



UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTION PROGRAM
FACT SHEET

Institutional Review Board (IRB) fees for commercially-sponsored projects

Effective November 1, 2001 the UCSD Human Research Protection Program will begin billing commercial sponsors for IRB review and ongoing monitoring of sponsored projects conducted by UCSD faculty and staff. This Fact Sheet is in the format of a "Frequently Asked Questions" summary.

Q. What projects are affected by the review charges?

A. New commercially-sponsored clinical trials agreements submitted on or after November 1, 2001 to the UCSD School of Medicine Office of Contracting/Legal Liaison (see: <http://medicine.ucsd.edu/legal/>) will include, as part of the negotiation process, the notification to the sponsor that UCSD will issue an invoice for IRB review of the project. All existing clinical trials contracts will be honored, however if budgets are re-negotiated for an ongoing clinical trial, an IRB review fee may be generated if a new project submission to the IRB results from the revised contract.

Q. How much is the charge and what does it cover?

A. The UCSD campus recharge committee has approved a flat rate fee of \$1400 which covers initial review and all subsequent IRB actions such as review of amendments and changes to consent forms, for a period up to 2 years (the maximum approval time for projects at UCSD, after which a new project submission is required.) This fee is based on the actual cost of services provided and on comparability with equivalent services provided by other UC campuses and commercial IRB organizations.

Q. Will UCSD investigators be billed for IRB review?

A. No. The invoice for IRB review will be sent by the UCSD Bursar's Office to the sponsor, not to the principal investigator. For this reason, it is important that UCSD investigators delete from their project budgets any item labelled "IRB review fee." Investigators may wish, however, to retain a budget item for "IRB document preparation" or "Regulatory review submission preparation."

Q. Does payment of the IRB review fee by a sponsor guarantee project approval?

A. No. The IRB performs an independent review that follows the policies and procedures outlined in the Code of Federal Regulations relating to human subjects protection. The review fee will be assessed of project sponsors regardless of the outcome of the review.

Q. What will the income generated by the IRB fee be used for?

A. Income to the Human Research Protection Program that results from the review fee will be applied to improving the efficiency, effectiveness, and speed of the IRB review process. This will include new computer and information technologies that enable online submission of IRB applications, amendments, and adverse event reporting, an electronic document infrastructure for IRB records, as well as educational and technical enhancements for UCSD investigators and for IRB committee reviewers.

For further information, contact the UCSD Human Research Protection Program office at 858-455-5050, or e-mail hrrp@ucsd.edu