

P&P: FO 305 Version No: 1.0 Effective Date: 12/05/2025	BILLING FOR IRB SERVICES	Supersedes: Document Dated: n/a
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1. POLICY

It is the policy of the University of California, Berkeley (UCB) Office for Protection of Human Subjects (OPHS) that Institutional Review Board (IRB) services must align with the principles of being good stewards of the taxpayer money which supports OPHS and the UCB IRBs. As such, IRB services which are provided in the furtherance of industry-sponsored research initiated by the industry sponsor must be paid for by the industry sponsor.

Specific Policies

1.1 Industry Funded Research

- 1.1.1 UC may not use taxpayer money to subsidize industry activities.
- 1.1.2 When an industry partner both funds and initiates (e.g. writes the protocol, directs the research, determines the research aims, and objectives, etc.) a human subjects research activity, IRB review, approval, and ongoing oversight is deemed to primarily benefit the industry partner.
- 1.1.3 Industry partners may also include protocols submitted by entities with a contractual agreement with UCB that may include the use of UCB facilities.
- 1.1.4 In such cases, UCB's involvement is akin to provision of a service.
- 1.1.5 As such, all costs associated with OPHS' and the UCB IRBs' review, approval, and ongoing oversight of such human subjects research protocols must be covered by the industry partner.

1.2 Federally Funded Research

- 1.2.1 UCB includes costs related to compliance activities, including OPHS' and UCB IRBs' review, approval, and ongoing oversight of such human subjects research protocols in its Facilities & Administration (F&A) costs included in the federally negotiated F&A rate.
- 1.2.2 As such, costs associated with OPHS' and UCB IRBs' review, approval, and ongoing oversight of such human subjects research protocols are covered by the F&A costs included in the awarded grant or contract and a separate fee is not charged.
- 1.2.3 In accordance with NOT-OD-16-109, UCB and OPHS reserves the right to implement additional fees above and beyond those included in the federally negotiated F&A rate when it agrees to serve as the IRB of record for non-UCB institutions, including other UC campuses.
- 1.2.4 Additionally, when UC Berkeley is asked to rely on an outside IRB and the federal funder has agreed to pay IRB review fees, a fee will be charged in accordance with the fee schedule.

1.3 Unfunded Research Initiated by UCB Affiliates

- 1.3.1 In accordance with the Belmont Report, UCB believes that all human subjects research initiated by UCB affiliates, regardless of funding, should undergo IRB review and receive IRB approval or an exempt determination prior to being conducted.
- 1.3.2 As such, costs associated with OPHS' and UCB IRBs' review, approval, and ongoing oversight of such human subjects research protocols are covered by the University.

1.4 Research for Which UCB is not Engaged

- 1.4.1 OPHS and the UCB IRBs are primarily funded by the University and federal F&A costs which are both forms of taxpayer money.
- 1.4.2 As such, OPHS and the UCB IRBs may not offer IRB review, approval, and oversight services for research in which UCB is not engaged.
- 1.4.3 UCB is considered engaged whenever one or more of the scenarios discussed in the [CPHS Guidelines on Engagement in Human Subjects Research](#) is met.

2. SCOPE

These policies and procedures apply to all UC Berkeley engaged human subjects research reviewed by OPHS/CPHS and/or an outside IRB.

3. RESPONSIBILITY

OPHS staff carry out these responsibilities under the supervision of the OPHS/Research Subject Protection Director.

4. PROCESS OVERVIEW

An OPHS administrative staff member will pre-review all applications for applicability of this policy. Those to which a fee applies will be referred to the OPHS staff billing coordinator. If the study is eventually approved, the OPHS billing coordinator will contact the UCB Industry Alliances Office (IAO) to obtain contact information for the appropriate billing contact. The protocol and billing information is communicated to the Vice Chancellor for Research's Office (VCRO) billing contact to initiate the billing process. Payment is expected within 31 days of the invoice.

5. APPLICABLE REGULATIONS AND GUIDELINES

UC Grants and Contracts Manual Chapter 8: <https://www.ucop.edu/research-policy-analysis-coordination/resources-tools/contract-and-grant-manual/chapter8/index.html>

NIH Notice NOT-OD-16-109: Scenarios to Illustrate the Use of Direct and Indirect Costs for Single IRB Review under the NIH Policy on the Use of a Single IRB for Multi-site Research <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-109.html>

CPHS Guidelines on Engagement in Human Subjects Research: <https://cphs.berkeley.edu/engagement.pdf>

Compliance Committee Review Fee Schedule. Please contact OPHS at ophs@berkeley.edu for the current fee schedule.