

Clinical Trials Administration Committee (CTAC)

Meeting Minutes

June 5, 2024

12:00 – 1:00 pm

Zoom Conference Call

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

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

2. Updates:

- a. IRB Metrics & Process (McClintock):** Mr. McClintock began the discussion by noting that performance metrics for the OIRB remain steady. He then noted that recent attention has been spent addressing a variety of HR-related issues. Dr. Kimberly inquired about the ongoing Regulatory Pilot with CRSP and Pediatrics to which Ms. Fitz-Gerald replied that it's continuing at present and that metrics related to it can be provided at the next meeting.

Actions:

1. Ms. Fitz-Gerald to provide an update to the Committee on the CRSP/Pediatrics Regulatory Pilot.
 2. Mr. McClintock to provide a list of specific examples to Dr. Kimberly, Mr. Marchant, and Dr. Rizk to aid in the conduction of a 'root cause' analysis for prolonged review times.
 3. Identify ways to improve efficiencies in both internal operations as well as departmental submissions.
- b. OSP Operations (Hedberg):** Ms. Hedberg was unavailable so the topic was deferred to the next meeting.
- c. OnCore Operations (Specht):** Ms. Specht began by mentioning that the system upgrade was completed in May as planned. She then noted that the Financials module implementation continues with a focus on ensuring that researchers understand the importance of proper financial management of trials. Ms. Specht also stated that the OnCore team had received some terrific feedback on the training conducted so far. She then moved to the importance of timely visit

keeping in the system and recent discussions that had taken place with other institutions to understand the broadness of the challenge UAB faces in this space. While improvement has been made, a plateau has been reached and additional measures are needed to ensure continued improvement. Ms. Specht asked Mr. Marchant to comment. Mr. Marchant reminded the Committee of last month's discussion highlighting the importance of keeping visits within 2 business days to ensure appropriate billing for the participant's benefit, as well as that of the Health System and the study. To aid in the understanding of this effort, Mr. Marchant and Dr. Rizk will be meeting with Departmental research leaders across the institution to highlight data which reflects each area's historical performance and to discuss barriers that require addressing to improve. Dr. Kimberly inquired about the time needed to physically keep visits in OnCore, to which Dr. Rizk replied that while it's minimal, it is but one of a number of activities a Coordinator must do to complete study visits. Dr. Bertram commented about the need for a report from HSIS by OCCC that consolidates the understanding of the various components of a visit so they may know when activities have been completed. This led to a brief discussion about the various ways in which visits are conducted across campus and the number of persons involved.

Actions:

1. Continue implementation of the use of the Financials module across campus.
2. Dr. Rizk and Mr. Marchant to initiate meetings across campus to socialize the importance of and need for better management of visits in OnCore and to gather information from the end users on the hurdles that stand in the way to research staff abiding by the expectation that visits are occurred within 2 business days.

3. Research Scheduling in IDX (Brown): Ms. Brown updated the Committee on the efforts from the past year in regards to consolidating scheduling for both standard of care (SOC) and research patients in ambulatory clinics, which aids in understanding the state of needs for clinic space. A pilot was conducted last year in Rheumatology using a faux provider template. This method proved challenging for investigator providers given the multiple views and highlighted the need for a single view enabling investigator providers to see all patients, both research and SOC, on a single template. The need for it to not negatively impact the ambulatory performance metrics, which are routinely monitored, was discussed including avoidance of adversely affecting downstream billing practices. The new plan to create a single template which enables investigator providers to see all possible patients for a given location on the same day was proposed and approved by an ambulatory advisory committee in early May. Next steps include building these templates and outlining Best Practices for their use. Additional discussions arose relative to OCCC's scheduling model, which highlighted some variance across campus in systems and methods.

Action:

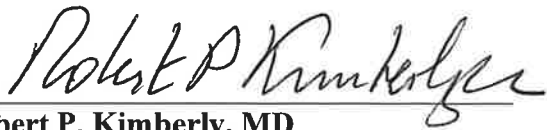
1. Ms. Brown to move forward with the creation of a multi-purpose scheduling template to enable providers who also serve as investigators to see all patient types in a single view and to provide progress updates to CTAC periodically.

4. Reminder-Budget Tool Seminar (Fitz-Gerald): Ms. Fitz-Gerald reminded the Committee of the Research Seminar on June 6th at Noon via Zoom where the new budget tool will be discussed. She encouraged everyone to let others know to ensure a sizeable audience and uptake. She shared the [link](#) in the chat for those who had not yet registered and noted that the documentation would be made available via the [Clinical Trials Kiosk](#) and secured by BlazerID.

5. Summer CTAC Schedule (Kimberly): Dr. Kimberly noted that as the summer season arrives and many families travel, we consider consolidating the July/August meeting as done in years past. The Committee members agreed and Dr. Kimberly advised to watch for a poll from Mr. Trombley for feedback on the best option of July 17th or 24th at the usual time (Noon).

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

7. **Next meeting:** 7/24/24.

A handwritten signature in black ink, reading "Robert P. Kimberly". The signature is written in a cursive, flowing style.

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