

**Clinical Trials Administration Committee (CTAC)**  
**Meeting Minutes**  
**April 6, 2022**  
**12:00 – 1:00 pm**  
**Zoom Conference Call**

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

1. **Review of CTAC minutes from March 2<sup>nd</sup> meeting:** The minutes were reviewed and approved.

2. **Updates**

- a. **OnCore Enterprise** (Specht/Gordon): Ms. Specht announced that Ms. Lisa Williams had concluded her service with the OnCore team and that candidate applications are being actively reviewed with interviews upcoming.

Ms. Specht noted that several of the OnCore Team attended the Onsemble Conference last week in Savannah, GA. She reported that the conference provided valuable experience and information for all of the team in attendance. Of the presentations, the most notable was from the Duke team which presented on their recent process improvement project for OnCore Calendars and Financials. After evaluating their current process, Duke found issues which diminished the efficiency of the process: the OnCore Calendars were too complicated for study teams to manage efficiently and the study teams were not using financials or entering budgets in ways that were useful for them.

To resolve these issues, Duke evaluated the way the calendars were built. The calendars were complicated because they were used to communicate billing information to the clinical billing team in addition to study management. They determined that they could create two versions of the calendar: one complex calendar to hand off to the clinical billing team at the very beginning of the process and then a second version that would be used for study management.

In addition, they determined that the study team was spending excessive time building inefficient budgets in the OnCore system. By evaluating the time it took for the study team to build the budget in OnCore, they determined that if the OnCore team built the budget on the study team's behalf, this would save both groups quite a bit of valuable time.

Ms. Specht noted that while these solutions may not work for UAB, directly, Duke's model is similar to ours in that they use the OnCore Calendar to communicate to the clinical billing team and the study teams build their own budgets. Like UAB, Duke does not have a central budget team. By building the budget in OnCore for the study team, Duke was able to set up the budget in OnCore in a way that is effective and useful for the study teams in managing their financials, without taking over

the role of management of the budget from the team. The Duke team used collaboration, creative thinking, and a deep dive into their processes in order to make things easier and more efficient for all users. This presentation provided valuable insight for moving forward with Oncore Financials at UAB.

Mr. Gordon talked about Advarra's plans to create some much needed enhancements that will enable UAB to improve upon reporting functionality. Mr. Gordon plans to reach out to various areas to get deeper insight on needs once this functionality has expanded.

**Actions:**

1. Internal evaluation to be conducted by OnCore team to identify areas for further improvement.
2. Mr. Gordon to reach out to CTAC members for assistance in expanding reporting functionality once Advarra enhancements complete in Q4 of 2022.

- b. **IRB Metrics & Process** (McClintock): Mr. McClintock stated that they are currently finalizing metrics for Q2 of FY22 which is expected to show that while they are meeting or near meeting most [RAPID](#) targets. They will continue to push improvements, especially relating to Expedited, Full Board, and Commercial IRB reviews. Initial efforts in a pilot for 'real-time' IRB review have revealed potential time reductions. He also reported that discussions continue with the CTAC subcommittee on engaging patients as potential participants based on EMR data. An analysis of the external landscape shows that quite a variance exists in how institutions approach this question. He mentioned that CTAC subcommittee recommended that it engage the CCTS community advisory boards next to get their feedback. Dr. Croker thanked the IRB for their ongoing 'office hours' made available to researchers for targeted Q/A and followed by inquiring about whether the IRB had looked at the correlation between those who reach out to review times of submission due to being more informative. Mr. McClintock stated they had not, but found it to be an excellent idea worth pursuing.

**Actions:**

1. Continue efforts to improve IRB throughput rates and enact process changes to enable such improvement.
2. Report back the results of engaging community advisory boards as part of the effort to re-examine internal positions relative to utilization of EMR data to aid in recruitment efforts.

- c. **myUABresearch** (Cotten): Ms. Cotten reported that the project is currently on hold to enable the team to focus on IRAP-specific issues that have become apparent in recent weeks. Currently, there is no definitive timeline for its re-engagement or what path UAB may take going forward.

