Evaluation of Investigator-Initiated Clinical Research

This is a review process for new unfunded or underfunded investigator-initiated research projects. It is designed to facilitate and improve the quality of investigator-initiated research, as well as efficiency of PCRU use as the costs of conducting clinical research have increased in the face of recent expansion of the CFRI/PCRU. This formal review process will apply to projects that most likely would require a full board IRB review. These new projects will be reviewed by the PCRU Advisory Committee, which is composed of CFRI PCRU leadership and a rotating slate of active faculty users of the PCRU. It is recommended that this review process to be completed prior to the IRB submission for applicable studies.

The process will proceed as follows:

1. The study PI will prepare a summary of the proposed study to include: Purpose, Background/Rationale, Study/Project Population, Research Design, Study Procedures, Outcome Measures, Timetable for Completion, CFRI and PCRU resources needed (i.e., Informatics, Biostatistics, IRB assistance, Study Nurses, special equipment/facilities, etc.), cost estimate, and plans for securing extramural funding.
2. This summary will be submitted to the PCRU Advisory Committee at least 2 weeks before the meeting. Meetings are held usually on the second Wednesday of each month. Submit an electronic copy of the summary to Lisa Sentiff, IRB Regulatory Coordinator-(Lisa.Sentiff@lebonheur.org); office # 287-4645.
   *If the study application has been submitted to IRB, you do not need to submit a separate study summary. We will prepare it based on the IRB application and distribute to the committee members.
3. The PI will attend the meeting and briefly present the study (15 minutes with Powerpoint, if desired), followed by questions from the Committee.
4. The Committee members will then evaluate the project for support by the PCRU based on the following:
   a. Scientific merit
   b. Feasibility
   c. Importance to program/institutional research agenda advancement
   d. Synergy with other ongoing clinical/translational research
   e. Likelihood of generating significant extramural funding
   f. Availability of other funding
   g. Size of budget
   h. Use and availability of PCRU resources and personnel

If approved, the project will undergo a final more detailed budget and feasibility analysis and move forward. The PCRU Advisory Committee will send a letter of approval to the UT IRB. If disapproved, the PI will receive a written critique and be advised whether appropriate revision is likely to result in an approved study. It is suggested that IRB submission follow this review, but if timing is critical, exceptions can be made by notifying the Committee Chair (dblack@uthsc.edu) in advance.