

Applying to the IRB at Saint Luke's Hospital-Kansas City

Application Process

Applications for IRB review must be submitted in hard copy (paper) format. The IRB requests signed original copies of all documents. We do not accept electronic submissions.

All IRB forms are on the SLHS website under Clinical Research/Resources for Investigators – Forms and Documents. <http://www.saintlukeshealthsystem.org/resources-investigators-forms-documents>

You may type directly on the pdf documents, save the document to your personal files, print the completed form, and obtain required signatures.

There are two basic submission forms: one for prospective research (8 pages) and one for retrospective research (3 pages). Additional required documents are described on the cover page of each document.

HIPAA Regulations

At Saint Luke's Hospital, the IRB serves as the Privacy Board for assuring compliance with HIPAA regulations in the area of research. We require use of our own Authorization to Use and Disclose Protected Health Information for Research which is also on the SLHS website.

Training Requirements for Research Personnel

Saint Luke's Hospital-Kansas City participates in the Collaborative Institutional Training Initiative at the University of Miami (CITI Program). All key study personnel must complete courses in human subject protection (every 3 years) and conflict of interest (every 4 years).

Conflict of Interest Disclosure Requirement

All key study personnel must disclose financial interests at least annually. Disclosures are made on the Saint Luke's Health System website. A financial disclosure Power Point training presentation is on the same page as the clinical research forms and documents. <http://www.saintlukeshealthsystem.org/resources-investigators-forms-documents> Step-by-step instructions for completing the form are included in the presentation.

Consent Forms

Saint Luke's does not use an informed consent template; however, a sample informed consent document is available on the SLHS website (cited above) for investigator initiated studies. We routinely review sponsors' consent forms and will review most any informed consent form but ask that the document include all elements of informed consent as listed on page 1 of the IRB submission form for prospective research.

Meeting Dates/Submission Deadlines

The IRB typically meets twice monthly on the 2nd and 4th Fridays during January – November and once during December. Submission deadlines are three weeks + one day prior to the meetings. Meeting schedule is subject to change as needed, so checking with the IRB Office is recommended.

Ancillary Reviews

In addition to IRB review, your project may require review by other individuals and/or committees prior to IRB approval:

- Central Office of Research Administration – reviews projects outside the areas of cardiology, cardiovascular surgery and oncology *prior to IRB review*
- Scientific Review Committee at Saint Luke's Cancer Institute reviews oncology related studies *prior to IRB review*
- Radiation Safety Committee – for projects in which individuals will be subjected to ionizing radiation (*reviewed concurrent with IRB review*)
- Institutional Biosafety Committee (IBC) – for projects involving recombinant DNA (*IBC approval required prior to IRB review*)
- Nursing Research Council – studies initiated by nursing staff (*approval required prior to IRB review*)
- Financial Conflict of Interest Committee – reviews disclosed financial interest to determine if a potential conflict exists and how best to manage such conflict (*typically done concurrent with IRB review, but may review financial interests at any time*)

IRB Contact Information

Questions regarding the submission process may be addressed to the IRB Office, 816-932-3661 or mhorn@saint-lukes.org