FAQs (Updated 02/21/204)

Commercial IRB Review
FDA-regulated, Industry-Sponsored and Multi-site Clinical Trials

Click here to skip to review questions received after 01/25/2024

OVERVIEW AND BACKGROUND:

While investigators have always had the option to cede UCLA Institutional Review Board (IRB) review and approval to a single IRB, in June 2023, the UCLA Human Research Policy Board (HRPB) recommended that, in anticipation of finalization of the September 28, 2022 FDA proposed rule, FDA-regulated, Industry-sponsored, multi-site research conducted at UCLA use a single IRB. This change, previously announced in the November 6, 2023 HR News will help facilitate human research by allowing investigators to avoid duplicative IRB review while at the same time protecting the rights and welfare of human research participants.

Effective January 25, 2024, all NEW FDA-regulated research Industry-sponsored, multi-site conducted at UCLA will use a single IRB, per the June 2023, UCLA Policy Board (HRPB) recommendation. Accordingly, investigators must identify an external IRB, (e.g., Advarra or WCG) that will serve as Reviewing IRB for these research studies. Investigator must submit a request to rely on an external IRB in BRUIN IRB.

Q-01. What research studies are affected by the UCLA HRPB Commercial IRB recommendation?

Answer -01: NEW studies meeting the following characteristics will defer to an outside IRB for review:

a. FDA-regulated
b. Industry-sponsored
c. Multi-site

Q-02. What is the effective date for the UCLA HRPB Commercial IRB recommendation?

Answer -02: 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. UCLA IRB will no longer review NEW submissions meeting this criteria; rather the Investigator must submit a request to rely on an external IRB in BRUIN IRB.
Q-03. What happens if I have an affected submission in process in webIRB but not yet approved?

Answer -03: NEW FDA-regulated, Industry-sponsored, multi-site research submissions that are submitted before January 25, 2024 will be reviewed and approved by a UCLA IRB.

All NEW FDA-regulated, Industry-sponsored, multi-site research submissions on or after January 25, 2024, will be advised to withdraw the submission and create a request to rely on an external IRB in BruinIRB. *See Q-22 for additional discussion.

Q-04. Will I have to transfer IRB oversight for my currently approved FDA-regulated, Industry-sponsored, multi-site research that was previously approved by UCLA IRB?

Answer -04: No. FDA-regulated, Industry-sponsored, multi-site research submissions that were approved before January 25, 2024 will remain under the oversight of UCLA IRB and will continue to be subject to all UCLA HRPP policies and procedures, including the requirement for annual continuing approval, submission of amendments and post-approval reporting.

Q-05. What external IRBs can serve as the Reviewing IRB for these studies?

Answer -05: UCLA has service agreements with various commercial IRBs and can enter into agreements with AAHRP Accredited IRBs with whom we do not currently have existing service agreements.

UCLA has established service agreements with the following commercial IRBs:
- Advarra
- WIRB-Copernicus Group

Each commercial IRB has their own submission requirements, which are detailed on their websites. UCLA PIs are required to submit their applications directly to the commercial IRB along with all supporting documents, including the UCLA OHRPP "External Review Accepted" letter.

If your Industry-Sponsor has partnered with another external IRB, please email irbreliance@research.ucla.edu to confirm that the required reliance agreement is in place.
Q-06. How does this all work in terms of sequence of events?

Answer -06:

1. Industry Sponsor identifies clinical sites for participation in a clinical trial.
2. Industry Sponsor selects a commercial IRB to serve as Reviewing IRB.
3. Reviewing IRB reviews and approves the clinical trial protocol, including a template consent form to be followed by participating clinical sites. An approval notice is issued for the study.
4. Reviewing IRB will review site submissions for each clinical site.
5. Each clinical site PI will follow local requirements related to the request to rely on an external IRB. The PI will be required to provide documentation of acceptance of the request to rely on an external IRB from their local institution to the Reviewing IRB. *See Q-07 for additional discussion.*
6. Reviewing IRB will approve each clinical site and approve a site-specific consent form to be used at the site.

Q-07. How do I obtain a UCLA OHRPP “Acknowledgement of External Review” letter that is required for my submission to the external IRB?

Answer -07: The UCLA study team must register the request to rely in BruinIRB, the electronic submission system. The submission will require the investigator to upload the approval letter from the Reviewing IRB, the protocol approved by the Reviewing IRB, and create a UCLA-specific consent form that incorporates required template as outlined in the UCLA Consent Form Checklist for Reliance on External IRBs.

