

**Clinical Trials Administration Committee (CTAC)**  
**Meeting Minutes**  
**June 7, 2023**  
**12:00 – 1:00 pm**  
**Zoom Conference Call**

In attendance:	Bertram (O’Neal)	Kimberly (HSOM/CCTS)
	Boles (HSOM)	Logan (University Compliance)
	Fitz-Gerald (CCTS)	Marchant (CTAO)
	Gilbert (SOD)	Matthews (OVPR)
	Goss (SHP)	McClintock (IRB)
	Horn (OVPR)	Schwebel (OVPR)
	Irvin (SOPH)	Specht (OnCore)
	Joiner (DOM)	

Unable to attend:	Brown (Health System)	Nichols (SOO/OVPR)
	Croker (CCTS)	Pitts (Health System)
	Gordon (HSIS/CCTS)	Rizk (CCTS/CTAO)
	Jackson (Health System Compliance)	Smith (SON)
	Lee (DOM)	Wasko (SOB)
	Miller (OVPR)	

**1. Review of CTAC minutes from May 3<sup>rd</sup> meeting:** The minutes were reviewed and approved.

**2. Updates:**

**a. OnCore (Specht):** Ms. Specht began her comments by mentioning that the weekly Q/A sessions have been paused for the time due to inactivity. These sessions will be re-started as the Financials initiative moves forward. She updated the committee on the planned version update. The OnCore team has identified several bugs in the new version, most notably in the BioSpecimen Management (BSM) module, and the update has been postponed until the vendor (Advarra) can address them. In the meantime, a security patch update will be implemented.

Mr. Marchant asked whether a goal for the ‘late CTBN’ efforts had been established to which Ms. Specht responded that it had been deprioritized with the focus on implementation of the Financials module expansion across campus. She emphasized that as the Financials module is used more widely, timelines and processes will also improve bringing all the efforts together more effectively.

In the context of OnCore Financials, Dr. Kimberly informed the committee that discussions have begun between University and Health System leaders to revisit the Research ChargeMaster. These efforts include considering a differentiation between federal and industry sponsors in terms of Health System charges.

**Actions:**

1. Work with Advarra to resolve technical issues with the Advarra software that preclude the version update.
2. Continue the initiative to expand on the use of the Financials module across campus.
3. Anticipate future updates on the Research Chagemaster.

**b. IRB Metrics & Process (McClintock):** Mr. McClintock stated that the efforts to socialize a recently developed generic phone script to use in reaching out to potential participants are

underway with a CCTS Seminar held this past Thursday. This was conducted by Christina Blackmon and included Coordinators from the Clinical Research Support Program (CRSP) enacting a couple of scenarios that showed how to and how not to appropriately use the phone script in a dialogue with a patient over the phone. The script is expected to go live in early July. Mr. McClintock continued by saying that the OIRB is down to 3 vacancies with the anticipation that they will be filled by candidates from outside the office, which will mean no additional vacancies will be created. Overall, he has found that turnover across the office has hovered around 6% through the past 3 years, which many find to be within a reasonable range. Lastly, Mr. McClintock said a review of commercial IRB activities continues. The turnaround times for submissions to WCG (from date of submission to OIRB to date of approval by WCG) have declined by 20% quarter-to-date over the past quarter. This effort will continue to be monitored to better understand the trend.

**Actions:**

1. Continue efforts to improve IRB throughput rates and enact process changes to enable such improvement.
2. Complete the phone script dissemination.
3. Finalize the agreement with Advarra to standardize expectations with the other primary commercial IRB (WIRB).

**d. Radiology Over-reads (Bolding):** Deferred.

3. **Budget Workshop Recap (Fitz-Gerald):** Ms. Fitz-Gerald noted that the workshop had just completed its first day. Twenty-three people attended in-person at the Shelby Building along with 55 persons attending remotely via Zoom, including several from across the CCTS Partner Network. Among the topics covered today were study feasibility, team communications, OSP review, budget creation, OnCore Financials, and use of pending accounts. The workshop will continue tomorrow with speakers from Tulane in addition to UAB leading talks on budget negotiation and grant management. A new workgroup will begin evaluating budgets post-trial to discern takeaways which can be applied to future budget development. Dr. Kimberly inquired about access to the workshop material to which Ms. Fitz-Gerald replied that it had been recorded and is being prepared for the [Clinical Trials Kiosk](#) with the individual sessions listed separately for ease of reference.

**Action:**

1. Committee members asked to let their respective areas know that the workshop will be available on the Kiosk for on-demand learning as desired by those interested.
2. A budget review workgroup to be created by Ms. Fitz-Gerald to conduct ongoing reviews of completed trial budgets to garner lessons learned to help inform future budget efforts.

4. **IllumiCare Pilot (Marchant):** Mr. Marchant reminded the committee that the developmental pilot study enabling identification of potential study eligible participants at the Point-of-Care has recommenced after a pause for contractual discussions between the vendor (IllumiCare) and the Health System. Providers will receive notification at the point of care if a patient is potentially eligible for a study based on information in the EMR that aligns with the protocol's inclusion/exclusion criteria. This notification can prompt action at the provider's discretion. The pilot includes the following areas: Family Medicine/Prime Care, Nephrology, Cardiology, Rheumatology, and Gastroenterology. Discussions are underway with Prime Care to determine the breadth coverage given the large number of providers in Prime Care at multiple locations.

**Action:**

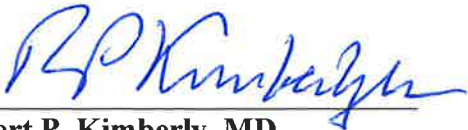
1. Continue the developmental pilot with the specified groups to determine the feasibility, usability and value-add of the app in recruiting patients at the point of care.

**5. Quick Notes:**

- a. OSP National Search (Schwebel):** Dr. Schwebel shared that a priority candidate has been identified following on-campus visits and that Dr. Brown is in advanced negotiations. It is hoped that a finalist is in place by mid-summer.

**6. New Business/Open Floor (Kimberly):** Dr. Kimberly noted that with summer's arrival and the next regularly scheduled meeting slated for the day after Independence Day, it might be best to move the meeting to late July in order to have a combined July/August meeting. With agreement of the Committee, the combined July/August meeting will take place at Noon on the 3<sup>rd</sup> Wednesday in July, July 19<sup>th</sup>, via Zoom. A new calendar appointment will be distributed by Dr. Kimberly's office.

**9. Next meeting:** July 19<sup>th</sup>.



**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