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.ucir.compliance/human-research-protection/researchers/activities-irb-review.html

On-line Applications and Forms

**HUMAN RESEARCH PROTECTIONS**

**Institutional Review Board**

- "A" Biomedical
  - Mihaela (Mani) Nistor, CIP Administrator
    949-824-3711
    mni@uci.edu

- Anuradha Mathur
  Senior Analyst
  949-824-9819
  anuradhm@uci.edu

- Ariana Vazquez
  Analyst
  949-824-6068
  avazquez@uci.edu

**Institutional Review Board**

- "C" Social - Behavioral
  - Melissa Camarena
    Administrator
    949-824-4797
    mcamare@uci.edu

- Will Kettler
  Senior Analyst
  949-824-7114
  wkettler@uci.edu

- NEW OPEN POSITION
  - Silvia Gonzalez
    Analyst
    949-824-6662
    silviag@uci.edu

- Team IRB "C"
  Biomedical Expedited and Exempt Submissions
  - Joy Chu, CIP Administrator
    949-824-3067
    jchu@uci.edu

- NEW OPEN POSITION
  - Senior Analyst
    Calleen Kao
    949-824-0665
    calleen.kao@uci.edu

**HUMAN RESEARCH PROTECTIONS STAFF**

- Single IRB / Cooperative IRB Review
  - Valerie Sanchez, CCRP, CIP
    Administrator
    949-824-7375
    valerie.rs@uci.edu

- Angela Oh
  IRB Reliance
  Senior Analyst
  949-824-6269
  angeloi@uci.edu

**Fast Facts**

- Office of Research
  141 Innovation Drive, Suite 250
  Phone: (949) 824-6068, (949) 824-2125 or (949) 824-6662
  Fax: (949) 824-3400

**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 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. 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
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.

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 an Non-Human Subject Research determination form found at the HRP website: http://www.research.ucir.com/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.

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 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. CTPRM). See http://www.research.ucir.com/compliance/human-research-protections/irb-partners-and-contacts/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.ucir.com/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.ucir.com/compliance/human-research-protections/researchers/lead-researcher-eligibility.html for more details.