



## Research Protections Instructions

UC Irvine undergraduate students should consult with their UC Irvine Faculty Mentor 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 Mentor have questions after reading these instructions, please contact UROP for assistance: [urop@uci.edu](mailto: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 Mentors, 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 UROP's recognition and funding opportunity 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:

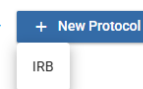
Steps You Need to Take for UROP	Steps You Need to Take for UCI Office of Research					
<p>Verify in your online application the <b>status of your IRB process</b> by the deadline of the UROP recognition and funding opportunity you are applying to (e.g., REF, IRT, or SURP).</p> <p>The status of your IRB process can include information such as whether your project qualifies as “Exempt” or is undergoing IRB review.</p>	<p>Review the <a href="#">Do You Need IRB Review?</a> information with your UC Irvine Faculty Mentor. Your faculty mentor will determine if the project qualifies as "Exempt."</p> <table border="1" data-bbox="609 1186 1412 1690"> <thead> <tr> <th data-bbox="609 1186 1023 1291"><u>If the project IS “Exempt:”</u></th> <th data-bbox="1023 1186 1412 1291"><u>If the project DOES NOT qualify as “Exempt:”</u></th> </tr> </thead> <tbody> <tr> <td data-bbox="609 1291 1023 1690"> <p>Complete and submit the “Administrative Determination-Exempt Self-Determination” form and supplementary documents in Quali Research Protocols (KRP).</p> <p><b>IRB approval is <u>NOT</u> needed, but IRB registration is still necessary <u>before you begin your research.</u></b></p> </td> <td data-bbox="1023 1291 1412 1690"> <p>It must be added to an existing protocol or undergo an IRB review process and must be approved.</p> <p><b>IRB approval <u>IS</u> needed <u>before you begin your research.</u> Follow the instructions on the IRB website, as needed.</b></p> </td> </tr> </tbody> </table> <p><b>Note from UROP:</b> IRB registration or approval is not required by the time you submit your application for the UROP recognition and funding opportunity you're applying to (e.g., REF, IRT, or SURP). However, registration or approval is needed <b>before you begin your research.</b></p>		<u>If the project IS “Exempt:”</u>	<u>If the project DOES NOT qualify as “Exempt:”</u>	<p>Complete and submit the “Administrative Determination-Exempt Self-Determination” form and supplementary documents in Quali Research Protocols (KRP).</p> <p><b>IRB approval is <u>NOT</u> needed, but IRB registration is still necessary <u>before you begin your research.</u></b></p>	<p>It must be added to an existing protocol or undergo an IRB review process and must be approved.</p> <p><b>IRB approval <u>IS</u> needed <u>before you begin your research.</u> Follow the instructions on the IRB website, as needed.</b></p>
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## My research qualifies for “Exempt Self-Determination” (i.e., IRB review not required), what do I do next?

Self-determination is made by completing the “Administrative Determination-Exempt Self-Determination” form in **Kuali Research Protocols (KRP)**. **Do not submit this form to UROP.**

Complete this form with your UC Irvine Faculty Mentor’s guidance to ensure all information is accurate. Follow the steps below:

- 1) Refer to the [Kuali Research Protocols \(KRP\) User Guide](#) for detailed instructions and screenshots for guidance on how to use KRP.
  - a. Please use **Google Chrome** or **Firefox** web browsers for optimal performance.
- 2) Log in to the [Kuali Research Protocols \(KRP\)](#) website using your UCInetID & password.
- 3) Select “New Protocol → IRB”
  - a. See “Start a New Protocol” in the [Kuali Research Protocols \(KRP\) User Guide](#) for tips
- 4) Type Project Title (100 words max), Lead Researcher/Investigator, and Lead Unit
  - a. Lead Researcher (LR) name could be you, your UC Irvine Faculty Mentor, or their qualified designee. For more details, see [Lead Researcher Eligibility](#).



**IRB - General Information**

**Project Title (100 words max):**  
Type here

**Lead Researcher/Investigator:**  
For guidance, view [Lead Researcher Eligibility](#).

**Lead Unit (i.e., Department, Organized Lead Unit, [Center](#) or [Institute](#)):**

Kuali Research (KR) follows the [KFS Organizational Unit Hierarchy](#).

