

Clinical Trials Administration Committee (CTAC)

Meeting Minutes

November 7, 2018

12:00 – 1:00 pm

FOT 12 Large Conference Room

In attendance:

Bertram (CCC)	Kimberly (SOM/CCTS)
Brown (OVPR)	Ladores (SON)
Cotten (OVPR/OSP)	Marchant (CTAO)
Croker (CCTS)	Mack (SOM)
Farough (Health System)	Miller (OVPR/IRB)
Fitz-Gerald (CCTS)	Nabors (SOM/CCTS)
Gerrity (OVPR)	Redden (SOPH)
Joiner (DOM)	Saleh (SOM)
	Sandefur (OnCore)

Unable to attend:

Bates (Health System Compliance)	Motl (SHP)
Bragg (University Compliance)	Mugavero (SOM)
Dransfield (SOM)	Nichols (SOO, OVPR)
Gilbert (SOD)	Schwebel (CAS)
Gordon (HSIS)	Wasko (SOB)
Horn (OVPR)	

1. **Review of CTAC minutes from October 3rd meeting:**

- a. Approved as read without further modification.

2. **Updates / Reports**

- a. **OnCore** (Sandefur): Reminder that Wave 3 implementation was completed in September. The Financials subproject is on track with an expected completion in Q1 2019. Expansion of OnCore to trials without clinical billables is anticipated to follow the financials project; scope is currently being discussed..

Actions: (1) CTAC members desiring a demonstration of OnCore should contact John Sandefur for scheduling.

- b. **Pending Accounts** (Marchant): Trend analysis for 2018 reflects increased utilization by Departments. Overall utilization currently sits at 74% for all accounts (83% when accounts recently created in October and reside in the ~45 day grace period are removed). The immediate goal is have an 85% overall utilization rate as reflected in the October minutes. Faculty and Staff effort allocation continue to lag behind but are increasing as well. The 3 largest holders of Pending Accounts are Department of Medicine, Comprehensive Cancer Center, and Department of Dermatology with 36, 22, and 19 accounts respectively. Their efforts are greatly appreciated.

- Actions:** (1) Continued team-based communication about Pending Accounts.
(2) CTAC members encouraged to continue communicating to their respective Departments and Schools about the importance of utilization for all expenses, including salary.

- c. **Research Study Summary** (Marchant): Trend data for Research Study Summaries of clinical trials, posted in the electronic medical record and accessible through the banner bar for patient safety purposes, show a marked increase allowing us to meet our goal of 90%. Current data register 91% in November. Communication is ongoing with Departments which have a discrepancy between Summaries needed and Summaries on-hand according to the PowerTrials administrator. Dr. Saleh suggested review of Research Study Summaries with the Emergency Department to ensure ongoing awareness and use by ED physicians.

- Actions:** (1) Meet with Chair of Emergency Department (Sanford) to reinforce provider awareness of Research Summaries in the EHR to ensure appropriate and effective utilization.

- d. **Clinical Billing Review** (Marchant): Trend data show the weekly backlog of trials in CBR's queue since April continues to decline. Median wait time is currently 4 business days with a mean of 7 days and a range of 1-69. Annual educational meetings with study teams to ensure best practices were completed in October.

- Actions:** (1) Quality Control procedures whereby a sample of studies that Qualified for Modified review are given a Full review began in November.

- e. **TTA-OSP/IRB: SRA Report** (Cotten/Miller/Gerrity/Brown): The Report has been circulated across campus.

- **OSP:** Melinda Cotten reported that a major contributor to current workloads is the number of sub-awards being processed by OSP. She noted that the recommendations outlined will not affect the TTA relative to clinical trial agreements in OSP.

- Actions:** (1) OSP plans to create a Research Administration Network to improve communication across administrative units;
(2) The opportunity to stratify OSP volume by complexity as a measure to improve workflow may be considered.

- **IRB:** Jonathan Miller reported that the OVPR is fulfilling some of the recommendations in the report including creating an Advisory Council for the OIRB and filling vacancies in the office. Provost Benoit has requested that national AAHRPP data be gathered to benchmark performance against national best practices.

- Actions:** (1) Interviews for a new Director are underway with the goal of a decision within the next month;

- (2) Evaluate “what’s going right” and which research groups are doing well with IRB submissions to assist in identifying internal best practices;
- (3) Undertake a process improvement initiative with the new Director.

- Further discussion SRA will be an agenda item for the December CTAC.

3. ClinicalTrials.Gov Registration (Gerrity/Miller)

Jonathan Miller reported that there are currently 3 definitions by which one could determine the need for registration (FDA, NIH, ICMJE). The NIH may expand registration / reporting expectations to include prospective basic science studies involving human subjects (RFI deadline 11/12/18; NOT-OD-18-217). The question before CTAC is to determine the criteria by which UAB studies are expected to register in ClinicalTrials.Gov. Lauretta Gerrity expressed concern about study team time needed to complete registration.

Actions: (1) A subcommittee (Raheel Farough, David Redden, Mark Marchant, Jonathan Miller), led by Jonathan, will explore alternatives to using NIH guidelines.

- (2) Lauretta Gerrity will circulate COGR response to RFI on prospective basic science studies.

4. Proposed Changes in F&A (Cotten)

Discussions are well advanced to revise the policy whereby all Investigator Initiated Trials (IITs), regardless of sponsor, are charged IDC at the Other Sponsored Activity (OSA) rate of 36%.

Action: (1) Mike Bertram will convene a subgroup to examine the impact on IIT feasibility. Bertram noted that there may be considerable clinical care costs associated with the trial’s activities for which IDC would not be attributed.

5. Operating Accounts (Mack)

LaKisha Mack reviewed the proposed revised procedures for implementation of Clinical Trials Operating Accounts. The Operating Accounts will provide a mechanism for assigning aggregated effort for faculty across multiple industry-sponsored trials. The Operating Accounts will also provide a mechanism to better understand the full costs of clinical trials, including faculty and staff effort.

Action: (1) CTAC to review the revised procedures document (distributed with the meeting agenda) and convey comments to LaKisha Mack.

6. Clinical Research Career Ladder (Marchant).

The implementation team continues to meet monthly and is finalizing the draft version of the career ladder following feedback from several

stakeholders across campus. Compensation will conduct their analysis in the next stage to complete the ladder. The evaluation tool within the REDCap tool provided by Duke is currently being tested within CRSP and modified to make it more specific to UAB's needs. CCC will serve as the pilot site for the project.

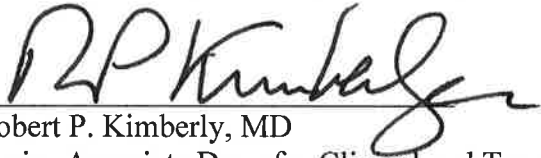
- Actions:** (1) Have Compensation conduct their analysis of the various pay grades
(3) Finalize the evaluation tool by which employees will be mapped to the appropriate positions on the career ladder

7. New Business:

- a. None at this time

8. Next meeting:

- a. December 5th 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