UCIRVINE

Increase in IRB Fees for Industry-Sponsored Clinical Trials

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

Initial Review - Full Committee	$ 2200.00
Initial Review - Expedited	$ 1000.00
Continuing Review - Full Committee	$ 825.00
Continuing Review - Expedited	$ 500.00
Continuing Review 7-Year De Novo - Full Committee	$ 1500.00
Continuing Review 7-Year De Novo - Expedited	$ 725.00

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 Applications that meet the above criteria and are received prior to April 1, 2012 will remain on the old fee structure:

Initial Review - Full Committee	$ 1500.00
Initial Review - Expedited	$ 500.00
Continuing Review - Full Committee, including 7-Year De Novo	$ 500.00
Continuing Review – Expedited, including 7-Year De Novo	$ 500.00

IRB fees are not assessed on IRB modifications/amendments to approved studies or exempt studies.

IRB fees will not be 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 and authorized by signature of the Lead Researcher on the IRB application form. 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 about the new IRB Fee structure, please contact Karen Allen, Director, Research Protections at 949-824-1558 or karen.allen@uci.edu.