

THE EXEMPT SELF-DETERMINATION PROCESS AT UCI

September 01, 2025

To Whom it May Concern:

The Exempt Self-Determination process may be used to self-determine certain types of exempt research at UCI, including exempt research conducted through the <u>Undergraduate Research</u>
Opportunities Program (UROP). Exceptions do apply. Please refer to the Exempt Self-Determination webpage. The Exempt Self-Determination process is initiated through ZOT IRB.

As part the Exempt Self-Determination process, if a study is eligible for self- determination, UCI IRB review is not required and will not be provided. In an effort to reduce administrative burden, the IRB has delegated this responsibility for *specific exempt categories*, to UCI Faculty Researchers. Should a sponsor inquire if the Exempt Self-Determination process, once complete, equates to an official UCI IRB confirmation of exemption, the answer is, "yes."

For studies that are submitted to the IRB where the Exempt Self-Determination process 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 ZOT IRB unless 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, Principal Investigators (PI) must submit an IRB Application in ZOT IRB.

UROP students using the Exempt Self-Determination process in ZOT IRB to conduct exempt research should contact UROP for questions related to the use of the tool. As part of using the Exempt Self-Determination process at UCI, PIs and Faculty Sponsors (as applicable) provide their assurance that they will follow relevant Human Research Protection Program (HRPP) policies and procedures, as provided in the Human Research Protections (HRP) Toolkit.

If you have any questions or comments, please contact HRP Staff.