UCI Undergraduate Research Opportunities Program

Research Protections Instructions

UC Irvine undergraduate students with human or animal subjects should consult with their UC Irvine Faculty Advisor to determine if Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) approval is needed. If you and your UC Irvine Faculty Advisor have questions after reading these instructions, please contact UROP for assistance: urop@uci.edu or (949) 824-4189.

Click on the headings below to learn more about each approval process:

- Institutional Review Board (IRB): Research Involving Human Subjects
- Institutional Animal Care and Use Committee (IACUC): Research Involving Animal Subjects

Institutional Review Board (IRB): Research Involving Human Subjects

Is my research project "Exempt" from IRB approval?

"Exempt" research involves **less than minimal risk to human subjects**. With some exceptions, UC Irvine Faculty Advisors, working together with their student researchers, may **self-determine** whether their research qualifies as "Exempt."

How can I determine if my research qualifies for "Exempt Self-Determination?"

Review the following links to determine whether your research qualifies for self-determination:

- UCI Office of Research: Do You Need IRB Review? A Quick-Start Guide
- UCI Office of Research: "Exempt" Categories

What should I keep in mind as I apply for a UROP award and determine IRB approval for my research project?

You will be following **two** parallel processes involving **both** the Undergraduate Research Opportunities Program (UROP) and the UCI Office of Research. Consider the following:

Steps You Need to Take for UROP	+	Steps You Need to Take for UCI Office of Research	
Verify in your online application the **status of your IRB process** by the deadline of the UROP award you are applying to (e.g., REF, IRT, or SURP). You will indicate on the UROP application if your project qualifies as "Exempt", already has IRB approval, or is undergoing IRB review.		Review the **Do You Need IRB Review?** information with your UC Irvine Faculty Mentor. Your Faculty Mentor will determine if the project qualifies as "Exempt."	
		If the project IS "Exempt:" Complete and submit the "Administrative Determination-Exempt Self-Determination" form and supplementary documents in ZOT IRB. **IRB approval is NOT required, but IRB registration is still needed *before you begin your research*.**	**If the project DOES NOT qualify as "Exempt:"** It must be added to an existing protocol or undergo an IRB review process and must be approved. **IRB approval IS required *before you begin your research*. Consult with your Faculty Mentor for guidance.**
		Note from UROP: IRB registration or approval is not required by the time you submit your application for the UROP award you're applying to (e.g., REF, IRT, or SURP). However, registration or approval is needed **before you begin your research**.	

My research qualifies for "Exempt Self-Determination" (i.e., IRB review and approval not required), what do I do next?

Self-determination is made by completing the "Administrative Determination-Exempt Self-Determination" form in **ZOT IRB.** ***Do not submit this form to UROP.***

Prior to completing the form in ZOT IRB, make sure you complete the PROTOCOL NARRATIVE – Exempt Research Self-Determination as this will need to be uploaded into ZOT IRB.

Complete the Protocol Narrative and ZOT IRB form with your UC Irvine Faculty Mentor's guidance to ensure all information is accurate. Follow the steps below:

1) Refer to the ZOT IRB Researcher's Guide for detailed instructions and screenshots for guidance on how to use ZOT IRB.
    a. Review the HRP Toolkit, which houses all critical-IRB related documentation in one place. Some new templates and information you will find are: User Guides & Manuals, Standard Operating Procedures (SOPs), and Principal Investigator Worksheets.

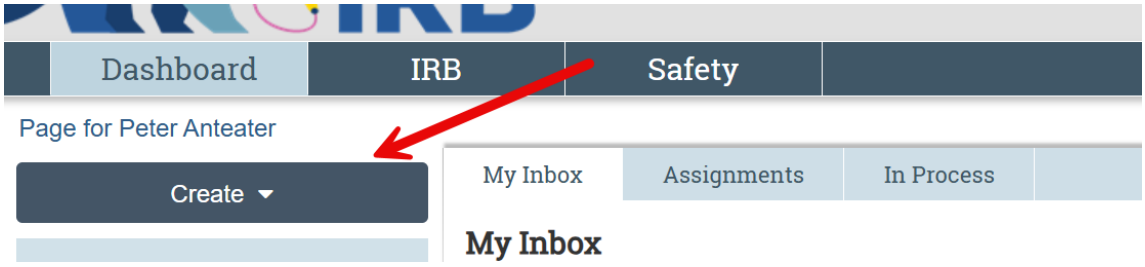
2) Log in to the ZOT IRB website using your UCInetID & password. You will then be on your Dashboard, which is the starting point for finding items and performing many basic tasks.