Investigators are also responsible for all required applications to applicable ancillary committees (such as CIRC, ISPRC, MRSC, Coverage Analysis, etc.). In some cases, ancillary reviews must be finalized before the “External Review Accepted” letter may be released. *See Q-20 for additional discussion.*

Q-08. For studies where IRB review is ceded to an external IRB, will I still submit continuing reviews, amendments, and post-approval reports to UCLA IRB?

Answer -08: Continuing review is not required at UCLA for studies reviewed by an external IRB. However, Annual PI Assurances must be completed on a yearly basis within the electronic submission system to maintain active registration of the reliance with the University.

Amendments will be required for the following only:
- Change in PI and other study personnel.
- New or additional ancillary review required.
- New or changes in HIPAA determinations (made by UCLA)
- New or changes in Conflict of Interest (COI)
- New or change in funding.

Reminder – If changes to the study do not involve these local context issues, do not submit an amendment. The Reviewing IRB is responsible for reviewing and approving all
other changes. Any other amendments submitted will be returned and asked to be withdrawn.

**Studies supported in OnCore** - For amendments that are not required to be submitted to the UCLA IRB but have undergone external IRB approval for protocol and/or informed consent/assent form changes, study teams will utilize the activity, “Study Update Information,” activity button to post the most recently approved documents to OnCore.

Proposed revisions or changes submitted through this process neither require nor will receive standard UCLA OHRPP review of an amendment and should only be used to provide updated documents approved by the reviewing IRB.

See our [PAR guidance](#) and review the UCLA [relying PAR decision tree](#) in order to determine if a PAR is required at UCLA.

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**Q-09. How do UCLA investigator responsibilities differ when IRB review is ceded to an external IRB?**

**Answer -09:** The UCLA investigator remains responsible for:

- Following the IRB approved protocol.
- Ensuring all UCLA personnel are qualified and meet UCLA education/training requirements.
- Not modifying the protocol or materials without first obtaining review and approval from the Reviewing IRB.
- Accepting responsibility for the conduct of the study at UCLA, the ethical performance of the project, and the protection of the rights and welfare of the human participants who are directly involved with UCLA personnel; and
- Obtaining any required ancillary approvals before commencing the research.

Review [Relying Investigator Responsibilities Checklist](#) for further information.

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**Q-10. Who pays for the cost of the external IRB review?**

**Answer -10:** 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.
Q-11. What support is available to help study teams with this change?

Answer -11: The IRB Reliance team has been expanded to help support clinical trials researchers following this procedure.

The IRB Reliance team can provide guidance related to existing review agreements, preparing and submitting the request to rely registration in BruinIRB, and any questions related to the overall oversight and management of Industry-sponsored, multi-center FDA-regulated clinical trials.

Training and support sessions:

IRB Office Hours are held regularly and the Reliance Team will be available to provide assistance. Register here to attend one or more IRB Office Hour sessions.

The IRB Reliance team is also available to schedule departmental educational sessions. For more information contact, Rebecca Flores Stella, Assistant Director, Reliance & Regulatory Management, Rebecca.stella@research.ucla.edu or irbreliance@research.ucla.edu.

*See Q-27 for additional discussion*
Q-12. Do I need to upload participant/patient-facing materials, such as recruitment documentation and/or survey and questionnaires?

Answer -12: The UCLA IRB Reliance team does not serve as a reviewing IRB and so does not have a role in reviewing these materials. When UCLA relies on an external IRB, the IRB Reliance team does not need to review recruitment or patient-facing documentation. This type of documentation is reviewed by the Reviewing IRB.

Q-13. Do I need to provide CIRC documentation in my submission if an investigator is noted as having a conflict?

Answer -13: If an investigator has declared a financial interest that requires review by CIRC, the final CIRC determination notice must be uploaded in the BruinIRB Reliance application, Page Local Site Documents, Item 3. If a final determination letter is not available at the time of submission, UCLA Reliance Team will advise CIRC that a financial disclosure has been made as part of a reliance request and request CIRC comment. Final issuance of the acknowledgement notice will be held until the CIRC final determination letter has been uploaded and any CIRC-related revisions to the consent form have been made.

Q-14. Do enrollment memos (memos from CRO/Sponsor indicating enrollment has started, been paused, closed, or increased) need to be uploaded?

Answer -14: No, enrollment memos do not need to be submitted to OHRPP via BruinIRB. These should be submitted to the Reviewing IRB.

Q-15. Are there any specific deadlines for reliance submission to ensure review by a certain date?

