

Agenda
CRU Meeting Agenda
Aug 22, 2016, 12:00 PM

Attending: Dr. Timothy Turkington, Antonina Poole, Jennifer Korzekwinski, Gemini Janas, Dr. Martin Tornai, Dr. Jim Voyvodic, Dr. Bastian Driehuys, Dr. Donald Frush, Karen Trofi, Dr. Daniel Barboriak, Steven Shipes

I. Introduction

Dr. Barboriak discussed the below research activity summary.

- Activity Summary –
 - 209 approved studies in IRB 43 full committee; 166 expedited; 30 exempt
 - 318 Subjects enrolled for 2016, (6 NIH, 62 Federal, 228 Industry, 28 Internal)
 - 303 Research Associated Scans performed throughout health system in July 2016
 - Patient safety update -
 - Safety events from our last meeting:
 - SAE008_Pro00050668 “patient was not consented prior to use of Enterprise stent”
Action taken-“does not represent an Unanticipated Problem Involving Risk to Subjects or Others (UPIRTSO). Protocol deviation for the purposes of urgent medical care. No further action is required.”
Gemini Janas explained the circumstance of how subjects would not be consented before using the device.
 - SAE001_Pro00056088 “Enrollment number exceeded”
Action Taken-“does not represent an Unanticipated Problem Involving Risk to Subjects or Others (UPIRTSO). No further action is required. “
Steve Shipes explained that circumstance of the planned retrospective data was exceeded.
 - SAE057_Pro00016040 “Thrombocytopenia”
Action Taken-“does not represent an Unanticipated Problem Involving Risk to Subjects or Others (UPIRTSO). No further action is required. “
Jennifer Korzekwinski explained that circumstance of why the safety event was filed.
 - New Safety Event:
 - SAE058_Pro00016040 –“Several subjects from 2009 and 2010 had a Holter Monitor in place at the correct time points per protocol, but data did not record. Sponsor requesting a protocol deviation be filed.” The IRB declared IRB has declared that the problem/event does not represent an UPIRTSO. No further action is required.
Jennifer Korzekwinski explained that circumstance of why the safety event was filed and how the time points were missed.

Motion to approve Previous meeting notes.

Motion to approve by Dr. Tornai and seconded by Dr. Turkington. Dr. Tornai suggested some typo corrections and “repeat name edits”. Everyone present voted and approved. No objections.

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

- Dr. Allen, Pro00075986, Liver Surface Nodularity
- Dr. Bashir, Pro00075944, Imaging core lab for Madrigal Protocol MGL-3196-05
- Dr. Koweek, Pro00075442, CT-FFR QC Project
- Dr. Mammarrappallil, Pro00071989 Limited Z- axis, CTPA
- Dr. Borges-Neto, Pro00075595, Systolic and Diastolic mechanical dyssynchrony
- Dr. Marin, Pro00075346, DECT Diagnostic Accuracy

Dr. Barboriak discussed the research studies that have approved since our meeting on Aug 2, 2016.

III. **Prospective Studies**

- Dr. Petrella, Pro00074911, Intracortical DTI for Alzheimer's Disease

Dr. Voyvodic was the reviewer and explained the study and its purpose. There will be 20 healthy controls for early to mid-stage Alzheimer's. Looking for changes in intracortical DTI to see if they have cognitive deficits.

- Low risk, short session for BIAC scanner
- Dana Sanders had no problems with the finances

After discussion it was decided that the CRU approval is pending on the PI's changes to the following:

- 1) Editing changes suggested to research summary
- 2) Provide more detail on primary hypothesis and statistical analysis and provide power analysis as appropriate

IV. **Federal/Foundation Studies**

- none

V. **Seed Fund Requests**

- None

VI. **Research marketplace**

<http://sites.duke.edu/radiologycru/>

VII. **Quick updates:**

VIII. **Old Business:**

- Research Marketplace

Dr. Barboriak discussed the research marketplace and showed website. Audience is NIH, Pharm companies, outside radiology CRU etc. Proposed changes were suggested to have pages with "Interests and Services" and possibly a Modality section

- Review of seed funds

Dr. Barboriak discussed the status of the Seed Fund questionnaire that would be sent to recipients after their research is done.

- Research Work Group

Steve Shipes discussed the purpose and status of goals of the work group. The plan is to demo the wiki site of research protocols at the next meeting.

IX. New Business

- CRU customer service initiative

Dr. Barboriak and Steve Shipes discussed the goal of reaching out to those who use the CRU to if we are meeting their needs or how we can improve.

Dr. Voyvodic suggested that we first have a statement of what CRU does and mission of what our goals are.