**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

Issued: July 1, 2003

Revised: March 17, 2008

**Revised: May 3, 2019**

**Summary:**

The Office of Research will assess fees for the Institutional Review Board (IRB) review related to clinical trials initiated and supported by industry sponsors. 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. IRB fees are not charged to 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 (FDA)). The Department of Health and Human Services' Office for Human Research Protections (OHRP) and the FDA provide oversight of institutional human research protection programs. UCI accepts federal funding and, thus, falls under the terms of these regulations. Commensurate protections are in place for non-federally supported research.

The IRB fee supports the increasing costs of IRB operation and research oversight not otherwise covered by the overhead assessment.

**Amount of Fee**

Refer to [Human Research Protections Policy # 6](https://www.research.uci.edu/compliance/human-research-protections/hrp-policy-library/hrppPolicies.htm) for the IRB review fee schedule. The rates will be reviewed annually and adjustments made as necessary. Additional F&A costs are assessed on the IRB review fee.

**Implementation**

A predetermined fee is assessed for IRB review of studies fully or partially supported by for-profit, commercial entities. For-profit sponsors routinely allow such a fee in their budgets. Studies that are fully internally funded or supported by non-profit entities are exempted from the IRB review fees. 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.

**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, Office of Research Operations electronically issues an Interdepartmental Recharge Invoice to the appropriate account/fund. Questions regarding the appropriateness of the charge should be directed to the Executive Director of Research Protections or the Executive Director for Sponsored Projects.

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