**Action:**

1. Keep CTAC apprised of progress once more information is known.

- d. **Data Coordinating Centers** (Kimberly/Nichols): Dr. Kimberly reminded the Committee that DCCs have been deemed appropriate activities for investigators by UAB leadership in circumstances where scholarship is involved and regulatory requirements are met. The charter for a group to work with Department chairs and Deans in assessing proposed DCC-like activities is being developed by Drs. Kimberly and Nichols and will be distributed for review by May's CTAC meeting. Ms. Cotten noted the importance of assessing the capacity of Financial Affairs to meet the expectations of each proposed study and the inclusion of a representative from Financial Affairs on the DCC advisory group as needed, with which Dr. Kimberly agreed.

**Action:**

1. Develop a Charter for the advisory group, including membership and operating procedures.
2. Constitute the group to assure ready availability when needed.

- e. **Device Trials Investigator Agreements (Kimberly):** Dr. Kimberly reminded the Committee of the minimal variance seen in these 1572-like agreements in the device trial space in comparison to actual 1572s for pharmaceutical trials. Because of the nature of what they outline, there is little risk to the University in their language. Currently, John Daniel and Katie Crenshaw are compiling materials about the agreements to distribute to Departments surrounding process and expectations, which will point to the agreements being treated as a regulatory document except in certain, infrequent situations when certain words are present like 'Declaration of Helsinki'. Dr. Kimberly reported that these materials are expected to be ready for review at the May CTAC meeting.

In the context of the Letter of Agreement (LOA) process for device trials, Ms. Cotten inquired whether the hospital was kept apprised of times that Sponsors asked the site to cover the cost of a device that is not FDA-approved. Ms. Specht, who recently served on the process-reengineering committee for LOAs, responded that the hospital is aware and sees all applicable materials including protocol, budget, etc. during the review. A separate discussion will take place to confirm the process is clear to all impacted parties.

**Actions:**

1. Offices of Counsel and Compliance to finalize the process document to enable review at the May CTAC meeting.
2. Follow-up discussion to be held relative to LOA processing to ensure relevant information and requirements are known and met.

- f. **TIN Webinar: EMRs in Recruitment (Horn):** Ms. Horn opened the discussion with a brief overview of the [Trial Innovation Network](#) (TIN) which included the [Recruitment Innovation Center](#) (RIC). The RIC hosted a [webinar](#) by members of the [Regenstrief Institute](#) in Indianapolis earlier this week on the use of EMRs in recruitment which outlined 5 basic strategies. Mr. Gordon reminded CTAC that all strategies were dependent upon a reliable, reproducible and consistent computable phenotype. In some cases, these recruitment strategies are dependent on the institutional nuances in policy and procedure. Dr. Croker commented that if desired, a presentation at May's CTAC would be possible on the '[Informatics Gateway](#)'.

**Actions:**

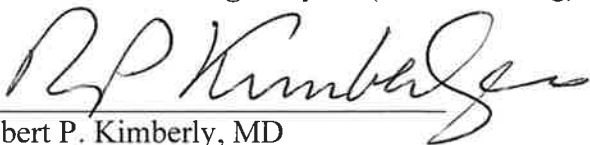
1. View the webinar on the use of EMRs in recruitment.
2. Presentation to be provided at May's meeting on UAB's 'Informatics Gateway'.

**3. Reminders**

- a. Quarterly Lunch & Learn (Fitz-Gerald): It will be held on April 12<sup>th</sup> beginning at 11:30am. Registration information available [here](#).
- b. Clinical Trials Day (Croker): Event to be held in WTI Lobby on May 20<sup>th</sup> from 7:30-9:30am with food, speakers, information, and giveaways.

**4. New Business/Open Floor:** No additional items raised at this time.

**5. Next meeting:** May 4<sup>th</sup> (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-Heersink SOM