

HRPP Contacts

IRB-A

Kristina Grimaldi, 949-824-6068

Matt Kinder, 949-824-9819

Tahseen Mozaffar, MD, Chair,
714-456-2332

IRB-B

Theresa Sanchez, 949-824-2125

Cheree Dubose, 949-824-5622

Samantha Pash, 949-824-2576

Kenneth Linden, MD, Chair,
714-456-3720

IRB-C

Matthew Alcalá, 949-824-6662

Alicia Tieman, 949-824-7114

Jessica Sheldon, 949-824-4779

Ruth Mulnard, RN, DNSc, FAAN, Chair,
949-824-7016

IRB-D

Kin Hang, 949-824-0665

Valerie Miran, 949-824-7109

Laverne Estanol, 949-824-3831

Assistant Director Human Research Protections

Beverly Esparza, 949-824-5746

Director Human Research Protections

Karen Allen, 949-824-1558

Assistant Vice Chancellor Research Administration

Christina Hansen, 949-824-5677

Did you know...

When revising documents to submit with a modification request, it is strongly recommended that you use the most recent IRB approved editable versions posted on the Document Depot.

Also, please **DO NOT** submit additional modification requests until any pending requests are approved and the editable documents are posted to the Document Depot.



December 2008

UNIVERSITY of CALIFORNIA • IRVINE

Human Research Protection Program

News Brief



Happy Holidays from the HRP Staff



Important Changes Effective in 2009

Beginning in January 2009, there will be several improvements to our IRB templates and procedures. Many of the changes were recommendations from our 2008 AAHRPP evaluation. Below is a summary of some of these changes:

IRB Deadlines:

The **IRB full committee deadlines** will fall on **Tuesdays** starting in 2009. This change will give IRB members sufficient time to review the revisions submitted by investigators in response to the HRP staff pre-review comments.

Protocol Narratives:

- Two separate protocol narratives will be available. An abbreviated narrative specifically for **Exempt research** and an **Expedited/Full Committee narrative**.
- To qualify as Exempt, the research must fall into one of the six (6) federally-defined [exempt categories](#). These categories present the lowest amount of risk to potential subjects. The newly developed protocol narrative for exempt research will assist investigators in determining whether their research is exempt.
- The Expedited/Full Committee narrative is similar to the existing narrative with some minor revisions. For example, questions related to the scientific merit of the study have been refined.
- It is recommended that when submitting a new IRB application, investigators complete and upload the new Exempt protocol narrative or the revised Expedited/Full Board narrative. Effective **February 2009** any new IRB application submitted with the old narrative format may be held pending submission of the appropriate new narrative.

Consent Form Template:

The consent templates will be modified to include descriptions of common risks including a breach of confidentiality and template language for data retention. Effective **February 2009** investigators are required to ensure that new consent documents include the updated informed consent language.

Emergency Use Requests:

- The [April/May HRPP News Brief](#) detailed the procedure for requesting permission for an Emergency Use Request. It is strongly recommended that investigators wanting to use an investigational drug or device under the [FDA's emergency use option](#), consult with an IRB Chair or the HRPP staff to ensure that the circumstances meet the FDA's requirements. [The Emergency Use form](#) must be submitted to the IRB within 5 working days of the emergency use. The completed form, along with any exceptions to the requirement to obtain informed consent, will be reviewed by the IRB at a convened meeting to confirm that the circumstances followed the regulatory requirements.
- The [Emergency Use Template Consent Form](#) has been revised to include the additional required elements of informed consent.

GOOD NEWS!!

*Announcing a new
HRP Team !*

IRB D will facilitate the review of biomedical Exempt and Expedited human research protocols.

This new team will ensure the protection of human subjects while improving the IRB review process for minimal risk research.

IRB D submissions will be reviewed by a subcommittee of the biomedical IRBs. Reviews will take place on a weekly basis.

The anticipated turnaround is 3-5 weeks depending on volume as well as the completeness of the submission.

ICTS Scientific Review Committee

The **Institute for Clinical and Translational Science (ICTS)** will form two scientific review committees to facilitate the review of human subjects research. While the IRB is responsible for ensuring that risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; the charge of the **ICTS Scientific Review Committee (SRC)** is to:

- review for scientific validity all UCI human research studies to be conducted by **College of Health Science (COHS) faculty** that have not previously received scientific peer review. The ICTS SRC will review new IRB submissions from COHS including minimal risk research (exempt or expedited review) and greater than minimal risk research (full committee review);
- review any UCI human research study where the investigator is requesting ICTS resources regardless of whether the Lead Investigator is COHS faculty; and
- review any UCI human research study that will be conducted in any of the clinical sites of the COHS regardless of whether the Lead Investigator is COHS faculty.

Effective January 2009 new IRB applications that meet the above criteria require ICTS SRC review **prior to** IRB review. Submission of the IRB documentation to the ICTS is no longer sufficient to initiate IRB review. To avoid undue delay for investigators, the ICTS SRC has formed two committees. Each committee will meet once per month and each SRC meeting will be held in advance of a biomedical IRB meeting. Investigators requiring ICTS SRC review must submit their IRB documentation and any other requisite documentation to the ICTS SRC a week in advance of the intended biomedical IRB deadline. Submission [deadlines for ICTS SRC review](#) are posted on ICTS website. It is the investigator's responsibility to submit the documentation directly to the SRC Administrator, Lisa Twachtman at ltwachtm@hs.uci.edu. Submissions that receive SRC approval or require minor revisions can be included on the IRB meeting agenda, depending on the submission volume. Minor revisions memos from the SRC will be incorporated into the HRP Staff pre-review memo. Submissions that require resubmission to the SRC cannot be included on the IRB agenda. Investigators will work directly with the SRC to resolve the outstanding issues. The SRC has also developed a fast-track process (subcommittee process) for submissions not requiring full SRC review. Please see the [ICTS website](#) for more information about the SRC process.

IRB Protocol Submission Deadlines for January/February Meetings:

- IRB - C: December 19
- IRB - A: January 6
- IRB - B: January 27
- IRB - C: February 3
- IRB - A: February 10

Human Subjects Protections and Conflict of Interest

Per UCI policy, Lead Investigators must ensure that all co-investigators and research personnel involved in human subjects research disclose their financial interests with outside institutions when submitting an application for IRB review. This requirement applies to all studies, both sponsored and un-sponsored research. Moreover, disclosures must be submitted at initial submission and at continuing review.

Disclosable Financial Interests - Investigators, co-investigators and research personnel must report for themselves, their spouses and dependent children the following:

- **Ownership interest, stock, stock options, or other financial interest related to the research**, unless it meets all four of the following tests:
 - ◇ Less than \$10,000 when aggregated for the immediate family and
 - ◇ Publicly traded on a stock exchange and
 - ◇ Value will not be affected by the outcome of the research and
 - ◇ Less than 5% interest in any one single entity.
- **Compensation related to the research**, including salary, consultant payments, honoraria, royalty payments, dividends, loans, or any other payments or consideration with value, including payments made to the University Health Sciences Compensation Plan, unless it meets both of the following tests:
 - ◇ Less than \$10,000 in the past year when aggregated for the immediate family and the
 - ◇ Amount will not be affected by the outcome of the research.
- **Proprietary interest related to the research** including, but not limited to, a patent, trademark, copyright or licensing agreement.
- **Board or executive relationship (e.g., director, officer, partner, or trustee) related to the research**, regardless of compensation.

Best Wishes for a Happy, Healthy and Productive New Year!