

Minutes
CRU May 28, 2013 meeting
4 PM

Attendees

D Barboriak, B Kurth, S Hall, B Croft, G Curnow, B Driehuys, KR Choudhury, S Shipes, J Lo, W Freeland, D Frush, J MacFall, M Jenkins, P Trotter, G Janas, B Prince, C Kim

I. Introduction

- a. Activity Summary – 201 open protocols approved by the IRB
- b. Patient safety update
No reportable safety events
- c. Approval of 4/22/2013 minutes
Moved to approve (MacFall), seconded (Croft)

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

- J Hoang, Pro00045494, Incidental Thyroid Cancers Detected on Imaging: Ten-Year Trends and Evaluation of Risk Stratification Methods
- S Borges-Neto, Pro00045624, Value of Same-Day Imaging for Melanoma Lymphoscintigraphy under Two-Day Imaging Protocol
- M Mazurowski, Pro00045978, Analysis of breast images for survival prognosis, prediction of response to therapy and genomic/pathology correlation.
- T Jaffe, Pro00045697, Assessing the clinical and economic impact of non-oncologic CT imaging of the abdomen and pelvis in patients 85 years or older
- J Baker, Pro00045240, Value of Ultrasound in Female Patients with Nipple Discharge
No discussion

III. Seed fund projects

- J Petrella/J Prescott, Longitudinal Changes in Cognitive Status, Amyloid Burden, and Structural Connections in Alzheimer's Dementia. Exempt Status

Discussion about buying PCs regarding the whereabouts and availability of equipment already present for reuse. Dan Barboriak will ask Jeffrey Prescott to check with Chuck Maxfield and the division chiefs and account for what is available now. Approval was given for seed funding by the committee with that caveat.

Indirect costs will be added to seed funded studies starting on July 1.

IV. Defining Qualifying and Non-qualifying studies (evolving V70.7 problems)

- a. Issue discussed with Terry Ainsworth, Dan Sullivan, Jan Taylor, Dan Barboriak, and Barbara Kurth on 4/18/13.

Acknowledged. We will need to disseminate information to investigators as protocols are submitted to the eIRB. DOCR will be scrutinizing protocols for correct builds of grids and work with study teams to ensure correctness prior to release into Maestro Care.

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

Patient population / recruitment

Technology +/- pharmaceutical availability

Commitment to subject follow up

Financial risks / backstopping

- a. George Curnow – Financial modeling

- b. Review of outside documents

George Curnow and Susan Hall presented an example of a protocol that is on the verge of losing money as an example of how much we need to determine feasibility prior to accepting a trial contract into Radiology. General discussion followed.

VI. Centralized database for IRB protocols in radiology

Mockup of database presented by Steven Shipes

Tabled

VII. Quick updates

- a. Research resources – storage of laptops

- b. Human Subjects Research training form- have sent reminders again

- c. Statistical support-case controlled studies

- d. Identification of physician leadership for CT

- e. 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)

- f. Risk mitigation for 3/2 projects

Briefly mentioned

VIII. New Business

Don Frush discussed the imminent release of a yearly mandatory flu vaccine.

A partial list of Radiology employees (not faculty or hospital employees) who may be required to have the vaccine during the next roll out in 2013 has been sent to Don.

