Western IRB Sequence of Submission and Review

Checklist and Review Process for Study Teams

1. Start by confirming that the study is eligible for review by Western IRB (WIRB).
2. The applicable regulatory office confirms that all parties have agreed to the use of WIRB for the study.
3. If the study documents reference another IRB in the WCG corporation (such as Copernicus, Quorum or New England), please notify the IRB office. Our contract with WIRB allows for review by their affiliates if the study is part of their joint Single Review Solution Program. The IRB office will confirm eligibility.
4. The regulatory offices will submit the study to the KUMC IRB, following the steps below.
5. Submit a request in the eIRB system to use an external IRB. The study should be entered in eIRB as a WIRB study even if the internal documents reference the WCG affiliate.
6. Upload the following documents into the eIRB submission:
   a. Generic Request to Use an External IRB
   b. Study Protocol
   c. Consent previously approved by WIRB for the study as a whole.
   d. Proposed KUMC consent draft, created by customizing the previously-approved consent document(s) according to local context checklist for WIRB included in this packet. The proposed KUMC consent draft should be approved by the sponsor prior to submission.
   e. Any submissions to Ancillary Review committees (e.g., RSC).
      i. For quicker turnaround, study teams are strongly encouraged to submit applications to Ancillary Review committees prior to submitting in eIRB.
   f. Confirmation of the UKHSRR#
   g. Signed Administrative Certification form, unless the project will be electronically routed, e.g., Internal Medicine. Non-cancer studies do not need scientific merit review because it is handled by WIRB.
   h. PRMC review, for studies in the Cancer Center
      i. PRMC approval is required before IRB submission (or request to rely) for industry-sponsored trials.
      ii. PRMC approval can occur in parallel to IRB submission (or request to rely) for cooperative group studies.
7. IRB or Compliance Staff are responsible for the following steps:
   a. Confirm current human subjects training and current conflict of interest (COI) disclosures for all members of the study team. Per our agreement with WIRB, these must all be current before the WIRB submission.
   b. Initiate a COI review if there are relevant COI disclosures
   c. Notify ancillary reviewers within the eIRB system
   d. Confirm that the consent form has been appropriately adapted for KUMC local context.
   e. Confirm that the provisions related to payment for injury are aligned with KUMC contract language
   f. Return the submission to the study team/regulatory office if additions or corrections to the consent form are required
   g. Hold the release to WIRB until all ancillary reviews are completed and any additional consent form changes have been made
8. When the above steps have been completed, IRB staff will provide a signed Waiver of IRB Oversight form. It will be uploaded as a comment in the History tab of the study.
9. IRB staff will put the study into “Clarifications Requested” status so that responses can be submitted after WIRB review.

10. Once WIRB approves the involvement of KUMC investigators and approves a version of the consent form for KUMC, the regulatory office uploads the KUMC-specific WIRB approval letter and the KUMC-specific consent form into eIRB.

11. After all approvals have been obtained and uploaded, then reliance on the external IRB is confirmed.

12. IRB staff will generate an acknowledgement letter which will be available in the main study workspace in eIRB.

13. The study may begin when it has been activated by the regulatory office and the sponsor.

**After Initial Review:**

1. After the external IRB is confirmed, then WIRB is the IRB of record for all future amendments, continuing reviews, adverse events, etc.

2. During the study, the local study or regulatory office is responsible for filing a **SITE Modification** in the eIRB system if there are changes that could impact the local context review. These may include:
   a. New KUMC principal investigator
   b. Changes to financial relationships that could create a conflict of interest for the study.
   c. Contractual changes related to payment for study-related injury
   d. Changes impacting HIPAA privacy or data security
   e. Changes impacting costs to participants

3. For personnel changes, the regulatory office should create a **SITE Modification** in the eIRB system. New personnel must be current on human subjects training and conflict of interest disclosures. A personnel acknowledgement letter will be available in the eIRB system.

4. Internal serious adverse events or a potentially serious issues of non-compliance should be reported in eIRB through the Report of New Information (RNI) function.

