Industry-Funded Clinical Trial Staff, Principal Investigators and Approvers

Table of Contents

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).
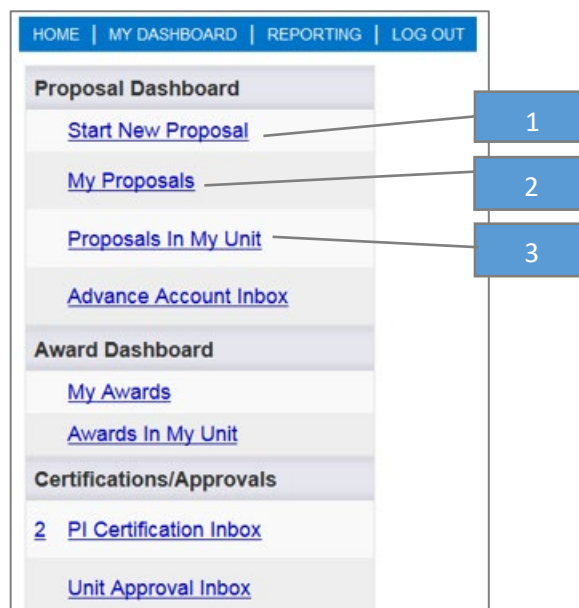
Cayuse SP Auto-generated Numbers

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.

>> Proposal Routing Status

Proposal No:	18-1140	Submission Deadline:	12/01/2017
Project No:		Proposal Specialist:	
Lead Investigator:	Kassie Obelleiro	Contract Specialist:	
Sponsor:	NIH National Institutes of Health Center for Scientific Review (Proposals Only--No Awards)	Account Manager:	
Project Title:	Actual title of the project		

View IPF

2.

| Approvals | Compliance | Status History | Advance Account | Awards | 📄 | 📎 |

2.a.

Please return this proposal to Unsubmitted status so the department may revise.

2.b.

Add Note

No notes have been added.

c. The added Note will display under Note.

>> Proposal Routing Status

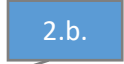|			
Proposal No:	18-1140	Submission Deadline:	12/01/2017
Project No:		Proposal Specialist:	
Lead Investigator:	Kassie Obelleiro	Contract Specialist:	
Sponsor:	NIH National Institutes of Health Center for Scientific Review (Proposals Only--No Awards)	Account Manager:	
Project Title:	Actual title of the project		

View IPF

| Approvals | Compliance | Status History | Advance Account | Awards | 📄 | 📎 |

Add Note

2.c.

Note	Recorded By	Date	Note Area	Category	Access
Please return this proposal to Unsubmitted status so the department ma...	Amie Admin	11/09/2017	Proposal	General	Admin Office All Parties

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.

Item List	18-1140	

View or Edit completed sections by clicking the name next to the check.

✔ General Information   **>>**
✔ Investigators/Research Team
✔ Budget
✔ Financial Conflicts of Interest in Research
✔ Regulatory Compliance
✔ Subrecipients
✔ Foreign Activity
✔ Special Interest
✔ Additional Questions
✔ Location of Sponsored Activities
✔ Proposal Abstract
✔ Proposal Attachments
✔ Approving Units
   Submission Notes   **5.**

Submit for Routing

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.

Activity Code	Definition
06 Other Service	Service activity.
07 Clinical Trial – Investigator Initiated	Self-explanatory.
08 Clinical Trial – Sponsor Initiated	Self-explanatory.
14 Other	Anything that does not fit Activity Codes 01-13.

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.

Instrument Type	Definition
Contract	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.
Non Monetary Agreement	An agreement that does not include money.
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")
11. F&A Rate(s) (determined by activity)
12. Are human subjects involved? If so, is there IRB protocol approval?
13. Location (i.e.; Building, laboratory, etc.) where the activities will occur
14. If there are outgoing subawards: Contact information for the Subawardees
15. Sponsor contact information – name and email address at a minimum for the person we are to negotiate the contract with

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/*)
7. Complete Principal Investigator Exception form, if applicable
8. Complete Exception to Policy for Clinical Study Contracts (https://www.ucdmc.ucdavis.edu/healthsystemcontracts/clinicaltrialscontracts/docs/exceptiontoPolicyforIntellectualProperty.pdf)

*These items, along with sponsor contact information, are **mandatory** for the Clinical Trial Contracts Office to begin review of any agreement.

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.**)
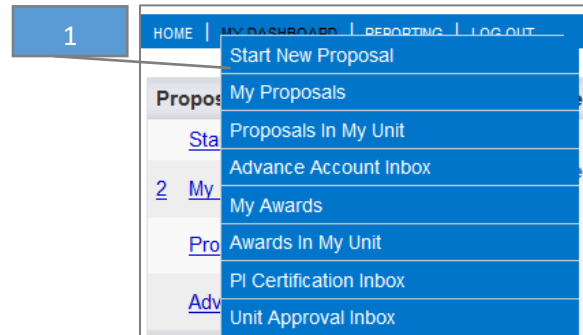
2. General information: Complete the fields indicated below.
   a. Sponsor: If the sponsor is not listed, select Miscellaneous Sponsor, type the Sponsor Name in Submission Notes (last step before routing) and follow Step 4 below.
   b. Admin Unit: Unit that will administer the grant.
   c. Short Project 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.*)

Item List   17-0190

View or Edit completed sections by
clicking the name next to the check.

