

Clinical Trials Administration Committee (CTAC)  
Meeting Minutes  
August 01, 2018  
12:00 – 1:00 pm  
FOT 12 Large Conference Room

In attendance:

Roberson for Bragg (UAB Compliance)	Ladores (SON)
Bertram (CCC)	Nichols (SOO, OVPR)
Croker (CCTS)	Marchant (CTAO)
Miller for Gerrity (OVPR)	Motl (SHP)
Farough (Health System)	Saleh (SOM/CTAO)
Fitz-Gerald (CCTS)	Redden (SOPH)
Gordon (CCTS/HSIS)	Sandefur (OnCore)
Joiner (SOM)	Wasko (SOB)
Kimberly (SOM/CCTS)	

Unable to attend:

Bates (Health System Compliance)	Mugavero (SOM)
Dransfield (SOM)	Nabors (SOM)
Gilbert (SOD)	Schwebel (CAS)
Mack (SOM)	

1. Review of CTAC minutes from July 11<sup>th</sup> meeting:
  - a. Role of minutes reviewed
  - b. Approved as read without further modification
  
2. Updates / Reports
  - a. **OnCore** (Sandefur): Wave 3 implementation and the Financial subproject discussed; automation (not elimination) of CTBNs clarified (notes attached)  
**Actions:** (1) Continued implementation of Wave 3 and Financials  
(2) Continued exploration of the nuances between Enterprise and CCC OnCore processes and how they can be harmonized.
  - b. **Pending Accounts** (Marchant): Communication with Departments and study teams continues. Written reinforcement of the use of pending accounts has been circulated by Medicine (email attached). The target date for full utilization is October 1<sup>st</sup>.  
**Actions:** (1) Continued team-based communication about pending accounts;  
(2) Expanded departmentally based written communication;  
(3) Use of “at risk” nomenclature if that better serves specific departmental culture.
  - c. **Clinical Billing Review** (CBR, Marchant): The goal of an 80% reduction in the backlog of studies by August 1<sup>st</sup> relative to the April 1<sup>st</sup> state of submissions has been achieved with a measured reduction of 86% on July 27<sup>th</sup>.  
**Action:** (1) Reduce mean wait time to 8 days;  
(2) Preparations have begun for the educational component of the reengineered process developed this past spring. It is slated to begin after Labor Day.

d. **Time to Activation** (TTA, Nichols and Miller+).

- a. The draft report from the Society of Research Administrators reviewing processes for both the Institutional Review Board (IRB) and Office of Sponsored Programs (OSP) has been received and additional points of information are being clarified.

**Action:** (1) Summaries of SRA reports expected by Labor Day.  
(2) The workflow for the creation and submission of the Research Study Summary will be harmonized with the expected updates in IRB workflow following the SRA report out.

3. **CTAC sub-committees**

- a. **Device Trials** (Kimberly). The CTAC subcommittee for device trials has met and the various steps and approvals necessary for device trials (as well as disconnects) identified.

**Action:** (1) The CTAC subcommittee agreed that device trials should be incorporated into the TTA process;  
(2) The PTAT (Procedures and Technology Assessment Team) group will meet to discuss how the Hospital LOA process can be expedited;  
(3) A subgroup will meet with investigators involved in Edwards Life Science to understand and expedite the Master Contract process.

- b. **Greenphire** (Marchant). The question pertaining to patient safety for participants in multiple studies, initially identified in Greenphire, was reviewed by the ad hoc CTAC subcommittee (Kimberly, Marchant, Sandefur, Bertram, Thomas, Miller). The capacity to see multiple studies in OnCore Enterprise and the "On Study" flag through PowerTrials within IMPACT was deemed sufficient to alert study teams to the potential of multiple studies.

**Action:** (1) Study teams will be reminded as part of continuing education to ask potential participants about other studies and to check in OnCore and the EMR.  
(2) The Greenphire process of removing potentially sensitive information from study titles was affirmed and will continue.

4. **Clinical Research Career Ladder** (Marchant). The working group for the career ladder has met and outlined a strategy for definition and implementation of a clinical research career ladder for staff. Mapping of current UAB positions (~80) to a newly proposed ladder will ensue.

**Action:** (1) The sub-committee is charged with providing monthly updates on progress.

5. **Clinical Trial Budget Standards** (Kimberly/Marchant). Bob and Mark have taken a grassroots approach by meeting with each SOM Department individually that conducts clinical trials as well as Departments in other Schools to discuss the initiative to set a standard floor for the charging of fees associated with direct costs for the conduction of clinical trials that will be paid by industry sponsors. The fee schedule is set to go 'live' this fall.

**Action:** (1) Cindy Joiner asked that Bob and Mark join the DOM task force on clinical trials for discussions at their August meeting.

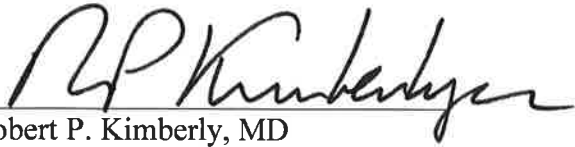
**6. New Business**

Update on the recruitment of the new IRB Director.

Invitation to the CCTS Open House, August 1<sup>st</sup>, 4:00 pm

**7. Next meeting:**

a. September 5<sup>th</sup> at Noon in FOT 12

A handwritten signature in black ink, appearing to read 'R.P. Kimberly', written over a horizontal line.

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