March 29, 2016 – San Antonio TRCC Summary Notes from Breakout Sessions

Informatics – Dr. Alfredo Tirado-Ramos (speaker)

Finished over the last three years advancements along the group goals since May 2013. They also arrived to a process for proposals to the Clinical Data Network. Looking forward, they would like to advance three goals:

1. Create a federated model system to connect sites for interoperability
2. Develop a scalable governance structure for infrastructure
3. Develop a sustainability model for the Clinical Data Network

BERD – Dr. Mohammad Rahbar (speaker)

Identified adaptive trial design previously as area of focus. Once the design is identified, they would like to apply the design to other applicable trials. Outcome adaptive trials are also a focus. Education and core course development is another area of focus. Developing a data coordinating center is an area of focus. Statistical methodology is another issue to work on tool development.

Biobanking & Core Labs – Dr. Samuel Hughes (speaker)

Identified overlap between the two groups to figure out solutions to mutual issues.

1. Streamlining processes in terms of a consortium of biobanks and core labs, creating best practices, regulatory issues, create a precedent of a biobanking consortium
2. Creating common language and nomenclature, for example the definition of specimen/sample
3. Working towards an accessible clinical data system with the Informatics group

Clinical Research Units & Clinical Trials IRB Group – Dr. John Roache (speaker)

Also identified overlap between the CRU and IRB breakout groups. Looked over goals from May 2013 and significant progress has been made over the last three years. As the network builds up multi-site clinical trials, focus needs to turn towards centralization of certain processes to streamline efficiencies. There is a need to develop master research agreements, as this will lessen the individual contract negotiations. Furthermore, then these agreements need to filter through each Clinical Trials Office. Agreements should be vetted through Dr. Bethlynn Maxwell for legal guidance in UT System. Training initiatives in regards to GCP, sharing training resources, etc. should be further explored.

Education & Mentoring – Dr. Blair Holbein (speaker)

Implementing required training for an online RCR course:

1. Develop reconfigured modules for RCR online course
2. Additional training requirements for scientific rigor and transparency, and this hopefully will be on a similar learning platform
3. Develop best practices for scientific integrity
4. Leveraging lessons learned to host a consortium level mentorship and training model

Community Engagement – Sharon Crosiant, Paula Winkler, and Sandra Burge (speakers)

In reviewing past goals and processes, our CE groups each noted how each of their different CTSAs view and define community engagement. NCATS has redefined the term community engagement, how do they fit in, and how do they interact and work on goals of the local, regional, and national stakeholders.

X02 application for volunteer registry is being readdressed as a potential group project, and they will move forward with developing a uniform registry. They are forming work groups to address issues that they expect to arise.

Evaluation & Metrics – Dr. Helen Parsons (speaker)

Common metrics pilot initiative was a previous goal the evaluation group worked together to collect. Currently, they need to revise and reproach this initiative, as now NCATS has been more formally mandating certain metrics for CTSAs to collect. This is where they are focusing their effort going forward:

1. Work together to implement NCATS common metrics and troubleshoot the rollout initiatives
2. Recognize the current FOA emphasizes collaboration to develop some TRCC specific metrics

PIs & Administration – Dr. Robert Toto (speaker)

The PIs will all attend the next NCATS PI meeting next month in April. One topic the PIs requested to discuss was the 30-day prior approval process required for all KL2 and PP human subjects study, but NCATS would not allow the topic to be further discussed at this venue. Better practices for sharing multi-site funding opportunities will be developed, as well as considering more nimble methods to increase funding across the TRCC. Also, marketing of Clinical Trials Xpress should be better marketed to faculty at all of the CTSA campuses. Upcoming TRCC meetings should refocus via the TRCC Executive Committee by the PIs joining groups and perhaps combining/integrating groups prior to the next TRCC meeting in fall of 2016 in Galveston.