

Clinical Trials Administration Committee (CTAC)
Meeting Minutes
July 24, 2024
12:00 – 1:00 pm
Zoom Conference Call

In attendance:	Bertram (OCCC)	Joiner (DOM)
	Boles (HSOM)	Kimberly (HSOM/CCTS)
	Brown (Health System)	Marchant (CTAO)
	Croker (CCTS)	Matthews (OVPR)
	Fitz-Gerald (CCTS)	McClintock (IRB)
	Gordon (HSIS)	Smith (SON)
	Horn (OVPR)	Specht (OnCore)
	Irvin (SOPH)	Wells (DOM)
	Jackson (Health System Compliance)	
Absent:	Gilbert (SOD)	Nichols (SOO/OVPR)
	Goss (SHP)	Pitts (Health System)
	Hedberg (OSP)	Rizk (CTAO)
	Lee (DOM)	Schwebel (OVPR)
	Logan (University Compliance)	Wasko (SOB)
	Miller (OVPR)	
Guests:	Deblasio (OCCC)	
	Moon (CCTS)	

1. **Review of CTAC minutes from June 5th meeting:** The minutes were reviewed and approved. Dr. Kimberly then proceeded to introduce Dr. Mike Wells from the Division of Pulmonary, Allergy, and Critical Care Medicine who leads the Lung Health Center and will be joining the Committee as a trialist representative. Dr. Wells provided a brief summation of his work and thanked the Committee of the opportunity.
2. **Updates:**
 - a. **IRB Metrics & Process (McClintock):** Mr. McClintock opened by reminding the Committee of the number of vacancies that the OIRB has been striving to fill in recent weeks. Two of the five positions have had offers extended and things are progressing for the other three. Mr. McClintock mentioned that turnaround times for reviews remain steady with the exception of Full Board reviews, which are slightly longer than last quarter and mostly explained by the retirement of a senior leader who oversaw much of this work. This will continue to be monitored and is anticipated to rebound quickly when full staffing has been achieved. He then discussed an internal evaluation of lengthy reviews through a ‘root cause analysis’. It showed eight studies that were identified as outliers (3 standard deviations or more longer than the mean review time); most had a larger number of times the office had to return it to the submitter for additional feedback. Two of these were determined to have budget issues with the Sponsor, while the other six are continuing to be evaluated to ascertain potential ways to expedite. Dr. Wells inquired about possibly adding new satellite facilities, such as St Vincent’s, to the IRB submission form

that fall within the UAB landscape. Mr. Matthews said the technology team would be happy to revise the current form as needed by the OIRB.

Actions:

1. Identify new ways to improve efficiencies in both internal operations as well as departmental submissions and enact the changes.
2. Mr. McClintock to work with the Research Technology & Communications team to add satellite facilities to the submission form as needed.

- b. OSP Operations (Hedberg):** In Ms. Hedberg's absence, Dr. Kimberly asked Mr. Matthews to comment on the eRA implementation. Mr. Matthews began by announcing that the contract with Huron was just fully executed so they are actively moving forward with pre-implementation planning which includes activities like change management, communications, and scope of work charters. He noted that the Grants & Contracts module along with Conflicts of Interest will be Phase I, which is anticipated to be completed by late summer 2025. Full implementation is currently expected to take approximately two years. Mr. Matthews additionally mentioned implementation of the [InfoReady](#) product that is scheduled for a soft roll-out this fall. Dr. Croker then mentioned the CCTS's willingness to help with securing feedback on the Huron platform from the CTSA institutional consortium and Partner Network members who also utilize the Huron platform. Mr. Matthews thanked her for the offer and anticipated making use.

Action:

1. Initiate implementation of the Huron eRA platform and keep the Committee apprised of progress over the upcoming months.

- c. OnCore Operations (Specht):** Ms. Specht mentioned that v16 of the Research ChargeMaster, which includes 2 pricing tiers (100% v 150% Medicare rates), is operating as planned so far and now has over 100 studies linked to it within OnCore. She announced that Lauren Bryant will be joining the Budget Workgroup led by Ms. Fitz-Gerald to bring knowledge of OnCore Financials to the discussions. The Financials implementation is ongoing. Ms. Specht then reminded the Committee of current efforts to educate departments on timely visit keeping through in-person discussions led by Dr. Rizk and Mr. Marchant. So far, two meetings were conducted in July with over a dozen more currently calendared in August. Mr. Marchant mentioned the institutional goal of 90% compliance by all Departments across the institution next summer. Dr. Kimberly added that the new ChargeMaster will benefit the Health System given the clinical billables tied to most of these visits. Lastly, Dr. Kimberly referenced recent analysis that showed financial initiatives since 2017 have aided in better budgeting and recouping of costs tied to clinical trial operations.

Actions:

1. Continue implementation of the Financials module across campus and track performance improvement by the Departments.
2. Dr. Rizk and Mr. Marchant to continue meetings across campus to socialize the importance of and need for better management of visits in OnCore.

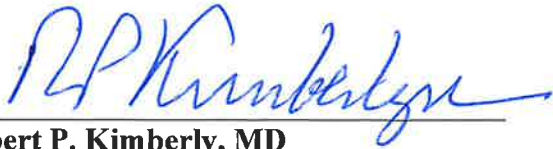
- 3. Pediatrics Regulatory Pilot (Fitz-Gerald):** Ms. Fitz-Gerald referenced the ongoing collaboration between the Clinical Research Support Program (CRSP) and some of the Divisions within the Department of Pediatrics which has shown so far a qualitative improvement in Pediatric operations. A quantitative analysis is underway with the assistance of the OIRB and is hoped to be ready by September's meeting for further discussion.

Action:

1. Ms. Fitz-Gerald in coordination with Mr. McClintock to compile and analyze data relative to the Pilot and report to the Committee in September the effect on turnaround times.

4. **New Business/Open Floor:** None proposed at this time.

5. **Next meeting:** September 4th



Robert P. Kimberly, MD

Senior Associate Dean for Strategic Initiatives
Chair, Clinical Trials Administration Committee

CC: Anupam Agarwal, MD

SVP for Medicine and Dean-Heersink SOM

Christopher Brown, PhD

VP-Research