Training Outline

• Overview of Cayuse SP
• Getting Started with a Clinical Trial Request
• Cayuse SP Hands-on Lab
  • Entering and Submitting a Clinical Trial Request for Review and Approval
• Demo: Certifying a Clinical Trial Request
• Returning of a Clinical Trial Request for Correction
• Q&A
• Resources
Overview of Cayuse SP
What is Cayuse SP?

• Launched for proposal submission to Sponsored Programs January 1, 2018

• New method for submitting Clinical Trial Requests effective upon notice from the Clinical Trials Contracts Office

• Online Routing
  • Principal Investigator
  • IPF Approver(s)
  • Admin Office Review and Approval
    • Sponsored Programs
    • Clinical Trials Contracts Office
What Does This Mean?

• No more Data Sheets and “wet” signatures
• Submit all materials for review electronically
• Can view the status of Clinical Trials requests online
• Can submit requests while out of the office
Getting Started with a Clinical Trial Request

• Review the *Handbook for Industry-Funded Clinical Trial Department Contract & Grant Staff, Principal Investigators and Approvers*: [http://spark.ucdavis.edu/training/cayuse-end-users_ct-specific/](http://spark.ucdavis.edu/training/cayuse-end-users_ct-specific/)

• Ensure your Unit is set-up
  • View Research Contacts from [https://ucdavis.cayuse424.com](https://ucdavis.cayuse424.com)
  • Ensure an IPF Approver is listed

• Have the complete Clinical Trial request ready

• Complete **all** applicable IPF fields
  • Even if not marked with a red *
Cayuse SP Lab

- Starting/Submitting a Clinical Trial Request
- Certifying a Clinical Trial Request (PI)
Lab Ground Rules

• Use Mozilla Firefox
• Login to the testing site
  • Do NOT go to the live site
• Login as the fake user (on next slide)
  • Do NOT login as yourself
• Use the fake PI (Charlie Apple)
  • Do NOT select real PIs
• Stay on the same tab as the group/instructor
  • Do NOT skip ahead
• Remember this is the testing environment
  • Do NOT check unit role assignments
  • Do NOT look for investigators or other users
Log-in to Cayuse SP
Following instructions on the Lab Exercise Handout

1. Login to https://ucdavis-uat.cayuse424.com with the following information.
   a. User name: amieadmin
   b. Password: catcat
2. Select Cayuse SP.
3. Select Start a New Proposal from the Dashboard
4. Complete the General tab:
   a. Sponsor: Merck & Co Inc
   b. Skip the rest of the fields in the Sponsor Information section
   c. Admin Unit: Med: Psychiatry & Behavioral Science
   d. Primary Admin Contact: Amie Admin
   e. Short Project Number: 123456 (Note: This is where you enter the Protocol Number.)
   f. Activity Code: 07 Clinical Trial – Investigator Initiated
   g. Proposal Type: New – UC Davis Health (Note: You will always select this for anything going to the Clinical Trials Contracts Office for review and approval.)
   h. Instrument Type: Contract
   i. Submission Deadline: Current Date
      i. Skip Submission Deadline Time
   j. Skip Submission Method
   k. Title of Project: 123456 Ambien Trial (Note: The Protocol Number auto-populates. Enter the Protocol title after the number.)
   l. Do not Pair
   m. Select Save
5. Complete the Investigators/Research Team tab
   a. Add the Lead Principal Investigator (PI)
      i. Name: Charlie Apple
      ii. Person Months: 0.36
         iii. Change the Home Unit to Med: Psychiatry & Behavioral Science
      iv. Role: Lead Principal Investigator
      v. Sponsored Effort: 3%
      vi. Cost Shared Effort: 0% or skip
      vii. Allocation of Credit: 100%
      viii. Select Save Personnel
   b. Add Amie Admin (Note: In a real request, you would add yourself here so that you may access the associated Award when it is entered.)
      i. Name: Amie Admin
      ii. Person Months: 0
      iii. Home Unit: May remain the same unless inaccurate (Skip)
      iv. Role: Proposal Editor
      v. Sponsored Effort: 0%
      vi. Cost Shared Effort: 0% or skip
      vii. Allocation of Credit: 0%
      viii. Select Save Personnel
Clinical Trial Request: General tab

