

Minutes
CRU April 22, 2013 meeting
4 PM

Attendees

D Barboriak, B Kurth, S Hall, B Croft, G Curnow, B Driehuys, T Wong, KR
Choudhury, J Voyvodic, S Shipes, R Nelson, M Cheney, J Lo

I. Introduction

- a. Activity Summary – 195 open protocols approved by the IRB
- b. Patient safety update
No reportable (to Duke IRB) safety issues
- c. Approval of 3/25/2013 minutes
Approved; clarified that \$1000 to Radiology/ study did not include federally funded research.

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

- E Vinson, Pro00045151, Displaced labral-chondral flap tears of the inferior glenoid: appearance on MR imaging with clinical and operative correlation.
Approved by CRU Director in eIRB

III. Seed fund projects

- J Petrella/S Kuzminski, Pro00043560, Detection of Subconcussive Brain Injury in High School Football Players Utilizing Diffusion Tensor Imaging
Approved unanimously (Lo made motion, Wong seconded)
- D Marin/A Mileto, Gemstone Spectral CT Imaging for renal lesion characterization – a phantom study.
Approved unanimously (Lo made motion, Nelson seconded)

IV. Defining “billing risk” studies

- a. The evolving definition of “billing risk” and designating research studies for insurance
- b. V70.7 coding issues discussed with Mark Stacy, Peter Kranz, James Provenzale, Steven Chen, Ketha Brooks, Dan Barboriak, and Barbara Kurth on 4/18/13.
Kurth will clarify issues with Terry Ainsworth

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. Review of outside documents

All committee members asked to review feasibility sample documents attached to agenda email. Need one volunteer to work on a checklist for Radiology CRU or one will be appointed.

VI. Centralized database for IRB protocols in radiology

- a. Review of form
- b. Sign off process?

VII. Risk mitigation for 3/2 projects

- a. loss of confidentiality (HIPAA compliance, PHI and data security essentials e.g. encryption, de-identification of images)
- b. human subject protection (IRB approval, proper ICF consenting process, documentation of consent)
- c. key personnel training requirements
- d. Regulatory Binder requirements (documentation of ALL research activities)

Barboriak, Kurth and Nelson will get together to come up with a plan.

VIII. Quick updates

- a. NEXT MONTH'S CRU MEETING IS ON TUESDAY MAY 28th AT 4PM IN USUAL PLACE
- b. Faculty Development Seminar April 29th 7:30am Rm 2902 Children's Health Center: "Getting Your Research Project Off the Ground: Tips on Navigating the CRU, CPC & IRB" Chesney / Nelson
- c. Human Subjects Research training from- will be getting a more complete roster of those who have taken the training from DOCR hopefully before the July deadline
- d. Statistical support-case controlled studies
- e. Inventory of electronic devices
Barboriak will follow up with Maxfield and Griffin
- f. Identification of physician leadership for CT
- g. 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)

IX. New Business

