

Minutes
CRU June 24, 2013 meeting
4 PM

Attendees

D Barboriak, B Kurth, B Croft, B Driehuys, KR Choudhury, S Shipes, J Lo, W Freeland, J MacFall, G Janas, B Prince, C Kim, J Voyvodic

I. Introduction

- a. Activity Summary – 201 open protocols approved by the IRB
- b. Patient safety update
None reported
- c. Approval of 5/28/2013 minutes
Approved

II. Review of Approved projects (no seed fund requests or issues)

- D Enterline, Pro00046337, IMRIS Intra-Operative Computed Tomography Scanner: Optimizing Positioning and Interaction with the Trumpf TruSystem Surgical Table, full committee review, abbreviated IDE
- J Hoang, Pro00045494, Incidental Thyroid Cancers Detected on Imaging: Ten-Year Trends and Evaluation of Risk Stratification Methods, retrospective
- B Chin, Pro00046253, Image Quality in PET / CT with list mode data, exempt
- C Spritzer, Pro00046595, Comfort Talk™ Training Intervention for the Amelioration of Claustrophobia and Disruptive Patient Motion in MRI, exempt

III. Seed fund projects

Add process for basic science reviews

The process for reviewing Basic Science projects with seed fund requests is that Barbara Croft receives an application and budget, assigns 2 scientific reviewers and scores them. Scores go to Dan Barboriak. Barbara Kurth and Wendy Freeland do not see these prior to the approval/disapproval by the committee. Dr. Paulson will give the final approval. Once approved, Wendy is informed so that she can give the protocol a seed fund code. This was applied to:

The proposal was approved by the committee with a voice vote.

IV. EPIC MaestroCare for Clinical Research

Discussion of problems and efficiencies

V. Centralized database for IRB protocols in radiology

Mockup of database presented by Steven Shipes

Steve's an example of a protocol review document was shown. The committee and staff in the various clinic areas will need to see what elements in the review should be on a wiki page for perusal prior to a research scan. This needs to include incidental

findings. What to do with incidental findings must be in ALL research protocols with a Radiology component.

VI. Feasibility check list for Radiology studies prior to eIRB submission

Patient population / recruitment

Technology +/- pharmaceutical availability

Commitment to subject follow up

Financial risks / backstopping

- Barboriak – workflow model

The diagram was presented, discussed and we just need to begin to use it to see if it works and what might need to be changed.

VII. Quick updates

- a. Statistical support-case controlled studies

Kingshuk needs access to MC

- b. Identification of physician leadership for CT

- c. Need a policy created specifying that all Radiology personnel on a study team be trained for the designated role (acting as a CRC but untrained)

This should be solved by the necessity of going through MC. Access and security will be determined by the training that people get from MC. If they have not been trained for a particular role (e.g. CRC) they will not be able to perform that roll.

- d. Risk mitigation for 3/2 projects

A meeting has been scheduled for this discussion.

VIII. New Business

A policy for volunteers (particularly children of Investigators) is being developed by?