Answer -15: No. The review of a request to rely in BruinIRB is an administrative clearance: full board review is not required. Therefore, there are no corresponding submission or review dates. Submissions are considered as they are received. Study teams can expect to receive feedback from the reliance team within five (5) business days.
Q-16 If the UCLA IRB does not stamp approval/expiration dates on the UCLA-specific consent forms, do my study’s approved consent forms expire?

Answer-16: The review of the UCLA-specific consent form(s) is an administrative check to ensure that California state and UC-relevant policies are addressed. The Reliance Team will confirm that required and/or applicable template language in the UCLA Consent Form Checklist for Reliance on External IRBs was incorporated and/or ensure that any noted deviations from our Checklist were approved by the corresponding party.

The Reviewing IRB (e.g., Advarra or WCG) will review and approve the UCLA-specific consent form(s) and assign an approval period for the consent form(s) which corresponds with the external IRB’s approved continuing review period. UCLA OHRPP does not require that the stamped version of the UCLA-specific consent form(s) be submitted to BruinIRB as an amendment.

Changes to the UCLA-specific consent form(s) that require UCLA OHRPP review would include:

- Edits to reflect a change in PI
- Edits to reflect a new funding source
- Edits to the required UCLA template language noted in the UCLA Consent Form Checklist for Reliance
- Edits that would require comment from a UCLA ancillary committee (e.g., radiation risk language, cost related to participation, subject injury, new/revised conflict of interest, etc.)

Q-17 Why don’t consent forms approved by commercial IRBs, such as Advarra or WCG, include an expiration date?

Answer-17: There is no regulatory requirement to include notation of the expiration date on the approved consent form. The consent form is considered accurate and approved until a revised version is released. Once released, the most current version of the consent approved by the external IRB must be used. To determine if a previously approved consent form is available for a particular protocol or request to preview it, contact Client Services or review the most recently approved consent form in the portal for the external IRB (e.g., CIRBI or Connexus).

Q-18 Is it acceptable for the clinical site to convert the MSWord version of the consent to a PDF for distribution to study participants?

Answer-18: Yes, it is acceptable to convert the consent to PDF format.
Q-19: Will there be a list of the agreements with commercial IRBs other than Advarra/WCG that we can reference?

Answer-19: Yes. The BruinIRB application includes a dropdown listing of all external IRBs with whom we have previously relied.

In addition to our master agreements with Advarra, WCG, UC campuses, NCI CIRB, UCLA OHRPP can rely on SmartIRB participating institutions on a case-by-case basis. You can utilize the SmartIRB Participating Institutes website to search for any institution or commercial IRB that UCLA can cede IRB Review to under the SmartIRB agreement.

Q-20: How can we submit ancillary review applications without an IRB Number?

Answer-20: When a BruinIRB submission is created, it is automatically assigned a BruinIRB ID number (IRB-##-####). You can utilize this IRB number for the ancillary review applications. This number remains the same before and after submission.

Q-21: What is the best time to submit your request to rely- should I wait until all ancillary approvals (e.g., MRSC, IBC, COI, hPSCRO) are in place?

Answer-21: The online system used by some ancillary review processes, e.g., Safety Net, will require you to submit your request to rely in order for you to associate your review request with your BruinIRB#. However, most ancillary reviews can be completed concurrently. The final Acknowledgement of External Review notice will be held until all required ancillary reviews are completed.

Q-22: Do all applicable ancillary reviews have to be completed before we can submit to the commercial IRB?

Answer-22: Yes. Generally, Ancillary reviews that may impact information disclosed in the UCLA-specific consent form (e.g., MRSC, CIRC, IBC) or are required to meet UCLA policy requirements (ISPRC, SRC) must be completed by the respective ancillary before the Reliance Analyst may release the final Acknowledgement Notice of external IRB review. The Local Context review will identify those ancillary reviews that must be completed before the final notice is released. The Acknowledgement notice will be required by Advarra and WCG before they approve the activation of UCLA as a clinical site.

Q-23: Why must all ancillary committees issue final approval before the Acknowledgement Notice for my reliance request may be released?

Answer-23: Like research studies under the oversight of UCLA IRB, the reliance review process ensures that all oversight committees are given the opportunity to agree to the activation of the study relying on an external IRB. As many of these reviews impact the content of the UCLA-specific consent form, their review and comment are necessary. The current process also provides assurance to the Reviewing IRB that all stakeholders support the activation of the study at UCLA.

As the UCLA Reliance program continues to build experience and collect data on the overall timeline, we will work with the institution to evaluate study activation times.
Q-24  Is the study team able to accept the risk language provided by the Sponsor and approved by the commercial IRB?

