

Clinical Trials Administration Committee (CTAC)
Meeting Minutes
January 5, 2022
12:00 – 1:00 pm
Zoom Conference Call

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

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

2. **Updates**

- a. **OnCore** (Gordon): Mr. Gordon reminded the Committee of Mr. Sandefur's retirement last month and announced that his replacement is Ms. Ashley Specht who will begin on February 1st. He also mentioned that the OnCore upgrade, planned for mid December, had been delayed to enable certain security patches and other work with Cerner. The OnCore upgrade should be ready in a few weeks.

Actions:

1. Finalize the annual upgrade of the software.
2. Continue with accrual and visit management initiatives.

- b. **IRB-Advarra Engagement** (McClintock): Mr. McClintock updated the Committee on the recent completion of consultation services provided by Advarra to aid in decreasing the backlog of Expedited and Exempt studies in the queue for review. The throughput time had previously been in the 50-60 day range for those study types, and the office is now seeing a 30-35 day range for review. Additional process improvements have been implemented since last Spring, and the CTAC group commended the IRB on its progress.

Dr. Croker inquired about ongoing efforts surrounding eConsent policy/process to which Mr. Miller responded that the formalization of those processes with Adobe-Sign are underway to better enable the University's use of new tools, especially in the era of COVID and remote activities. Further discussion of REDCap focused on whether additional efforts are needed to educate the University population on its availability and functionality in various areas, including eConsenting. Mr. Gordon mentioned that HSIS is currently implementing a version with appropriate security for patient data inclusion. This led to the recognition that further discussion may be needed to align the primary players in this space to ensure adequate understanding by all involved in its use.

Actions:

1. Maintain workflow process improvements and accelerated throughput rates relative to TTA to ensure efficient operations.

2. Gather stakeholders to discuss ways to improve engagement and functionality of REDCap across UAB including Mr. Miller, Mr. McClintock, Dr. Croker, Dr. Nichols, Mr. Marchant, Dr. Kimberly, Mr. Gordon, DOM IT and Campus IT.

- c. **myUABresearch** (Cotten): Ms. Cotten opened by stating that the business process reengineering with the consultant was completed. A determination was made to go with a phased approach with an existing database which enables the users to continue using a single system through the implementation. Implementation has begun on the Conflict of Interest module. The system upgrade to 9.0.1.0.1 has started as well. Ms. Cotten also reminded the Committee that they can follow along with the progress in real time on the [website](#). Additionally, she made a couple of comments about OSP operations. Firstly, Ms. Cotten mentioned that the new NIH Biosketches and Other Support documents go into effect on [January 25th](#). In closing, Ms. Cotten commented that with the upcoming absences of a couple of members of the industry contracts team, they have decided to outsource some of the reviews to MedaSource to ensure adequate throughput during the hiatus. Contract discussions and finalization of a Scope of Work (SOW) is underway.

Action:

1. Monthly reports to continue until completion of implementation across all modules.

3. **Data Coordinating Centers and Study Management** activities (Kimberly/Nichols): Dr. Kimberly pointed to opportunities that periodically arise for UAB research teams to serve as a data coordinating center for various clinical trials. The University expectation, based on discussions with Office of Counsel, is that some level of scholarly activity should be incorporated into the work by the UAB faculty and staff and are encouraged. Initiatives and programs that lack research, scholarship and the advancement of knowledge and that are exclusively business activities do not conform with those University expectations.

Dr. Kimberly noted that Departments are likely best equipped to assess the opportunities for scholarship and the capacity of study teams to fulfill their obligations in the research, operations and regulatory space (when needed). He posed a question to the Committee on how to provide support to those Departments wishing assistance in evaluating such work and whether CTAC in its institutional-wide organizational structure, likely through a working group, would be best suited for such support. Given the breadth of the components, it was determined that a broad swath of expertise be engaged in the reviews such as data security, regulatory, financial, etc. Recognizing that the volume of such engagements is relatively small and infrequent, it was mentioned that the best approach would be an ‘ad hoc’ gathering of the reviewers that should occur in a swift manner to ensure timely responses to the applicants so as to not become a deterrent, much less a barrier, to the process.

Action:

1. Propose an *ad hoc* review group strategy for DCC activities to Drs Brown and Vickers.

4. **Accrual Workgroup/Recruitment Plan Assistance** (Fitz-Gerald): Last month’s CCTS Lunch & Learn included a discussion by Ms. Fitz-Gerald about a new service by CRSP to study teams to provide assistance with the development of recruitment plans. Ms. Fitz-Gerald stated that 3 requests have been received to date. The plan is to have consults with 3 members of CRSP (including regulatory, budget, and coordinator support) in its development of recruitment plans and that the assistance is provided at no cost to study teams. Specific recruitment efforts may be provided at a cost if the study team desires to engage CRSP for this work. This effort is available for not only new protocols but also for existing ones if recruitment is not going as expected. Study teams will need to be aware for existing protocols, though, that any changes to the IRB-approved recruitment plans or materials will require an amendment to be approved by the IRB prior to those changes being implemented. New information is being placed on the *Clinical Trials Kiosk* along with a new email address for requests. In the meantime, requests may be sent to CRSPtraining@uabmc.edu.

Action:

1. Disseminate messaging relative to recruitment specialist availability to colleagues in your area.

5. **Device Trials Investigator Agreements** (Kimberly): Dr. Kimberly talked about recent issues in the conduction of device trials whereby lengthy time has been taken in the start-up process reviewing Investigator Agreements submitted by Sponsors. These Agreements are the device trial version of pharmaceutical trials' FDA Form 1572. In a recent internal review of several of these Agreements, it was determined that they are extremely similar in nature despite not being standardized by the FDA. Work is ongoing with Office of Council to come to an institutional understanding of the level of scrutiny needed in reviewing these and the speed with which that scrutiny should be applied.

Action:

1. Dr. Kimberly to meet with John Daniel and Helena Christine on finalizing a plan for reviewing device trial Investigator Agreements going forward to improve efficiency in the process.

6. **New Business/Open Floor:** Dr. Gilbert inquired about the status of a prior discussion regarding UAB's in-state travel reimbursement policy. As a reminder, the in-state policy differs from the out-of-state policy by providing only a daily per diem to travelers as opposed to covering the actual costs of travel. Given the ongoing increase in lodging costs, the policy often prevents travelers from recouping the full cost of their travel. Ms. Horn mentioned a follow-up discussion with Financial Affairs which led to the recommendation to negotiate lodging costs in advance of the stay. Dr. Gilbert replied that more was needed to change the actual policy which is governed at the State level. Dr. Kimberly responded that additional discussions would be had with Drs. Vickers and Brown to discuss the potential negative economic impact on in-state clinical research.

Action:

1. Further discussions with Drs. Brown and Vickers. An update will be provided at the March meeting of CTAC.

7. **Next meeting:** February 2nd (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