- Select Start a New Proposal from the Dashboard
- Complete the *applicable fields on the* General Information page
  - Sponsor: Select “Miscellaneous Sponsors” if the sponsor is not listed
    - **Do NOT** select No Sponsors
  - Admin Unit: **Do not** select a Unit listed with a parenthesis at the end; instead follow the instructs in the parenthesis
    - Example:
      | Code  | Description                                      |
      |-------|-----------------------------------------------|
      | 20    | Med: Intl Med *(Use the PIs Int Med Dept.)*    |
      | 049207| Med: Intl Med- Cardiovascular *(Use 049205)*   |
    - For Code 20: Find and select the PI’s Internal Med Department
    - For Code 049207: Find and select code 049205
Clinical Trial Request: General tab

**Sponsor Information**

- **Sponsor:** Merck & Co Inc
- **Funding Opportunity/Sponsor application No:**
- **Sponsor Program Name:**
- **Proposal Guideline URL:**
- **Prime Funding Agency:**

**General Proposal Information**

- **Admin Unit:** Med: Psychiatry & Behavioral Sci
- **Primary Administrative Contact:** Amie Admin
- **Project No:**
Clinical Trial Request: General tab

- Short Project Name: ALWAYS Protocol Number
  - Internal Identifier
- Project Start and End Dates: Should match the UBT
- Proposal Type: ALWAYS “New – UC Davis Health”
- Submission Deadline: Select the current date
- Submission Type: Skip
- Title of Project: ALWAYS “Protocol # - Full Protocol Title”
- DO NOT “Create a Paired Proposal” or “Pair with a 424 Proposal”
- Select Save
Clinical Trial Request: General tab

- **Short Project Name:** 123456
- **Project Start Date:** 08/01/2018
- **Project End Date:** 08/31/2019
- **Activity Code:** Click Here to Choose Activity Code
  08 Clinical Trial - Sponsor Initiated
- **Proposal Type:** New - UC Davis Health
- **Instrument Type:** Contract

How will this proposal be submitted?
- **Select Submission Method:** ...

Affiliated Unit(s) (if applicable):
- Click Here to Choose Affiliated Unit(s)

- **Sponsor Deadline:** 06/08/2018
- **Title of Project:** 123456 Ambien Trial

Create a Paired Proposal  Pair with a 424 Proposal  Un-Pair with 424 Proposal

Save
Clinical Trial Request: Investigators/ Research Team tab

• Drives the Approving Units list
  • Will route to approval by IPF Users of the listed units
  • Unless a person is given the Proposal Editor or Other Participant – Not Routing role

• Lead Principal Investigator and Principal Investigator must certify the IPF

• Person Months: If unknown, use the link to calculate

• Sponsored Effort: Effort being charged to this proposal

• Cost Shared Effort: Not Applicable

• Allocation of Credit: “Intellectual” credit for reporting purposes
  • Must equal 100% across all key personnel
  • Lead Principal Investigator determines the allocation
Clinical Trial Request: Investigators/ Research Team tab

- ✔ Add all Key Personnel (anyone submitting a Form 800)
- ✔ Ensure their Unit is correct
- ✔ Follow the instructions in “()” after the unit name
  - ✔ Generally – select the unit code listed in “()”
- ✔ Add those needed edit access as a Proposal Editor
- ✔ Add yourself as a Proposal Editor so you can access the “Award” – Funded Agreement

- ✗ Do not add all project personnel
- ✗ Do not just assume the default unit is correct
- ✗ Do not select a “Non Admin/Home” unit
- ✗ Do not include a unit with language such as “(Use ######)”
Clinical Trial Request: Investigators/Research Team tab
Clinical Trial Request: Budget tab

