Clinical Trials Administration Committee (CTAC)
Meeting Minutes
October 5, 2022
12:00 – 1:00 pm
Zoom Conference Call

In attendance:	Bertram (OCCC)	Joiner (DOM)
	Boles (SOM)	Kimberly (SOM/CCTS)
	Croker (CCTS)	Marchant (CTAO)
	Fitz-Gerald (CCTS)	McClintock (IRB)
	Gilbert (SOD)	Pitts (Health System)
	Gordon (HSIS/CCTS)	Schwebel (OVPR)
	Goss (SHP)	Smith (SON)
	Horn (OVPR)	Specht (OnCore)
	Hurst (Health System)	Wasko (SOB)
Unable to attend:	Cotten (OVPR/OSP)	Miller (OVPR)
	Jackson (Health System Compliance)	Nichols (SOO, OVPR)
	Lee (DOM)	Rizk (CTAO)
	Logan (University Compliance)	
Guests:	Katie Bradford (CCTS)	

1. **Review of CTAC minutes from September 7th meeting:** The minutes were reviewed and approved.

2. **Updates**

   a. **OnCore** (Specht): Ms. Specht reminded the Committee that the new Financial Analyst started in mid September. She updated the current status of occurring participant visits in OnCore in a timely fashion. Occurring visits in OnCore generates Clinical Trial Billing Notices (CTBNs) which are used to inform the billing offices of how clinical activities should be billed. Mackenzie Roberts is leading that effort based on the receipt of a weekly report. Efforts to date have been successful in seeing a reduction based on overall volume of late CTBNs (152 to 62). Further discussions are needed to determine the institutional goal by which the effort will be measured going forward.
   Actions:
      1. Continue weekly OnCore Q/A sessions to provide ongoing training to the clinical research community.
      2. Identify an institutional goal for the acceptable percentage of CTBNs that may be late and what the appropriate reasons would be to allow for the delayed submission.

   b. **IRB Metrics & Process** (McClintock): Mr. McClintock announced that the IRB has filled all of their positions for the first time in several months and that they are now focused on training efforts to ensure a quick onboarding process for the new team members. He declared that the statistics regularly monitored for the RAPID initiative are holding steady, but he is hopeful that as the new staff get fully trained, that a continued decrease in time will follow. Several efforts are underway related to guidance development including the areas of social media, eSignatures for ICFs, and submission quality improvement. In order to continue seeing

improvements in initial submissions from study teams, Mr. McClintock is planning to having more targeted communications to glean feedback on where problem areas may lie for teams and how the IRB may assist in smoothing some of those 'bumps' in the process. In closing, Ms. Fitz-Gerald mentioned that the IRB would be giving a presentation in the Research Seminar Series (RSS) on October 20th about best practices and that the presentation would be recorded and available online following the live presentation via Zoom.

Actions:

1. Continue efforts to improve IRB throughput rates and enact process changes to enable such improvement.
2. Committee members encouraged to provide feedback to the IRB for ways to improve the submission forms/process by reaching out to Mr. McClintock.

3. **EMR Access-Traveler Badge Process** (Marchant): As follow-up to a discussion topic raised in the September meeting, Mr. Marchant and Ms. Jackson met with the leadership responsible for the Travelers Badge process in the Health System. This process identifies which licensed non-Health System employees are credentialed to be in Health System space, such as clinics in Kirklin Clinic or Whitaker. While the process is well defined, it was determined that more education is needed to ensure everyone across the clinical research landscape is aware of it, especially given the high number of new staff being onboarded. Besides the information currently available on the Clinical Trials Kiosk, Travel Badge staff are tasked with creating additional information such as a workflow document and form links. They have been connected with Ms. Bradford from CCTS Communications to assist in the placement of these on the site. Additionally, it was determined that more in-person training is needed so they are working with Ms. Fitz-Gerald to get added to the schedule for the Research Seminar Series in the coming months.

   Action:

   1. Travel Badge staff at the Health System to work with Ms. Bradford and Ms. Fitz-Gerald to get more education materials distributed on the orientation process through upcoming seminars as well as the Clinical Trials Kiosk.

4. **Internal Fee Schedule Update** (Marchant): Mr. Marchant reminded the Committee of the Fee Schedule currently available to researchers to assist in the creation of budgets when working with industry sponsors and the need to update it given it is now three years old. Efforts are underway to review the information to ensure it is current by both internal and external means by not only looking at recently negotiated budgets but also Fee Schedules from other AMCs made available from colleagues. The expectation is to have the Schedule made available for use by the first quarter of 2023. Dr. Joiner inquired about the status of the Study Management, Maintenance, and Close-out Fees to which Dr. Kimberly replied that while no revisions have been made to date, all aspects of the Schedule are on the table for consideration with follow-up discussions expected to take place if modifications in this area are found to be needed.

   Action:

   1. Further review and modification to the Internal Fee Schedule to continue with a Q1 2023 anticipated launch.

5. **New Business/Open Floor:**
   a. Dr. Kimberly mentioned that the Task Force working with the Office of Sponsored Programs (OSP) on industry-sponsored clinical trial agreements and time to activation (TTA) submitted its report to Dr. Chris Brown on October 4th for review and consideration. Additionally, Dr. Kimberly mentioned that budget negotiations by Departments continue to be a sticking point in the TTA process. More information will be disseminated to the Committee as it is discovered on potential ways to improve this important process.

6. **Next meeting:** November 16, 2022

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, Interim SVP for Medicine and Dean-Heersink SOM