

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 Federalwide 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 serve as the IRB of record for the project. A determination is made as to whether the site needs its own Federalwide Assurance.
 - a. In most instances, the site will be required to file a FWA. If the research involves federal funding, all sites must obtain an FWA.
 - b. 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 FWA to cover the site.
 - 7. The Office of Compliance initiates a memorandum of understanding with the site. The memorandum outlines the oversight responsibilities of each party.
- 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. At times, KUMC research may involve collaboration with an individual who is not associated with an institution or organization. When such 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.

13.4 Reciprocity with Wichita Hospitals

- I. KUMC has entered into agreements by which investigators on the Wichita campus may rely on the IRBs at Wichita hospitals for review and oversight of minimal risk research.
- II. KUMC investigators must complete the common application for minimal risk research used by KU School of Medicine-Wichita, Via Christi Hospital, and the Wichita Medical Research and Education Foundation (WMREF)/Wesley Hospital. Applications have been developed for retrospective and prospective research.
- III. HSC staff on the Wichita campus confirm that the project meets federal definitions of low or minimal risk. All KUMC personnel must be current on their human subjects training and conflict of interest disclosure before being approved to rely on the hospital IRB(s).
- IV. Once obtained, the KUMC investigator submits a copy of the Via Christi or WMREF approval letter.

13.5 KUMC Investigators Collaborating on Non-KUMC Research

- I. The HSC must evaluate the research activities of KUMC personnel who collaborate with a non-KUMC institution.

- II. The HSC staff will evaluate the activities of the KUMC investigator to determine if those activities engage the institution in human subjects research. HSC staff will refer to the OHRP document “Guidance on Engagement of Institutions in Human Subjects Research” in making the determination.
- III. If the activities of the KUMC investigator do not engage the institution in human subjects research, the HSC staff will issue a letter certifying that the KUMC HSC is not required to approve the research.
- IV. If the activities of the KUMC investigator cause the institution to be engaged in human subjects research, the investigator’s involvement in the collaboration may not begin until the KUMC HSC has approved or until an agreement to rely on the other IRB has been negotiated.

Reference:

45 CFR 46.114