3) From your Dashboard, you will see:

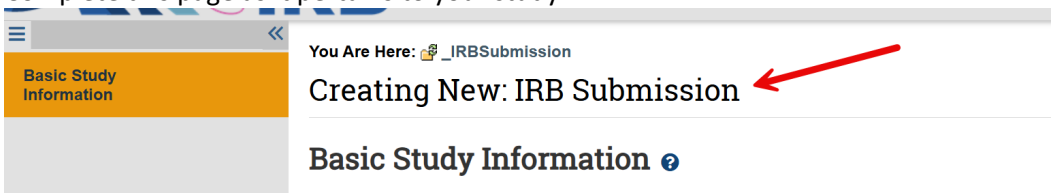
    - My Inbox
    - My Reviews
    - Create menu and buttons
    - Recently Viewed items
    - Personalize Table

    For more information about these key items on your Dashboard, please see the ZOT IRB Researcher's Guide.

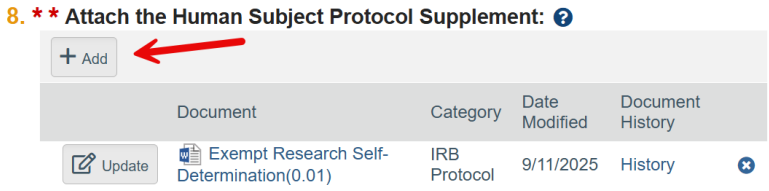
4) Select the "Create" button on your Dashboard to create a new study



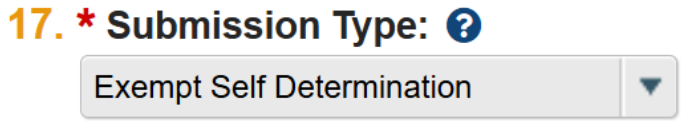
5) Creating New: IRB Submission:
Complete this page as it pertains to your study



Prompt #8 will ask you to "Attach the Human Subject Protocol Supplement". This is where you will upload the completed PROTOCOL NARRATIVE – Exempt Research Self-Determination



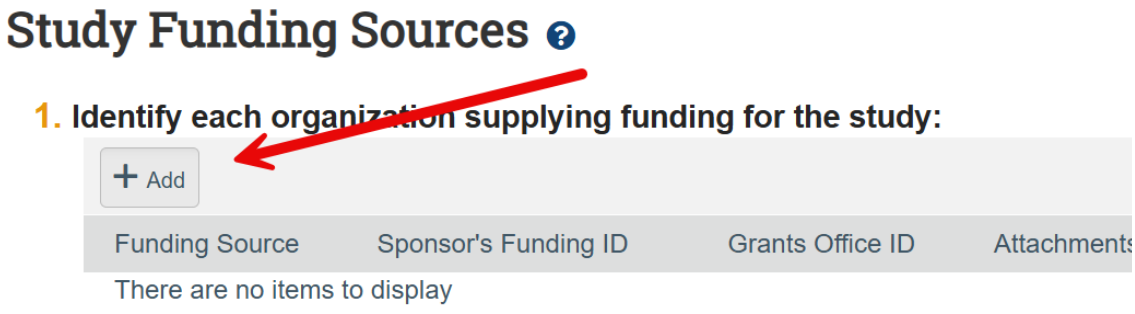
Prompt #17 "Submission Type" is where you would select "Exempt Self Determination"



