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.
**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.

**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.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.

**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.

**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.

**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.