IRB Reliance FAQs

1. **What is an IRB reliance agreement?**
   An IRB reliance agreement allows one IRB to review research that is occurring at multiple sites or research that involves personnel from multiple institutions. The reliance agreement avoids duplication of effort by establishing an arrangement for one IRB to review the research on behalf of other IRBs. IRB reliance means that instead of the KUMC IRB reviewing the research, we **rely** on the review of another IRB.

2. **When are reliance arrangements applicable?**
   There are two circumstances where reliance requirements apply:
   - When we conduct research at non-KUMC locations and external personnel are part of the study team, or
   - When external personnel participate in KUMC research on our campus

3. **Why are reliance agreements necessary?**
   Each institution is responsible for research conduct by its own personnel, regardless of where the research occurs. When KUMC personnel conduct human subjects research, the institution has two options:
   - Review the research through the KUMC IRB, or
   - Arrange for another qualified IRB to review the project

   KUMC personnel may not conduct human subjects research until approval has been obtained from one of the above reviews and all other institutional requirements have been met.

4. **Which IRBs have already made reliance arrangements with KUMC?**
   KUMC has multiple arrangements for IRB reciprocity. Current arrangements include:
   - National Cancer Institute Adult IRBs
   - US Oncology IRB
   - CTSA Regional Partners
   - PCORI partners (Great Plains Cooperative IRB Consortium)
   - Neuronext network
   - Western/Copernicus IRB
   - KU Lawrence campus
   - IRBs for Via Christi and Wesley hospitals in Wichita

5. **When should I request single IRB review?**
   Please request a single review as early as possible, even in the planning stages.
   - For new studies, the PI should pursue this step before submitting the protocol to *any* IRB for review.
   - When a new site or external collaborator is added to a study that is already approved at KUMC, please contact the KUMC IRB as soon as the site or collaborator is identified. The KUMC IRB office can work with the other IRB to see if they will rely on our review.

6. **How do I request a single IRB review?**
   If you are requesting that KUMC IRB cover the study activities at external sites or cover the activities of external collaborators, this information will be indicated in the questions on the eIRB Smart Forms and the Project Description when you submit your proposal.

   If you are requesting oversight by an external IRB, submit the request through the eIRB system, choosing the external IRB on the Basic Information page. Once an external IRB is chosen, the eIRB system will automatically truncate the application process to obtain minimal additional information. In addition to completing the smart forms on the eIRB application, upload the form entitled "Request to Use an External IRB" along with the study protocol, drug information, if applicable, and the proposed consent form and recruitment materials if they are available.

   For Wichita studies requesting single IRB review with Via Christi, Wesley Medical Center and/or Wichita State University: Instead of submitting the study in the eIRB system, please complete the paper Common Form Application and email them to the IRB Administrator.

7. **What criteria are used to determine which IRB oversees the project?**
   When institutions negotiate a Memorandum of Understanding (MOU) that covers multiple studies, the decision criteria are spelled out in advance. Depending on the terms of the MOU, a Reviewing IRB might be designated for all studies that are covered by that MOU. In other MOUs, the Reviewing IRB is determined based upon protocol-specific factors, such as the location of the patients, the location of the highest-risk procedures or the location of the principal investigator.

   When an MOU is arranged for a single study, the designation of the Reviewing IRB is made on a case-by-case basis. Factors may include the risk level or the location of the patients; the decision also may depend on whether one of the IRBs has a particular expertise.

8. **What if the collaborating organization does not have its own IRB?**
   If the non-KUMC site does not have an IRB, the KUMC IRB may serve as the IRB of record if the organization agrees to KUMC oversight. At times, the collaborating organization may have to file a Federalwide Assurance before the arrangements can be made.

9. **What is a Federalwide Assurance (FWA)?**
   An FWA is an agreement between an organization who conducts human subjects research and the federal Department of Health and Human Services (DHHS). Through the FWA, the organization agrees to abide by all regulations governing human subjects research. If serious problems occur, DHHS has the authority to revoke an FWA and stop human subjects research at that organization.

10. **When does the collaborating organization need its own FWA?**
    In most instances, a collaborating organization will be required to file a FWA. If the research involves federal funding, all sites *must* obtain an FWA.