✔   General Information   >>

Investigators/Research Team

Budget

Financial Conflicts of Interest
in Research

Regulatory Compliance

Subrecipients

Foreign Activity

Special Interest

Additional Questions

Location of Sponsored
Activities

Proposal Abstract

Proposal Attachments

Approving Units

Submission Notes

[Submit for Routing]

3.a.

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. (*Note: 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.

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 the Base amount for the 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.
4. **Do not enter anything in the Fee fields.**
5. Leave the Use Calculated Values box checked.

Budget Categories

		Current Period	Entire Project
SPONSOR DIRECT COSTS:		$ 0	$ 0
BASE for F&A Rate (1):		$ 0	$ 0
BASE for F&A Rate (2):		$ 0	$ 0
BASE for F&A Rate (3):		$ 0	$ 0
Use calculated values: ☑	**INDIRECT COSTS (F&A):**	$0	$0
	FEE:	$ 0	$ 0
Use calculated values: ☑	**TOTAL SPONSOR PROPOSED COSTS:**	$0	$0
	Internal Cost Sharing:	$0	$ 0
	Third-Party Cost Sharing:	$0	$ 0
	TOTAL PROJECT COSTS:	$0	$0

3.c.vi.1.
3.c.vi.2.
3.c.vi.3.
3.c.vi.4.
3.c.vi.5.

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* If there is additional cost sharing in subsequent years, the total may be reflected in the Institutional Cost Sharing value for the Entire Project.

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.

Additional Resources

* In addition to resources available in the administering unit (generally excluding recharge services), will you be using personnel, space, equipment or other resources? If yes, add them to the Investigator/Research Team page if possible. If not possible to add them there, mark yes and add them below.

◯ Yes   ◯ No

3.c.vii.

[Save]   [Reset]

3.c.viii.

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.

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

3.d.i.

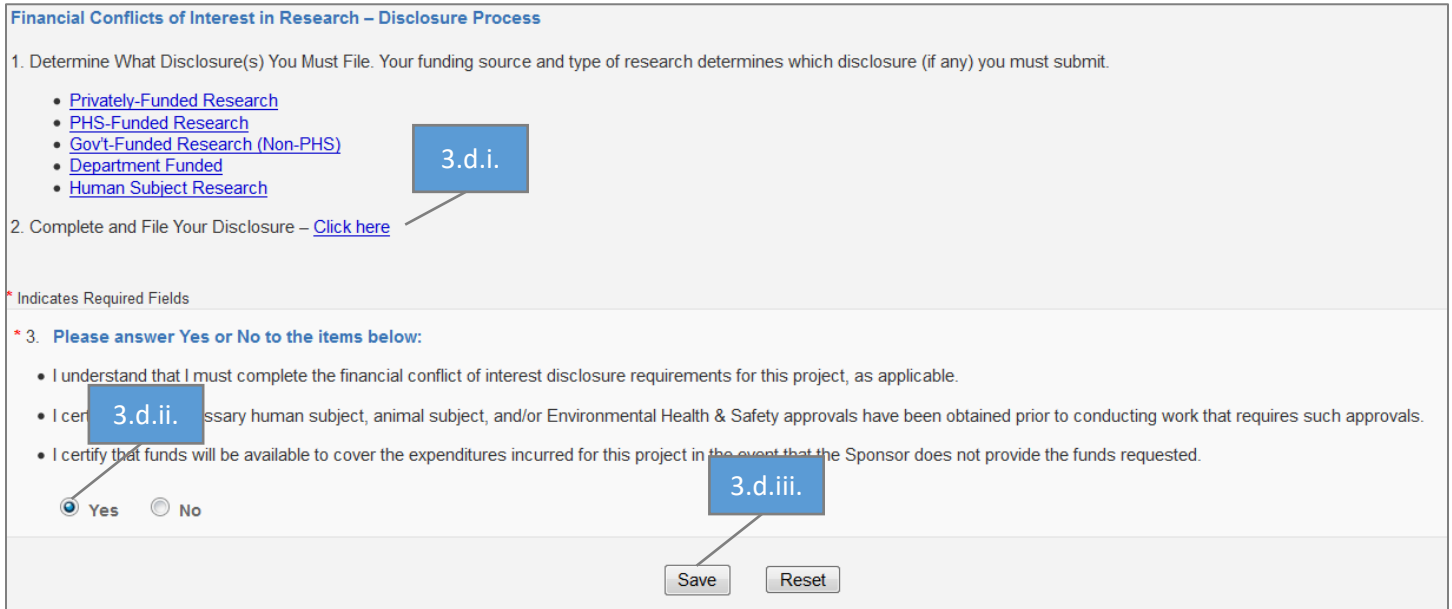2. Complete and File Your Disclosure – Click here

* 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 cer **3.d.ii.** ssary 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.