- **Budget**
  - Select the Summary form
  - The Sponsor Direct Costs should match the UBT
  - The F&A Base(s) should be the same as Sponsor Direct Costs
  - Do not enter anything the Fee field
  - Uncheck “Use Calculated Values” if calculations are incorrect due to rounding
  - Select Save
Clinical Trial Request: Budget tab

<table>
<thead>
<tr>
<th>Overview</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Budget Form:</strong></td>
</tr>
<tr>
<td><strong>Select one of the above:</strong></td>
</tr>
<tr>
<td><strong>Project Dates:</strong></td>
</tr>
<tr>
<td><strong>Start:</strong></td>
</tr>
<tr>
<td><strong>End:</strong></td>
</tr>
</tbody>
</table>

| Comments: | (512 chars max) |

<table>
<thead>
<tr>
<th>Cost Sharing</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Does this proposal include funds or contributions in the form of required cost sharing or required cash matching?</td>
</tr>
<tr>
<td>For Internal Cost Sharing: please select <strong>Int'l Cost Sharing</strong> as the unit, enter the total amount of all internal cost sharing for the Period and then for Project Total and upload the cost sharing commitment letter(s) in Proposal Attachments.</td>
</tr>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>F&amp;A Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Current Period</strong></td>
</tr>
<tr>
<td>F&amp;A Rate (1):</td>
</tr>
<tr>
<td>F&amp;A Rate (2):</td>
</tr>
<tr>
<td>F&amp;A Rate (3):</td>
</tr>
</tbody>
</table>

| * Use calculated values: | ✓ |
| * Effective Rate: | 26 % | 26 % |

* The Effective Rate is for reporting purposes. To report different rates than those calculated, uncheck the box and enter the percentage values.
### Clinical Trial Request: Budget tab

#### Budget Categories

<table>
<thead>
<tr>
<th>SPONSOR DIRECT COSTS:</th>
<th>Current Period</th>
<th>Entire Project</th>
</tr>
</thead>
<tbody>
<tr>
<td>BASE for F&amp;A Rate (1):</td>
<td>$250,000</td>
<td>$250,000</td>
</tr>
<tr>
<td>BASE for F&amp;A Rate (2):</td>
<td>$25,000</td>
<td>$25,000</td>
</tr>
<tr>
<td>BASE for F&amp;A Rate (3):</td>
<td>$0</td>
<td>$0</td>
</tr>
</tbody>
</table>

Use calculated values: ✅

**INDIRECT COSTS (F&A):**

<table>
<thead>
<tr>
<th>FEE:</th>
<th>Current Period</th>
<th>Entire Project</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>$6,500</td>
<td>$6,500</td>
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<tr>
<td></td>
<td>$0</td>
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</table>

Use calculated values: ✅

**TOTAL SPONSOR PROPOSED COSTS:**

<table>
<thead>
<tr>
<th>Internal Cost Sharing:</th>
<th>Current Period</th>
<th>Entire Project</th>
</tr>
</thead>
<tbody>
<tr>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Third-Party Cost Sharing:</th>
<th>Current Period</th>
<th>Entire Project</th>
</tr>
</thead>
<tbody>
<tr>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
</tbody>
</table>

**TOTAL PROJECT COSTS:**

<table>
<thead>
<tr>
<th>Current Period</th>
<th>Entire Project</th>
</tr>
</thead>
<tbody>
<tr>
<td>$256,500</td>
<td>$256,500</td>
</tr>
</tbody>
</table>

#### 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
- [x] No

[Save] [Reset]
Clinical Trial Request: Financial Conflicts of Interest tab

- Financial Conflicts of Interest in Research
  - Complete the applicable COI Disclosures online now or at a later time.
  - Select Yes to indicate that the PI has filed or will file the applicable COI Disclosures
  - 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