If the research is minimal risk, the site does not typically conduct research and additional collaboration is not anticipated with that site, then KUMC may choose to extend its own FWA to cover the site.

11. Who negotiates the terms of the reliance agreement?

The reliance agreement is jointly negotiated by the HRPP and KUMC legal counsel. The HRPP has reliance templates to facilitate the process.

12. Who signs an IRB reliance agreement?

Reliance agreements are signed by Institutional Officials from both parties.

13. Can a reliance agreement cover more than one study?

Yes. If multiple studies are anticipated with a new collaborator, the reliance agreement can be crafted to cover a specific scope of studies.

14. Are there studies that are not eligible for a reliance agreement?

Reliance decisions are made on a case-by-case basis. To date, KUMC has chosen not to rely on another IRB for surgical trials or device studies.

15. What happens after the agreement is signed?

If the KUMC IRB is the Reviewing IRB, then the IRB Office will work with the external site to obtain the necessary information to review the study on their behalf. Our IRB may ask for information about facilities, qualifications of personnel, characteristics of the local study population or special regulatory requirements at the site. Federal regulations refer to this process as obtaining "local context information."

When KUMC is relying on the external IRB, KUMC must provide similar local context information to the Reviewing IRB. The KUMC IRB Office also will advise the Reviewing IRB about specific language that needs to be added to the consent form to reflect KUMC's involvement and cover HIPAA requirements, if applicable.

16. **What are my additional responsibilities if I am the Overall PI for a study at multiple locations?**

In addition to general responsibilities of serving as an investigator, the Overall PI has the following responsibilities:

- Coordinate the conduct of the study at all sites.
- Train study personnel and communicate protocol requirements on an ongoing basis.
- Provide approved study documents for use at all sites.
- Maintain current information to monitor safety of the study
- Monitor protocol compliance at all sites.
- Gather status reports from all sites for continuing review
- Obtain prompt reports of serious adverse events or protocol deviations that could impact safety or data integrity (Another way to say this is to ensure prompt reporting of reportable events from all site PIs)
- Inform the KUMC IRB of any changes to performance sites or collaborating investigators/study personnel, any change in the nature of the study activities being performed at the external sites; or closure of a site

17. If I am the Overall PI, do I have to have a separate consent forms for each site?

Arrangements for consent forms will be decided on a case-by-case basis. If most of the study details are the same for all sites, then typically one consent form can be used. When the study details are very specific to each site, it likely will be beneficial to subjects if each site has its own consent form.

18. **What are my additional responsibilities if my study is being overseen by an external IRB?**

In additional to general responsibilities of serving as an investigator, the Site PI has the following responsibilities:

- Ensure that your entire team follows the policies of the Reviewing IRB.
- Comply with all protocol requirements
- Communicate early and often with the Overall PI

19. When can I start my study?

If you are using an external IRB, you may start your study when:

- The external IRB approves the project, ***and***
- Local implementation is approved. Local implementation will be approved once our institutional requirements have been met. Examples of institutional requirements include a signed contract or sub-award; ancillary reviews such as radiation safety or nursing impact; material transfer agreements or data use agreements.

20. What should I do when an adverse event occurs?

- Implement actions to eliminate any immediate threat of harm to subject
- Follow the protocol-specific plans for reporting the event to the Overall PI and the Reviewing IRB
- Implement any steps required by the Reviewing IRB

21. What should I do if I have a serious protocol deviation?

- Implement actions to eliminate any immediate threat of harm to subject
- Follow the protocol-specific plans for reporting the event to the Overall PI and the Reviewing IRB
- Report to the KUMC Human Research Protection Program so that we can coordinate with the reviewing IRB and address contractual issues, if applicable
- Implement any steps required by the Reviewing IRB

22. Where can I find more information?

The KUMC IRB Office welcomes the opportunity to talk with investigators about IRB reliance arrangements. You may contact us at (913) 588-1240 or humansubjects@kumc.edu

In **Wichita**, contact the Research Compliance Office at (316) 293-2610 or jryan3@kumc.edu.