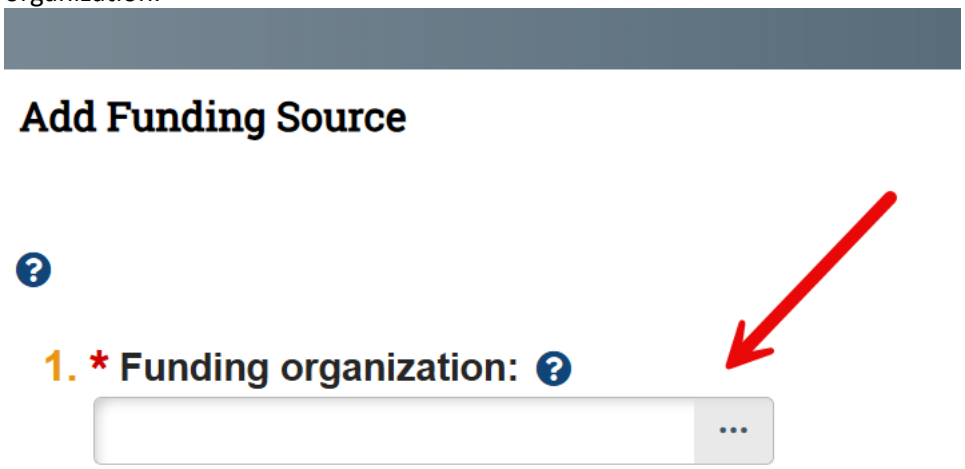
Click "Continue" at the bottom of the page once the "Basic Study Information" page is completed.

6) Study Funding Sources:
ALL UROP studies must add "Undergraduate Research Opportunities Program (UROP) as a funding source (see the steps below). This is a required field in the system, so you must add UROP regardless of whether or not you are requesting or receiving funding.

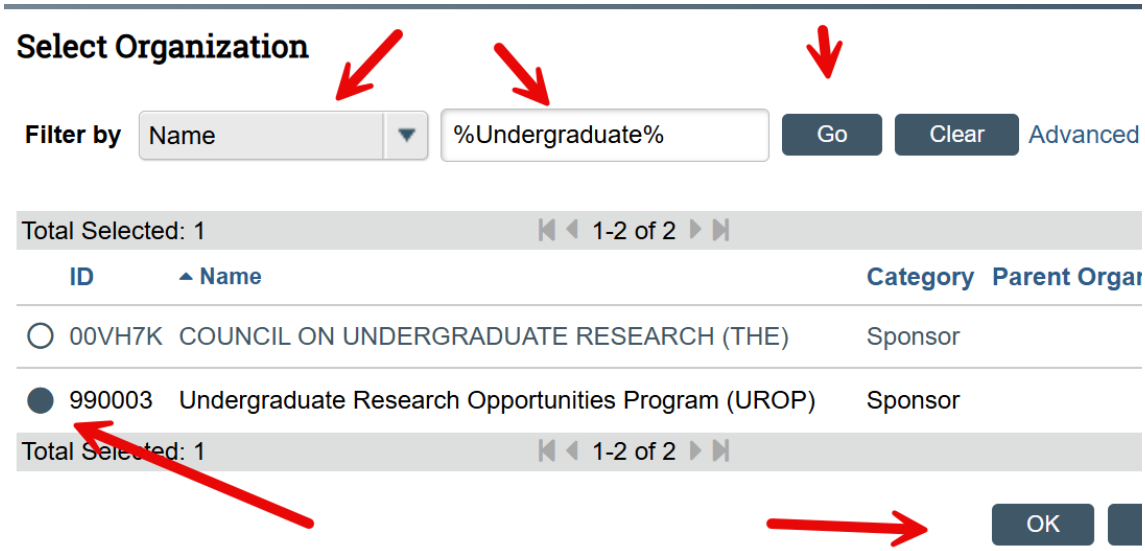
Select "Add"



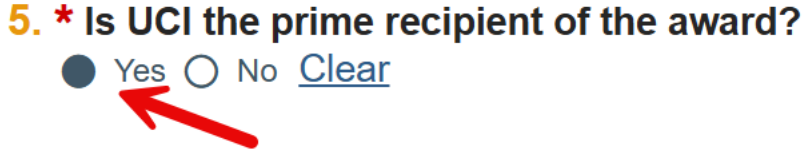
A pop-up page will appear, ONLY answer #1 and #5 on this page. For #1, find the funding organization:



A pop-up for "Select Organization" will appear. Filter by NAME, enter %Undergraduate%, click "go". The following options should appear, then select UROP (see below screenshot) and "OK".