3.d.iii.

⦿ 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.

3.e.i.

* Does this research involve **HUMAN SUBJECTS?**
   ● Yes   ○ No

   * IRB applications must be submitted via IRBNet. Have you submitted an application to the IRB for this project?
   ● Yes   ○ No
   Please provide your IRBNet ID(s) below:

   List the application numbers below: (Note: Use commas to separate values)

3.e.ii.

Animal Subjects

* Does this research involve **VERTEBRATE ANIMALS?**
   ● Yes   ○ No

   * Has your research team submitted an application to the IACUC for this project?
   ● Yes   ○ No

      * List the application numbers below:

      * List the species involved with this project:
      If multiple species are involved, please use the comma as a separator.

3.e.iii.

Hazardous Research Materials

* Does the proposal involve research with any of the following? (please check all that apply)
   • When appropriate, provide the **BUA number(s)** as an attachment in the **Proposal Attachment** section.
   • If you would like more information on Biological Use Authorizations (BUAs), please visit the UC Davis BUA webpage.
   • Please note that the review process performed by the Biological Safety Office for submitted BUAs can take up to 8 weeks.
   • If you have any questions or concerns about **BUAs**, please email the **Biological Safety Office** at biosafety@ucdavis.edu.

   ☐ Chemical Hazards (flammable, pyrophoric & water reactive chemicals, oxidizing/reducing agents, poisons, carcinogens, etc.)
   ☐ Neuroxins/Select Agents (botulinum neurotoxins, botulinum neurotoxin-producing species of Clostridium, or preparations or pharmaceuticals containing botulinum neurotoxins, etc...)
   ☐ Biohazardous Materials (recombinant or synthetic nucleic acids, infectious agents, human or non-human primate cells, tissues, or body fluids)
   ☐ Nanomaterials
   ☐ Radioactive Materials
   ☑ None

3.e.iv.

[Save]   [Reset]

     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.*)

>> Subrecipients

If this proposal involves one or more Subaward(s) for which funds are requested, please add the Subaward entity(ies) below, and provide the following items with your proposal.

These items should be attached to your proposal (see Proposal Attachments page).

1. Subawardee's Statement of Work
2. Subawardee's Budget (including Budget Justification)
3. Letter of Commitment signed by Subawardee's Authorized Official
4. Commitment Form:

- Subrecipient Commitment Form; or
- FDP Subrecipient Pilot – Supplemental Project Information Sheet; or
- Multiple Campus (MCA) Commitment Form

5. For each anticipated subawardee, answer the following questions and include the responses in your documentation attachments for that subawardee:

- What was the basis for selection of this subawardee?
  (competitive solicitation or sole source based on unique qualifications, equipment, know how, or integral part of a collaborative research team)

- Will any of these subaward/subcontract relationships result in an agreement between the University and
  (1) a current University employee or
  (2) a current employee's near relative (i.e., spouse or registered domestic partner, or dependent children) or
  (3) an entity in which you or your near relative owns or controls or possesses a financial interest?
  (4) a former University employee?
  If the response to any question 1-4 is "yes", please complete the conflict of interest form and submit approved form to Sponsored Programs (applicable policy: UCD PPM 350-90).

NOTE: If no subawards are proposed, please click the No Subcontractors button to complete this section.

Add Subcontractor

Subcontractor: [   ] [3.f.i.1.]

[Add Subcontractor] [3.f.i.2.]

🔍

List of Subcontractors: (to edit the list, remove the entry and re-select)

There are no subcontractors added to the proposal

[No Subcontractors] [Reset]

---

              3. Select Authorize Subcontractor List.

Add Subcontractor

Subcontractor: [   ]

[Add Subcontractor]

🔍

List of Subcontractors: (to edit the list, remove the entry and re-select)

Subcontractor	
Agricultural Labor Relations Board	Remove

[3.f.i.3.]

[Authorize Subcontractor List] [Reset]

ii. If no subrecipients, select No Subcontractors.

>> Subrecipients

If this proposal involves one or more Subaward(s) for which funds are requested, please add the Subaward entity(ies) below, and provide the following items with your proposal.

These items should be attached to your proposal (see Proposal Attachments page).

