

THE EXEMPT SELF DETERMINATION PROCESS

November 2021

To Whom it May Concern:

The Exempt Self-Determination Tool may be used to self-determine certain types of exempt research at UCI, including exempt research conducted through the [Undergraduate Research Opportunities Program \(UROP\)](#). Exceptions do apply. Please refer to the [Exempt Self Determination Tool webpage](#) on this topic. The Exempt Self-Determination Tool is initiated through Kuali Research Protocols ([KRP](#)).

As part the Exempt Self-Determination Tool process, UCI IRB review is not required and will not be provided. For studies that are submitted to the IRB where the Exempt Self-Determination Tool may be used instead, the study will be returned to the researcher to self-determine. In addition, amendments to studies that have undergone the self-determination process are to be maintained independently. No amendments should be submitted in [KRP](#). Do submit an IRB Application if a change to the self-determined protocol results in the study no longer being eligible for self-determination. For exempt or expedited studies that require UCI IRB review, Lead Researchers must submit an IRB Application in [KRP](#).

UROP students using the Exempt Self-Determination Tool in [KRP](#) to conduct exempt research should contact UROP for questions related to the use of the tool.

As part of using the Exempt Self-Determination Tool, Lead Researchers and Faculty Sponsors (as applicable) provide their assurance that they will follow relevant Human Research Protection Program (HRPP) policies and procedures, among other criteria. For a copy of the assurance, please review the following page.

If there are any questions, please [contact HRPP Staff](#).

-The UCI HRPP

**AS PART OF THE EXEMPT SELF DETERMINATION PROCESS AT UCI, THE LEAD
RESEARCHER AND FACULTY SPONSOR (AS APPLICABLE)
ASSURES THE FOLLOWING:**

As Primary Lead Researcher and Faculty Sponsor, we have ultimate responsibility for the performance of this study, the protection of the rights and welfare of the human subjects, and applicable UCI policies, as well as state statutes for research involving human subjects.

I hereby assure the following:

1. The information provided in this application is accurate to the best of my knowledge.
2. The information provided in this application has been discussed and shared with my Department Chair. Any requests for changes based on this discussion are included in this application upon submission.
3. All named individuals on this project have read the procedures outlined in the protocol, are aware of and have reviewed relevant HRPP Policies and Procedures and understand their role on the study.
4. All named individuals on this project have completed the required electronic educational research tutorials and have been made aware of the "Common Rule" (45 CFR Part 46) and acknowledge the importance of the Belmont Principles - Respect for Persons, Beneficence and Justice in conducting research involving human participants. Also UCI has signed the Federalwide Assurance (FWA) that is available for review on the Human Research Protections (HRP) website.
5. Minor changes to the research that do not increase risk to participants, or significantly alter the study aims or procedures, such as the addition or removal of students researchers, do not require additional self-confirmation of exemption or approval from the IRB. Major changes that increase risk or constitute substantive revisions to the research including procedural changes will require a new self-confirmation of exemption or approval from the IRB.
6. When conducting research at a non-UCI location outside of California (but within the United States), Lead Researchers must comply with the requirements and policies of the location and State laws regarding human research procedures.
7. When collaborating with another entity (e.g., another UC, CHOC, CSUF, or a local school district), the collaborators who are engaged in human research activities are responsible for securing their own (non-UCI) IRB exemption/approval.
8. The Exempt Self-Determination, consent documents including recruitment materials and data collection materials will be maintained by the Lead Researcher or Faculty Sponsor for 10 years beyond the completion of the research. If you will cease your affiliation with UCI during this 10 year period and intend to transfer your identifiable data to a new institution, please notify your Faculty Sponsor and Department to determine whether this is permissible.
9. This research study is subject to routine monitoring by the Human Research Protections (HRP) unit of the Office of Research. Through the Education Quality and Improvement Program (EQUIP) program, HRP staff conduct periodic quality improvement monitoring and educational outreach.