USEFUL UCI IRB WEBSITE LINKS
Activities that Require IRB Review and Approval
On-line Applications and Forms
http://www.research.uci.edu/forms/index.html
Required Training and Education

HUMAN RESEARCH PROTECTIONS

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.

Research involving human subjects must undergo review by the Institutional Review Board (IRB). The IRB is charged with the responsibility of reviewing human subjects research and ensuring compliance with federal regulations, state laws, and UCI/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 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 to promote complete review of the research activities conducted at UCI.

IRB Members are appointed by the Vice Chancellor for Research who is the UCI Official responsible for the human research protections program. The Human Research Protections (HRP) staff provides administrative support to UCI's IRBs. In addition to working with the IRBs, HRP staff also work directly with investigators and their administrative staff to facilitate submission of the required IRB documentation.

**Human Research Protections Staff**

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**Fast Facts**

UC Irvine

Institutional Review Board

Office of Research
141 Innovation Drive, Suite 250

Phone: (949) 824-6068, (949) 824-2125 or (949) 824-6662
Fax: (949) 824-3400

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 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 least annually.

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. Researchers can learn more about this process on the Human Research Protections (HRP) website: https://research.uci.edu/compliance/human-research-protections/researchers/levels-of-review.html

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

Does Research Qualify as Human Subjects Research?

Any researcher who is unsure whether his/her research constitutes human subjects research should review the Non-Human Subject Research Determination Form found at the HRP website: http://www.research.uci.edu/compliance/human-research-protections/docs/Request-Determination-Non-Human-Subjects.doc. If written confirmation of non human subject research is required, the form may be submitted to the IRB for review. HRP staff will determine if the study is human subjects research. If a project does not qualify as human subjects research HRP staff will issue a letter stating that the project does not require IRB review.

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 Office of Research website. Each Full Committee meets once per month.

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.