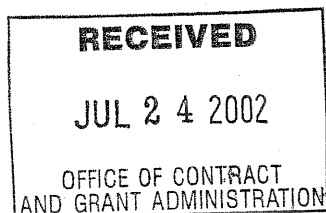




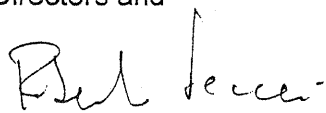
# MEMORANDUM

Office of the Chancellor  
140501



July 19, 2002

To: Deans, Department Chairs, Organized Research Directors and Investigators

From: Roberto D. Peccei, Vice Chancellor for Research 

Subject: Implementation of IRB review fees for industry-sponsored clinical trials

After much consideration and following discussion with the Human Research Policy Board (HRPB), the campus has decided to implement a fee for review of human subject protocols submitted to the Medical Institutional Review Boards (IRBs) in connection with industry-sponsored clinical trials. In making this decision, UCLA joins an increasing number of academic institutions that levy fees for review of certain human subject protocols.

IRB fees will be applicable only to those studies that UCLA classifies as clinical trials. These are studies:

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

IRB fees will not be imposed on clinical studies supported by the National Institutes of Health (NIH) or other government agencies, on investigator-initiated studies, or on industry-sponsored studies that do not meet the UCLA definition of clinical trials.

Fees of \$1,500 for review during the initial year of the study, and \$350 for each year of renewal, have been established. The fees will be phased in as new clinical trial agreements are negotiated. These fees will be charged on a per-study basis and will remain constant, regardless of the number or complexity of reviews required for each study. They will not apply to ongoing studies.

It is our understanding that at many other academic institutions where IRB fees are charged, the fees are shown as a separate budget category distinct from other project costs and invoiced separately. In negotiating new clinical trials, we will assume that the sponsor will provide separate reimbursement for IRB fees. Accordingly, the fees should be reflected as a separate line item in the contract budget. Extramural Fund Management (EFM) will generate invoices when the study is funded and an account/fund number is established. No charge will be assessed for proposals that are not funded. Monies received will be deposited into an account accessible only by the

Office for the Protection of Research Subjects (OPRS). These monies represent important additional resources needed to provide improved service to faculty researchers as demand for IRB reviews continues to increase, for example, the support of a third Medical IRB.

Budgeted IRB fees should reflect the anticipated length of the study. That is, the budget for a one-year study should reflect a \$1,500 fee, whereas budgets for multiple year studies should be based on fees of \$1,500 plus \$350 for each additional year. IRB fees for the first year will be charged at the inception of the study and continuing fees at the time of each annual renewal. Should an ongoing study be amended to extend the period of performance, additional IRB fees will be charged when the amendment is executed.

Independent of the IRB fees, investigators may also want to budget costs for activities related to the administration of the study as a separate item, if support for these activities is not already included in the personnel category. This would include activities such as preparation of applications for initial and continuing IRB reviews, protocol amendments, and adverse event reporting.

We anticipate that in a small number of cases, pharmaceutical companies may not agree to a separately budgeted and invoiced clinical trial fee. If this should occur, please be advised that once an agreement has been executed, EFM will transfer IRB fees out of the project account/fund to OPRS as part of the project award process.

The decision to implement an IRB fee was not made lightly. It was made, in part, in recognition of the increasing costs of institutional regulatory compliance. Additionally, we know that many industrial sponsors are accustomed to paying for IRB charges and, in fact, are already doing so elsewhere. I would be happy to address any questions you might have about this decision.