

QUICK TIPS FOR USING A COMMERCIAL IRB

KUMC investigators may request permission to conduct a study that is under the review of a commercial IRB. The steps below provide an overview of key requirements. Study teams are encouraged to refer to details posted on our webpage "[Rely On An External IRB For My Collaboration](#)" for further guidance.

1. Use of a commercial IRB requires a local administrative review for compliance and contract purposes.
2. KUMC has contracts with Advarra IRB and WCG IRB. If your sponsor requests the use of another commercial IRB, please contact the IRB Reliance team at IRBreliance@kumc.edu for guidance.
3. Confirm the sponsor has provided the commercial IRB study-wide approval letter and the approved study-wide consent document(s) that will be adapted for each site.
4. Before submitting in myIRB, obtain any applicable ancillary approvals, such as:
 - a. UKHSRR# ID number
 - b. Radiation Safety Committee approval
 - c. Conflict of Interest Committee approval
 - d. PRMC approval, for cancer-related studies
5. Create KUMC-specific draft consent form(s).
 - a. Edit the study-wide consent document(s) by following the instructions on our "Boilerplate Consent Language for External IRBs" guidance document posted on our [Reliance Forms and Templates](#) webpage. (Please do not customize sponsor draft consents that have not been approved for study-wide use by the external IRB.)
 - b. Make the KUMC-specific edits only to the consent form sections as instructed in the boilerplate document. Do not make KUMC edits to any other sections of the consent form.
 - c. Obtain confirmation that the sponsor has approved the KUMC-specific consent changes. The confirmation should be in a separate email. This email document is required to be included in your submission to KUMC **and included in your submission to the external IRB** to verify that the consent changes have already been worked through with the Sponsor/CRO.
 - d. If applicable, obtain confirmation from finance that KUMC-specific language for cost, payments, and injury are acceptable.
6. Before submitting in myIRB, confirm that everyone on the study team is current on human subjects training and conflict of interest disclosures. Our contracts with the commercial IRBs do not allow us to release studies to them before these compliance requirements are met. Significant delays can be avoided if all study team members are current.
7. Complete the Request to Use an External IRB form posted on the [Reliance Forms and Templates](#) page. Avoid delays by confirming the accuracy of the checklist on the last page of the document. **If any of the steps on the checklist are missing, the submission will be returned without review.**

8. Upload all documents required by the checklist at the end of the Request to Use an External IRB form. Do not upload other study documents.
9. Respond to any clarifications sent back by the Reliance team.
10. Submit to the commercial IRB only after you have the permission letter sent through the myIRB system. Please do not make any changes to the initial submission at this point while it waits in the “Clarifications Requested (Pre-Review)” stage.
11. After the commercial IRB has approved KUMC as a site and issued a KUMC-specific consent document(s), then please upload the approval letter and consent document(s) in the myIRB system.
12. The KUMC Reliance team will process the request and send a final release letter that acknowledges oversight by the external IRB. After you have this acknowledgement letter, a signed contract, and sponsor permission, you may start your study.
13. During the study, update the myIRB system if any local changes or reportable events occur. Updates should be limited to those items specified in Step #8 on our webpage “[Rely On An External IRB For My Collaboration](#)” or on the “[Quick Tips For External Updates](#)” document.
14. The study can be closed in the myIRB after the external IRB has issued a closure letter. Only the closure letter from the external IRB should be uploaded to close a study.

Please don't hesitate to contact the KUMC IRB Reliance Team with any questions:
IRBreliance@kumc.edu