5. Following WIRB’s continuing review, the regulatory office should update the eIRB system with the new WIRB renewal letter, upload the latest version of the protocol (if it has been revised since initial approval), and enter the new study expiration date. This can be done by editing the **STUDY** page and saving. It does not require that anything is ‘submitted.’
Customizing the WIRB Approved Consent Template for University of Kansas Medical Center (KUMC)

The items listed below indicate the areas of the WIRB approved consent that should be changed for use by KUMC investigators. Note the changes below are listed using a ‘header’ format on the consent document. Adjust as appropriate when a Question/Answer format is used. Language in yellow highlight should be inserted verbatim.

INTRODUCTION
KUMC requires the following elements below to be included:

- Name and contact info of the KUMC investigator
- Medical records bar code should appear at the top of page 1 as follows:

![Medical records bar code]

- Modify the contact information on page 1 and other pages as needed, for example:

  PHONE NUMBER(S): John Smith, MD 913-xxx-xxxx 913-588-5000 (24 hours); ask for the [medical specialty] attending physician on call and tell the physician that you are in this research study.

PAYMENT FOR PARTICIPATION
If study involves payment, insert the following text:

You will receive $xx.xx for each completed study visit. If you complete the entire study, payment may be up to $xxx.xx. If your participation in this study ends early, you will be paid only for the visits you have completed.

You will be given a ClinCard, which works like a debit card. After a study visit, payment will be added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at an ATM or at a store. No one at KUMC will know where you spent the money.

You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A
Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600 or more in a calendar year.

If reimbursements are offered, insert the following paragraph:

Reimbursement for travel expenses may be available. [Insert details]. All reimbursements will need to be pre-approved by the study team. You will be asked to keep your receipts in order to receive reimbursement.

Your personal information will be kept on a secure computer. It will be removed from the computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. It will be kept completely confidential.

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AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES
Whether the HIPAA authorization is embedded in the main body of the consent form or presented as a stand-alone document, the following parties must be added as having access to identifiable data:

• Groups at KUMC that monitor research studies.
• Western IRB
• The University of Kansas Health System Medical Record Department
• The KUMC Research Institute

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RISKS OF STUDY PROCEDURES
When the study involves radiation, include radiation risk language specified by the KUMC Radiation Safety Committee.

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COSTS ASSOCIATED WITH BEING IN THE STUDY
Include study-specific cost language approved by the KU Health System billing group.

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SOURCE OF FUNDING FOR THE STUDY
When there is an investigator or institutional conflict of interest related to the study, include disclosure language specified by the KUMC Conflict of Interest Committee.

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COMPENSATION FOR INJURY
Include the study-specific compensation for injury negotiated by KUMC. If the sponsor will cover the costs of study-related injuries/illnesses, include the following as the last paragraph in the section:

For the sponsor to pay these medical expenses, they will need to know some information about you like your name, date of birth, and social security number. This is because [the sponsor] has to check if you
receive Medicare, and, if you do, report the payment it makes to Medicare. [The sponsor] will not use this information for any other purpose.

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CERTIFICATE OF CONFIDENTIALITY
If NIH has issued a Certificate of Confidentiality (CoC) for this study, include the following three paragraphs. If the consent form already includes CoC language, replace it with the language below:

This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). This protects the researchers from being forced to give out personal information about you for legal proceedings. This does not stop you from voluntarily releasing information about yourself or your participation in this research.

One exception to the Certificate is if you agree that we can give out research information that identifies you. Your information will be shared for the purposes listed in this consent form. Other exceptions are information we must report if we learn about child abuse or neglect or if we think you might harm yourself or others.

Information about your research participation may be included in your medical record. The Certificate of Confidentiality does not prevent releases of information in your medical record for routine purposes such as treatment or billing purposes. Any research information in your medical record might be included when copies are sent for routine purposes.

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CONSENT FOR SURROGATE DECISION-MAKERS
When the study involves adult subjects with decisional impairment, incorporate the text below within the LAR signature block:

I am being asked to approve participation in a research study for someone who is not able to make his or her own decision. I will be given a signed copy of this consent form.

I understand that I may not authorize participation in this study if the individual has previously expressed wishes to the contrary, either orally or in writing.

I am (please initial one of the following categories):

________ Legal guardian or Durable Power of Attorney for Healthcare Decisions
________ Adult or emancipated minor’s spouse (unless legally separated)
________ Adult child
________ Parent
________ Brother or sister [only when study includes KUMC Missouri sites]
________ Adult relative by blood or marriage