



Research Administration

Human Research Protection Program

Human Research News

January 10, 2024 (Revised)

1) **January 25, 2024 – UCLA Will Use Commercial IRBs for FDA Regulated, Multi-Site, Industry Sponsored Clinical Trials**

- The FDA has [proposed revisions](#) to their requirements to harmonize with the revised common rule. As a result, they have proposed to require single IRB review for multi-site projects.
- In anticipation of the final rule, the UCLA HRPB agreed that commercial IRBs will be used for the oversight of FDA Regulated, Multi-Site, Industry Sponsored Clinical Trials **starting January 25, 2024**.
- Please note that these studies will be charged the updated review fees for industry sponsored clinical trials that utilize a reliance mechanism. Please see the reminder below.
- Please review the [FAQs for the Commercial IRB Review](#) for detailed information on this [change](#).
- OHRPP has also been contacting investigators and study teams that may be impacted by this change to offer a targeted training on this process. If your team will be impacted by this change and you feel that your group would benefit from a targeted training (and have not yet been contacted by our office), please email irbreliance@research.ucla.edu.

2) **Reminder - Updated OHRPP/IRB Review Fees started September 1, 2023**

- Applies to *industry-sponsored clinical trials* only
- A 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

- The flat fee for UCLA IRB review covers initial review as well as all AMs, CRs and PARs
- A fee of **\$2000** will be charged for any industry sponsored clinical trial that utilizes a *reliance mechanism* for the IRB review and approval. This fee will only be charged once per study.
- 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.

3) Reliance Team updates

- ORHPP welcomes our new Assistant Director of Reliance & Regulatory Management, Rebecca Flores Stella. Rebecca was previously the Administrator for MIRB2. We are grateful for Rebecca taking on this role as our office increasingly reviews for and relies on other IRBs.
- We also welcome two new Reliance Senior Analysts, Gerard Aquino (previously from MIRB2) and Ryan Garcia who will be new points of contact for reliance submissions and inquiries.
- For reliance questions, please continue to contact irbreliance@research.ucla.edu

4) OHRPP's "Learn at Lunch" –

- To help study teams prepare to submit to Commercial IRBs, we are welcoming representatives from Advarra and WCG to speak on their IRB submission process and resources available for research teams using their services. They will each have one session in January and a repeat session in February. We encourage everyone to sign up for one session from each IRB.

"Submitting to Advarra as sIRB"

Presenter: Andrew Saunders, Associate Director, Client Services, Institutional Services at [Advarra](#)

1) Date: **Wednesday, January 17, 2024**

Time: **Noon-1pm**

Location: **Zoom** ([Register](#) for this meeting)

2) Date: **Thursday, February 15, 2024**

Time: **Noon-1pm**

Location: **Zoom** ([Register](#) for this meeting)

"Submitting to WCG as sIRB"

Presenter: Andy Parkhurst, IRB, Institutions Partnership Manager at [WCG](#)

1) Date: **Monday, January 22, 2024**

Time: **Noon-1pm**

Location: **Zoom** ([Register](#) for this meeting)

2) Date: **Monday, February 12, 2024**

Time: **Noon-1pm**

Location: **Zoom** ([Register](#) for this meeting)

5) Outside Education Opportunities

"SMART IRB SMART TALK: The Impact of Single IRB on Study Teams"

In this SMART Talk, study team members will discuss their experiences with single IRB, covering the good, the bad, and the downright ugly, including lessons learned, and what can help make the process work well.

Date: **Wednesday, January 17, 2024**

Time: **11am**

Location: **Zoom** ([Register](#) for this meeting)

6) OHRPP Office Hours

- Representatives from our reliance team will be available at **all OHRPP office hours** in January and February to help you with your single IRB/reliance questions. We have added additional days and times in February – see schedule below.
- [Register once](#) to join any session:

Upcoming Office Hours:

- Thursday, January 18 at 2pm
- Thursday, February 1 at 2pm
- Monday, February 5 at 4pm (sIRB questions only)
- Thursday, February 15 at 2pm
- Tuesday, February 20 at 4pm (sIRB questions only)
- Thursday, February 29 at 2pm

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