Any study involving cancer must be approved by the SKCC Protocol Review Committee (PRC) prior to Institutional Review Board (IRB) submission. Additionally, most studies must be approved by a Multidisciplinary Disease Group (MDG) Committee prior to PRC submission (exception noted below in Step 1). The following steps describe the process from MDG submission to PRC submission.

**Step 1 – Submit to MDG**

*If the study is a retrospective chart review or a correlative lab trial that will utilize banked blood and tissue (and doesn’t require informed consent), skip Step 1 and go ahead to Step 2.*

To submit to an MDG, e-mail the protocol to the appropriate MDG Committee Coordinator.

MDG Committee information including a list of MDG leaders and coordinators may be accessed here: http://isley.kcc.tju.edu/intranet/clinicaltrials/start-up.php

The MDG Committee Coordinator will notify the PI of the MDG Committee’s decision by e-mail. The Committee Coordinator will also register the study in JeffTrial and provide the PI with the JeffTrial protocol number so that he/she may begin tracking the study.

**Step 2 – Complete the MCSF**

The Master Cancer Committee Submission Form (MCSF) must be completed for all studies involving cancer. Please follow the form carefully as there are sections that are not applicable for all studies and may be marked “N/A.” This form is used for all studies including, but not limited to, industry sponsored studies (i.e. “Pharma studies”), NCI National Clinical Trials Network (NCTN) studies (formerly called Cooperative Group studies), and investigator-initiated trials (IITs) including retrospective and correlative lab studies.

The MCSF may be accessed here: http://isley.kcc.tju.edu/intranet/clinicaltrials/start-up.php

Please be aware that the MCSF requires signature approval from one of the MDG Committee Leaders (if MDG Committee approval was required). To expedite the process, you may choose to complete the MCSF prior to the MDG Committee meeting so that you can obtain the MDG Committee Leader’s signature at the meeting when the study is approved. Alternatively, you may wait until after MDG Committee approval to complete the MCSF and then go back to the leader for signature.

**Step 3 – Submit to PRC**

All studies involving cancer (including precancerous lesions), including retrospective chart reviews and correlative lab trials, must be submitted to PRC. Retrospective chart reviews, correlative lab trials, and NCTN studies will receive expedited review. All other studies will go to the full committee for review.
The PRC meets every second and fourth Monday of the month. Documents must be submitted to PRC by 9:00am Monday two weeks prior to the meeting. PRC meeting dates and corresponding deadlines may be accessed here: [http://isley.kcc.tju.edu/intranet/clinicaltrials/start-up.php](http://isley.kcc.tju.edu/intranet/clinicaltrials/start-up.php)

Please be aware that PRC Reviewers will contact the PI to address questions that came up during their review. It’s important for the PI to respond to the reviewer’s inquiries as soon as possible so that any issues may be addressed prior to the PRC meeting. If all issues are satisfactorily addressed ahead of time, there’s a greater chance that the study will be approved at the meeting.

**How to Submit to PRC**

**Retrospective Chart Reviews**  
E-mail the following documents to PRC@jefferson.edu:

- Completed MCSF
- Completed OHR-3
- Completed OHR-4
- Protocol summary

**All Other Studies**  
E-mail the following documents to PRC@jefferson.edu:

- Completed MCSF
  - The signature page may be scanned and included in the e-mail, or faxed to 215-923-9974
- Current protocol
- Consent form (only if it is an IIT being coordinated by the Protocol Support Unit’s Regulatory Team)