Clinical Trials Administration Committee (CTAC)
Meeting Minutes
April 5, 2023
12:00 – 1:00 pm
Zoom Conference Call

In attendance:	Bertram (O'Neal)	Kimberly (HSOM/CCTS) Marchant (CTAO)
	Boles (HSOM)	Matthews (OVPR)
	Croker (CCTS)	McClintock (IRB)
	Fitz-Gerald (CCTS)	Miller (OVPR)
	Gilbert (SOD)	Nichols (SOO, OVPR)
	Gordon (HSIS/CCTS)	Rizk (CTAO)
	Goss (SHP)	Schwebel (OVPR)
	Horn (OVPR)	Specht (OnCore)
	Jackson (Health System Compliance)	Wasko (SOB)
	Joiner (DOM)	
Unable to attend:	Brown (Health System)	Logan (University Compliance)
	Irvin (SOPH)	Pitts (Health System)
	Lee (DOM)	Smith (SON)
Guest:	Oliver (CCTS)	

1. **Review of CTAC minutes from March 8th meeting:** The minutes were reviewed and approved.

2. **Updates**

   a. **OnCore** (Specht): Ms. Specht discussed the Onsemble conference hosted by the platform's vendor Advarra where they were able to learn from other AMC users of OnCore. Stanford has initiated an effort to implement the Financials module. The OnCore team plans to engage both Stanford as well as Advarra's subject matter expert to consider our Financials utilization and workflows to look for operational efficiencies. Work continues on the CTBN optimization goal in order to determine a baseline for acceptable 'late CTBNs'. Additionally, work continues on the upgrade with the technical administrator (Steve) still engaged with Advarra on configuring possible solutions for an ongoing vendor issue. Ms. Specht closed initial comments by mentioning that the lead calendar builder (Jennifer) will be joining the Q/A sessions to ensure all aspects of OnCore operations are covered. The discussion concluded with a few comments about the extent of use of Financials by the various Departments across campus.
   Actions:
      1. Continue weekly OnCore Q/A sessions to provide assistance and ongoing training to the clinical research community.
      2. Identify the manageable target percentage of late 'occurred' visit entries and report at the May meeting.
      3. Continue efforts to complete the latest system upgrade.

   b. **IRB Metrics & Process** (McClintock): Mr. McClintock reminded the Committee that for several months the IRB had been fully staffed and had the opportunity to expand by adding two additional positions. However, recently announced departures and a retirement planned for July 1st have created new position vacancies. Following some internal promotions, the IRB will be looking to fill three positions in the coming weeks. Mr. McClintock mentioned that the

previously discussed 'Top 10' list had been rebranded as 'IRB Submission Tips and Best Practices'. To continue its efforts to reduce review times, the IRB plans to have targeted communications with submitters whose actions reflect items outlined in the document to aid in improvement long-term. Attention then turned to the metrics distributed with the meeting reminder that highlighted an improvement for Full submissions (113 days to 86) as well as those that go through Advarra (86 days to 75). An item of note, raised by Dr. Kimberly, showed an ongoing downward trend in overall volume for several submission types from FY19 to FY22. Mr. McClintock replied that this will require further analysis to determine a potential root cause for the apparent decrease in submissions, which is in contrast to a steady numbers of new protocols coming to OnCore and to the upward trend of research expenditures overall.

Actions:

1. Continue efforts to improve IRB throughput rates and enact process changes to enable such improvement.
2. Conduct a deeper analysis into why submissions appear to be trending down over the past few years and determine if there are any primary areas responsible for this pattern.

c. **Regulatory Support Pilot** (Croker): Dr. Croker reminded the Committee of the pilot initiative in regulatory support involving the CCTS's CRSP regulatory support persons and four Divisions in Pediatrics led by Dr. Dan Feig. After more than six months of engagement, IRB provided review times for participating Divisions, pre and post partnership. The IRB data reflect an overall decrease in review time. Additionally, interviews were conducted among the 'actively engaged' group, which found an overall sense of improved operations, satisfaction with re-direction of regulatory responsibilities and appreciation for the pilot outcomes. Dr. Croker agreed that specific data will be made available at the May meeting for review by the members.

Action:

1. The IRB review timeline data to be reviewed at the May meeting.

3. **IllumiCare Pilot** (Gordon, Marchant, Rizk): Mr. Marchant reported that activities have resumed after a pause for contract discussions between the vendor and the Health System. The pilot sites have been contacted and refresher presentations are being conducted with faculty and coordinators to ensure awareness of the process. The Committee was reminded that the purpose of the pilot is to send a push notification to providers at the point of care that the patient currently before them is a potential candidate for a clinical trial in recruitment phase. This tool uses protocol-provided inclusion/exclusion criteria to mine the patients' digital health records to determine suitability for recruitment. This is a developmental partnership with the vendor. The five pilot sites include Nephrology, Family Medicine/Prime Care, Cardiology, Gastroenterology, and Rheumatology.

Action:

1. Continue work with the pilot sites to launch the application and begin enabling real-time push notifications to providers about potential study candidates at the point of care.

4. **Quick Notes**

a. **OSP National Search** (Schwebel): Dr. Schwebel notified that following a review of applicants, three were chosen for on-site discussions and presentations, one of whom will be here next week. Unfortunately, two of them have had to cancel. The Committee was encouraged to attend Candidate C's open presentation, which will be held on Tuesday April 11th at 9:30am in the Finley Conference Center at Kaul 270. Dr. Schwebel expects other candidates will be scheduled for on-campus visits in the coming few weeks.

b. **Project eRA** (Matthews): Mr. Matthews noted that there was no new information to report since his last update. The procurement strategy is still under review by senior leadership. The new

Executive Director of OSP/Associate Vice President of Research is expected to provide input into the process.

5. **Clinical Trials Day** (Oliver): Ms. Oliver reminded the Committee that Thursday May 18th will be celebrated at UAB as Clinical Trials Day. While the entire day will have a celebratory nature, the formalized event will be held from 7:30-9:30am in Wallace Tumor Institute lobby where there will be breakfast served along with brief remarks by several leaders along with informational booths for attendees. Ms. Oliver outlined a triathlon challenge for the Committee to encourage its engagement in spreading the word about the event where 'medals' will be awarded depending on the level of success (attached). Closing remarks were made by Mr. Marchant and Ms. Oliver surrounding the social media activities encompassing the day in order to tie it to the larger annual Clinical Trials Day of international prominence which will be held on Saturday May 20th.

6. **New Business/Open Floor** (All)**:** Dr. Croker notified the committee that NCATS is leading a formal request for information (RFI) on the design, conduct, and reporting of decentralized clinical trials (DCTs). This RFI invites comment on how DCTs may be designed to be more effective, efficient and equitable to bring more interventions to all people in a faster way. Of note, the RFI welcomes inputs on ways to bolster access and participation by diverse and underrepresented groups. The Committee was invited to either respond to Dr. Croker by May 4th or directly to the RFI by 11:59pm on May 12th.

   Lastly, Ms. Fitz-Gerald announced that the next CCTS Lunch & Learn will be held on Tuesday April 11th at 11:30am via Zoom. Information on registration may be found here.

7. **Next meeting:** May 3, 2023

Robert P. Kimberly, MD
Senior Associate Dean for Clinical and Translational Research
Chair, Clinical Trials Administration Committee

CC: Chris Brown, PhD, VP-Research
Anupam Agarwal, MD, SVP for Medicine and Dean-Heersink SOM