Answer-24: Yes. As part of our agreement to rely, UCLA commits to accepting the Sponsor template consent form except for edits made to comply with the UCLA required template language as outlined in the UCLA Consent Form Checklist for Reliance. The Reliance team will discourage any edits that go beyond those outlined as part of the UCLA Consent Form Checklist.

Q-25  What if my Sponsor does not work with a commercial IRB?

Answer-25: Sponsor is responsible for ensuring that IRB approval is obtained, whether it is completed at UCLA or by a commercial IRB. UCLA would advise of our new procedure and provide the updated Letter to Sponsor as documentation of this new practice.

The decision to cede IRB review for industry-sponsored clinical trials considered this possibility and it was agreed that UCLA would no longer serve as reviewing IRB for these studies.

The change in practice was promulgated by a desire to streamline the activation of industry sponsored clinical trials but also to minimize the use of UCLA resources in the review of research where our IRBs have minimal impact.

In these cases, you would need to work with the Sponsor to identify a commercial IRB to complete the review of their protocol. Most sponsors have existing agreements with commercial IRBs, so it is best that you work with your Sponsor representative to identify their preferred commercial IRB partner. Once this approval is secured, you would submit a request to rely on that external IRB.

Sponsor can obtain commercial IRB approval for a particular site or the overall study. This change in practice should not impact the ability of UCLA to participate in this trial. It is really a matter of who the Sponsor is paying to conduct the IRB review.

Q-26  My study was previously submitted in webIRB for review by UCLA IRB, however, it was withdrawn due to lack of correspondence. Will I have to restart the entire review process after January 25, 2024?

Answer-26: No. An industry-sponsored, FDA regulated, multi-site study submitted in webIRB before 1/25/24, but withdrawn due to a lack of responses to IRB requests, which is later re-activated will remain under the oversight of UCLA IRB once reactivated.

When the study is ready for re-consideration by the IRB, the study team will use the activity “Reactivate” to return the submission to the “Pre-submission” state and allow required edits to be completed. Once all edits and relevant uploads are completed, the study team will use the activity “Submit” to forward the response/edited version of the submission for IRB re-consideration.
Q-27 Under the new model who is responsible for the review of AEs/ audit reports, etc.?

Answer-27: The external IRB serves as the reviewing IRB is responsible for the review of adverse events, deviations, DSMB and monitoring reports, subject complaints, and any other reportable event related to ongoing compliance with the approved protocol. The UCLA Relying Investigator must review the submission guidelines of the reviewing IRB.

Once the reviewing IRB has made a determination, the outcome of their review may then be submitted to the UCLA IRB (via a PAR application), depending on the determination made by the reviewing IRB. Please review the PAR decision tree in order to determine if a PAR is required at UCLA.

The exception to the above is when there has been a breach of UCLA records regulated by HIPAA or FERPA, as UCLA has a responsibility to address these breaches per the federal regulations.

Q-28 How can I obtain more training on the use of Bruin IRB?

Answer-28: IRB Office Hours are held the 1st, 3rd, and 5th (if applicable) Thursday of each month at 2:00 pm via Zoom. This is an excellent resource for a BruinIRB tutorial or specific questions on a problematic submission.

Additionally, multiple user guides for BruinIRB are available on the OHRPP website.

Finally, the IRB Reliance team is happy to schedule a departmental training to review how BruinIRB supports reliance submissions. Request a session by contacting irbreliance@research.ucla.edu.

Q-29 What additional training resources are available to study staff new to reliance?

Answer-29: Please review the following OHRPP videos posted to the OHRPP Educational Library on YouTube for additional guidance:
1. Preparing a Request to Rely on a Commercial IRB
2. Preparing Submissions to Advarra
3. Preparing Submissions to WCG
Q-30  Does a commercial IRB such as Advarra or WCG automatically process Sponsor’s subsequent amendments to the protocol, revised consent forms or revisions to other study documents for all relying sites?

Answer- 30  No. Handling of amendments will vary Sponsor to Sponsor.

Most Sponsors/CRO will request that updates to approved study documents be approved at the Protocol Level and then disseminated to all sites. In this case, you will receive a notification from the Commercial IRB advising that updated study documents are available for implementation at your local site and no further submission to WCG will be necessary.

However, in some cases, a Sponsor will instruct each site to submit individual submissions for the approval of updated study documents. Sponsor will provide the participating sites the revised documents and ask them to submit a modification request to the external IRB.

The external IRB will NOT add anything to the consent header or footer to reflect the updated consent version number or version date. Study team must add this information to the amended ICF when they submit the revised consent to the Reviewing IRB.