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 all 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]
Clinical Trial Request: Regulatory Compliance tab

- Regulatory Compliance
  - Human Subjects: Select yes and complete pop-up fields
  - Animal Subjects (not applicable to Clinical Trials Contracts Office)
  - Hazardous Material: Select any and all that apply
  - Select Save
Clinical Trial Request: Regulatory Compliance tab

**Human Subjects**

* 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: (Note: Use commas to separate values)

List the application numbers below:
123456, 215346

**Animal Subjects**

* Does this research involve **VERTEBRATE ANIMALS**?
  - [ ] Yes  
  - [ ] No

**Hazardous Research Materials**

* Does the proposal involve research with any of the following? (please check all that apply)

- If "Biohazardous Materials/Select Agents and Toxins" is selected, then a Biological Use Authorization (BUA) is likely required. Please provide the BUA number in the **Proposal Attachment** section.

- If you would like more information on Biological Use Authorizations (BUAs), please visit the [UC Davis BUA webpage](https://www.ucdavis.edu/bua/) or contact the Biological Safety Office at biosafety@ucdavis.edu.

- Please note that the review process performed by the Biological Safety Office and the Institutional Biosafety Committee can take up to eight weeks.

- Biohazardous Materials/Select Agents and Toxins (recombinant or synthetic nucleic acids, infectious agents, and human or non-human primate cells, tissues or body fluids) / (https://www.selectagents.gov/SelectAgentsandToxinsList.html)

- Chemical Hazards (flammable, pyrophoric & water reactive chemicals, oxidizing/reducing agents, poisons, carcinogens, etc.)

- Human Anatomical Tissues or Specimens (requires preapproval from Anatomical Materials Review Committee (AMRC))

- Nanomaterials

- Radioactive Materials

- [ ] None

[Save]  [Reset]
Clinical Trial Request: Subrecipients tab

- **Subrecipients**
  - If there are outgoing subawards
    - Enter all (outgoing) Subawardees
    - Select “Miscellaneous Sponsors” if not listed
    - Select Authorize Subcontractor list
  - If there are none
    - Select No Subcontractors

```
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

Reset
```
Clinical Trial Request: Foreign Activity tab

- When in doubt, select yes
- Select Save

* Indicates Required Fields

1. Does the project involve conducting proprietary research with a potential military application?
   - Yes
   - No

2. Does the project involve:
   a. Sending, transporting, transmitting, or carrying any material or equipment outside the United States (examples include: computers, GPS, biologicals, diagnostic kits, reagents, or data)?
      - Yes
      - No
   b. Travel outside the US by any research personnel? If the answer is yes, please attach a list of destination countries at the attachments tab on your proposal.
      - Yes
      - No
   c. Importing, exporting, or transmitting any goods, services, technology, or funds to or from (or travelling to) any of the countries from the OFAC list (including, but not limited to Iran, North Korea, Syria, Libya, and Cuba)?
      - Yes
      - No

3. Some types of research may have export control implications even if all work is conducted within the U.S.

   Do you anticipate that the project work may involve:
   a. Non-commercial encryption or information security software?
      - Yes
      - No
   b. Any equipment, technology, materials or software specifically designed, modified, or adapted (even slightly) for a military purpose or that may involve national security?
      - Yes
      - No
   c. Any classified materials, equipment, technology or data?
      - Yes
      - No
Clinical Trial Request: Special Interest tab

- Special Interest
  - Answer all question and select Save
    - Note: Question 5 should be answered yes

```
>> Special Interest

* 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
```

Save  Reset
Clinical Trial Request: Additional Questions tab

- Additional Questions
  - Answer all questions and select Save

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is this Proposal in response to a Limited Submission call?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>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</td>
<td>Yes, No</td>
</tr>
<tr>
<td>3. Does this Proposal anticipate use of a Garamendi facility?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>4. Did this Proposal benefit from RISE and/or IFHA support?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>5. Did this Proposal benefit from research generated from Academic Senate Faculty Grants (New Research Initiatives and Small Grants in Aid)?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>6. Health Relatedness</td>
<td>Human Health</td>
</tr>
</tbody>
</table>

