

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 that all proposed human research studies are 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”). If you are conducting human subjects research then 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 at: http://www.research.uci.edu/forms/docs/irb-forms/3_RequestDeterminationNon-HumanSubjects.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 will need to submit a new IRB application or be added to an existing protocol. If you need to be added to an existing protocol, the Lead Researcher on that protocol will need to add you to the research team by completing a “Modification Application,” available online at: <http://www.research.uci.edu/compliance/hscro/modifications-to-approved-research-hscro.html>. To verify that you have been added to a protocol, use the Human Subjects (IRB) Protocol Database Query <http://www.research.uci.edu/compliance/tracking-protocols.html> to search for your assigned protocol.

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 will review the core concepts and major principles for conducting human subjects research. You can access these tutorials online at: <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. More information on the levels of review is available online at: <http://www.research.uci.edu/compliance/human-research-protections/researchers/levels-of-review.html>.

Step 4. Review IRB Forms and Application Procedures

The Human Research Protections Web site, located online (<http://www.research.uci.edu/compliance/human-research-protections/index.html>), has helpful information on getting started, the protocol review process, and other research conduct issues. To submit to the IRB you will 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, 5171 California, Suite 150, Irvine, CA 92697.

Questions?

If you have questions about the IRB process please consult with your faculty mentor, review the Human Research Protections Web site, 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 by 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 will 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 the 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 will review the core concepts and major principles concerning animal research. You can access the tutorial online at apps <http://apps.research.uci.edu/tutorial/>. It is important to become thoroughly familiar with the major concepts concerning animal research.

Step 3. Addition to Existing Protocol (if needed)

If you need to be added to an existing protocol, the Lead Researcher on that protocol will need to add you to the research team by ‘Modifying’ the existing Protocol. Please check : <http://www.research.uci.edu/compliance/hscro/modifications-to-approved-research-hscro.html> for ways to do this. To verify that you have been added to a protocol, use the Animal Subjects (IACUC) Protocol Database Query to search for your assigned protocol. This can be found online at: <http://www.research.uci.edu/compliance/protocol-search.html>.

IRB & IACUC Resources

Regulatory Compliance Homepage

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

Online Research Tutorials

<http://apps.research.uci.edu/tutorial/>

IACUC Web sites:

Animal Care and Use Program Homepage

<http://www.research.uci.edu/compliance/animalcare-use/index.html>

IACUC Modification

<http://www.research.uci.edu/compliance/hscro/modifications-to-approved-research-hscro.html>

Animal Subjects (IACUC) Protocol Database Query

<http://www.research.uci.edu/compliance/protocol-search.html>

IRB Administrators:

IRB A- Biomedical (949) 824-3711

IRB B- Biomedical (949) 824-2576

IRB C- Social and Behavioral (949) 824-4779

IACUC Administrator:

(949) 824-8170

IRB Web sites:

Human Research Protections Homepage

<http://www.research.uci.edu/compliance/human-research-protections/index.html>

IRB Applications and Forms

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

Especially for Student Researchers

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

IRB Modification

<http://www.research.uci.edu/compliance/hscro/modifications-to-approved-research-hscro.html>

Human Subjects (IRB) Protocol Database Query

<http://www.research.uci.edu/compliance/protocol-search.html>

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