Applying to the IRB at KU Medical Center

Application Process
Applications are submitted electronically through our eCompliance system.
Information is available at: http://www.kumc.edu/compliance/human-research-protection-program/institutional-review-board/ecompliance--eirb-overview.html

Pre-Submission Consultations
Investigators are encouraged to take advantage of our pre-submission consultations. The consultations provide help in evaluating the feasibility of a project and possible regulatory implications; pre-review of the IRB application, protocol and consent form; assistance with answering provisos; and general questions about IRB and other regulatory requirements. To schedule an appointment, please contact the HRPP Director at (913) 588-0942 or the IRB Office at (913) 588-1240.

Recruitment Resources
Prior to IRB approval, investigators may request de-identified information from our HERON database about the number and characteristics of patients who fit the study's eligibility criteria. A HERON query must be sponsored by a KUMC faculty member. For more information about the HERON database, you may refer to the link at:
http://frontiersresearch.org/frontiers/biomedical-informatics

After IRB approval, investigators can request names of potential study candidates from the Frontiers patient registry. This registry obtains basic medical history from patients and community members who are willing to be contacted about research participation. For more information about the Frontiers research registry,
refer to: http://frontiersresearch.org/frontiers/

Access to the Electronic System
In order to gain access to the electronic IRB system as an external investigator, you will need an affiliate account in the identity management system. Contact the university department or center with which you will collaborate and the administrative staff can request an affiliate account for you.

IRB Meeting Schedule and Deadlines
The IRB meets weekly. Meeting dates are posted at: http://www.kumc.edu/compliance/human-research-protection-program/institutional-review-board/ecompliance--eirb-overview.html

Human Subjects Training Requirements
Training in human subjects protection must be completed every three years. KUMC accepts CITI or NIH training.

Conflict of Interest Disclosure Requirements
Investigators and all study team members must be current on their annual conflict of interest disclosure. KUMC uses a "zero-dollar" threshold for disclosing all financial relationships related to research. *Please note that this threshold applies not only to KUMC personnel but also to all collaborators.* A financial interest of any amount must be reported if it relates to research. Collaborators from other institutions must make their conflict of interest disclosure in our eCompliance system, which is the same electronic system used to submit IRB applications.

Consent Form Templates

The KUMC IRB requests the use of our templates posted at: http://www.kumc.edu/compliance/human-research-protection-program/institutional-review-board/informed-consent/consent-templates.html

Scientific Merit Review

Studies that received NIH funding or funding through another peer-review process are accepted for scientific merit without further review. Other studies must have a scientific merit review by the department chair or other internal committee.

Ancillary Reviews

As applicable to your project, additional reviews may be needed by the following groups. Approval from these groups must be obtained before final IRB approval is granted.

- HIPAA Compliance – for projects involving protected health information
- Conflict of Interest Committee – for projects in which study team members or the institution have a financial relationship with the study sponsor or related to the investigational product
- Radiation Safety Committee – for projects involving radiation or radioactive materials
- Institutional Biosafety Committee – for projects involving recombinant DNA.
- Protocol Review and Monitoring Committee – for cancer-related studies
- Nursing Impact – for projects involving an inpatient population
- As applicable, external investigators may be asked to provide a letter of support from their home institution in support of the IRB submission.

KUMC Policy on Adverse Event Reporting

Internal adverse events must be reported if they are unexpected and related to the research. *External adverse events* must be reported if:

- The KUMC PI determines the event is unexpected, the event has implications for the conduct of the study, and the sponsor agrees to add the new information to the consent form;

  or

- The sponsor has determined that the event constitutes an unanticipated problem involving risk to subjects or others and has proposed an action plan to address the problem.

KUMC Policy on Reporting New Information in Research

New information impacting the welfare of participants, other than adverse events discussed above, must be reported so that the IRB can determine whether or not the information indicates new risks to subjects or potential non-compliance. Examples of new information include protocol violations, monitoring reports, breach of confidentiality, complaints, adverse findings in an audit, or incarceration of a research subject. A full description of reporting requirements is posted http://www.kumc.edu/compliance/human-research-protection-program/institutional-review-board/reporting-new-information--events.html

IRB Contact Information

For more information, you may email: humansubjects@kumc.edu