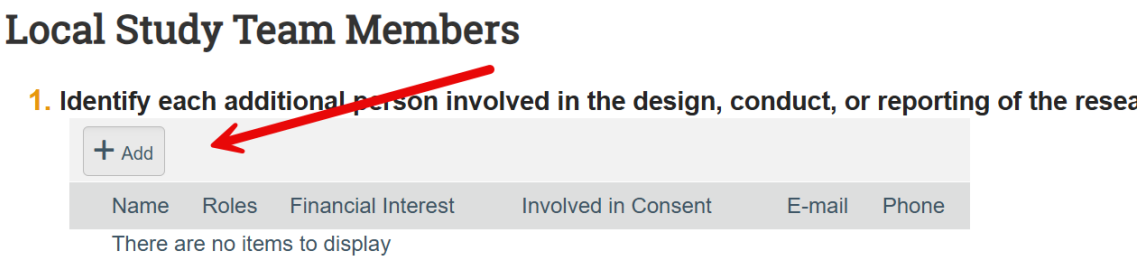


For #5 answer "yes" and then select "OK" at the bottom of the screen



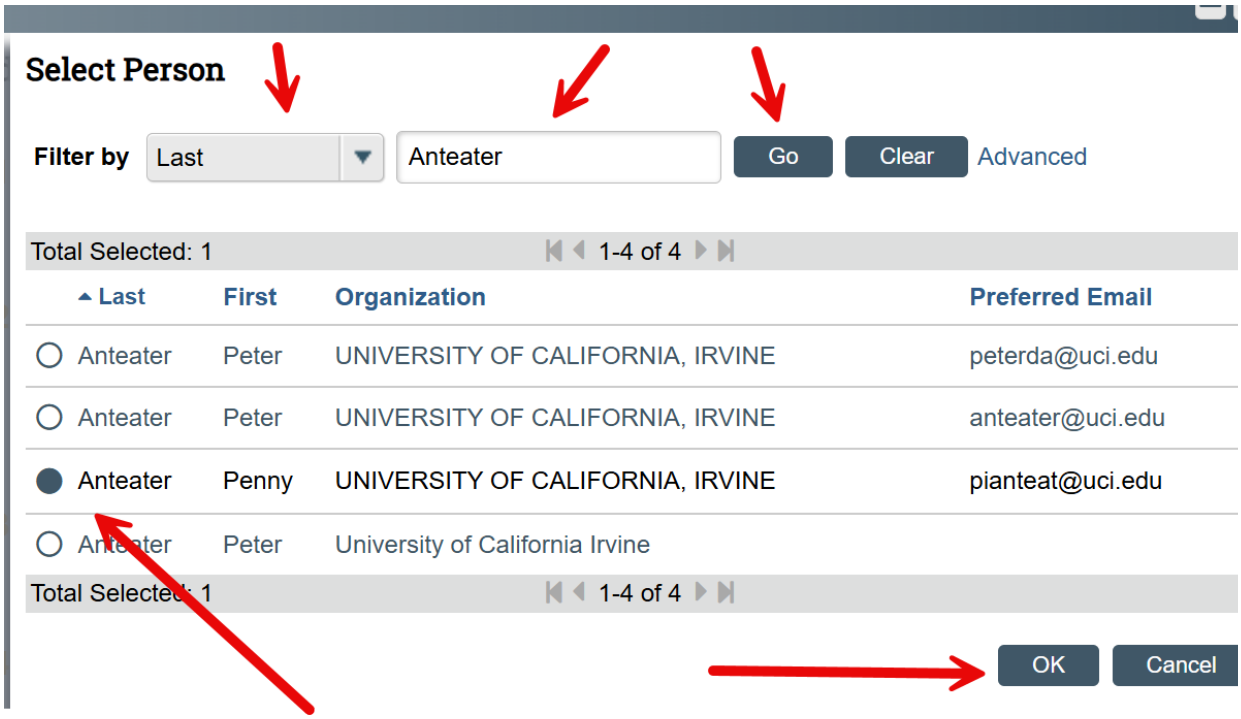
7) Local Study Team Members:
This page is where you would add your Faculty Advisor (see screenshots below):

Select "Add"

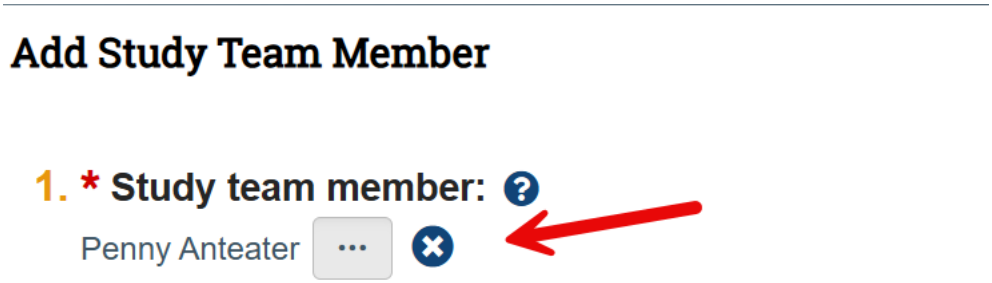


A pop-up for "Add Study Team Member" will appear. For #1, search for your Faculty Advisor.

