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: Relying on an External IRB

1. Use of a commercial IRB requires a local administrative review for compliance and contract purposes.
2. KUMC has contracts with Advarra IRB and Western IRB (now called 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 approval letter and the approved study-wide consent document(s) that will be adapted for each site.
4. The request to use an external IRB is submitted in the KUMC eIRB system. Before submitting in eIRB, 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" posted on our Reliance Forms webpage.
    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 and included in your submission to the external IRB.
    d. If applicable, obtain confirmation from finance that KUMC-specific language for cost, payments, and injury are acceptable.
6. Before submitting in eIRB, 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 our Reliance Forms webpage. 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 the documents required by the checklist. 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 eIRB system.

11. After the commercial IRB has approved KUMC as a site and issued KUMC-specific consent document(s), upload these documents in the eIRB system.

12. The KUMC Reliance team will process the request and send a final letter that acknowledges oversight by the external IRB. After you have your acknowledgement letter, a signed contract, and sponsor permission, you may start your study.

13. During the study, update the eIRB system if any local changes or reportable events occur. Updates should be limited to those items specified on our webpage: Relying on an External IRB

14. The study can be closed in the eIRB after the external IRB has issued a closure letter. Only the closure letter from the external IRB should be uploaded to close a study.

We welcome your feedback about using an external IRB. Please don't hesitate to contact the KUMC IRB Reliance Team with any questions: IRBreliance@kumc.edu