Western IRB/Copernicus IRB Sequence of Submission and Review

Checklist and Review Process for Study Teams

1. Start by confirming that the study fits our current contract with Western IRB (WIRB). Our contract covers Phase 3 or 4 multicenter, industry-sponsored drug or biologic trials.
2. The applicable regulatory office (Research Institute or Cancer Center) confirms that all parties have agreed to the use of WIRB for the study.
3. If Copernicus IRB is requested, please notify the IRB office. Our contract with WIRB allows for review by Copernicus if the study is part of their joint Single Review Solution Program. The IRB office will confirm eligibility.
4. The Research Institute or Cancer Center regulatory offices will submit the study to the KUMC IRB, following the steps 5 and 6 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 review may be subsequently passed on to Copernicus.
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 or nursing impact)
    f. 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.
    g. 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 a confirmation letter and attach it in the History section.
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 study update 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 study update 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. The eIRB system will send a continuing review reminder to the study team 15 days before WIRB's expiration date. Following WIRB's continuing review, the regulatory office should update the eIRB system with the new WIRB renewal letter IRB and any updated study documents.

CUSTOMIZING THE WIRB/COPERNICUS-APPROVED CONSENT TEMPLATE FOR KUMC

Main Consent Form ***[The items listed below indicate the areas of the WIRB/COPERNICUS 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.]***

Overview/ Introduction

- ☐ Name and contact info of the KUMC investigator
- ☐ Medical records bar code on page 1 only
- ☐ Number of subjects to be enrolled at KUMC

Background and Purpose

- ☐ Discussion regarding how the test article works and why it might be [more effective, reduce symptoms, improve survival, etc.] is included.

Procedures

- ☐ For KUMC, present the study groups in a bulleted list, noting the dose associated with each group.
- ☐ If applicable, explain that communicable diseases will be reported to Kansas Department of Health as required by law.

Expectations

- ☐ When the sponsor requires this section, we specify the language change, "…you will be asked to…" rather than "expected to"
- ☐ In the list of examples, we specify the subject will be asked to take the study product as "instructed" rather than "expected"

Risks

- ☐ For KUMC, the risk section begins with the following paragraph:
  The study **[drug/device/biologic/intervention]** may cause side effects or other problems. The researchers will be checking your medical information during the study to watch for side effects. However, you should tell the research team about anything that is bothering you or any changes in your health since the last visit. The researchers may be able to take steps to reduce side effects. You may experience none, some, or all of the side effects listed below. There may be other side effects or risks that are not yet known.
- ☐ If applicable, allergic risks should be described using the KUMC template language. Sample language for an outpatient study is as follows:
  Allergic Reaction Risks
  Sometimes, people have serious allergic reactions to drugs. A severe allergic reaction could be life-threatening and may result in death. Symptoms of allergic reactions include:
  - Swelling of the mouth, throat or eyes
  - Rash
  - Difficulty breathing
  - Coughing

- Wheezing
- Sudden drop of blood pressure
- Seizures
- Flushing
- A fast pulse
- Sweating

You should call 911 if you think you are having a severe allergic reaction. Please also contact the study team if you have any of these or other side effects during the study.

Risks of Study Procedures

- ☐ No local changes for most study procedures
- ☐ As applicable, this section should use the radiation risks specified by the KUMC Radiation Safety Committee.

Pregnancy Risks

- ☐ For KUMC, the pregnancy risk section begins with the following paragraph, if the study involves females of child-bearing potential:
  If there is known teratogenicity, discuss that information at the beginning of this section. Otherwise, begin this section as follows:
  The [study drugs/ procedures, etc.] used in this study might hurt an unborn child or a child who is breast-feeding. You cannot be in this study if you are pregnant or nursing a baby. You cannot be in this study if you are trying to get pregnant. You will have a pregnancy test before the study starts. You must use birth control during the study and for [___weeks/months] after your last dose of study drug. The approved methods of birth control are: [list per the WIRB-COPERNICUS template]
- ☐ For KUMC, please add abstinence as an approved method.
- ☐ Retain all other WIRB/COPERNICUS- approved pregnancy risk language.

Costs

- ☐ Use the study-specific cost language approved by the KU Health System billing group

Compensation for Participation

- ☐ For KUMC, change the term 'compensation' to 'payment'
- ☐ We have specified language on how to describe payments, the ClinCard system, the RI, 1099 language, reimbursements, if applicable, and use of a secure computer:
  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.

OR

You will not receive any monetary compensation for your participation in this study.

- ☐ Regardless of whether participants are being paid, when the study involves specimens, for KUMC, add this paragraph about ownership of samples:
  The specimens collected during this study will be provided to the study sponsor. If a commercial product is developed from this research, the profits will belong to the sponsor. There are no plans to provide financial payment to you should this occur.

Source of Funding for the Study

- ☐ This section is specifically added for KUMC if not already present
- ☐ The first paragraph discussed payments going to the team and the RI
  The sponsor, ***[sponsor name]*****,** will pay the research team and KUMC Research Institute, Inc. for conducting this study. Payments will be used for research purposes only.
- ☐ If needed, a COI disclosure paragraph would also go in this section, using language specified by the KUMC Conflict of Interest Committee

Compensation for Injury

- ☐ As noted above, please change 'compensation' to 'payment'
- ☐ IRB staff will check with the KUMC Research Institute to confirm the proposed language matches what has been negotiated in the contract
- ☐ IRB staff will confirm this section contains a statement that subjects do not give up any legal rights by signing this form.
- ☐ When the sponsor will be paying for study-related injuries, add the following paragraph to this 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.
- ☐ This section should end with our standard institutional paragraph:
  If you think you have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC) or one of its affiliates, you should contact the Director, Human Research Protection Program at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. You may also telephone (913) 588-1240.

