

Human Subjects Research

Human subjects research is any research or clinical investigation that involves human subjects.

- **Research** is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- **Clinical investigation** is any experiment that involves a test article and one or more human subjects and is subject to FDA regulations and oversight.
- **Human subject** is a living individual about whom an investigator (whether professional or student) conducting research:
 - (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
 - (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
- **Test article** is any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to FDA regulations.



USEFUL UCI IRB/ HRP LINKS

HRP Home Page

<https://research.uci.edu/human-research-protections/>

KR Protocols

<https://uci.kuali.co/protocols/portal/protocols>

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WORKING 100% REMOTE SINCE 2020!

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HUMAN RESEARCH PROTECTIONS (HRP)



UC Irvine Institutional Review Board

Fast Facts

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[http://www.research.uci.edu/
compliance/human-research-
protections/index.html](http://www.research.uci.edu/compliance/human-research-protections/index.html)

UCI

About the Institutional Review Board (IRB)

Research involving human subjects must undergo prospective review by the IRB. The IRB is charged with the responsibility of reviewing human subjects research and ensuring compliance with federal regulations, state laws, and UC/UCI policies. The role of the IRB is to protect the safety and welfare of human subjects. UCI has five IRB committees in total.

There are two main committees for biomedical research (IRBs "A" , "B"), the third (IRB "C") reviews social/behavioral/ educational research and the fourth (IRB "E") reviews matters of alleged noncompliance. A fifth committee handles overflow as needed (IRB "WB"). Each committee is composed of scientists, non-scientists, and community members with varying backgrounds and expertise. UCI also allows for the use of commercial IRBs. All UCI human subject research must submit through the UCI IRB first—regardless of the requested IRB of record.

IRB Members are appointed by the Vice Chancellor for Research who is the UCI Official responsible for the human research protections program. Some HRP Staff are also IRB members.

HRP Staff provide administrative support to UCI's IRBs. HRP Staff also help coordinate the commercial IRB review process, and protocols requesting a cooperative or single IRB (sIRB) review. HRP work directly with Researchers to help facilitate research.

Levels of IRB Review

Federal regulations divide human subjects research into three categories, based on the potential risks/discomforts to subjects.

Each level of review has a corresponding requirement for institutional approval or registration. The three levels of review —

Exempt, Expedited, and Full Committee—are described below. Full details are at: <https://research.uci.edu/human-research-protections/do-you-need-irb-review/levels-of-review/>

Exempt: Research categorized as "exempt" from the federal regulations still requires IRB review. Exemption is confirmed and the research is registered with the IRB for three years. To qualify at UCI, research must fall into 6 federally-defined exempt categories. These categories of research generally involve virtually no risk to subjects. Examples of exempt level research include collection of anonymous or non-sensitive information via survey or interview; analysis of publicly-available dataset; extraction of de-identified data from medical records; and observation of public behavior.

Some exemptions may be self determined. Effective September 1, 2021, Researchers interested in a self determination of exemption will utilize **Kuali Research Protocols to make this determination at:** <https://uci.kuali.co/protocols/portal/protocols>.

Expedited: To qualify for Expedited review, research must fall into 9 federally-defined expedited categories. Research that qualifies for Expedited review involve no more than minimal risk. For example, Expedited level research may involve collection of certain biological samples; focus group interviews; collection of blood from healthy volunteers; collection of information from existing records; analyses of voice recordings; and studies using non-invasive procedures normally used in clinical practice (e.g., EEG, ECG).

Full Committee: Proposed human subjects research that does not qualify for either exempt or expedited review must be submitted for full committee review. Per federal regulations, a quorum of the IRB Committee must review all human subjects research that involves more than minimal risk to subjects at intervals appropriate to the potential risk to subjects, but at least annually.

Expedited and Exempt: Once approved or confirmed exempt (including self-determinations), research can be approved up to 3 years depending on several factors.

IRB Application Process

Effective September 1, 2021, Researchers interested in conducting human subjects research must **submit an IRB Application through Kuali Research Protocols at:** <https://uci.kuali.co/protocols/portal/protocols>.

The IRB application process guides the investigator through a series of questions designed to illicit specific information required by human research regulations, state laws and local policies.

For help with initiating or completing the IRB Application in Kuali Research Protocols, email Electronic Research Administration at: era@research.uci.edu.

Review and Approval Correspondence from the IRB

Lead Researchers, faculty sponsors and administrative contacts, if applicable, receive detailed feedback **via e-mail** within 5 to 10 working days from the date of IRB review if minor changes or significant changes to the application are requested. For applications that are approved, approval documents are e-mailed to the Lead Researcher within 6 days of processing by HRP Staff. **Human research activities must not begin until IRB approved documents are received.**

Does Research Qualify as Human Subjects Research?

Any researcher who is unsure whether their research constitutes human subjects research should complete the Kuali Research Non-Human Subject Research Module: <https://uci.kuali.co/protocols/portal/protocols> For a confirmation of whether the project is or is not human subject research, the researcher must submit the module. An email confirmation indicating the status of the project will be provided to the researcher.



Deadlines for Submission

There are no submission deadlines for applications qualifying for Exempt or Expedited review. These applications are reviewed on a rolling basis.

Submission deadlines for Full Committee reviews are posted on the [main HRP webpage](#). Each Full Committee meets once per month.

IRB documentation must be received by the HRP no later than 5:00 p.m. on the deadline day to be considered for review at the next scheduled Committee meeting.

Full Committee meetings agendas are limited to 25 items.

Please allow 30 to 60 days lead time for **review** of full committee applications.

Prerequisite Requirements

Other Required UCI Reviews

Before submitting the *IRB Application*, other prerequisite reviews/approvals may be required. See <https://research.uci.edu/human-research-protections/clinical-research/other-institutional-requirements/>

Human Research Education Requirements

All study team members must complete one or more UCI human research tutorials in order to be approved to perform human subjects research at UCI. See <https://research.uci.edu/human-research-protections/irb-application-process/training-and-education/> for details.

Lead Researcher Eligibility

At UCI, faculty with paid appointments of 50% or more may serve as Lead Researcher on a human research protocol. Students, volunteer faculty members, and staff may assume the role of Lead Researcher as long as they are affiliated with UCI and have a Faculty Sponsor who fulfills the Lead Researcher eligibility criteria. See <https://research.uci.edu/human-research-protections/irb-application-process/lead-researcher-eligibility/> for more details.