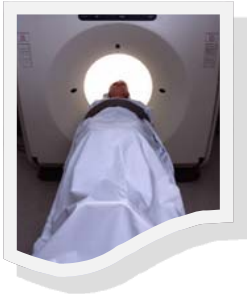


Human Subjects Research

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 (1) a living individual about whom an investigator conducting research obtains (a) data through intervention or interaction with the individual; or (b) identifiable private information; or (2) an individual who is or becomes a participant in research, either as a recipient of the test article or as a control.
- **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 WEBSITE LINKS

Activities that Require IRB Review and Approval

<http://www.research.uci.edu/compliance/human-research-protections/researchers/activities-irb-review.html>

On-line Applications and Forms

<http://www.research.uci.edu/forms/index.html>

Required Training and Education

<http://www.research.uci.edu/compliance/human-research-protections/researchers/training-and-education.html>

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HUMAN RESEARCH PROTECTIONS



Institutional Review Board

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UCI

About the Institutional Review Board (IRB)

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 UC/UCI policies. The primary role of the IRB is to protect the safety and welfare of human subjects. UCI has five IRB committees: three review biomedical research (IRBs "A", "B" and "WB"), the third (IRB "C") reviews social/behavioral research and the fourth (IRB "E") reviews matters of alleged noncompliance. Each committee is composed of scientists, non-scientists, and community members with varying backgrounds to promote complete and adequate review of the research activities conducted at UCI. Members are appointed by the Vice Chancellor for Research who is the UCI Official responsible for the human research protections program. Faculty researchers engaged in human subjects research are encouraged to volunteer for IRB service. 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



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: <http://www.research.uci.edu/compliance/human-research-protections/researchers/levels-of-review.html>

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 five years. To qualify, research must fall into six (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.

Expedited: To qualify for Expedited review, research must fall into nine (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 biological samples such as hair, saliva, or tissue; 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).

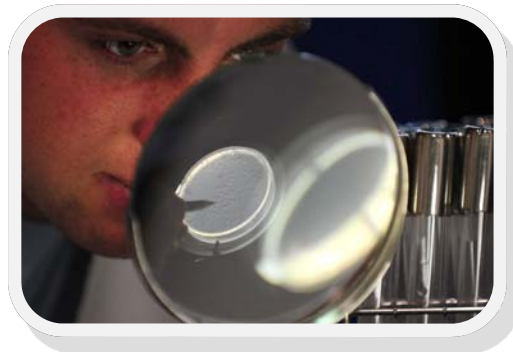
Full Committee: Proposed human subjects research that does not qualify for either exempt or expedited review must be submitted for full committee review. Per federal regulations, a quorum of the IRB Committee must review all human subjects research that involves more than minimal risk to subjects.

Expedited and Full Committee research once approved by the IRB requires continual review at intervals appropriate to the potential risk to subjects, but at least annually.

IRB Application Process

Investigators interested in conducting human subjects research must submit an electronic application for IRB review to Human Research Protections (HRP).

The web-based **IRB Application (APP)** process guides the investigator through a series of questions designed to illicit specific information required by human research regulations, state laws and local policies. Detailed instructions and suggestions for completing the application and website references are provided.



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 5 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 his/her research constitutes human subjects research should contact the HRP staff listed on the back of this flyer or submit a 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>. HRP staff or an IRB Chair will determine if the study is human subjects research. If a project does not qualify as human subjects research the IRB can 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.

Hard copy 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. Full Committee agendas fill up quickly so new IRB applications may be deferred to the next meeting date. 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 (e.g. CTPRMC). See <http://www.research.uci.edu/compliance/human-research-protections/irb-partners-and-affiliates/other-uci-reviews.html>.

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 <http://www.research.uci.edu/compliance/human-research-protections/researchers/training-and-education.html> 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 <http://www.research.uci.edu/compliance/human-research-protections/researchers/lead-researcher-eligibility.html> for more details.