

## UROP Research Protections Instructions

Students should **consult with their Faculty Mentor** to determine if Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) approval is needed.

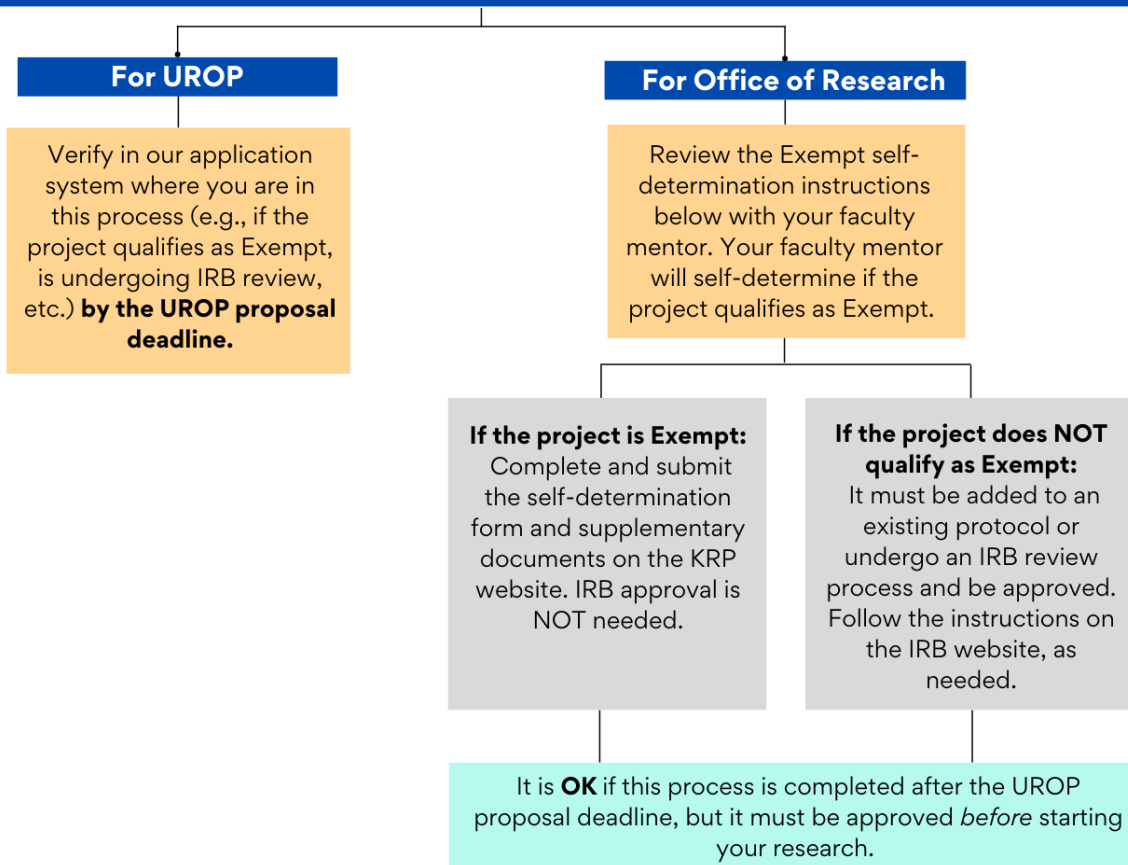
### Research involving Human Subjects:

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

**Review the following guidance to determine whether your research qualifies for self-determination.**

- [Do You Need IRB Review? A Quick-Start Guide](#)
- [Exempt Self-Determination](#)

**NOTE: You will be following two parallel processes:**



**SEE NEXT PAGE FOR INSTRUCTIONS**

Self-determination is made by completing the **Exempt Self Determination in Kuali Research Protocols (KRP)**. **Do not submit this form to UROP**. Complete this form with your Faculty Mentor's guidance to ensure all information is accurate.

- Refer to the [KRP User Guide](#) for detailed instructions and screenshots for guidance on how to use KRP.
  - Please use **Google Chrome or Firefox** web browsers for optimal performance.
- Log in to the [Kuali Research Protocols \(KRP\)](#) website using your UCInetID & password. Select:
  1. New Protocol → IRB (See “Start a New Protocol” in the [User Guide](#) for tips).
  2. Enter the Lead Researcher (LR) name and department in the Lead Researcher and Lead Unit fields. This could be you, your Faculty Mentor, or their qualified designee. For more details, see [Lead Researcher Eligibility](#).
  3. Under “Submission Type,” select “Administrative Determination” → “Exempt Self-Determination.”
  4. 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.
    - ✓ If you meet the exemption requirements, a **Green** text confirmation statement will appear on your form in the “Self-Determination Eligibility” section (see example on next page). This is confirmation that you are exempt from the IRB review and approval requirement.
    - ✓ If your 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.
  5. **Submit** the Exempt Self-Determination form 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. Also 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 KRP.**

If you and your Faculty Mentor have questions, please contact UROP for assistance: [urop@uci.edu](mailto:urop@uci.edu) or (949) 824-4189.

## Example: Screenshot of Exempt Status Confirmation in KR Protocols (KRP):

PROTOCOLS



← 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)

## Research involving Animal Subjects:

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

- See [Guidance for Determination of IACUC Review](#).
- **For UROP:** Verify in the UROP application system where you are in this process by the UROP proposal deadline (e.g., whether you have submitted your project for IACUC review, etc.).