Another pop-up will appear to "Select Person". Filter by "Last", type in your Faculty Advisor's last name and click "Go". Then select the your Faculty Advisor and click "OK" at the bottom of the screen.

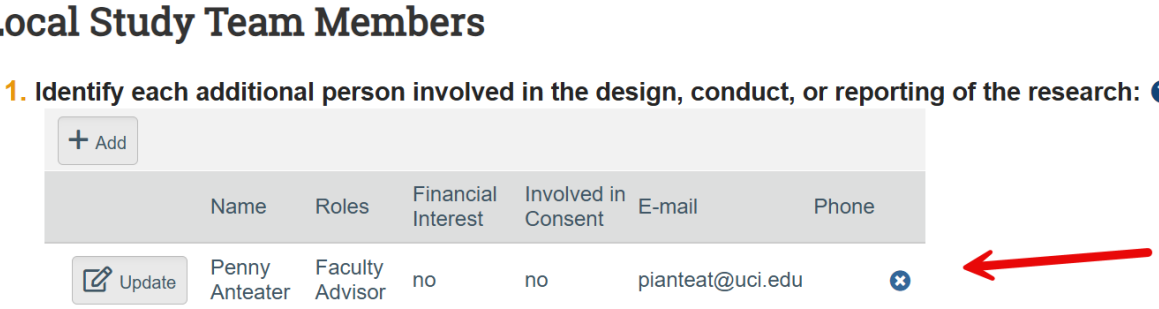


Your Faculty Advisor should now appear under #1.



Next select “Faculty Advisor” for #2

Complete the rest of this page as it relates to your Faculty Advisor’s role and responsibilities for the study. Select “OK” at the bottom once completed. You will be redirected to the “Local Study Team Members” page and will see the following:



8) Study Scope:
Questions #1 & #2 will be answered “no” for all exempt self-determination studies.

Study Scope

1. * **Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?**
   ○ Yes ● No Clear

2. * **Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?**
   ○ Yes ● No Clear

Next you will complete the Exempt Self-Determination questions as they pertain to your study. Questions will auto-populate depending on your answers.

For question #8 please select which Exempt categories apply to your research.

8. * **Select the category(ies) that apply to the research:**

Go to forms menu | Print | He

- ☐ 1) Research, conducted in established or commonly accepted educational settings and specifically involves normal educational practices that are NOT likely to adversely impact students opportunity to learn
- ☐ 2i) Research that includes only interactions involving educational tests (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures, or observation of public behavior including visual or auditory recording) if the information obtained is recorded by the investigator in such a manner that the identity of the human subjects CANNOT readily be ascertained, directly or through identifiers linked to the subjects
- ☐ 2ii) Research that includes only interactions involving educational tests (cognitive, diagnostic, aptitude, achievement survey procedures, interview procedures, or observation of public behavior including visual or auditory recording) if any disclosure of the human subjects responses outside the research would NOT reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, educational advancement, or reputation
- ☐ 3iA) Research involving benign behavioral interventions in conjunction with the collection of information from an adu subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectivel agrees to the intervention and information collection and the information obtained is recorded by the investigator in such a manner that the identity of the human subjects CANNOT readily be ascertained, directly or through identifiers linked to the subjects
- ☐ 3iB) Research involving benign behavioral interventions in conjunction with the collection of information from an adu subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectivel agrees to the intervention and information collection and any disclosure of the human subjects responses outside th research would NOT reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, educational advancement, or reputation
- ☐ 4i) Secondary research for which consent is not required: Secondary research uses of identifiable private informatio or identifiable biospecimens, if the identifiable private informat
- ☐ None of the above categories apply to the research