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
Clinical Trial Request: Location tab

- Location of Sponsored Activities
  - On-campus Locations: Sacramento and Davis campus buildings; most campus leased buildings as well
  - Must total 100% across all quadrants
  - Do not enter location of Subawardee(s)
Clinical Trial Request: Proposal Abstract tab

- Proposal Abstract
  - Select “No” to sharing
  - Abstract: Type “N/A”
  - Select Save
Clinical Trial Request: Proposal Attachments

- Sponsor budget: Include “sponsor budget” in the file title/document name
- Internal budget (UBT): Include “internal budget” in the file
- Protocol
- Editable Draft Agreement (as a Word document)
- If there are subawards: Budget, subrecipient monitoring form and subrecipient commitment form
- Complete Exception to Policy for Clinical Study Contracts (https://www.ucdmc.ucdavis.edu/healthsystemcontracts/clinicaltrialscontracts/docs/exceptiontoPolicyforIntellectualProperty.pdf)
- Complete Principal Investigator Exception form (https://research.ucdavis.edu/wp-content/uploads/Form-105_2018.pdf), if applicable
- Appropriate compliance forms (Form 800 and 700U) should be filed in the eCOI Online Disclosure System (https://or-forms.ucdavis.edu/)
Clinical Trial Request: 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
- Editable Agreement
- Exception to Policy

Add Attachment

Click Browse to select a file: [Choose File] No file chosen

Document Type: [Select Document Type]
Clinical Trial Request: Proposal Attachments

<table>
<thead>
<tr>
<th>Attachment</th>
<th>File Type</th>
<th>Upload Type</th>
<th>Attachment Type</th>
<th>Access</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponsor_Budget.docx</td>
<td>Budget (UCD Health)</td>
<td>IPF</td>
<td>Proposal</td>
<td>All Parties</td>
</tr>
<tr>
<td>Exception to Policy.docx</td>
<td>Other</td>
<td>IPF</td>
<td>Proposal</td>
<td>All Parties</td>
</tr>
<tr>
<td>Editable Agreement.docx</td>
<td>Agreement (UCD Health)</td>
<td>IPF</td>
<td>Proposal</td>
<td>All Parties</td>
</tr>
<tr>
<td>Internal Budget.pdf</td>
<td>Internal Budget</td>
<td>IPF</td>
<td>Proposal</td>
<td>All Parties</td>
</tr>
<tr>
<td>Sponsor_Protocol.docx</td>
<td>Protocol (UCD Health)</td>
<td>IPF</td>
<td>Proposal</td>
<td>All Parties</td>
</tr>
</tbody>
</table>
Clinical Trial Request: Approving Units

• Review for Accuracy
  • The only “Non Admin/Home” units that are OK will indicate as a “roll up”

• Reorder as needed
  • Keep as many at level 2 as possible
  • If Admin Unit in SVM
    • School of Veterinary Medicine (Unit Code: 50) should be listed last
  • If Admin Unit is not in SVM but Investigators in SVM
    • School of Veterinary Medicine (Unit Code: 50) should be listed after all participating SVM units
  • If Admin Unit in SOM
    • School of Medicine (Unit Code: 43) should be listed last
  • If Admin Unit is not in SOM but Investigators in SOM
    • School of Medicine (Unit Code: 43) should be listed after all participating SOM units
Clinical Trial Request: Approving Units

The units listed below will be notified to authorize this proposal record. Please be certain every unit and/or campus resource involved with or used by this proposal is listed on this screen before submitting the proposal record for routing. Failure to include all affected resources/units may result in the necessity of rerouting for approvals.

OR

One of the following offices will authorize this proposal on behalf of the University. Do not add them as approving units.

