

**University of California, Irvine
Human Research Protections
Standard Operating Policies and Procedures**

Policy Number: 6

Title: IRB Fees for Industry-Supported Applications

Date of Last Revision: 01/29/09, 09/25/09, 02/03/12, 05/01/16, 08/01/17, 05/03/19, 03/04/22, 09/12/2022, 12/07/2022

Policy:

- I. The Human Research Protections (HRP) unit in the Office of Research will charge Institutional Review Board (IRB) fees for new clinical research submissions that are partially or fully supported by industry sponsors, including chart review studies.
- II. If UCI defers review to an independent IRB (e.g., WCG, Advarra), HRP charges a fee for administrative review and oversight.
- III. Effective September 1, 2021, NEW clinical research protocols partially or fully supported by industry sponsors will be charged a ONE-TIME fee at the time of UCI or sIRB approval.
 - A. There will be no fee for renewals.
 - B. There will be no fee for amendments.
 - C. There will be no fee for closing reports.
 - D. There will be no fee for unanticipated problems.
 - E. Currently approved protocols will no longer be charged.

This fee will adjust annually to align with HRP expenses. The rate will adjust up or down based on actual expenditures for the current fiscal year, and projected expenses for the following fiscal year. For budgeting purposes, Researchers should assume that the future fee will be at least 3% higher than the current rate.

- IV. IRB applications that are dependent on State, Federal, non-profit foundations, or fully supported by non-Industry Sponsor funds will be excluded from IRB fees.
- V. Under extenuating circumstances, the Associate Vice Chancellor for Research Administration or the Director of Research Protections may waive the assessment of IRB fees with a formal request from the Investigator and appropriate documentation to support such circumstances.
- VI. **It is expected that Investigators incorporate and negotiate applicable IRB fees into the research contract.**
- VII. IRB fees will be assessed as recharges to the account and fund number assigned to the research study. E-mail notification is provided to the investigator and the department business office regarding the amount and date of each charge.
- VIII. The collected IRB fees provide benefits to the campus research enterprise. IRB fees are used to pay for continued education and training opportunities for IRB Staff. IRB fees are used to provide compensation to the IRB Chairs and IRB members. A percentage of select IRB Staff salaries are dependent on IRB fees.