Clinical Trials Administration Committee (CTAC)
Meeting Minutes
October 6, 2021
12:00 – 1:00 pm
Zoom Conference Call

In attendance:	Boles (SOM)	Lee (DOM)
	Cotten (OVPR/OSP)	Marchant (CTAO)
	Croker (CCTS)	McClintock (OVPR/IRB)
	Farough (Health System)	Miller (OVPR)
	Gilbert (SOD)	Nichols (SOO, OVPR)
	Gordon (HSIS/CCTS)	Redden (SOPH)
	Gutierrez (CCTS)	Sandefur (OnCore)
	Horn (OVPR)	Schwebel (CAS)
	Kimberly (SOM/CCTS)	
Unable to attend:	Bates (Health System Compliance)	Joiner (DOM)
	Bertram (OCCC)	Logan (University Compliance)
	Busby (OCCC)	Motl (SHP)
	Dransfield (DOM)	Rizk (CTAO)
	Fitz-Gerald (CCTS)	Wasko (SOB)
Guests:	Bradford (CCTS)	
	Westfall (DOM)	

1. **Review of CTAC minutes from September 1st meeting:** The minutes were reviewed and approved.

2. **Updates**

   a. **OnCore** (Sandefur): Mr. Sandefur informed the committee that the implementation of both OnCore Phase 2 and the Financials is complete. The OnCore team is completing the testing of the annual update of the software. Reports addressing 'un-managed' visits to ensure appropriate billing practices by the Health System are now being distributed each Friday to study teams; these reports identify visits that are 'past due' for management in the system. The reports are followed up on a 14-day and then 28-day window as a reminder and include copies to the Principal Investigator. Given these recent efforts, Mr. Sandefur noted that a large proportion (~85% by one estimate) of un-managed visits has been addressed since the inception of the initiative. A short discussion was had on how to best message this information to leadership within the Health System.

   Action:
   1. Complete preparations for the annual upgrade of the software.

   b. **IRB** (McClintock): Mr. McClintock reported that work is ongoing with the Advarra representatives who are assisting with reducing the backlog of submissions within the office. To date, they have completed about 30% of their allocated hours which entail about 50% of their reviews. Since last month's meeting, the office has finalized the hiring of 4 new staff which reduces the number of vacancies to 2. In addition to the backlog of work, Advarra is also expected to provide insight on current processes within the office and where efficiencies may be gained. Dr. Gilbert inquired about the origin of the backlog to which Mr. McClintock reviewed a number of contributory factors. There are no expectations that the backlog will rebuild following Advarra's departure.

   Action:
   1. Advarra's work to continue until backlog addressed or allocated contracted hours complete.

c. **Project eRA** (Cotten): Ms. Cotten reported that InfoEd was on campus earlier this week to meet with instituitional leadership about technical components, as well as the scope of work for the implementation of their product. A key decision to be determined is how to address the 7 terabytes of data in the current system as we transition to the new one. Ms. Cotten mentioned that an attribute of the new system will enable a process whereby some of the current submission forms will no longer be necessary, such as the Extramural Checklist and Responsible Personnel List. Recent meetings have been held with other institutions that enabled demonstrations of their systems to see how they worked in real-time and what could be learned from those implementations. These included UNC-Charlotte, Weill Cornell, and Temple. It was reported that the system will be known as 'myUABresearch'. In addition to the numerous other areas of the project under discussion, Ms. Cotten mentioned that there has been a great deal centered around the needs relative to training and resourcing given a great deal of time is currently demanded by RTC staff addressing questions about the current system, despite information being available online to the research community. Mr. Marchant inquired about the anticipated timeline for the roll-out, to which Ms. Cotten stated that the preferred method would be to 'go-live' with all modules at once, but that would push things out 18-24 months. Given this, it is more likely to be a step-wise roll-out by the various modules potentially starting within 4-5 months. Lastly, Ms. Cotten mentioned that given the size of UAB's animal resource program activities, there are a number of questions to be addressed because InfoEd does not have another client with such a large portfolio (~30,000 cages).

Action:

1. Monthly reports to continue until completion of implementation across all modules.

3. **Trial Accrual Strategies** (Kimberly): Dr. Kimberly reminded the committee of the ongoing activities by the workgroup over the past couple of months, as well as Ms. Horn's report last month on a pilot in conjunction with Digital Media. He also noted national interest being placed on the topic, given the industry's struggles with uninformative trials. This led Dr. Kimberly to circle back to the earlier discussion on OnCore's capabilities to create reports which now includes one on accrual status. Mr. Sandefur mentioned that a recently created report provides a monthly update to PIs that outlines the current status of recruitment for individual trials and compares it against the contracted total. By distributing this regularly, adjustments in recruiting strategy are able to be made if needed. Discussion centered around how best to use the information to enhance success in trial implementation. The goal is to be a 'preferred' site for trial conduction by Sponsors and therefore, we should make every effort possible to meet, if not exceed, enrollment on all trials undertaken by investigators across campus. Dr. Kimberly closed the discussion by mentioning that the NIH has enacted a task force on the topic and that UAB is among the participants to help guide the national conversation.

   Action:

   1. Refine the process by which the accrual data from OnCore can help guide decision-making and appropriate follow-on actions relative to accrual.

4. **Training Strategies** (Kimberly): This item was deferred until next month in the interest of time.

5. **New Business/Open Floor:** No new items proposed by Committee.

   Action:

   1. Dr. Kimberly called upon the committee to send potential agenda items for next month's meeting via email.

6. **Next meeting:** November 3rd (Zoom meeting)

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

CC: Chris Brown, PhD, VP-Research
Selwyn Vickers, MD, Senior VP-Medicine and Dean-SOM