

Clinical Trials Administration Committee (CTAC)
Meeting Minutes
September 1, 2021
12:00 – 1:00 pm
Zoom Conference Call

In attendance:

Bertram (OCCC)	Joiner (DOM)
Boles (SOM)	Kimberly (SOM/CCTS)
Busby (OCCC)	Marchant (CTAO)
Cotten (OVPR/OSP)	McClintock (OVPR/IRB)
Croker (CCTS)	Miller (OVPR)
Farough (Health System)	Nichols (SOO, OVPR)
Fitz-Gerald (CCTS)	Redden (SOPH)
Gilbert (SOD)	Rizk (CTAO)
Gordon (HSIS/CCTS)	Sandefur (OnCore)
Gutierrez (CCTS)	Schwebel (CAS)
Horn (OVPR)	Wasko (SOB)

Unable to attend:

- Bates (Health System Compliance)
- Dransfield (DOM)
- Logan (University Compliance)
- Motl (SHP)

Guests:

- Bradford (CCTS)
- Westfall (DOM)

1. **Review of CTAC minutes from August 4th meeting:** The minutes were reviewed and approved.

2. **Updates**

- a. **OnCore** (Sandefur): Mr. Sandefur stated that both the Expansion and Financials implementations were complete. Currently, the team is focused on testing as it relates to the annual update of the software which is slated for ‘go-live’ in early October. The new version will impact some functionality relative to the vendor payments portion.

Action:

1. Continue preparations for the annual upgrade of the software.

- b. **Project eRA** (Cotten): Ms. Cotten reported that demonstrations have been scheduled with two external institutions which have implemented the InfoEd product recently, including modules of special interest such as ‘animal resources’. Planning meetings are being scheduled with InfoEd as the team continues forward in implementation. Lastly, Ms. Cotten reported that the Project Manager (Michael Hill) overseeing the implementation has departed, so that a search is underway for his replacement.

Action:

1. Monthly updates to CTAC on progress toward full implementation of all modules.

- c. **IRB Update** (McClintock): Mr. McClintock began by mentioning that staffing continues to be an issue for the IRB. As the IRB moves forward in filling these vacancies, improvement in time to activation (TTA) is expected. Of the five current vacancies, which include an Assistant Director position, four are nearing finalization of being filled, which will put the office in much better position by October. As carry-over from last month, Mr. McClintock noted that engagement with Advarra is progressing in order to address the backlog of submissions with the office. The formal

launch started with a meeting on August 16th; after reviewing internal policies and procedures with the consultants, the team of three is actively reviewing submissions.

Action:

1. Advarra to address backlog of submissions which will enable the IRB to meet institutional expectations as it pertains to TTA.

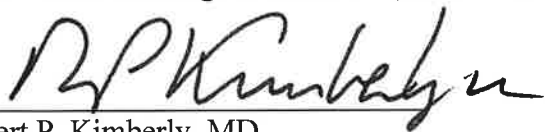
- d. **Trial Accrual Strategies** (Kimberly): Dr. Kimberly called upon Ms. Horn to report on the OVPR's engagement with the University's Digital Media office in a pilot project. Ms. Horn reported that Digital Media is currently working on two clinical trials by creating digital advertising to aid in recruitment efforts. This work will be compared to that conducted by external agencies, that are approved by the University. Points of comparison include pricing, timing, and effectiveness. It was noted that these services can be costly so investigators must be cognizant to include appropriate amounts in their budgets. Dr. Rizk mentioned her recent experience with industry sponsors' efforts to create their own digital campaigns which must be vetted by the IRB. Mr.'s Miller and McClintock referenced ongoing efforts by the UAB IRB to create guidance and policy around the topic to aid investigators. These efforts have recently been delayed due to staffing changes but are expected to move forward in the coming weeks with guidance anticipated this fall. Given the complexity of policy creation, that will not likely be seen until 2022.

Actions:

1. Digital Media pilot to continue to better understand internal capacities to aid recruitment efforts across campus.
 2. IRB to formalize guidance and policy around digital media use.
3. **CTAC Update: President's Risk Cabinet** (Kimberly): Dr. Kimberly discussed the slides (attached) he presented earlier in the week to the President's Risk Cabinet, which is given to them annually. He began by outlining the goals of the University's Clinical Trials Initiative. This was followed by the various broad components that includes items such as Trial Opportunities, Participant Recruitment, Workforce Development, and Tools & Processes. Additionally, the role and make-up of CTAC was discussed since its official chartering by the Cabinet in 2018. Next, Dr. Kimberly covered a couple of areas of possible risk for the institution including ClinicalTrials.gov reporting and timely visit-keeping in OnCore for billing purposes. Relative to OnCore visit-keeping, Dr. Kimberly reminded the Committee that the expectation is for all visits to be recorded within two business days. Lastly, Dr. Kimberly showed the tremendous growth UAB has experienced over the past eight years as expenditures have continued to rise, even throughout the pandemic period.

Action:

1. Continue monitoring and messaging to the research community the importance of timely reporting of investigator-initiated trials to ClinicalTrials.gov and recording visits in OnCore.
4. **New Business/Open Floor:** No new items proposed by Committee.
 5. **Next meeting:** October 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-SOM