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, food additive, color additive, electronic product, or any other article subject to FDA regulations.
Expedited review involve no more than minimal risk. For example, 9 federally
Exempt: Some exemptions may be self determined.
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 medical records; and observation of public behavior. 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.

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.

Exempt and Expedited: Once approved or confirmed exempt (including self-determinations), research can be approved up to 3 years depending on several factors. Effective September 1, 2021, Researchers interested in a self determination of exemption from the federal protections/researchers/levels/Exempt.html#Exempt. For more details.

Prerequisite Requirements

Before submitting the IRB Application, other prerequisite reviews/approvals may be required. See http://www.research.uci.edu/compliance/human-research-protections/irb-partners-and-affiliates/other-uci-reviews.html for details.

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.