



OHRPP UPDATE

EXPANDING USE OF COMMERCIAL IRBS FOR INDUSTRY-SPONSORED CLINICAL TRIALS

JANUARY 2024

UCLA RELIANCE PROGRAM

- IRB reliance supports the use of a single IRB review to meet the requirements of existing IRB regulations for all participating sites in a multi-site trial.
- Current Reliance Arrangements
 - SMART IRB
 - UC MOU
 - UCLA CTSI IRB
 - NCI CIRB
 - UCLA-RAND MOU
 - Commercial IRBs

EXPANSION

In June, 2023, the UCLA Human Research Policy Board (HRPB) recommended that, in anticipation of finalization of the September 28, 2022 [FDA proposed rule revisions](#), FDA-regulated, Industry-sponsored, multi-site research conducted at UCLA use a single IRB.

Effective **January 25, 2024**, all NEW FDA-regulated, Industry-sponsored, multi-site research conducted at UCLA will use a single IRB, per the June 2023, UCLA Policy Board (HRPB) recommendation. Investigator must submit a request to rely on an external IRB (e.g., Advarra, WCG, etc.) in BRUIN IRB.

Note:

1) Existing UCLA IRB-reviewed protocols will **not** be converted to reliance applications.

IMPLEMENTATION

STEP #1:

1st February MIRB meeting is last meeting that Board can guarantee an industry-sponsored, multi-center clinical trial **new submission** will be reviewed by UCLA IRB.

IRB Committee	DEADLINE	MEETING DATE
MIRB1	January 23, 2024	February 14, 2024
MIRB2	January 16, 2024	February 7, 2024
MIRB3	January 24, 2024	February 8, 2024

Meeting submission deadlines for each of the medical IRBs will impact how each committee will handle the transition. MIRBs will review any new submission is received prior to January 25th.

STEP #2:

As of **January 25, 2024**, all affected applications in “Pre-Submission” and all affected new submissions will be directed to submit a request to rely on a commercial IRB in BruinIRB.

BUDGET CONSIDERATIONS

The Industry-sponsor assumes responsibility for the cost of sIRB for all participating sites; however, your clinical trials budget should include the UCLA administrative fee for processing an initial reliance review of \$2000.00.

New [IRB Review Fees](#) – Effective September 1, 2023

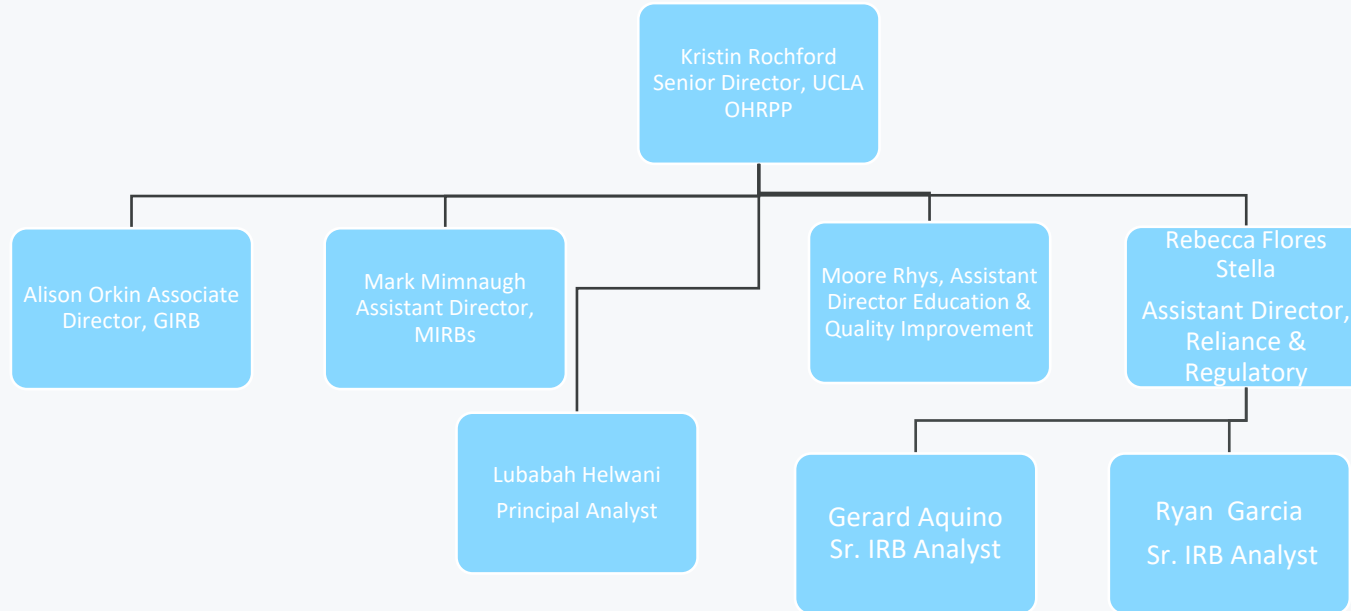
BRUIN IRB SUBMISSION

The UCLA study team must [register the request to rely in BruinIRB](#).

- [How To Submit a Request to Rely on a Commercial IRB](#)
- UCLA-specific consent form that incorporates required template as outlined in [Consent Form Checklist for Reliance on External IRBs](#).

Investigators remain responsible for all required applications to applicable ancillary committees (such as CIRC, ISPRC, MRSC, Coverage Analysis, etc.).

UCLA IRB RELIANCE TEAM



RESOURCES AND SUPPORT

[FAQs for Commercial IRB Review](#) on **UCLA IRB Reliance website**

IRB Office Hours will be held weekly in February 2024 with members of the Reliance Team.

Advarra will hold submission training sessions during Learn at Lunch Sessions on:

Wednesday January 17, 2024 12:00- 1:00 pm

Thursday, February 15, 2024 12:00 -1:00 pm

WCG will hold submission training sessions during Learn at Lunch Sessions on:

Monday, January 22, 2024 12:00- 1:00 pm

Monday, February 12, 2024 12:00 -1:00 pm

**See [FAQs](#) for registration links for the above sessions*

RESOURCES AND SUPPORT

IRB RELIANCE TEAM

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