1. Subawardee's Statement of Work
2. Subawardee's Budget (including Budget Justification)
3. Letter of Commitment signed by Subawardee's Authorized Official
4. Commitment Form:

   - Subrecipient Commitment Form; or
   - FDP Subrecipient Pilot – Supplemental Project Information Sheet; or
   - Multiple Campus (MCA) Commitment Form

5. For each anticipated subawardee, answer the following questions and include the responses in your documentation attachments for that subawardee:

   - What was the basis for selection of this subawardee?
     (competitive solicitation or sole source based on unique qualifications, equipment, know how, or integral part of a collaborative research team)

   - Will any of these subaward/subcontract relationships result in an agreement between the University and
     (1) a current University employee or
     (2) a current employee's near relative (i.e., spouse or registered domestic partner, or dependent children) or
     (3) an entity in which you or your near relative owns or controls or possesses a financial interest?
     (4) a former University employee?
     If the response to any question 1-4 is "yes", please complete the conflict of interest form and submit approved form to Sponsored Programs (applicable policy: UCD PPM 350-90).

NOTE: If no subawards are proposed, please click the No Subcontractors button to complete this section.

Add Subcontractor

Subcontractor: [   ]

[Add Subcontractor]

List of Subcontractors: (to edit the list, remove the entry and re-select)

There are no subcontractors added to the proposal

3.f.ii.

[No Subcontractors]   [Reset]

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.

>> Special Interest

3.i.i.

* Indicates Required Fields

* 1. Are Human Stem Cells involved in this proposal?
   ○ Yes   ⦿ No

* 2. Does this project involve scuba diving?
   ○ Yes   ⦿ No

* 3. Does this project involve operation of a boat?
   ○ Yes   ⦿ No

* 4. Does your proposal require acquisition of an HPC cluster or similar servers? If yes, please add a description on the Budget page under Additional Resources.
   ○ Yes   ⦿ No

* 5. Has the sponsor provided a draft agreement to fund this project? If so, please attach it on the Proposal Attachments page.
   ○ Yes   ⦿ No

* 6. Does this project involve Sustainability Research?
   ○ Yes   ⦿ No

* 7. Is this proposal an SBIR (Small Business Innovative Research Program) or an STTR (Small Business Technology Transfer Program)?
   NOTE: at least thirty percent (30%) of the work of the STTR must be performed at UC Davis.
   ○ Yes   ⦿ No

3.i.ii.

[Save]   [Reset]

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.

>> Additional Questions

3.j.i.

3.j.ii.

* Indicates Required Fields

* 1. Is this Proposal in response to a Limited Submission call?
  ○ Yes   ◉ No

* 2. Do you anticipate having to lease new space to complete the activity described in this proposal? If so, please include in the Additional Resources on the Budget page.
  ○ Yes   ◉ No

* 3. Does this Proposal anticipate use of a Garamendi facility?
  ○ Yes   ◉ No

* 4. Did this Proposal benefit from RISE and/or IFHA support?
  ○ Yes   ◉ No

* 5. Did this Proposal benefit from research generated from Academic Senate Faculty Grants (New Research Initiatives and Small Grants in Aid)?
  ○ Yes   ◉ No

6. Health Relatedness

3.j.iii.

Please indicate the primary area of health relatedness that applies to your proposal.

[Human Health ▼]

7. Please select additional areas that also describe your activity (check all that apply).

If you choose the primary area again in the drop-down list, that will be treated as "other".

☐ Companion Animal Health
☑ Food Animal Health
☑ Environmental Health
☐ Equine Health
☐ Food Safety
☐ Human Health
☐ Wildlife Health

3.j.iv.

[Save]   [Reset]

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%.*)

>> Location of Sponsored Activities

Please indicate the location(s) where your research will occur and assign a percentage to each location.

- Percentages should reflect the portion of budgeted salaries that will be expended in that location.
- Enter as many as apply in each quadrant below.
- Do not include subawardee locations on this page.

Note: If activities occur in a Davis or Sacramento campus facility, do not also add the state and country as separate locations.

The sum of percentages in all locations must equal 100%. It currently adds up to 0.00%. Please add or remove locations accordingly.

Campus Locations

If any sponsored activities occur on campus, please ent[ ]g and the percentage of work that will be done there.

Click Add after each entry.

| 3.k.i. |

Location: [   ]
Percent of Work: [   ]% [Add]

| 3.k.ii. |

There are no Campus Locations added to the proposal.

Use of ORUs, SRPs, Core Facilities, and ANR

Select below if proposal activities require use of or access to one or more Organized Research Units (ORU), Strategic Research Programs (SRPs), core facilities or ANR facilities (and ANR is not a subawardee). Provide the % of the project that will be physically conducted at each of these locations. If there will be no physical access or use, but the project or PI is affiliated with one or more of these unit(s), please identify these units and select 0%.

Location: [Select... ▾]
Percent of Work: [   ]% [Add]

There are no ORUs, SRPs, Core Facilities, or ANR resources added to this proposal.

Domestic Off-Campus Locations

If any sponsored activities occur within the United States but in buildings/locations not owned or leased by UC Davis, please enter each state and the percentage of work that will be done there.

- Subaward locations should not be entered here.
- Click Add after each entry.