- Select the lead unit with 3 asterisks (\*\*\*)
- UCSB hSCRO Researchers: Select \*\*\*UC Santa Barbara (UCSB)\*\*\*

**ATTENTION!** For new submissions, Department Chair (DC) or Organized Lead Unit Director (OLUD) sign-off in KRP is required before final committee approval will be granted. For more information, visit the [listserv](#).

× Cancel

→ Next

- 5) Under Submission Type, select **“Administrative Determination or Registration” → “Exempt Self-Determination.”**

**Submission Type:**

**IMPORTANT!** Be sure to select the correct 'Submission Type'. When 'Submission Type' is changed, the contents of the form will be cleared and replaced with a set of new questions specific to the submission type.

**Administrative Determination or Registration includes:**

- Non-Human Subjects Research Self-Determination
- Exempt Self-Determination
- Relying IRB Screener
- Requests to Rely on Non-UCI IRB Review



- Administrative Determination or Registration
- Institutional Review Board (IRB) Review
- Human Stem Cell Research Oversight (hSCRO) Review
- [HRP STAFF USE]

**Submission for Administrative Determination or Registration:**



- Non-Human Subjects Research Self-Determination
- Exempt Self-Determination
- Relying IRB Screener
- Request to Rely on non-UCI IRB Review

a. Answer the questions on the form and verify if the research qualifies as [“Exempt” Categories Eligible for Self-Determination.](#) If yes, mark which category it falls under.

**6) Exemption Status**

a. If you **meet the exemption requirements**, a **Green text confirmation statement** will appear on your form in the “Self-Determination Eligibility” section (see image below). This is confirmation that you are “Exempt” from the IRB review and approval requirement.

PROTOCOLS UCI kwali RESEARCH

← Back Manage Protocols → IRB: #5351 Test 4

Protocol Activity Log Permissions

Jump to:

- Project Details ✓
- Submission Screener ✓
- Study Team
- Project Funding
- Exempt Self-Determinatio...
- Clinical Trials
- Non Technical Summary
- Other UCI Committee Revi...
- Subject Population(s)
- Pre-Screening without Con...
- Recruitment Methods
- Informed Consent Process
- Sample Size
- Project Locations
- Project Procedures
- Risk Assessment
- Alternatives to Participation
- Participant Compensation
- Confidentiality of Researc...
- Lead Researcher Certificat...

**Exempt Self-Determination Tool**  
— educational advancement, or reputation

**Category 3:** Research involving **benign behavioral interventions** in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

**One of the following criteria must be met:**

- 3(A) 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
- 3(B) 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

**Category 4:** Secondary research for which consent is not required: **Secondary research uses of identifiable private information or identifiable biospecimens**, if the following criterion is met:

- 4) The identifiable private information or identifiable biospecimens are publicly available

**Self-Determination Eligibility**

**The responses, as indicated above, meet the criteria for Exempt Self-Determination.**

**UCI IRB review is not required and will not be provided. Research activities may begin as soon as the form is submitted in KRP.**

A confirmation of registration will not be sent. The study status in KRP will remain as "submitted" or "resubmitted".

Should the study sponsor require evidence of IRB review for an exempt self-determination, please provide the sponsor [this letter](#) along with a printout/PDF of the submission in KRP.

**NEXT STEPS:**

- Complete the remainder of the self-determination form and submit to register the study in KRP.
- The contents of the remainder of the form must be consistent with the responses provided in the above Exempt Self-Determination Tool.
- **IGNORE!** If prompted to attach documents to the form, please ignore. These prompts are intended for IRB submissions only. Instead, please maintain the documentation on file as noted below.
- Once submitted, maintain in a separate research record all supplemental documentation, as prompted in the form. This documentation may be requested by Human Research Protections (HRP)

- b. If your UC Irvine Faculty Mentor determines the project **does NOT qualify as “Exempt” and requires IRB review and approval**, you may wish to consider if it is possible to change the project design such that it would qualify for “Exempt” self-determination.

7) **Submit** the “Administrative Determination-Exempt Self-Determination” on the KRP website.

#### **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 the KRP website.
- ✓ Save a copy of your completed protocol.
- ✓ A confirmation email of registration from KRP will **NOT** be sent.
  - Your study status will remain as “submitted” or “resubmitted” on the KRP website and will not change.
- ✓ **IRB review and approval is 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 submitted in Quali Research Protocols (KRP).**

## **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.***

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### **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 Mentor:

- [Do You Need IACUC Review?](#)
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### **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.***