



OHRPP Updates

July 13, 2023

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Increase in IRB Review Fees/New Reliance Fee



FDA Proposed Rule for use of SIRB



OHRPP Announcements



Increase in IRB Review Fees

A change in the rate of the IRB fees charged for industry-sponsored clinical trials will be effective as of September 1, 2023

- **The new fee of \$3,200 will be charged for *UCLA IRB review* of industry-sponsored clinical trials that meet the following conditions:**
 - Designed to assess in humans the safety, efficacy, benefits, adverse reactions, and/or other outcomes of drugs, devices, diagnostics, treatments, procedures, medical evaluations, monitoring or prevention measures; and
 - Fully supported by an industry sponsor; and
 - Meet the University contractual requirements for industry-supported clinical trials.

New Reliance Fee

- **As of September 1, 2023, there will be a new fee of \$2,000 charged for any industry-sponsored clinical trial *that utilizes a reliance mechanism* for the IRB review and approval.**
 - Although not reviewed by a UCLA IRB, these arrangements take time and effort of OHRPP staff
- **The number and complexity of human research protocols at UCLA has increased substantially in recent years. Each of these studies requires review and ongoing oversight by an IRB.**
- **The new fee structure for industry-funded research was given careful consideration, including analysis of fees charged by other Universities and UC campuses, and discussion with IRB Chairs and research administration staff.**
- **The new fees will only be charged once per study**

Increase in IRB Review Fees

- **The IRB fee is to be budgeted as a separate line item in the contract budget and reimbursed by the Industry sponsor at the time of contract execution.**
 - The invoicing and collection of the fee will be managed by UCLA's Research Administration with assistance from School of Medicine Clinical Trials Contracts and Strategic Relations (CTC&SR) team.
 - The fees collected will be deposited into an account used for support of the Office of Human Research Protection Program (OHRPP).
- ***IRB review fees are not charged* for clinical studies supported by the National Institutes of Health (NIH) or other government agencies, investigator-initiated studies, or industry-sponsored studies that do not meet the UCLA definition of a clinical trial.**

FDA Proposed Rule for Use of SIRB

- **On September 28, 2022 the FDA released two Notices of Proposed Rulemaking (NPRM) to align sections of the FDA's human subjects protection regulations with the revised Common Rule.**
- **The FDA is proposing to replace current requirements for FDA-regulated cooperative research with new requirements that would require any institution located in the United States participating in FDA-regulated cooperative research to rely on review and approval by a single institutional review board (IRB) for that portion of the research that is conducted in the United States.**
- **The UCLA Human Research Policy Board met on June 1, 2023 and unanimously voted for this requirement to become policy in advance of the FDA's final rule with an implementation date slated for Fall 2023.**



OHRPP Office Hours

- OHRPP Quality Improvement Unit staff are hosting *half-hour open Q/A sessions every other week* to answer your questions
- *Upcoming sessions*
 - Thursday, August 17, 2023 2pm
 - Thursday, August 31, 2023 2pm

Register once and you can join any session.



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