Clinical Trials Administration Committee (CTAC)
Meeting Minutes
January 9, 2019
12:00 – 1:00 pm
FOT 12 Large Conference Room

In attendance:	Bertram (CCC)	Kimberly (SOM/CCTS)
	Bragg (UAB Compliance)	Marchant (CTAO)
	Cotten (OVPR/OSP)	Mack (SOM)
	Croker (CCTS)	Miller (OVPR/IRB)
	Farough (Health System)	Nichols (SOO, OVPR)
	Fitz-Gerald (CCTS/CRSP)	Redden (SOPH)
	Gilbert (SOD)	Saleh (SOM/CTAO)
	Gerrity (OVPR)	Sandefur (OnCore)
	Gordon (HSIS)	Schwebel (CAS)
	Horn (OVPR/OIE)	Wasko (SOB)
	Joiner (DOM)	
Unable to attend:	Bates (Health System Compliance)	Motl (SHP)
	Dransfield (SOM)	Mugavero (SOM)
	Ladores (SON)	Nabors (SOM/CCTS)

1. **Review of CTAC minutes from December 5th meeting:** Approved as read with 1 exception raised by Dr. Gerrity that was tabled to later in the agenda.

2. **Updates**
   a. **OnCore** (Sandefur): The Financials subproject is moving forward with an expected completion of implementation by June. OnCore version 15.4 upgrade is planned for April. Expansion of OnCore to trials without clinical billables will follow the financials project in Q3 2019. The OnCore team demonstrated the system for Mr. Farough and a representative of the billing office in December; he found the system very insightful and impressive. A demonstration was conducted earlier this week for members of the Hospital Compliance staff and one is planned for the OSP team.
      Actions: (1) Investigation into how the recent national requirement by CMS to publish hospital rates may impact the information provided to Departments through the OnCore ChargeMaster for budget negotiations.

   b. **PowerTrials Research Study Summaries** (Kimberly): In follow-up discussion with Dr. Janyce Sanford (Chair of Emergency Dept.), she does not currently have quantifiable data in terms of 'click rate' on summaries; she has indicated that summaries are important for patient safety even if viewed by only 1 health care provider during the care of a patient.

Actions: (1) Dr. Kimberly will continue to engage the Emergency Department for feedback on its use.

c. **Operating Accounts** (Mack): No additional feedback was received from CTAC last month. A discussion with Stephanie Mullins to finalize the implementation process for issuing and managing Operating Accounts is scheduled for January 11th.

d. **Time to Activation/SRA Impact** (Nichols): The TTA data analysis was reviewed at last month's meeting. Dr. Nichols referenced a smaller group that would be meeting to discuss actions to be taken based on those data. Mrs. Cotten mentioned that they are reviewing studies within the Office of Sponsored Programs (OSP) that have been in queue for 60+ days to determine the best way forward.

Mr. Miller reported that the new IRB Director, Adam McClintock, would be starting on January 28th. He also noted that the implementation date for of the Revised Common Rule is January 21st. Additionally, there will be a Quality Improvement Plan implemented within the OIRB as well as a more granular look at ways to capture better metrics for reporting purposes within the office.

Actions: (1) Define and capture better performance metrics within the Office of the Institutional Review Board (OIRB).
(2) Implement a Quality Improvement Plan within the OIRB.
(3) Determine how to expedite studies within OSP that have been in queue 60+ days.

e. **Clinical Research Career Ladder** (Marchant): Draft Career Ladder is with Compensation for analysis of positions across the various tracks to set salary bands. Analysis is to be completed in late January. Testing has been completed of the Employee and Manager Assessments and edits made through REDCap. Assessments will be retested later this week. Both the Communication Strategy and Mapping Process are being refined. Once these items are complete, pilot testing will begin in CCC which is anticipated as early as February.

Actions: (1) Complete Mapping Process document and begin communications across campus prior to piloting within CCC.

3. **Subcommittee Reports**

a. **Standard Budget Fees** (Kimberly): The FY19 Study Management Fee has been adjusted following discussions with Central Administration and Department Chairs. Dr. Gerrity emphasized the importance of having affected units informed about the Study Management Fee, and Dr. Kimberly and Mr Marchant reviewed the discussions with Chairs and study teams during the summer and fall of 2018. Dr. Joiner and Dr. Bertram suggested that the continuing communication plan include clarification of the 2016 memo which discussed the increase in IDC from 26% to 30%. Dr. Schwebel suggested clarification of the definition of a 'clinical billable'.

Dr. Kimberly noted that all applicable documents impacted by the change would be modified as needed to ensure consistency in messaging. He also noted that the financial workgroup for FY20 has begun its work and will report its findings to CTAC.

Actions: (1) Finalization of memos reflecting an institutional requirement for all industry-initiated and sponsored clinical trials to include a Study Management Fee.
(2) Development and implementation of the continuing communication plan (see #4 below).

b. **F&A for Investigator-Initiated Trials (IIT)** (Bertram): An analysis was conducted by Dr. Bertram and Mrs. Cotten with assistance from others to determine the difference in IDC charged in 2018 for IITs with a 30% rate on a base of Total Direct Costs (TDC) as opposed to a potential 36% rate applied only to Modified TDCs (MTDC). The modeling showed that across 51 trials across 22 Departments/Divisions would have been impacted and that the overall IDC charge would decrease by ~$130K..

Actions: (1) CTAC supported the change to a 36% IDC rate on MTDCs for investigator-initiated trials if that is the final recommendation of the F&A Committee..
(2) Dr. Bertram and his workgroup will look further at the budgeting and categorization of trial expenses for optimal and appropriate determination of MTDC.

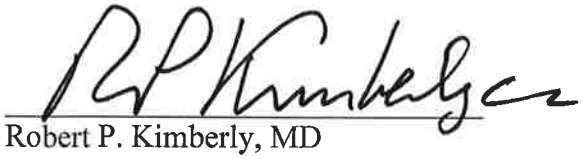
c. **ClinicalTrials.Gov Registration** (Miller): The subcommittee met on December 7th to consider the University's position on which trials to register in ClinicalTrials.gov as a matter of University policy. The recommendation is to include those trials as required by the FDA, NIH, HHS, and ICMJE and to the extent required for posting of consent forms under the revised Common Rule.

Actions: (1) CTAC endorsed the subcommittee's recommendation. Education materials and a training plan with a decision tree that outlines which trials on campus should be registered by investigators will be developed by the subcommittee.

4. **Communications Strategies** (Kimberly): A number of methods are needed to communicate CTAC initiatives across campus in order to reach all constituents. Those may include, but are not limited to, emails, electronic newsletters, town halls, and existing regular meetings across Schools, Departments, Divisions, Centers, etc. Mr. Farough suggested that Executive Administrator meetings would be a strategic starting place since faculty and/or staff often go to Executive Administrators as a source of information. The importance of effectively communicating across all constituencies was stressed in order to enable successful initiatives.

5. **New Business:**
   a. None at this time

6. **Next meeting:**
   a. February 6th at Noon in FOT 12



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