Location: [Select... ▾]
Percent of Work: [   ]% [Add]

There are no Domestic Off-Campus Locations added to the proposal.

Out-of-Country Locations

If any sponsored activities occur outside the United States, please enter each country from the list below and the percentage of work that will be done there.

- Subaward locations should not be entered here.
- Click Add after each entry.

Location: [Select... ▾]
Percent of Work: [   ]% [Add]

There are no Out-of-Country Locations added to the proposal.

[Reset]

l. 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.

>> Proposal Abstract

* Indicates Required Fields

With your permission, this abstract will be used to help match faculty researchers with potential collaborators and funding resources and to help identify expertise and areas of research interests.

It may also be used to search key words in order to provide reports to UC Davis administrative offices regarding research on specific subjects.

The abstract should be plainly written and in sufficient detail to summarize the proposed activity. There is no need to write a special abstract for this purpose. The abstract or proposal summary for your proposal will be sufficient.

The abstract should not contain ANY institutional or sponsor proprietary information, such as description of a potentially patentable invention (e.g., a new and useful process, machine, article of manufacturing, composition of manufacture, or related improvements).

If so indicated below, [...] be available to the public--the public being defined as UC Davis personnel who have access to this proposal record.

* 1. I give permission to make [...] accessible:

[ ] Yes   [●] No

3.l.i.

* 2. Abstract:

3.l.ii.

N/A

3.l.iii.
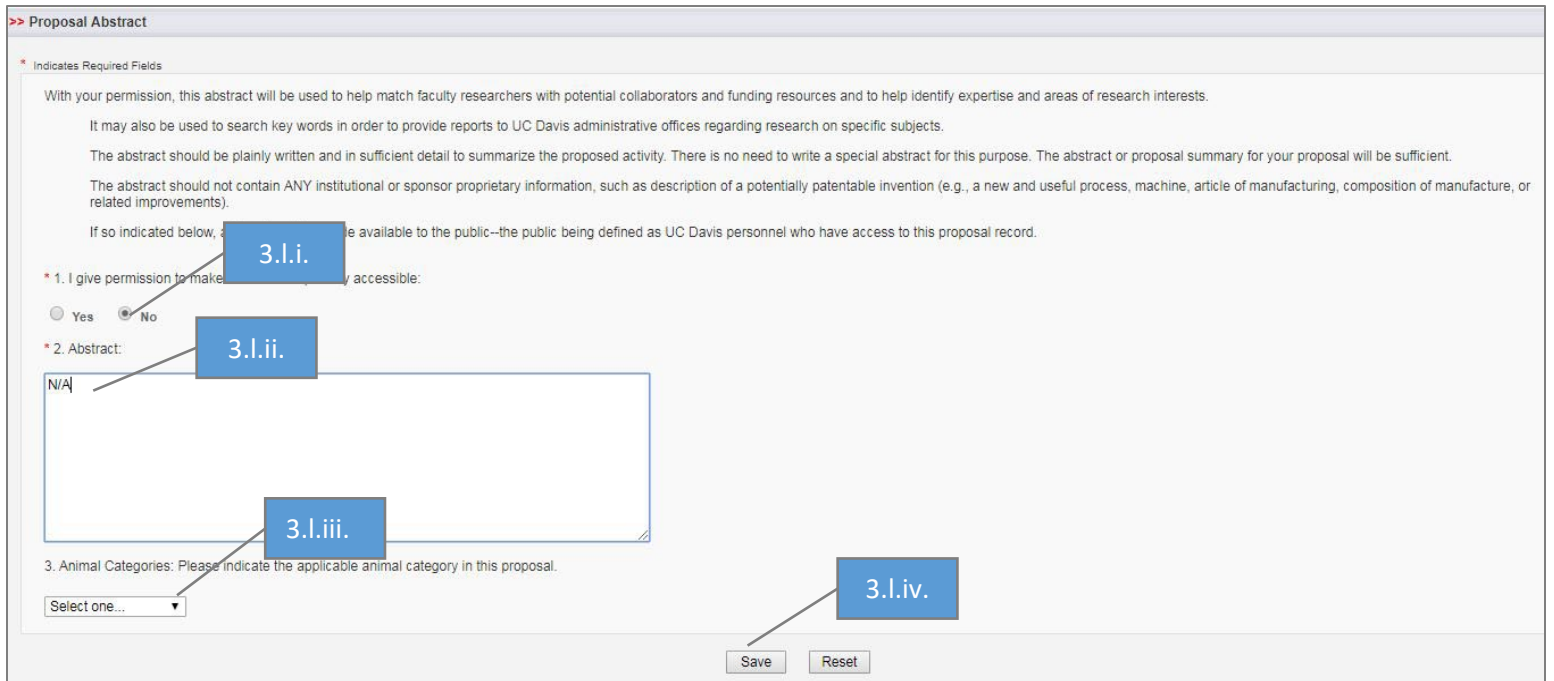
3. Animal Categories: Please indicate the applicable animal category in this proposal.

