Effective April 1, 2012, the Human Research Protections unit in the Office of Research will increase its Institutional Review Board (IRB) fee as follows:

<table>
<thead>
<tr>
<th>Service</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Review - Full Committee</td>
<td>$2200.00</td>
</tr>
<tr>
<td>Initial Review - Expedited</td>
<td>$1000.00</td>
</tr>
<tr>
<td>Continuing Review - Full Committee</td>
<td>$825.00</td>
</tr>
<tr>
<td>Continuing Review - Expedited</td>
<td>$500.00</td>
</tr>
<tr>
<td>Continuing Review 7-Year De Novo - Full Committee</td>
<td>$1500.00</td>
</tr>
<tr>
<td>Continuing Review 7-Year De Novo - Expedited</td>
<td>$725.00</td>
</tr>
</tbody>
</table>

This new fee structure applies to IRB Applications received on or after April 1, 2012 and that meet the following criteria:

- Designed to assess the safety, efficacy, benefits, adverse reactions, and/or other outcomes of drugs, devices, diagnostics, treatments, procedures, medical evaluations, monitoring or preventive measures; and
- Fully or partially supported by an industry sponsor; and
- Meets UCI contractual requirements for industry-supported clinical trials.

IRB fees are:

- **NOT** assessed on IRB modifications/amendments to approved studies or exempt studies.
- **NOT** assessed on clinical studies supported by the National Institutes of Health or other governmental or non-profit entities, on investigator-initiated studies that are not fully or partially supported by an industry sponsor, or on industry-sponsored studies that do not meet the above criteria.

In preparing budgets for new clinical trials, investigators should include the amount of the IRB fees to be incurred during each year of the trial. These fees are in addition to any costs the investigator might want to include for administrative activities that would be provided by the study team, such as preparation of the IRB applications and related transactions.

IRB fees are assessed as recharges to the account and fund number assigned to the clinical trial. E-mail notification is provided to the investigator and the department business office regarding the amount and date of each charge.

If you have questions please contact Karen Allen, Director, Research Protections at 949-824-1558 or karen.allen@uci.edu.
Effective October 15, 2011, individuals engaged in human subjects research must complete a Collaborative Institutional Training Initiative (CITI) educational course. Completion of a CITI course is required prior to the submission of an IRB application for individuals who intend to engage in human subject research at UCI.

Effective February 15, 2012, a CITI Refresher course is required for individuals who completed the Human Research Tutorial more than five years ago.

There are five CITI course options for researchers:

- Biomedical Basic course
- Biomedical Refresher course
- Social/Behavioral Basic course
- Social/Behavioral Refresher course
- Community-Based Researcher course (this course is for community members unaffiliated with UCI and unaffiliated with another research or academic entity)

CITI courses can take 1—3 hours to complete and can be completed over multiple sessions.

UCI researchers may complete either a Biomedical course or a Social/Behavioral course based on which course is most applicable to their research. **UCI researchers must register with CITI using their UCI Net ID as their CITI Username (if available) and UCI email address as their preferred email (required) as the IRB database links to CITI through an individual’s UCI email address.**

For UCI individuals who previously completed a CITI course within the past five years, they should go back to CITI and affiliate with UCI. **They also must update their profile for UCI to include their UCI email address.** Some individuals may need to complete additional modules depending on whether they previously completed the CITI modules required by UCI. For non-UCI individuals (faculty, staff, students) they can complete:

- Community-Based Researcher course (this is a new course) – acceptable only for community members who are unaffiliated with UCI or with another research or academic entity; or
- Provide evidence of completion of their institution’s education requirement

We receive nightly updates from CITI therefore it can take up to 24 hours for CITI completion to be reflected in HPS. CITI is not the only educational tutorial—don’t forget the HIPAA Research tutorial if Protected Health Information (PHI) is involved! Completion of the HIPAA Research tutorial is noted immediately. If you have additional questions regarding the tutorial requirements or the CITI course please contact the Human Research Protections staff.

**Human Research Records Retention**

Researchers are required to retain all study records for a minimum of three years past the close of the study. This includes approved IRB documents, as well as case-report forms, tapes or transcripts, and all other data-collection instruments and source documents.

UC General Counsel recommends longer retention periods for certain research records:

- Research records involving the generation, disclosure, and/or use of Protected Health Information (PHI) should be retained for six years.
- When children are research participants research records must be retained for seven years after all children enrolled in the study reach the age of majority [age 18 in California].
- Research records involving pregnant women must be retained 25 years.
- Investigators conducting FDA-regulated studies are required by regulation to retain records for periods which may be significantly longer than six years after study closure of the IRB protocol at UCI.

See Records Retention Requirements for more details.
**Education & Reminders:**

**HIPAA RESEARCH AUTHORIZATION**

**DOES YOUR IRB-APPROVED STUDY REQUIRE HIPAA RESEARCH AUTHORIZATION?**

HIPAA Research Authorization: HIPAA is the acronym for the Health Insurance Portability and Accountability Act of 1996. The intention of HIPAA is to protect patients from inappropriate disclosures of “Protected Health Information” (PHI) that can cause harm to a person’s insurability, employability, etc. HIPAA affects only that research which accesses, uses, creates, or discloses PHI. The IRB acts as a Privacy Board to review the use/disclosure of PHI and to determine whether the subjects should sign a HIPAA Research Authorization Form or if a Waiver of Authorization may be granted.

When the IRB determines that subjects should sign a HIPAA Research Authorization form in order to access, use, create or disclose PHI for research, subjects are to sign the UC HIPAA Research Authorization Form as part of the informed consent process. Other non-affiliated medical centers and institutions may also require that researchers use their version of the authorization form to access their medical records.

For new studies, a completed HIPAA Research Authorization form is required at initial submission to the IRB. Once the study is approved by the IRB, the HIPAA Authorization form can be accessed in the “IRB docs depot.” For older studies, go to “ORA Applications and Forms” and then “IRB Forms” to access the UC HIPAA Research Authorization Form to download a form.

**Remember:**

The UC HIPAA Research Authorization form is not the same as the HIPAA Medical form that patients sign when receiving medical care.

The UC HIPAA Research Authorization form is study specific.