

13.0 Collaborative Research

13.1 Research conducted at non-KUMC sites

I. FWA and IRB requirements

- A. When a KUMC investigator is conducting research at a non-KUMC site, the HRPP will determine whether the site is “engaged” in research. The following actions will be taken when the non-KUMC site is engaged in research:
 - 1. The HRPP will inquire about whether the site has filed a Federal Wide Assurance (FWA) with OHRP.
 - 2. The HRPP will inquire about whether the site maintains its own IRB and if that IRB also must give prior approval of the research.
 - 3. The HSC will review the research project. If the non-KUMC site has its own IRB that also must review the project, the study may not commence until HSC has documentation of the other IRB’s approval.
 - 4. If the site does not have its own IRB, the HSC may assume sole responsibility for the project. The KUMC Principal Investigator is responsible for ensuring that the non-KUMC site files an FWA, if one is not already in place. The KUMC Principal Investigator obtains the site’s signature on a Human Subjects Research Review Authorization Agreement to document the site’s reliance on the HSC. The KUMC Institutional Official signs the agreement on behalf of KUMC.
- B. When the non-KUMC site is “not engaged” in research:
 - 1. The investigator must provide a letter of support from the site documenting approval for the research to occur.

II. Investigator responsibilities

- A. When a KUMC investigator conducts research at non-KUMC sites, the study protocol must discuss the investigator’s plans for ensuring compliance at the other sites. For example, the protocol should discuss how the principal investigator will ensure compliance with human subjects regulations including, but not limited to, adherence to the study protocol, training off-site personnel, ensuring proper informed consent, securing IRB approval at all institutions before implementing changes to the protocol, monitoring adverse events or other unanticipated problems, and general coordination of study conduct.
- B. Prior to study approval, study personnel at the non-KUMC site must demonstrate training in human subjects protection and must have a current conflict of interest disclosure on file.
- D. If the site has its own IRB, the KUMC investigator is responsible for promptly notifying the HSC if there is a change in the approval status from the non-KUMC IRB.
- E. At the time of continuing review, the KUMC investigator must submit documentation that the project is still approved at any non-KUMC site that has its own IRB.

13.2 KUMC Research involving unaffiliated investigators

- I. Unaffiliated investigator agreements
 - A. When an unaffiliated investigator is collaborating on a KUMC project, the HRPP will negotiate an Individual Investigator Agreement.
 - B. The HRPP will provide all required documentation to the investigator, including a copy of the Belmont Report, 45 CFR 46, applicable KUMC policies, and a copy of the KUMC FWA.
- II. Training and conflict of interest reporting
 - A. Prior to the unaffiliated investigator's involvement in the study, the investigator must demonstrate current training in human subjects protection and must have a current conflict of interest disclosure on file.

13.3 Reciprocity with KU-Lawrence campus

All KUMC faculty, staff or students who propose human subjects research must obtain prior approval from the KUMC Human Subjects Committee (HSC). An exception exists for certain studies conducted solely on the KU-Lawrence campus.

1. For human subjects research that takes place solely on the KU-Lawrence campus, the KUMC principal investigator may request permission to rely on the KU-Lawrence HSC. The request is made by submitting a copy of the study protocol and the form entitled "Request to Rely on KU-Lawrence HSC."
2. The request is reviewed by the KUMC IRB Administrator or the Director of the Human Research Protection Program.
3. The request to rely on the KU-Lawrence HSC will be considered if the following criteria are met:
 - a. The principal investigator and all study personnel have completed current training in human subjects protection.
 - b. The principal investigator and all study personnel have filed a current Conflict of Interest Disclosure, and no conflicts exist.
 - c. Interactions with subjects will occur solely on the Lawrence campus; KUMC patients will not be recruited or enrolled.
 - d. Plans to secure paper and electronic research records on the KUMC campus comply with HIPAA privacy and security requirements (if applicable).
 - e. Security is ensured for the storage of human biologic materials on the KUMC campus (if applicable).
 - f. An administrative review of the protocol confirms the accuracy of items a – e, and the protocol does not involve test articles or study procedures associated with extraordinary risk or investigational surgical procedures. At the discretion of administrative staff, the HSC chair or other HSC members may be contacted for assistance.
4. If the above six criteria are met, the KUMC IRB Administrator or the Director of the Human Research Protection Program will approve the request to rely on the Lawrence

- HSC. The principal investigator will be informed that the project cannot be initiated until the KUMC HSC receives documentation of the approval from the Lawrence campus.
5. The KUMC HSC will maintain a copy of the approved request form, the protocol, and the KU-Lawrence approval letter. The KUMC HSC will require a copy of continuing reviews and final study closure. To support appropriate oversight by KUMC, the Lawrence HSC will notify the KUMC HSC of the following events:
 - a. The project is suspended or terminated for cause
 - b. There is a finding of serious non-compliance associated with the study;
 - c. A report is made to OHRP concerning an unanticipated problem.

Reference:

45 CFR 46.114