Select one... ▼

3.l.iv.

Save   Reset

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**

When applicable, please attach the following documents:

- Proposal Announcement Guidelines (RFP, RFA, etc.)
- Budget (in Excel)
- Form 800
- Subcontractor documentation (letter of commitment, budget, budget justification, scope of work)
- Representations & Certifications

For industry-sponsored clinical trials, please attach the following documents:

- Sponsor Protocol
- Final Sponsor Budget
- Final Internal Budget

Add Attachment

| | | 3.m.i.1. | 3.m.i.2. | 3.m.i.3. |

Click Browse to select a file: Browse... quick_reference_card.pdf

Document Type   Proposal Announcement Guidelines (RFP, RFA, etc.) ▼   Add   Reset

No attachments have been added.

No Attachments

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 is it 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 IPF is being routed to the School of Medicine, re-order it to after all School of Medicine units.*)
iv. Select Authorize Unit Listing.

o. 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. This is **MANDATORY**.
      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.*)

Please add any additional information that may be pertinent to processing this proposal.

Submission Note: 3.o.i.

This is a note.

3.o.ii.

Add Note

No notes have been added.

p. 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.

Item List   17-0043

>> Submission Confirmation

View or Edit completed sections by clicking the name next to the check.

3.p.i.

you wish to submit this Proposal Record?

✔ General Information
✔ Cayuse 424 Proposal
✔ Investigators/Research Team
✔ Budget
✔ Financial Conflicts of Interest in Research
✔ Regulatory Compliance
✔ Subrecipients
✔ Foreign Activity
✔ Special Interest
✔ Additional Questions
✔ Location of Sponsored Activities
✔ Proposal Abstract
✔ Proposal Attachments
✔ Approving Units
✔ Submission Notes

3.p.ii.

Submit for Routing

Clicking YES will do four things:

1. The Proposal Record will be locked and can no longer be edited (except by the Admin Unit);
2. The Proposal Record will be routed to all affiliated units for review and concurrence; should any of these units reject the Proposal Record you will be notified by email of the rejection and for what reason(s);
3. The PI(s) will be notified by email that they must certify the Proposal Record in Cayuse Sponsored Projects; and
4. Ultimately, the Proposal Record will arrive in SPO for final review and approval.

Throughout these steps you, your PI, and any other contributing members listed on the Proposal Record will be able to track its review and approval status in Cayuse Sponsored Projects.

Once all affiliated units have approved the Proposal Record, you will receive an email indicating that it was s... received in SPO. If the proposal can be electronically submitted then no further action is required on your part. However, if the Sponsor requires any part of the proposal be s... then any such copies, with original signatures as required, must be forwarded to SPO for a complete submission to be accomplished.

3.p.iii.

Yes   No

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 <u>require re-approval</u> from the IPF Approvers are:
    - o Budget Cost Share, Incorrectly Applied (match/in-kind) (not applicable to Clinical Trial Contracts)
    - o Effort Changed from Direct Charge to Cost-Share
    - o Key-personnel added to the project after routing to Clinical Trials Contracts Office
    - o Subawards added to the budget after routing to Clinical Trials Contracts Office
    - o Incomplete IPF/proposal (refer to Necessary Information and Documents)
    - o Other revisions representing a significant change in commitment of departmental and/or campus resources
- Minor revisions that <u>do not require re-approval</u> from IPF Approvers include, but are not limited to:
    - o Change in project title
    - o Change in project dates
    - o Edits to the abstract field
    - o 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

1. Go to My Proposals under My Dashboard.

HOME | MY DASHBOARD | REPORTING | LOG OUT

Propos	**1**
Start New Proposal	
My Proposals	
Proposals In My Unit	
Advance Account Inbox	
My Awards	
Awards In My Unit	
PI Certification Inbox	
Unit Approval Inbox	
Award Dashboard	Use
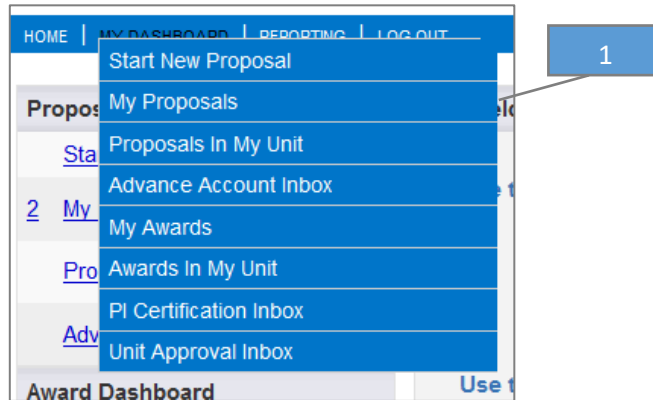
2. Select the PI Certification Inbox.

