



MEMORANDUM

TO: All Cancer Center Members
 FROM: John H. Glick, MD, Director Cancer Center *JHG*
 Glen Gaulton, MD, Vice Dean for Research and Research Training *GG*
 Emma Meagher, M.D., Chair of IRB *EM*
 DATE: September 2003
 RE: Submission of New Clinical Protocols

As you may know, in 1992, the National Cancer Institute mandated that all NCI Comprehensive and Clinical Cancer Centers have a formally approved Clinical Trials Scientific Review and Monitoring Committee (CTSRMC) in order to continue being funded and designated as a NCI-Comprehensive Cancer Center.

In accordance with this requirement, the Abramson Cancer Center's CTSRMC has been active for nearly 12 years. This committee is chaired by Douglas Fraker, MD, Chief of Surgical Oncology. The committee's responsibility is complementary to, but not overlapping with the University's IRB. The CTSRMC reviews the scientific merit of a trial, while the IRB reviews a trial based on ethical concerns, and specifically reviews the consent forms.

The NCI mandates that all cancer-related studies in patients be formally approved by the CTSRMC before it can be activated for accrual. This includes therapeutic clinical trials, as well as behavioral and cancer control studies in patients. This means that even if the IRB has reviewed the study, an investigator may not start accruing patients until the receipt of a written approval letter from the CTSRMC. Protocols that must be submitted to the CTSRMC for approval include all intramural studies, industry-sponsored studies, and any protocol that has not been peer reviewed by NCI or NIH. National cooperative groups protocols already approved by NCI are excluded from the approval process, but must be submitted to the CRSRMC for tracking.



How to Submit a Protocol to the CTSRMC and IRB:

- The Principal Investigator submits a protocol to the IRB and CTSRMC simultaneously using the appropriate submission forms.
 - To submit a study to the CTSRMC, send an IRB facesheet, protocol summary, full protocol, consent form, monitoring plan, and investigator's brochures, where applicable, to the CTSRMC Offices electronically (vsallee@mail.med.upenn.edu).
- If the IRB finds the protocol satisfactory, the protocol receives conditional IRB approval.
- The CTSRMC will review the protocol with one of four outcomes: full approval, approval with revision, deferment, and disapproval.
- When the protocol receives full approval by the CTSRMC, the PI receives a letter of approval, a copy of which goes to the IRB. Enrollment may now begin.

When a protocol receives approval from the CTSRMC with revisions, the PI is sent a letter outlining the revisions or clarifications recommended. After the PI makes the revisions, the revised protocol is sent to the CTSRMC Office. The Chair of the CTSRMC may grant full approval based on the changes made. When a protocol is disapproved, the PI may confer with the Chair to re-evaluate the scientific merit and overall design of the trial.

If you have any specific questions regarding the CTSRMC, please contact Vicki Sallee, Administrative Directors, CTSRMC, 215-349-5238, email vsallee@mail.med.upenn.edu, or, for more general information, Beverly R. Ginsburg, Executive Director of the Abramson Cancer Center, 215-349-8382, ginsburb@mail.med.upenn.edu.

We will continue to make every effort to have this review and approval process as easy and convenient as possible for investigators who are anxious to launch new studies, while adhering to NCI guidelines and related regulations.

cc: Joseph Sherwin