

Clinical Trials Administration Committee (CTAC)
Meeting Minutes
December 6, 2023
12:00 – 1:00 pm
Zoom Conference Call

In attendance:

Bertram (OCCC)	Jackson (Health System Compliance)
Boles (HSOM)	Kimberly (HSOM/CCTS)
Crocker (CCTS)	Logan (University Compliance)
Fitz-Gerald (CCTS)	Marchant (CTAO)
Gilbert (SOD)	Matthews (OSP)
Gordon (HSIS/CCTS)	Miller (OVPR)
Goss (SHP)	Schwebel (OVPR)
Horn (OVPR)	Smith (SON)
	Specht (OnCore)

Unable to attend:

Brown (Health System)	Nichols (SOO/OVPR)
Irvin (SOPH)	Pitts (Health System)
Joiner (DOM)	Rizk (CCTS/CTAO)
Lee (DOM)	Wasko (SOB)
McClintock (IRB)	

Guests:

Bolding (Radiology)
DeBlasio (OCCC)

1. Review of CTAC minutes from November 1st meeting: The minutes were reviewed and approved. Dr. Kimberly provided an opportunity for Dr. Bertram to introduce Ms. Ping DeBlasio who recently came to UAB from UPitt to oversee collaborative trial operations between the O'Neal CCC and the Health System. Welcome Ping!

2. Updates:

a. IRB Metrics & Process (McClintock): Deferred until January.

b. OSP Operations (Matthews): Mr. Matthews reminded the committee that our new [Associate Vice President for Research, Virginia Hedberg](#), will begin on January 15th. She is currently working with Office of Research leadership as she transitions out of her current role at the University of South Alabama in Mobile and into her position here. She is expected to attend her first CTAC meeting in February and will assume a regular cadence of attendance going forward. Mr. Matthews continued by discussing a new IRAP tool that has been put into production that enables a PI to look at the status of all of their industry contracts. The plan is to make that tool available to a PI's delegate as well. This option was encouraged by Dr. Bertram to truly make it useful to study teams. Mr. Matthews mentioned that the next OSP virtual office hours will be held on Thursday December 7th. This, as well as the schedule for other office hours, may be found on the [CCTS website](#). A new OSP training was announced for industry trial submissions, which may be found in the LMS. Lastly, contract language revision discussions continue with Legal, IRB, Financial Affairs, and others to help streamline industry contract negotiations.

Action:

1. Continue discussions to make meaningful revisions to standard industry contract language to aid in negotiation timelines.

- c. **OnCore Operations (Specht):** Ms. Specht announced that a memo (attached) from President Watts, Senior Vice President Agarwal, and Vice President Brown that requires the use of OnCore Financials for all industry-sponsored clinical trials was recently distributed across campus. The OnCore team is working diligently to aid Departments in getting trained to see this endeavor fully realized. Dr. Kimberly praised the historical efforts of the OCCC, which has been using the module for quite some time. Ms. Specht stated that any questions related to the effort may be emailed to the OnCore team at OnCoreFinancials@uabmc.edu.

Action:

1. Continue implementation of the use of the Financials module across campus.

- d. **Research ChargeMaster (Marchant):** Mr. Marchant reminded the committee of the plans to introduce a 2-tier ChargeMaster in OnCore for clinical trials with the 2nd tier specific to industry-funded trials at a rate of 150% of Medicare. All other trials will continue at the 100% Medicare rate. The go-live date has been set for January 29th. While communication relative to the effort has been socialized over the past few months, the actual go-live date will be announced at next week's Lunch & Learn on December 12th.

Action:

1. Continue efforts to ensure a smooth transition to the new 2-tiered Research ChargeMaster on January 29th.

- e. **Budget Harmonization (Fitz-Gerald):** Ms. Fitz-Gerald stated that a budget development tool continues to be created and tested. An expansion of the group that has been involved in this process for the last several weeks is expanding to allow more people to provide feedback on its usefulness. The tool has been segmented to enable its roll-out in phases, which is slated to begin in January with the administrative portion.

Action:

1. Contact Ms. Fitz-Gerald if you are interested in testing the budget tool at mfitzgerald@uabmc.edu.

- f. **IllumiCare (Marchant/Gordon):** Mr. Marchant reminded the committee of the ongoing pilot from the past several months for the Clinical Trials application developed by IllumiCare which is 1 of 3 apps currently in use with the electronic medical record. The Health System's contract, which has covered the cost of all the applications, expires at the end of December. This means the Trials app will be discontinued unless we come to an understanding surrounding cost for it. Discussions will take place over the next few weeks to ascertain the feasibility of continuing and potentially broadening use of the Trials app for participant recruitment purposes at the point of care.

Action:

1. Conduct discussions with IllumiCare for use of its Trials application into 2024.

3. **Radiology Over-Reads (Bolding):** Dr. Bolding updated the committee (slides attached) on efforts to develop a systematic approach for addressing incidental findings from clinically diagnostic images obtained during research studies. This was a topic originally raised at CTAC last fall. An over-read committee has been created and 3 stages of procedure development have taken place as follows: Acute (Nov '22 to Jan '23), Short-Term (Jan '23 to Dec '23), and Long-Term (Jan '24 and beyond). The committee oversees the process and ensures the added workflow is incorporated seamlessly and that

follow-up communication transpire to patient/participant appropriately. Dr. Bolding shared data from the past year on quantity of reads and how many they anticipate going forward. To ensure the added cost is not inhibitive, it was rolled into the current User Fee already being paid by researchers. Additional items like standard consent language were also addressed with the help of the IRB. Dr. Kimberly thanked Dr. Bolding and the entire team involved for this effort to ensure the safety of our participants.

4. New Business:

- a. Ms. Horn shared news about the upcoming [2024 Marchase Lecture & Award Event](#) to be held on January 9th at Noon in Spain Auditorium. Following it, you may also attend the Core Day Poster Session in West Pavilion Atrium.
- b. Mr. Marchant mentioned that interest and discussions continue to identify a vendor able to provide an ePayment solution for our research participants. He inquired if there were any committee members interested in engaging in vendor evaluations to which Mr. Logan and Dr. Gilbert responded positively. More to come on this topic as we go forward.
- c. Ms. Fitz-Gerald announced that the last CCTS Lunch & Learn for 2023 will be held on Tuesday December 12th at 11:30am via Zoom. Registration is required. Please contact Angela Henson for more information at afhenson@uabmc.edu.
- d. Dr. Kimberly closed the meeting by wishing everyone a wonderful holiday season as we close 2023 and look to the new opportunities that await in 2024.

5. Next meeting: January 3rd



Robert P. Kimberly, MD

Senior Associate Dean for Clinical and Translational Research
Chair, Clinical Trials Administration Committee

CC: **Anupam Agarwal, MD**

SVP for Medicine and Dean-Heersink SOM

Christopher Brown, PhD

VP-Research