- Sponsored Programs Office
- Office of Clinical Trials, School of Medicine
- Office of Graduate Studies

<table>
<thead>
<tr>
<th>Routing Order</th>
<th>Unit Code</th>
<th>Unit</th>
<th>Role(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>049205</td>
<td>Med: Int Med: Cardiovascular</td>
<td>Admin Unit, Rollup From 049205</td>
</tr>
<tr>
<td>2</td>
<td>049038</td>
<td>Med: Psychiatry &amp; Behavioral Science</td>
<td>Lead Principal Investigator, Rollup From 049205</td>
</tr>
<tr>
<td>2</td>
<td>20</td>
<td>Med: Int Med (Use the PI's Int Med Dept.)</td>
<td>Rollup From 20, Rollup From 049038</td>
</tr>
<tr>
<td>3</td>
<td>43</td>
<td>School of Medicine (Use 040000)</td>
<td></td>
</tr>
</tbody>
</table>

Authorize Unit Listing
Clinical Trial Request: Submission Notes tab

- Submission Notes
  - Sponsor name if selected “Miscellaneous Sponsors”
  - Sponsor contact information – address, contact, email and phone #
  - CRO contact information (if applicable) – name, address, contact, email and phone #
  - Subawardee contact information if selected “Miscellaneous Sponsors”
  - Any other notes
Clinical Trial Request: Submitting for Routing

• Submit for Routing
  • If someone other than the PI creates/edits the proposal, it is advised the PI perform this step then Certify the proposal

• Will Route for Certification and Approval
  • Principal Investigator
  • IPF Approver(s): Department and/or Dean, if applicable
  • Clinical Trials Contracts Office
Clinical Trial Request: Submitting for Routing

Check the Authorizing Person() list

No name under Authorizing Person = Trouble
Demo: Checking the Status and Certifying an IPF
# Cayuse SP IPF Statuses

<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>Proposal reopened for department to edit</td>
</tr>
<tr>
<td>Withdrawn</td>
<td>Proposal withdrawn by the Principal Investigator</td>
</tr>
<tr>
<td>Not Funded</td>
<td>Proposal not funded by the sponsor</td>
</tr>
<tr>
<td>Funded</td>
<td>Awarded</td>
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</table>
Clinical Trial Request: Submitting for Routing

<table>
<thead>
<tr>
<th>Proposal No:</th>
<th>10-3848</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project No:</td>
<td></td>
</tr>
<tr>
<td>Lead Investigator:</td>
<td>Charlie Angle</td>
</tr>
<tr>
<td>Sponsor:</td>
<td>Merci &amp; Co Inc</td>
</tr>
<tr>
<td>Project Title:</td>
<td>123456 Ambien Trial</td>
</tr>
</tbody>
</table>

**Proposal Routing Status**

**Proposal No:** 10-3848  
**Submission Deadline:** 6/30/2018  
**Proposal Specialist:**  
**Contract Specialist:**  
**Account Manager:**

The above proposal has been successfully submitted. All lead/principal investigators and approving units listed below have been notified and should electronically authorize (in routing order for units) this proposal before it is received by the UC Davis Sponsored Programs Office.

**Investigator(s) who must certify this Proposal**

<table>
<thead>
<tr>
<th>Investigator</th>
<th>Role</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Charlie Angle</td>
<td>Lead Principal Investigator</td>
<td>Certified on 06/11/2018 02:31 PM</td>
</tr>
</tbody>
</table>