Exit | Save | Continue

****IMPORTANT** – Question #9 You will be attesting that your answers within the application meet the criteria for self-determination. Make sure to check the box and read the instructions below the prompt. **DO NOT SUBMIT THIS PROJECT TO THE IRB. After checking the box, exit the page.**

9. * I attest that the above answers represent my final answers for self-determination. ☑

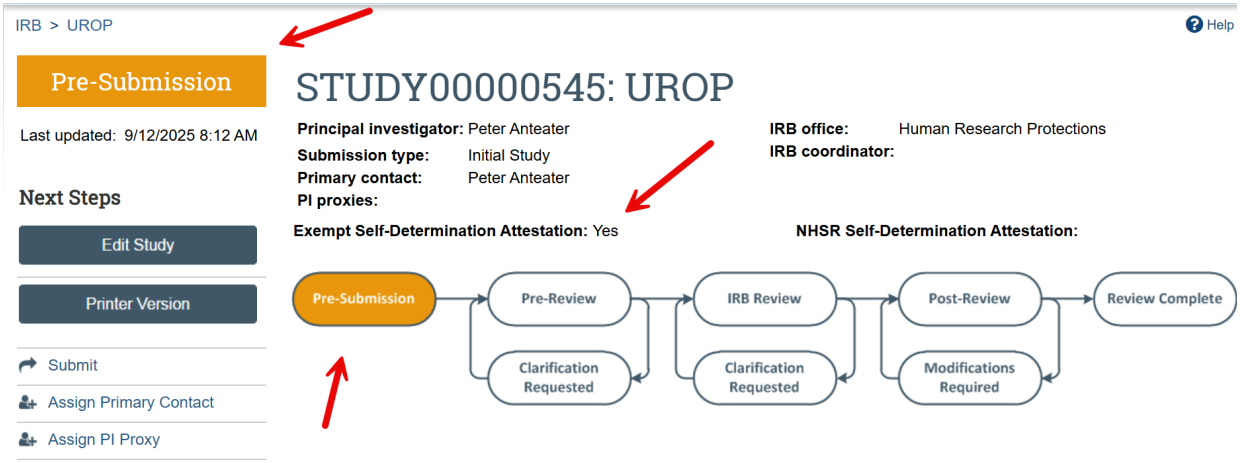
The responses, as indicated above, meet the criteria for Exempt Self-Determination. Project activities may begin immediately.

UCI IRB review is not required and will not be provided. Do NOT submit this project to the IRB. The study status will remain as "Pre-Submission" and a confirmation of registration will not be sent.

Should the study sponsor require evidence of a this determination, please provide them with a printout/PDF of the submission.

IMPORTANT! If there are changes to the study such that IRB review is required, a new protocol should be submitted with a reference to the self-determination.

The study status will remain as "Pre-Submission" and a confirmation of registration will NOT be sent to you. See an example below of how your study will appear in ZOT IRB:



IMPORTANT NOTES:

- ✓ Compile all supplementary documents (e.g., survey questions, fliers used to advertise your study, etc.) and save them in a separate file for documentation purposes.
  - **DO NOT** attach or upload them into ZOT IRB.
  - Use the HRP Toolkit for templates, guides, and worksheets

- ✓ Save a copy of your completed protocol by clicking "Printer Version".

- ✓ A confirmation email of registration from ZOT IRB will **NOT** be sent.
  - Your study status will remain as "pre-submitted" on the ZOT IRB portal and will not

change.

- ✓ **IRB review and approval are not required for "Exempt" projects, and you will NOT receive any kind of "approval" documentation.**
  - **You may begin your research as soon as the form is complete.**

Institutional Animal Care and Use Committee (IACUC): Research Involving Animal Subjects

Is my research project "Exempt" from IACUC approval?

If your research involves animal subjects, you must receive IACUC approval ***before you begin your research***. **There are no exceptions.**

How can I determine if my research requires IACUC review and approval?

For assistance in determining whether or not your planned activity requires review, visit the following webpage with your UC Irvine Faculty Advisor:

- Do You Need IACUC Review?

What should I keep in mind as I apply for UROP's recognition and funding opportunity and determine IACUC approval?

IACUC approval is not required by the time you submit your UROP recognition and funding opportunity you're applying to (e.g., REF, IRT, or SURP). However, ***approval is needed before you begin your research.***