Clinical Trials Administration Committee (CTAC)
Meeting Minutes
December 5, 2018
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)	Nabors (SOM/CCTS)
	Fitz-Gerald (CCTS)	Nichols (SOO, OVPR)
	Gerrity (OVPR)	Redden (SOPH)
	Gordon (HSIS)	Saleh (SOM)
	Horn (OVPR)	Sandefur (OnCore)
	Joiner (DOM)	Wasko (SOB)
Unable to attend:	Bates (Health System Compliance)	Ladores (SON)
	Dransfield (SOM)	Motl (SHP)
	Gilbert (SOD)	Mugavero (SOM)
		Schwebel (CAS)

1. **Review of CTAC minutes from November 7th meeting:**
   a. Approved as read without further modification.

2. **Updates / Reports**
   a. **OnCore** (Sandefur): The Financials subproject is on track with an expected completion in Q1 2019. Consolidated Research ChargeMaster discussions anticipate completion in early 2019, and training has begun. Expansion of OnCore to trials without clinical billables will follow the financials project in Q2/3 2019. OnCore version 15.4 upgrade is imminent
      Actions: (1) CTAC members desiring a demonstration of OnCore should contact John Sandefur. A demonstration is scheduled **12/13 9:00 am.**

   b. **PowerTrials Research Study Summaries** (Kimberly): In follow-up discussion with Dr. Janyce Sanford (Chair of Emergency Dept.), she is supportive of the initiative and is continuing to message to her Department personnel of the importance to use its functionality when caring for patients. Dr. Saleh inquired about the feasibility of system-provided data that reflect the usage of Research Study summaries (eg, click rates).

Actions: (1) Dr. Sanford will explore both narrative- and data-driven utilization of Research Summaries by her Department.

c. **Operating Accounts** (Mack): No additional feedback was received from CTAC following last month's meeting on the documentation provided during the meeting. A final request was made to have any additional comments provided to LaKisha Mack by close of business Wednesday December 5th.

Actions: (1) Clinical Trial Operating Account Procedure document to be finalized for implementation.

d. **Time to Activation/SRA Impact** (Nichols): The TTA data analysis conducted on June-September data for 3 time periods (2014, 2016, 2018) shows that review time has increased significantly for all three offices (CBR, IRB, OSP). Data does not take into account workflow process changes made in 2Q of 2018 given that studies included were routinely submitted prior to such intra-office changes. Data show how Lags and Holds often impact Time to Activation (TTA). OnCore calendar builds did not add to TTA. Dr. Nabors and Mr. Farough suggested that we consider not only process changes within administrative offices but also coordinated organizational changes across offices and within School-based teams.

Actions: (1) Explore the potential benefits of a Single Point of Entry mechanism so that all materials are submitted simultaneously.
(2) Consider sub-specialization for administrative office personnel to better understand the nuances of different types of trials.
(3) Consider stratification of procedures based on study complexity, similar to clinical case adjustments.
(4) Discussion of next steps with Drs. Brown, Vickers and Watts.

e. **Clinical Research Career Ladder** (Marchant): Draft Career Ladder has been forwarded to Compensation for analysis of positions across the various tracks. They anticipate analysis being complete in late January due to delays with upcoming holidays. Testing has been completed in CRSP and feedback gathered for the Employee and Manager Assessments enabled through a REDCap-based tool. Edits have been made manually on the Assessments and are being completed within REDCap. Preliminary communications have been conducted earlier in the fall across all affected Schools. CTAC members expressed desire to have further discussions to get a more granular understanding of the Ladder to ensure it meets goals of the project.

Actions: (1) More detailed follow-up discussion at a future CTAC meeting.

f. **Standard Budget Fees** (Kimberly): The FY19 standard start-up fee has been adjusted following discussions with Central Administration. Following meetings with Department Chairs within SOM, the initiative will move

forward with communication across all Departments and PIs. The anticipated timeline is early 2019.

Actions: (1) Dr. Kimberly to meet with select Department Chairs in coming days before proceeding with University-wide launch.

3. **Subcommittee Reports**
   a. **ClinicalTrials.Gov Registration** (Gerrity/Miller)

   Lauretta Gerrity reported on behalf of Jonathan Miller that the first meeting is scheduled for Friday 12/07. Additionally, she mentioned that Adam McClintock, the new Director of the IRB, will start on January 28th.

   Actions: (1) A subcommittee (Raheel Farough, David Redden, Mark Marchant, Jonathan Miller) will consider modifications to NIH guidelines for study trial registration.

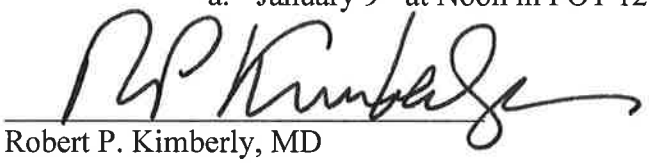
   b. **Proposed Changes in F&A** (Bertram)

   Based on preliminary analysis of data provided by Melinda Cotten, Michael Bertram reported little impact overall across the institution by an increase in F&A from 30% to 36% due to it being applied to MTDC only rather than to total direct costs (TDC). There may be variance in impact across different orgs within the institution.

   Action: (1) Michael Bertram's subcommittee will analyze the data further to formulate a recommendation of 30% (TDC) vs. 36% (MTDC) and a strategy to move it forward for implementation.

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

5. **Next meeting:**
   a. January 9th at Noon in FOT 12 (note change of date)



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CC: Chris Brown, PhD, VP Research
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