

HRPP Contacts

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Did you Know...

- There is a webpage especially for [student researchers](#)?
- HRPP staff are available for [in-service training](#)?
- You can [check](#) to see if all study team members have taken a required tutorial?
- AAHRPP [accreditation standards](#) are available on line?

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UNIVERSITY of CALIFORNIA • IRVINE

Human Research Protections Program

News Brief

IRB Task Force Recommendations Received

Susan V. Bryant, Ph.D., Vice Chancellor for Research, assembled a faculty IRB task force in January to make recommendations to improve and simplify the regulatory processes at UCI while maintaining the safety of human research subjects. The task force made several recommendations for restructuring the IRB function including:

1. Leadership change with more direct faculty oversight,
2. Streamlining processes to save time for researchers and IRB staff members,
3. Improve the transparency of the IRB process, and
4. Resources including staffing and training.

A number of the recommendations have been implemented. In conjunction with the upcoming appointment of a new Associate Vice Chancellor for Research Compliance, a group will be formed to consider the report and make further changes and improvements as appropriate.

UC Irvine Pursues AAHRPP Reaccreditation

Reaccreditation Starts Now - UC Irvine is in the process of conducting a self-assessment of its HRPP. We will submit our Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) application for reaccreditation in December 2007 and anticipate a site visit Spring 2008. UC Irvine's HRPP became AAHRPP accredited in September 2005. UC Irvine was the first university in California and the first UC campus to receive AAHRPP accreditation. In order to maintain accreditation, UC Irvine must renew every three years.

AAHRPP Accreditation has Value — AAHRPP accreditation enhances UC Irvine's reputation and the quality of our research and gives us a competitive edge with sponsors. OHRP and the FDA recognize the value of accreditation. Moreover, through the self-assessment process, UC Irvine HRPP continues to develop effective and efficient processes. Written policies and procedures have been developed to reduce the need for the IRB to make decisions on a case-by-case basis, and to provide guidance to investigators about human research protections issues and the IRB review process.

What is Human Subjects Research?

Understanding the definition of human subjects research is the first step in determining whether an activity will require Institutional Review Board (IRB) review and approval before it begins. 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.

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.

Clinical investigation is any experiment that involves a test article and one or more human subjects and is subject to FDA regulations and oversight.

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.

Need more information? Click on these links: [Definition of HS research](#) [Form for determining non-HS research](#)

Tips for Submitting Complete IRB Applications

One of the top ten reasons for [delays](#) in IRB review is an incomplete submission. Specific instructions, suggestions, and website references for completing each section of the application are provided in the [application instructions](#). A [submission checklist](#) also is available on the HRPP website. At minimum, a complete submission includes an IRB Application for Review and a Protocol Narrative.

IRB Application:

Complete the entire web-based application and give special consideration to the sections with appendices. Many of the check boxes in these sections generate forms that provide additional information necessary for IRB review.

IRB Protocol Narrative:

The IRB Application will prompt the user to download the Protocol Narrative. Alternatively, you can complete the [Protocol Narrative](#) in advance of starting the application. Remember to **save** the Protocol Narrative to your computer. Once saved, it is safe to upload the narrative to the electronic IRB Application module.

Informed Consent Document:

Studies that require a written informed consent document must have a consent form uploaded to the IRB Application. The investigator develops a consent document by following one of the [informed consent templates](#) on the IRB forms page.

- **Full committee studies** almost always require a written informed consent document. An informed consent document should be uploaded to the electronic IRB Application.
- **Expedited studies** require a written informed consent document unless a waiver of informed consent or a waiver of documentation of consent can be justified (See Appendices O and P in the IRB Application).
- **Exempt studies** do not require a written informed consent document. Often no consent is required, or verbal consent with a study information sheet or an introductory letter may be used when interacting with living individuals. If a study information sheet or letter will be used it should be uploaded to the electronic IRB Application. A [study information sheet template](#) is available from the IRB forms page on the HRPP website.

Tips for Student Research Projects

1. Determine if your activity constitutes [human subjects research](#).
2. Meet with your faculty mentor to discuss your research design and methods and how to complete your IRB application.
3. For studies that involve interactions with subjects, determine how you will recruit subjects and obtain [informed consent](#) (written or verbal).
4. Assure all study team members, including your faculty mentor have met the required human research tutorial requirements.
5. Review the [levels of review](#) on the HRPP website before starting your application. Most student research falls into the exempt and expedited research categories.
6. Use the [Submission Checklist](#) to assure all requirements have been met.
7. Submit early (at least 3 weeks in advance) to allow for clarification of issues and IRB review.
8. If you plan to conduct research off-site (e.g., at an elementary school) be sure to obtain written permission from the authorized individual of the site.
9. Assure that you obtain all of the required signatures on your IRB application. You will need a signature from your Faculty Sponsor (faculty mentor) and your Department Chair. Submit the original signed hard copy to the IRB.
10. Check your UCI email account (@uci.edu) for messages from the IRB.

Other Documents to Provide for IRB Review:

- Sponsor investigator brochures and master protocols
- The "Human Subjects" section of DHHS funding proposals
- Recruitment materials, such as advertisements and flyers
- Data collection instruments (e.g., questionnaires and surveys)
- Permission letters from offsite locations
- IRB approval letters from offsite collaborators
- Verbal scripts and study information sheets
- Assent forms for children
- Data extraction sheets for record / chart reviews