

# Use of Western IRB – Frequently Asked Questions

## **1. What is Western IRB (WIRB)?**

Western Institutional Review Board is an independent IRB, providing IRB services for academic and non-academic institutions. WIRB is fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). They are located in Olympia, Washington.

## **2. Which studies are eligible for review by WIRB?**

KUMC investigators may request the use of WIRB for Phase III and IV, multi-center, industry-sponsored drug or biologic trials.

## **3. Are we required to use WIRB for these studies?**

No, investigators may still choose to use the KUMC Human Subjects Committee for the review of these projects.

## **4. When can we start using WIRB?**

You may begin submitting new studies to WIRB in October 2008.

## **5. Will the KUMC HSC review these studies also?**

The KUMC HSC will not be involved in the review; however, there must be a level of local administrative review. Federal regulations hold the local institution responsible for the conduct of the research regardless of the IRB that reviews. To meet these federal requirements, there will be an abbreviated administrative review at the local level. Investigators will complete a [\*\*supplemental form\*\*](#) that covers training and conflict of interest disclosure for study personnel, location of the study, pharmacy information, and questions that relate to radiation safety, biosafety and other ancillary requirements.

The supplemental form will be reviewed administratively by personnel from the KUMC Human Research Protection Program (HRPP), within two business days. If a proposal is approved for submission to WIRB, then the KUMC Research Institute can assist the investigator with the submission.

## **6. How will studies be submitted to WIRB?**

The KUMC Research Institute (RI) will submit studies to WIRB on behalf of KUMC investigators. New protocols should be delivered to the RI. RI staff will coordinate the permission to use WIRB and assist the investigator in compiling the necessary regulatory documents and other items needed for WIRB submission.

## **7. What are the submission deadlines for WIRB reviews?**

There are no deadlines for WIRB. WIRB has 14 “panels,” and there are meetings every week day. The review will be assigned to an appropriate panel by WIRB personnel.

**8. Who will do the scientific merit review for studies submitted to WIRB?**

WIRB has a scientific merit process that precedes IRB review. When a submission is made to WIRB, there is a protocol triage process that includes an evaluation of merit. If there are questions about the scientific merit of a protocol, those issues are resolved with the sponsor before being put on an IRB agenda. KUMC investigators should be aware that there may be local evaluations of scientific merit by groups such as the GCRC Advisory Committee and the Cancer Center's Protocol Review and Monitoring Committee (PRMC). GCRC and PRMC requirements remain the same, even if Western IRB is used.

**9. When should a cancer-related project be submitted to the PRMC?**

As before, a cancer-related protocol should be submitted to the PRMC before submission to the IRB, whether the IRB will be WIRB or the KUMC HSC.

**10. How long does it take to get approval from WIRB?**

Investigators should allow about three weeks for approval from WIRB.

**11. How much will it cost to submit to WIRB?**

\$1750: Western IRB charge for initial review

\$ 500: Administrative fee to cover oversight by the KUMC HRPP

\$2500: Research Institute administrative and service fee.

**12. Who pays the fees?**

The sponsor will be responsible for these fees.

**13. Who will write the consent form for WIRB submissions?**

Staff at WIRB will write the consent form after it is submitted to WIRB. The KUMC investigator will submit the protocol and the sponsor's sample consent form, along with other required documentation. The consent will be drafted at WIRB, to meet WIRB and KUMC requirements. After WIRB approval, their staff will send the approved consent form to the KUMC investigator.

**14. How do we answer provisos from WIRB?**

KUMC personnel are not involved in the discussions between WIRB and the sponsor. Those communications are handled at WIRB. If the WIRB panel has questions about the protocol, they will communicate with the sponsor directly. Once all the conditions of WIRB approval have been met, then the KUMC investigator is notified.

**15. Does WIRB also handle the Radiation Safety, Biosafety and local Conflict of Interest reviews?**

No. Reviews for ancillary compliance requirements will still be handled at KUMC. HRPP personnel will use the administrative review to identify any local committees that need to have input into the review. At the time of submission, the Office of Compliance will notify WIRB that additional local reviews are pending. After those reviews are complete, WIRB will incorporate any additional language into the informed consent document or other protocol documentation.

**16. How will we be notified that WIRB has approved the study?**

The study approval is posted on the internal WIRB website, to which KUMC investigators will have access. The approval is “released” locally after the study contract is finalized and any local compliance requirements have been met.

**17. How much does WIRB charge for additional reviews during the conduct of the study?**

There is a charge of \$285 for changes to the research (including study amendments, consent changes, personnel changes, advertisements, etc.). To save cost, multiple changes can be incorporated into one amendment submission.

**18. How do I amend the protocol, report adverse events and request continuing review?**

Once WIRB has approved the study, all amendments, recruitment material, consent changes, adverse events, and continuing reviews are reviewed at WIRB. No separate submissions to the KUMC HSC will be needed during the study. When an investigator needs to file a protocol amendment, report adverse events or request continuing review, the Research Institute will assist with submission to WIRB. Investigators should submit items such as protocol amendments, ads, and adverse events to the Research Institute.

For the purposes of institutional oversight, the HRPP staff will have access to the WIRB website to monitor reports such as continuing review reports, local adverse events, reports of non-compliance, subject complaints, or other new information. HRPP staff will work with WIRB if any of these issues need to be addressed locally.

**19. How does WIRB oversee the conduct of the study at KUMC?**

Representatives from WIRB will visit KUMC on an annual basis, to interview study personnel and examine study records. Investigators who are using WIRB will be notified in advance, so they can be available for the visit.