

UCI ADMINISTRATIVE POLICIES & PROCEDURES

RESEARCH AND SPONSORED ACTIVITIES

Human Subjects Research

Section 485-2: IRB Review Fee Recharge Program

Responsible Office: Office of Research Administration

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Summary

On July 1, 2003, the campus instituted a program to charge for-profit sponsors a fee for the UCI Institutional Review Boards (IRB) review of new and continuing human subjects research protocols. Exempted from the fees are studies wholly funded by: public entities, such as Federally sponsored studies; cooperative group trials; private non-profit entities; gifts to the University; or internal sources. In 2008, this policy was revised to exempt from payment of the review fee, full committee protocols that have closed to enrollment and completed interventions or that are open solely for data analysis.

Background

Institutional Review Boards (IRBs) and their human subject protection programs are highly regulated operations requiring experienced researchers, highly skilled staff, and dedicated community and non-scientific representatives. All institutions performing human research with federal funding must comply with two sets of federal regulations (45 CFR 46, governing research supported by any federal agency, and 21 CFR 50 and 56, governing research on products regulated by the Food and Drug Administration). The Department of Health and Human Services' Office for Human Research Protections (OHRP) and the Food and Drug Administration provide oversight of institutional human research protection programs. UCI accepts federal funding and, thus, falls under the terms of these regulations.

The IRB fee supports the increasing costs of IRB operation and research oversight not otherwise covered by the overhead assessment. These fees provide funding:

- to increase support for and participation of clinical faculty as IRB members,
- to promote the value of the IRB, and
- to subsidize the costs of training and compliance.

Implementation

A predetermined fee is assessed for IRB review of studies supported by for-profit, commercial entities. For-profit sponsors routinely allow such a fee in their budgets.

Studies that are internally funded or supported by non-profit entities are exempted from the IRB review fees. At this time, federally supported studies and NCI-sponsored cooperative group trials are not assessed a review charge since the expense is considered part of Facilities and Administrative (indirect) costs rate.

Also exempted are protocols reviewed after February 1, 2008, for continuing review of research that was approved previously by the full IRB and:

- a. where the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; or
- b. where the remaining research activities are limited to data analysis.

Payment of the fee will not provide additional services (e.g., preferential review or faster response time), nor guarantee the outcome of the review.

Amount of Fee

The IRB review fee schedule is shown below. The fee level is consistent with rates at other university medical centers. The rates will be reviewed annually and adjustments made as necessary.

<u>Initial full committee review</u>	<u>\$1,500</u>
<u>Continuing or expedited review</u>	<u>\$ 500</u>

Additional F&A costs are assessed on the IRB review fee.

Processing of the Fee

In order to reduce the administrative burden on investigators and staff, ORA Sponsored Projects and IRB staff notes the anticipated funding source in the ORA databases and track the execution of the agreement with a for-profit sponsor. When the contract is finalized and the IRB approval is issued, RGS Operations electronically issues an Interdepartmental Recharge Invoice to the appropriate account/fund. Questions regarding the appropriateness of the charge should be directed to the ORA Director of Human Research Protections or the ORA Director for Sponsored Projects.

The ORA Director of Human Research Protections retains the right to waive or reduce the fee when justified under special circumstances. Such waiver requests must be made in writing and signed by the Lead Researcher. Any approved waiver does not establish a precedent for other actions unless the policy is amended.

Appeals may be directed to the Assistant Vice Chancellor for Research, ORA.