Human Subjects Research & the Institutional Review Board (IRB)
Submission Process for Undergraduate Researchers

The Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of human research subjects. Federal regulations require all proposed human research studies to be reviewed by the IRB. There are three IRB committees at UCI: two review biomedical research (IRB "A" and "B") and the third reviews social/behavioral research (IRB "C"). You must obtain IRB approval *before* you engage human subjects in your research.

Definition of Human Subjects Research: Human subjects research is defined as any research or clinical investigation that involves human subjects. A human subject is defined as a living individual about whom an investigator conducting research obtains information through intervention or interaction with the individual or obtains identifiable private information. Not all activities involving human subjects are considered "human subjects research." Activities that are not considered human subjects research are those that are designed for educational purposes where information obtained will not be presented or published and those activities that do not involve a presentation of an analysis, such as documentaries or dance performances. If you are still unsure as to whether your study is considered human subjects research, complete the IRB "Request for Determination of Non-Human Subject Research" document located online (http://www.research.uci.edu/ora/forms/hrpp/nonhsreview.doc).

Step 1. Meet with your Faculty Mentor
Before you begin the IRB submission process, you must meet with your faculty mentor to discuss the methods of your study and whether you need to submit a new IRB application or be added to an existing protocol. If you will be added to an existing protocol, the protocol's Lead Researcher must submit an electronic Modification (e-MOD) Request, available online (http://www.research.uci.edu/ora/hrpp/modificationstoapprovedresearch.htm). To verify that you have been added to a protocol, search for your assigned protocol in the Human Subjects (IRB) Protocol Database Query (http://www.research.uci.edu/ora/trackingprotocols.htm).

Step 2. Complete Tutorial(s)
Before you can submit an IRB application, you and your mentor must complete the Human Subjects Tutorial. If your study involves the analysis of protected health information (i.e. medical records), you must also complete the HIPAA Tutorial. These tutorials review the core concepts and major principles for conducting human subjects research. You can access these tutorials online (http://apps.research.uci.edu/tutorial/).

Step 3. Review the Risk Involved in Your Study
When reviewing applications, the IRB analyzes the potential risks and benefits of your study. It is important to discuss the methods of your study with your faculty mentor and formulate a plan that involves the least amount of risk possible without compromising the goal of the study. Pay particular attention to how subjects are recruited with special attention to special populations—including pregnant women, prisoners and children—and how you will collect and store identifiable data. Depending on the level of risk involved in your study, it will fall into one of three "levels of review": exempt, expedited or full-committee review. Information on the review levels is online (http://www.research.uci.edu/ora/hrpp/levelsofreview.htm).

Step 4. Review IRB Forms and Application Procedures
The Human Research Protections Web site, located online (http://www.research.uci.edu/ora/hrpp/index.htm), has helpful information on getting started, the protocol review process, and other research conduct issues. To submit to the IRB you need to complete an e-IRB Application online, the correct Protocol Narrative (there are two), and provide applicable appendices. All of the IRB applications and forms can be found online. Once you submit the e-IRB Application online, you must submit one hard copy of all of the above documents with original signatures (including the e-IRB Application) to: Office of Research Administration, IRB, 300 University Tower.

Questions?
If you have questions about the IRB process please consult with your faculty mentor, review the Human Research Protections Web site (http://www.research.uci.edu/ora/hrpp/index.htm), or contact the UROP Office. If you have detailed questions regarding your protocol submission, please contact the appropriate IRB administrators, whose contact information is located on the back of this page.

Animal Subjects Research & the Institutional Animal Care & Use Committee (IACUC) Submission Process for Undergraduate Researchers

The Institutional Animal Care and Use Committee (IACUC) is a faculty committee charged with reviewing and approving the use of animal subjects in research and teaching activities. The IACUC serves as an institutional compliance committee and is responsible for reviewing reported instances of regulatory noncompliance related to the use of animal subjects in research.

Definition of Animal Subjects Research: The U.S. Public Health Service (PHS) Policy by which UCI abides defines "**animal**" as any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes. Any research activity that fits this definition is subject to approval by the IACUC.

Step 1. Meet with your Faculty Mentor
Before you begin the IACUC application process, you must meet with your faculty mentor to discuss the methods of your study and whether you need to submit a new IACUC application or be added to an existing protocol. For the majority of IACUC submissions, undergraduate researchers are added to existing protocols.

Step 2. Complete Tutorial(s)
Before you can be added to an IACUC protocol, you and your mentor must complete the Animal Subjects Tutorial. The tutorial reviews the core concepts and major principles concerning animal research. You can access the tutorial online (http://apps.research.uci.edu/tutorial/).

Step 3. Addition to Existing Protocol (if needed)
If you will be added to an existing protocol, the protocol's Lead Researcher must submit a Request for IACUC Protocol Modification, as described online (http://www.research.uci.edu/ora/acup/protocolmodification.htm). To verify that you have been added to a protocol, search for your assigned protocol in the Animal Subjects (IACUC) Protocol Database Query (http://www.research.uci.edu/ora/trackingprotocols.htm#Animal).

IRB & IACUC Resources

Research Protections Homepage
http://www.research.uci.edu/ora/hrpp/

Online Research Tutorials
http://apps.research.uci.edu/tutorial/

IRB Administrators
IRB A - Biomedical (949) 824-9819
IRB B - Biomedical (949) 824-2576
IRB C - Social and Behavioral (949) 824-4779

IACUC Administrator
(949) 824-8170

Undergraduate Research Opportunities Program (UROP)

Student Services II, Suite 2300
Phone: (949) 824-4189
Web site: www.urop.uci.edu
E-mail: urop@uci.edu

IRB Web sites

Human Research Protections Homepage
http://www.research.uci.edu/ora/hrpp/index.htm

IRB Applications and Forms
http://www.research.uci.edu/ora/forms/

Especially for Student Researchers
http://www.research.uci.edu/ora/hrpp/studentresearchers.htm

IRB Modification
http://www.research.uci.edu/ora/hrpp/modificationstoapprovedresearch.htm

Human Subjects (IRB) Protocol Database Query
http://www.research.uci.edu/ora/trackingprotocols.htm#Human

IACUC Web sites

Animal Care and Use Program Homepage
http://www.research.uci.edu/ora/acup/index.htm

IACUC Modification
http://www.research.uci.edu/ora/acup/protocolmodification.htm

Animal Subjects (IACUC) Protocol Database Query
http://www.research.uci.edu/ora/trackingprotocols.htm#Animal