Confidentiality/Privacy Authorization

- ☐ 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 [or Copernicus] IRB
  - The University of Kansas Health System Medical Record Department,
  - The KUMC Research Institute

Voluntary Participation/Withdrawal

- ☐ The section uses the standard WIRB/COPERNICUS section with the following additions:
- ☐ When discussing the subject's right to withdraw permission for the use of PHI, use the following text:

  You have the right to cancel your permission for researchers to use your health information. If you want to cancel your permission, please write to **[PI Name].** The mailing address is **[PI Name],** University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS 66160. If you cancel permission to use your health information, you will be withdrawn from the study. The researchers will stop collecting any additional information about you unless they need information about a side effect of **[the study drug, device, treatment]**. They are permitted to use and share information that was gathered before they received your cancellation.
- ☐ At the end of this section, the following paragraph is inserted:

  Neither the sponsor, nor the investigator, nor the University of Kansas Medical Center will be obligated to provide you with any **[study drug]** or treatment if the study is stopped early. Your physician will decide about future treatment, if it is needed.

Consent/signature block

- ☐ Replace the template with the KUMC-specific language and signature lines as follows:

  Dr. *[PI name]* or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained the inconveniences, discomforts and risks described in this consent document.

  By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered.
  You will be given a signed copy of the consent form to keep for your records.

  _____
  Print Participant's Name

  _____ _____ _____
  Signature of Participant Time Date

  _____
  Print Name of Person Obtaining Consent

  _____ _____

Signature of Person Obtaining Consent Date

Consent for Parental Permission

- When needed, use the KUMC boilerplate signature block for parents.

CONSENT

Dr. [PI name] or the research team has given you and your child information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that your child may experience during this study.

By signing this form, you say that your child is freely and voluntarily consenting to participate in this research study. You have read the information and had your questions answered.
You will be given a signed copy of the consent form to keep for your records.

Date ___/___/___

Child's Name: _____

Child's Age: _____

Parent's Name:_____
(please print)

Parent's Signature:_____

Name of Person Obtaining Consent: _____
(please print)

Signature of Person Obtaining Consent:_____

CHILD ASSENT

If the study subjects will include children ages 7 – 17 who are expected to have capacity to agree to research, insert a brief Child Assent section here. A stand-alone adolescent assent also may be appropriate as determined by the reviewing IRB.]

Consent for Surrogate Decision-Makers

- When needed, use the KUMC boilerplate signature block for surrogates that aligns with Kansas state law.

CONSENT

Dr._____ or their associates have given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study. If the participant

becomes able to consent to research during the course of the study, the information in this form will be presented to them for their consent.

On behalf of the person for whom you are making decisions, you freely and voluntarily consent to participate in this research study. You have read and understand the information in this form and have had an opportunity to ask questions and have them answered. ***You will be given a signed copy of the consent form to keep for your records.***

As legal guardian or representative, I, _____,
Type/Print Name of Guardian/Representative

authorize the participation of _____ in this research study.
Type/Print Name of Participant

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

_____ Adult relative by blood or marriage

_____ _____
Signature of Legal Guardian/ Representative *Date*

_____
Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent *Date*

If the adult subjects may be capable of providing assent, add an assent section with details specific to the study as determined appropriate by the reviewing IRB. A sample follows:

ASSENT

I am being asked to be in a research study because I have Alzheimer's disease. The investigator and/or his assistants have explained the study to me and my caregiver.

If I decide to be part of this study, I will have XX visits at the University of Kansas Medical Center. I will receive a study drug through my vein. I will have some medical tests and answer questions that test my memory and thinking. Blood will be taken several times by sticking a needle in my arm, and I will have to give several urine samples.

My caregiver has read the consent form and has agreed for me to do this research study. If I sign my name, I am saying that I want to be in the study. I know that I don't have to do it even if my caregiver has given their permission. I know that I can stop being in this study even if I signed my name. If I want to stop at any time, all I have to do is tell my caregiver, the study doctor, or his assistants.

_____
Print Subject's Name

_____ _____
Signature of Subject Date

Optional Sub-study

- ☐ If applicable, this section about optional study activities is placed after the main consent signature block to help participants understand it is optional.
- ☐ For optional sub-studies, use the WIRB-COPERNICUS template language plus the following paragraphs as applicable:

  Even though these protections are in place, once your samples and information leave KUMC they may be used by other researchers or organizations who are not required to follow HIPAA rules. While it might not be protected by HIPAA, there may be other laws that protect your information from improper use. KUMC is not responsible for any sample or data that leaves its control.

  You may withdraw your consent to use the remaining samples and associate health information at any time by telling your study doctor. In this case, the sample will be [insert whether the sample will be destroyed or returned]. Samples or related information that have already been used by researchers cannot be returned or destroyed. However, no new information about you will be collected.

  Reports about this optional research will not be given to you or your doctor. These reports will not be put into your medical record. The future research will not have an effect on your care.

  If results are published, your name and other personal information will not be given

- ☐ End this section with a standard WIRB-COPERNICUS paragraph that subjects may decide not to participate and the checkboxes to indicate preference.
- ☐ At the end of this section, add a full signature block for the participant and the person obtaining consent