

Clinical Trials Administration Committee (CTAC)
Meeting Minutes
February 1, 2023
12:30 – 1:00 pm
Zoom Conference Call

In attendance:	Bertram (O’Neal)	Kimberly (SOM/CCTS)
	Croker (CCTS)	Marchant (CTAO)
	Fitz-Gerald (CCTS)	Matthews (OVPR)
	Gilbert (SOD)	McClintock (IRB)
	Gordon (HSIS/CCTS)	Miller (OVPR)
	Goss (SHP)	Nichols (SOO, OVPR)
	Horn (OVPR)	Pitts (Health System)
	Jackson (Health System Compliance)	Rizk (CTAO)
	Joiner (DOM)	Schwebel (OVPR)
	Logan (University Compliance)	Smith (SON)
Unable to attend:	Boles (SOM)	Lee (DOM)
	Brown (Health System)	Specht (OnCore)
	Irvin (SOPH)	Wasko (SOB)

1. Review of CTAC minutes from January 11th meeting: The minutes were reviewed and approved.

2. Updates

- a. **OnCore** (Gordon): Mr. Gordon began by stating that there is a new version of the system in ‘test’, which should take 4-6 weeks. He then mentioned that the weekly Q/A sessions continue. Dr. Kimberly posed a question about usage by university personnel for these sessions to which Mr. Gordon replied that Ms. Specht would report at March’s meeting. Mr. Gordon continued that the Onsemble Conference conducted by the vendor Advarra would be held in March and that the team planned to have a presence at it. He also announced that work continues on the late CTBN efforts with more to come on that topic at the March meeting. Mr. Marchant inquired about discussions related to cloud-based hosting of the system, which the vendor now offers. Mr. Gordon replied that consideration is very early but that he will continue investigating, including having discussions at Onsemble with both the vendor and other clients about their experiences.

Actions:

1. Continue weekly OnCore Q/A sessions to provide ongoing training to the clinical research community and have an update on usage metrics at the March meeting.
2. Identify the manageable target percentage of late ‘occurred’ visit entries and strategies for reducing delayed CTBN submissions and report at the March meeting.

- b. **IRB Metrics & Process** (McClintock): Mr. McClintock noted that review time for submissions remains steady. Dr. Kimberly inquired about the actual times in relation to the goals. Mr. Miller placed a [link](#) in the chat to elucidate those timelines. Mr. McClintock reminded the committee of last month’s report of outstanding positions on the staff and updated the group that the Assistant Director position had been approved and should be posted for recruitment soon. The other vacancies are already being actively recruited. He continued by stating that the previously discussed Phone Script is still under review and went before the Human Research Advisory Committee (HRAC) last week with minimal feedback other than to give more consideration to the response in the event that a patient inquires as to where his/her information was obtained. Dr.

Gilbert asked if it would be possible for the IRB to notify PIs when their studies are going before the Board in the event there is a question, so that it may be handled in real time. Mr. McClintock replied that he felt that was a good suggestion and that he would look into it further. In regards to the IRB metrics, Mr. Marchant inquired about discussions with WIRB relative to their data to which Mr. McClintock replied that data entry by IRB staff for WCG approvals artificially inflates the turnaround times. He indicated that this needs to be corrected in order to determine the realistic turnaround times. Additionally, he mentioned ongoing discussions with WCG in regards to interfaces to add efficiency to communications between them and UAB.

Actions:

1. Continue efforts to improve IRB throughput rates and enact process changes to enable such improvement.
2. Committee members encouraged to provide feedback to the IRB for ways to improve the submission forms/process by reaching out to Mr. McClintock and review the training previously conducted that is archived on the [Kiosk](#).
3. Mr. McClintock to investigate the data on RAPID website to ensure it reflects current timelines.
4. Mr. McClintock to determine feasibility of notifying PIs in advance of reviews and having phone numbers on hand for Board to contact in real time with questions to avoid delays.

3. Quick Notes

- a. **OSP National Search** (Schwebel): Dr. Schwebel reported that the search is nearing the completion of the phase for active receipt of applications for the role of Associate Vice President of Research and Executive Director of the Office of Sponsored Programs (OSP). He reminded the committee that February 9th is the deadline. After that, the committee will conduct confidential online interviews with the top applicants and then narrow the list to 3-4 for public onsite interviews with an expected finalist by mid-April and a likely start date in summer.
 - b. **Project eRA** (Matthews): Mr. Matthews reported that since his last report in January, no new developments have occurred. For the moment, work continues with InfoEd, who is the vendor of the current system (IRAP). He added that based on interactions with several other Universities, it is possible that we end up with more than one system as many Universities have adopted a 'best in class' approach for the various modules or even built their own system. At this point, all options are still to be considered.
 - c. **Accrual Project** (Rizk/Kimberly): Dr. Rizk mentioned that the OnCore reports are sent to PIs and unit administrators for the various therapeutic areas on a monthly basis. The reports indicate how respective trials are performing relative to time dependent accrual goals. Dr. Smith indicated that she is not receiving reports. Both Dr. Rizk and Mr. Gordon responded that they would follow-up on this.
4. **Clinical Trials Day** (Kimberly): Dr. Kimberly mentioned efforts have begun to plan this year's activities, which will be the 3rd iteration locally of the international event started in Europe several years ago. The local celebration will be held on Thursday May 18th from 7:00-9:00am in the lobby of the Wallace Tumor Institute (WTI). In addition to brief comments by President Watts, Dean Agarwal, Dr. Kimberly, and Dr. Sleckman, there will be food and informational booths for the attendees to enjoy. The committee was encouraged to schedule time on their respective calendars for the grand occasion.
 5. **March Meeting** (Kimberly): Dr. Kimberly reported that several committee members will be out of town on March 1st and inquired if moving to the next week would be feasible. Several committee members confirmed availability so the decision was made to defer the meeting to Wednesday, March 8th.

6. **New Business/Open Floor (All):** Mr. Marchant reminded the committee of President Watts's goal of achieving \$1B annually in research expenditures within the next 5-7 years. In order to meet this goal, all areas of research, including clinical trials, will need to grow activities. In addition to the focus on participant accruals, Mr. Marchant mentioned that our Schools will need to be thoughtful about faculty recruitment with a focus is placed on clinical trial PIs. Dr. Bertram added that efforts continue and should remain a focus as well relative to staff in this space, to which there was agreement among the committee.
7. **Next meeting:** March 8, 2023



Robert P. Kimberly, MD
Senior Associate Dean for Clinical and Translational Research
Chair, Clinical Trials Administration Committee

CC: Chris Brown, PhD, VP-Research
Anupam Agarwal, MD, SVP for Medicine and Dean-Heersink SOM