HOME | MY DASHBOARD | REPORTING | LOG OUT

Proposal Dashboard

Start New Proposal

My Proposals

Proposals In My Unit

Advance Account Inbox

Award Dashboard

My Awards

Awards In My Unit

Certifications/Approvals   **2**

2   PI Certification Inbox

Unit Approval Inbox
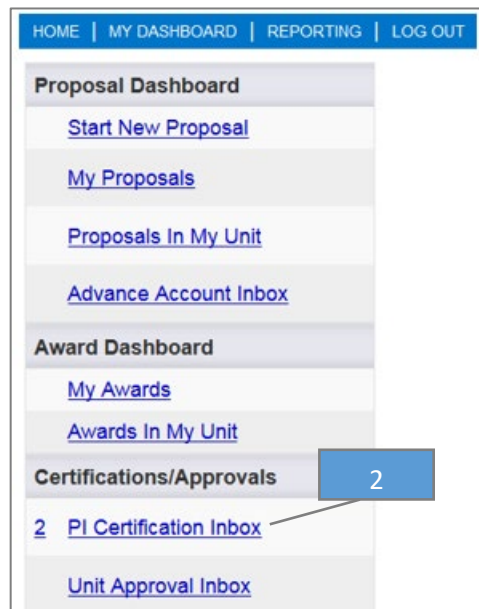
3. Select the appropriate Proposal Number.

To be Certified	Previously Reviewed

Below is a list of proposals that require your **3** s Lead or Principal Investigator.

Date Submitted ▼	Proposal No.	Project Name	Sponsor	Deadline	PDF
	17-0170	04/24/2017 Test kmo	Almond Board of California (Federal)	04/24/2017	📄

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.

| Approvals | Compliance | Status History | Advance Account | Awards |

Checking the Status of a Routed IPF
Internal Processing Form Status Definitions

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

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.

Approvals	Compliance	Status History	Advance Account	Awards		

The above propo[**6**]ccessfully submitted. All lead/principal investigators and approving units listed below have been notified and should electronically authorize (in routing order for units) this proposal bef[ ] by the UC Davis Sponsored Programs Office.

Investigator(s) who must certify this Proposal

Investigator	Role	Decision
Kassie Obelleiro	Lead Principal Investigator	Not Yet Reviewed

Unit(s) that must authorize this proposal

Order	Unit	Authorizing Person(s)	Authorizing Decision
1	Academic Assessment		Not Yet Reviewed
2	OVCR - Sponsored Programs	Dean Approver	Not Yet Reviewed
3	UC Davis Sponsored Programs Office	Admin Office	

Status History

Status	Person	Date
Changed to: Under Award Negotiation	Changed by: Bridget Strong	4/28/2017 12:34 PM
Changed to: Submitted to Sponsor	Changed by: Bridget Strong	4/28/2017 12:32 PM
Changed to: Submitted for Routing	Changed by: Kassie Obelleiro	4/28/2017 12:31 PM

6

7. View the Notes tab to see if there are any outstanding items.

General	People	Budget	Distributions	Proposals		

Add a Note

[text box]

Add Note

7

Notes List

Note Area Filter: Award ▼

Note	Recorded By	Date	Note Area	Category	Access
Received A, B, C and D. Received concurrence on E.	Grace Liu	04/26/2017	Award	General	Admin Office, All Parties
I request A, B, C and D. I need concurrence on E.	Grace Liu	04/26/2017	Award	General	Admin Office, All Parties

7

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.
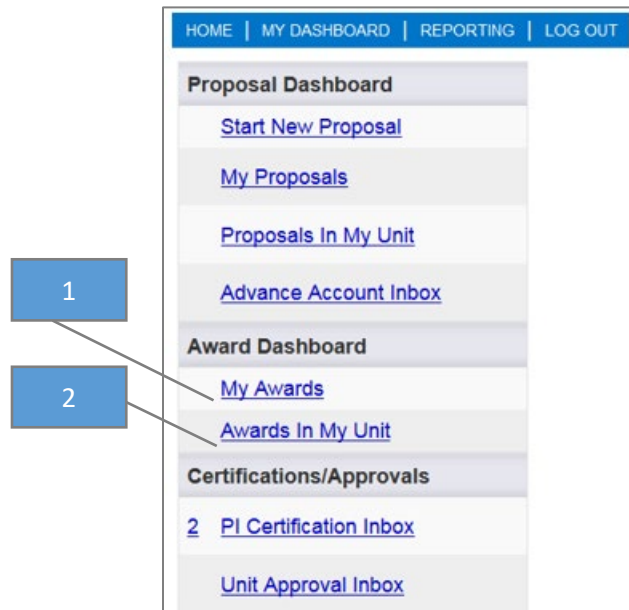
Submitting Award Modifications and Supplemental IPFs

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

Status	Definition
Pending	The award is not fully executed
Active	The award has been fully executed and routed to Contracts and Grants Accounting

