

Clinical Trials Administration Committee (CTAC)
Meeting Minutes
March 2, 2022
12:00 – 1:00 pm
Zoom Conference Call

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

1. **Review of CTAC minutes from February 2nd meeting:** The minutes were reviewed and approved.

2. **Updates**

- a. **OnCore Enterprise** (Gordon): Mr. Gordon noted that the upgrades to OnCore and Cerner were completed in February. The work on the Accrual Report data and format is nearing completion and testing of the next iteration is scheduled for release by Thursday March 24th. Implementation will be complete with the April cycle of monthly reports which will be distributed each 4th Thursday. Clean-up is underway to ensure that the study status is up to date for each trial given we are nearing the threshold of our next tier of pricing for the annual license with Advarra. The current number of trials is ~720 which sits just below the threshold of 750. The license will increase roughly \$200k annually once we surpass 750 but remain less than 1000.

Actions:

1. Distribute the next version of the monthly Accrual Reports to participating PIs.
2. Complete study status updates to ensure an accurate count of trials is reflected in our licensing.

- b. **IRB Process** (McClintock): Mr. McClintock began by stating he continues to monitor throughput rates for Convened and Expedited trials which exhibited a slight delay during the current fiscal quarter due to a COVID surge among staff which caused unexpected absences. The CTAC-IRB subgroup continues its meetings and has recently turned its attention to the institutional position on mining EMR data for recruitment purposes. Following a review of practices by other institutions as well as our own internal policies, there appears to be a range of practices across peer institutions.

Actions:

1. Continue improve IRB throughput rates and enact process changes to enable such improvement.
2. Re-examine internal positions relative to utilization of EMR data to aid in recruitment efforts.

- c. **myUABresearch** (Cotten): Ms. Cotten reported that an upgrade was recently completed. As a part of this effort, it was noted that the system was extremely slow to respond and determined to be due to SentinelOne, which has responsibility for malware protection. By turning SentinelOne off, the system has anecdotally been reported to be faster than ever. Recent discussions with the vendor InfoEd have revealed that 2 modules are not expected to be included in the implementation (Animal Management & Post-Award) as originally planned. While work continues to move forward with Conflict of Interest (COI), this has led to some internal talks about the future of the project given the desire to have a single system for all modules.

Action:

1. Continue implementation efforts for a replacement eRA system while keeping CTAC apprised of progress.

- d. **Data Coordinating Centers** (Kimberly/Nichols): Dr. Kimberly apprised the Committee that with the recent submission of the CCTS Progress Report, attention is being turned to the drafting of the Charter which will guide the implementation of DCCs across campus as previously discussed. It is expected to be complete next week and submitted to Drs. Vickers and Brown for review and approval.

Action:

1. Develop a Charter for the advisory group including membership and operating procedures and then constitute the group.

- e. **Device Trials 1572-like Investigator Agreements** (Kimberly): Dr. Kimberly indicated that Office of Counsel is comfortable presenting the process enabling PIs to sign the Agreements to the Provost and VPR.

Action:

1. Office of Counsel to arrange discussion with the Provost. Subsequent to approval, CCTS to disseminate the new information relative to these Agreements to applicable PIs and staff to ensure awareness going forward.

- f. **Feasibility/Recruitment Plan** (Fitz-Gerald): To date, Ms. Fitz-Gerald noted that 8 requests have been received for CRSP assistance with meetings having occurred for 2 of them. In all cases, the studies are ongoing and are struggling to hit their expected accrual goals. A key takeaway thus far noted by Ms. Fitz-Gerald is that the development of a plan for recruitment prior to study launch would be very helpful. Dr. Kimberly added that this is not a challenge unique to UAB and it would be appropriate for study feasibility (including recruitment planning) to be included in the Scientific Review process. Efforts are currently underway to collaborate with the University of North Carolina to compare Scientific Review efforts across the 2 institutions. Additionally, Dr. Kimberly mentioned that we will look to see how monthly Pending Account reports may be used to proactively engage study teams.

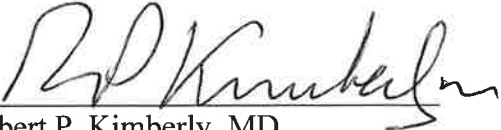
Action:

1. Continue efforts to raise awareness of Recruitment Plan Assistance by CRSP for study teams.

- g. **SOM Road Show** (Rizk/Marchant): Dr. Rizk stated that she and Mr. Marchant are roughly half way through the presentations that began in early January and are scheduled through late April. Mr. Marchant added that of the 23 meetings scheduled, 10 have been held to date. They shared the key topics being covered include Training, Communications, Process Improvements, and System Landscape. Attendance has been good as well as engagement by the faculty. These presentations are held during regularly scheduled faculty meetings to ensure that key stakeholders (PIs and referring clinicians) are present.

Action:

1. Continue Road Show presentations at Departmental and Divisional faculty meetings.
3. **In-State Travel Reimbursement** (Marchant): Mr. Marchant reminded the Committee that the issue of in-state travel reimbursement was brought to the Committee by Dr. Gilbert at the January meeting and the proposal on the table is to align the current reimbursement for in-state travel (per diem) with out-of-state travel (true cost based on receipts). Mr. Marchant noted that the proposal is in the hands of Financial Affairs for Mr. Burnett's review. If he agrees, it will then go to the UA System Board of Trustees for consideration. Several on the Committee agreed that it is an issue not simply for clinical researchers but all involved within University and State of Alabama activities given its impact on business.
Action:
 1. Mr. Marchant to keep Committee apprised of progress as updated by Financial Affairs.
4. **Clinical Trials Day** (all): Dr. Kimberly opened discussion by stressing the impact of UAB's marked growth on clinical trials in national standings (#6 currently among public universities) according to NSF HERD data based on annual expenditures. In order to recognize the importance of clinical trials, Dr. Kimberly inquired as to how best to celebrate National Clinical Trials Day both within UAB and across the community. Several suggestions were raised which included participant testimonials, community spotlight, and expressions of gratitude for staff and PIs. Mr. Marchant shared a [link](#) in the chat which notes, among other things, why May 20th was chosen for such an occasion.
Action:
 1. Planning to begin for ways to celebrate national Clinical Trials Day on May 20th.
 2. Send additional ideas for consideration to Mr. Marchant and Dr. Kimberly.
5. **New Business/Open Floor:** No additional items raised at this time.
6. **Next meeting:** April 6th (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