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