**Unit(s) that must authorize this proposal**

<table>
<thead>
<tr>
<th>Order</th>
<th>Unit</th>
<th>Authorizing Person(s)</th>
<th>Authorizing Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Med: Psychiatry &amp; Behavioral Science</td>
<td>Jerry Elder, Robert Hales, Sally Cormanoff, Matt Nguyen</td>
<td>Not Yet Reviewed</td>
</tr>
<tr>
<td>2</td>
<td>Med: Intl Med: Hematology &amp; Oncol</td>
<td>Mary Klineck, Theodore Wun,</td>
<td>Not Yet Reviewed</td>
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<tr>
<td>3</td>
<td>Med: Intl Med (Use the PIs Int Med Dept.)</td>
<td>Timothy Alberson</td>
<td>Not Yet Reviewed</td>
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<tr>
<td>4</td>
<td>School of Medicine (Use 049000)</td>
<td>Anuwar Eldembeigh, Tammi Olmsted, Teresa Coats</td>
<td>Not Yet Reviewed</td>
</tr>
<tr>
<td>5</td>
<td>UC Davis Sponsored Programs Office</td>
<td>Admin Office</td>
<td>Not Yet Reviewed</td>
</tr>
</tbody>
</table>

**Status History**

<table>
<thead>
<tr>
<th>Status</th>
<th>Person</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Changed to: Submitted for Routing</td>
<td>Kassie Oballeiro</td>
<td>6/11/2018 02:29 PM</td>
</tr>
<tr>
<td>Changed to: Unsubmitted</td>
<td>Kassie Oballeiro</td>
<td>5/10/2018 03:16 PM</td>
</tr>
</tbody>
</table>
Certify a Clinical Trial Request

- View in PI Certification Inbox
- View the IPF or PDF
- Certify (this is the new way to “sign”)
- The Proposal will continue to route without PI certification
Certify a Clinical Trial Request

**PI Certification Inbox**

Below is a list of proposals that require your certification as Lead or Principal Investigator.

<table>
<thead>
<tr>
<th>Date Submitted</th>
<th>Proposal No.</th>
<th>Project Name</th>
<th>Sponsor</th>
<th>Deadline</th>
<th>PDF</th>
</tr>
</thead>
<tbody>
<tr>
<td>5/9/2018</td>
<td>18-3417</td>
<td>04/16/18 Obelleiro UC Berkeley NIH</td>
<td>UC Berkeley</td>
<td>04/16/2018</td>
<td></td>
</tr>
<tr>
<td>4/06/2018</td>
<td>18-3419</td>
<td>123117 Obelleiro UC Berkeley NIH</td>
<td>UC Berkeley</td>
<td>12/29/2017</td>
<td></td>
</tr>
</tbody>
</table>

**Proposal Routing Status**

Proposal No: 18-3417

Project No:  

Lead Investigator: Kassie Obelleiro

Sponsor: UC Berkeley

Project Title: Is it possible to have too much coffee?

[View IPF] [Certify Proposal] [Administer Proposal]
Returning a Clinical Trial Request for Correction

What Changes Require Re-approval

Process
What Requires Re-approval?

• The following items will result in the proposal being rejected and **re-routed for approval**
  • 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*)
    • Incorrect IPF Approvals/Authorizations
    • Complete all IPF Proposal tabs and fields, even when no red *
  • Other revisions representing a significant change in commitment of departmental and/or campus resources
Process for Revision and Re-approval

1. IPF returned to Unsubmitted status
2. Department/PI makes needed revisions
3. IPF Submitted for Routing
4. IPF Department/Dean Approvals
5. Clinical Trials Contract Office Assignment and Review
Resources and Help

• Handbook for Industry-Funded Clinical Trial Department Staff, Principal Investigators and Approvers: https://spark.ucdavis.edu/training/cayuse-end-users_ct-specific/

• UC Davis Cayuse Landing Page: http://spark.ucdavis.edu/cayuse/

• Help Guides and Videos: http://spark.ucdavis.edu/training/

• Cayuse Listserv: https://lists.ucdavis.edu/sympa/subscribe/spark_info

• Help Request: ORCayuseHelp@ucdavis.edu

• eRA Help: SPOeRAHelp@ucdavis.edu

• Cayuse Training Sessions: http://spark.ucdavis.edu/training/