Agenda
CRU February 23, 2016 meeting
12:00 PM

Participants: Dr. Daniel Barboriak, Dr. Mustafa R Bashir, Dr. Kingshuk Choudhury, Dr. Bastiaan Driehuys, Dr. Lynne Koweek, Dr. Joseph Lo, Dr. James MacFall, Jennifer Korzekwinski, Steven Shipes, Samantha Womack, Christopher Vallanat

I. **Introduction**

- Activity Summary – 269 Total Studies 43 full committee; 162 expedited; 26 exempt
- Patient safety update - 2 SAEs submitted; 2 SAEs completed in IRB

SAEs Submitted

1. Pro00010319 - Humanitarian Device Exemption (HDE): Neuroform
   On 02/18/2016, a Neuroform stent was placed without the patient being consented prior to its use. The stent was used for the on-label indication; however, the location of the stent ended up being in an off-label location. The location was in the cervical portion of the carotid artery. Based off of previous imaging, it was anticipated that a precise stent would be used. During the procedure, it became too difficult to navigate the precise stent to the desired location, so the Neuroform stent was used due to its flexibility. Dr. Zomorodi was the physician who placed the stent. There were no complications/adverse events, and the patient and her family were notified about its use after the procedure.

2. Pro00065192 - Revolution 1.5 CT (SAE Submitted)
   Deviation Description: This is a sponsor reported event in which a GE Employee study conduct had deviated from via Sections 15.1 Management of Data and 16.1 Monitoring Plan. Although Duke does not have access to neither the Data Management Plan nor the Monitoring Plan, GE has determined that the chain of custody and plans were not adhered to. In order to maintain the integrity of the study a record of the deviation should be reported to Duke's IRB.
   SAE was explained by Jennifer Korzekwinski

SAEs Completed

1. Pro00025110 - Hyperpolarized 129Xe MRI
   IRB has declared that the problem/event does represent an Unanticipated Problem Involving Risk to Subjects or Others (UPIRTSO). The assessment and corrective actions are adequate. No further action is required. Dr. Barboriak and Dr. Driehuys commented on the process of IRB action.
2. Pro00050668 the deviation was s Humanitarian Use Device/Humanitarian Device Exemption for Codman EnterpriseTM Stent Vascular Reconstruction Device and Delivery System secondary to necessary medical care.
   No further action is required.

- 257 Research Associated Scans performed throughout health system in January
- Approval of January 26, 2016 minutes

Motion to approve by Dr. MacFall and seconded by Dr. Bashir. Everyone present voted and approved.

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

- Grimm, Pro00070112, Pathology Outcomes of High-Risk lesions.
- Grimm, Pro0007023, Outcomes of Mass and Asymmetry Morphology on Mammography.

II. **Prospective Studies**
- None

III. **Federal/Foundation Studies**
- **None**

IV. **Seed Fund Requests**
- None

V. **Research marketplace**
http://sites.duke.edu/radiologycru/

VI. **Quick updates**
- CRC position
- Regulatory and Protocol Review Position
- Feedback from CRU Compliance QA Committee
- Cold Calling
  Discussed that radiology staff other than technologists and nurses can ask patients if they would be interested in having someone speak with them about participating in a research trail.
- Training requirements for residents and fellows. Residents must take the course in order to be key personnel on research protoc0ls. Those who have taken the course were generally satisfied.

VII. **Old Business**
- Evaluation of seed grants – early 2016
  New Instructions to CRC reviewers Dr. Barboriak discussed emphasizing the importance of providing a hypothesis plus statistics

- Revisions to Seed Fund Forms Revisions have been made by Steve Shipes

VIII. **New Business**