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 <u>users listed on the Investigators/Research Team tab</u> or on which you are key personnel.
2. View the status of a Subaward/Subcontract for <u>users with Award Data Access.</u> in your unit.
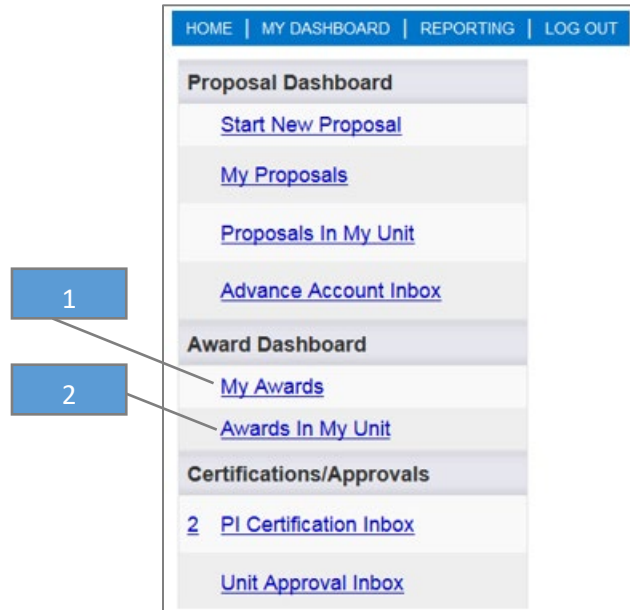
Checking the Status of a Subaward/Subcontract

Subaward/Subcontract Status Definitions

Status	Definition
(Awaiting) Admin Dept	Action is required by the Principal Investigator /department
(Awaiting) Award Mgr/Analyst	Action is required by the Award Analyst
(Awaiting) Subcontractor	Action is required by the Subcontractor/Subawardee
Fully Executed	The Subaward/Subcontract is fully executed and has been sent to CGA

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.

Project Administration

Project No:	A18-0020 (Prime Acct:)	Lead PI:	**Kassie Obelleiro**	Project Dates:	7/01/2017 – 6/30/2018	
Account Manager:				Total Anticipated:	$0.00	
Project Title:	060117 Test KMO			Total Obligated :	$0.00	

General | Awards | Budget Overview | Accounts | Personnel | Events | Proposals | Subcontracts | 📄 | 📎

Subcontracts for this project   **Add New Subcontract**

Subcontract No. ⇕		Account No.	Admin Unit	Status	FFATA Report Required	Organization	Sent Date	Execution Date	Total Dist.
A18-0020-S001	📄		Academic Assessment	Fully Executed	Yes	Agricultural Labor Relations Board	07/11/2017	07/19/2017	$200,000.00

View 1 - 1 of 1 |◄ ◄◄ Page 1 of 1 ►► ►|

6 → A18-0020-S001   **6.a.** → Fully Executed

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

>> Subcontract Administration

Subcontract No:	A18-1255-S002	(View Project)	FDP Templates:	📄
Subcontract Type:	Original		Amount:	$0.00
Status:	(Awaiting) Subcontractor		Last Updated:	2/15/2018 12:00 AM - Kimberly Smith
Project Title:	Preventing Firearm Violence: An Evaluation of Urban Blight Removal in High Risk Communities.		Primary Admin Contact:	Pamela Keach

General | Events | 📄 | 📎

7

[text box]   Add Note

Note	Recorded By	Date	Note Area	Category	Access
03/01/2018 - Initial Sub at Case pending signature - follow up query	Kimberly Smith	03/01/2018	Subcontract	General	Admin Office All Parties
02/15/2018 - Initial Sub sent to Case - pending signature	Kimberly Smith	02/15/2018	Subcontract	General	Admin Office All Parties
02/01/2018 - Subaward in queue/process/drafting	Kimberly Smith	02/01/2018	Subcontract	General	Admin Office All Parties
02/01/18 - Assigned K. Smith	Paula Noble	02/01/2018	Subcontract	General	Admin Office All Parties

8. Go to the Documents tab to retrieve the fully executed Subaward document(s).

>> Subcontract Administration

Subcontract No:	A18-0020-S001	(View Project)	FDP Templates:	📄
Subcontract Type:	Original		Amount:	$200,000.00
Status:	Fully Executed		Last Updated:	7/08/2017 11:24 AM - Kassie Obelleiro
Project Title:	060117 Test KMO		Primary Admin Contact:	

General | Events | 📄 | 📎   **8**

Add Attachment   **7**

Click Browse to select a file: [Browse...] No file selected.
Document Type   [Select Document Type ▼]   [>> Next] [Reset]

Attachment	File Type	Upload Type	Attachment Type	Access
Fully Executed Subaward.pdf Uploaded by:Kassie Obelleiro On:07/08/2017 At:11:25 AM	01 Fully Executed- Sub Initial	Admin Office	Award Subcontract	All Parties ❌

8

For Users with Award Data Accesss

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

Clinical Trial Amendment Chart for Department Administrators