

Clinical Trials Administration Committee (CTAC)
Meeting Minutes
October 3, 2018
12:00 – 1:00 pm
FOT 12 Large Conference Room

In attendance:

Bragg (UAB Compliance)	Joiner (SOM)
Bertram (CCC)	Kimberly (SOM/CCTS)
Cotten (OVPR/OSP)	Marchant (CTAO)
Farough (Health System)	Miller (OVPR/IRB)
Fitz-Gerald (CCTS)	Nichols (SOO, OVPR)
Gerrity (OVPR)	Saleh (SOM)
Gilbert (SOD)	Sandefur (OnCore)
Gordon (HSIS)	Schwebel (CAS)
Horn (OVPR)	

Unable to attend:

Bates (Health System Compliance)	Motl (SHP)
Crocker (CCTS)	Mugavero (SOM)
Dransfield (SOM)	Nabors (SOM)
Ladores (SON)	Redden (SOPH)
Mack (SOM)	Wasko (SOB)

1. Review of CTAC minutes from September 5th meeting:
 - a. Approved as read without further modification

2. Updates / Reports
 - a. **OnCore** (Sandefur): Wave 3 implementation completed; SiteMinder retired effective 9/31/2018 (archive available). The Financials subproject implementation discussed; timeline dependent on OnCore personnel and financial personnel availability.

Actions: (1) Upgrade system to Version 15 in early 2019
(2) Continued exploration of the nuances between Enterprise and CCC OnCore processes and how they can be harmonized
(3) OnCore demonstration for CTAC members
 - b. **Pending Accounts** (Marchant): Communication with Departments and study teams about the rationale for pending accounts continues. Written encouragement of the use of pending accounts has been circulated to major department Chairs and Vice Chairs for Research enabling a multi-faceted approach to keep all levels of leadership aware. Reminder to the group that there is a minimum expectation of 85% utilization for not only general expenses but also salary. Current utilization has hovered around 50% in recent months overall but is trending back up. Salary utilization remains in the 20-30% range.

Actions: (1) Continued team-based communication about pending accounts; the group suggested that an anticipated lag between account creation and first use be within 45 days

- (2) Teresa Bragg suggested that information about systematic delays in use of pending accounts be escalated to the appropriate Dean.
- (3) Teresa Bragg will continue the investigation of the use of pending accounts for sub-awards with Financial Affairs. The rationale for current policy is unclear.
- c. **Clinical Billing Review** (Marchant): Median wait time is currently 8 business days with a mean of 13 days and a Range of 1-50. 23 annual education sessions with research units were conducted in September. 7 more are scheduled in October.
 - Actions:** (1) Complete the annual educational component of the re-engineered triage and review process with study teams to ensure best practices
 - (2) Operationalize quarterly Quality Control procedure of comprehensive review of a standardized sampling of protocols: QC review will begin by November.
- d. **OSP and IRB developments** (Cotten, Miller): Melinda shared that the SRA Report will be reviewed with various leadership offices throughout October beginning on the 12th with the Research Advisory Council led by Kent Keyser. Jonathan also shared that interviews are expected to commence in late October for an IRB Director and that he expects an Advisory Council to be convened for the IRB as suggested in the SRA Report.
 - Action:** (1) Formal search reactivated for new IRB Director (Denise Ball serving as interim)
 - (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 implementation.

3. CTAC sub-committees

- a. **Device Trials** (Kimberly). Bob commented that the Research Resolution Council approved the terms of the Edwards master contract on 9/19/18 and that the contract has been returned to Edwards. The Hospital LOA process is being revised in order to streamline its timing as a component of TTA.
 - Action:** (1) The PTAT (Procedures and Technology Assessment Team) group will determine how the Hospital LOA process can best be expedited.
- b. **Greenphire** (Marchant). Mark reminded the group that the issue pertaining to Greenphire which highlighted participants' ability to enroll in multiple studies without the investigator teams knowing it would be best recognized through a combination of OnCore and PowerTrials since their use occurs much earlier in the trial lifecycle. The OnCore trainers are including that recognition as a fundamental part of OnCore training. No further action is required going forward by this sub-committee.

- 4. **Clinical Research Career Ladder** (Marchant). The implementation team continues to meet monthly and is currently vetting a draft version of the career ladder. The group has split into 2 subcommittees in order to create a formal communications strategy as well as

develop an evaluation tool in order to map current personnel to the newly created positions on the ladder. Data has been gathered from both HR and the respective Schools which determined that there are ~450 individuals potentially affected with nearly 100 titles operating in 51 organizations (Depts/Centers) across 7 Schools/Colleges. The initial pilot is set to take place once everything is finalized in the Cancer Center.

- Actions:** (1) Finalize the career ladder
(2) Complete the creation of a formal communications strategy
(3) Create an evaluation tool by which employees will be mapped to the appropriate positions on the career ladder

5. **Clinical Trial Budget Standards** (Kimberly). Based on negotiated continued support from partners for FY19, a tiered approach is feasible for the immediate future where 'small' studies would be appropriated \$3500 while 'large' studies would be expensed at \$7000. A question was raised by Laretta around the definition of these study sizes. Bob replied that it is currently under evaluation. Communication with all affected parties continues.

- Action:** (1) Further refine the process and timing of the Study Management Fee which will be used to cover costs for OnCore, CBR, and PowerTrials.

6. **New Business:**

- a. MUSC/Devana Solutions: A conference call will be held next week to discuss their efforts and how it may assist us in our clinical trials initiative.
- b. TrialsToday/XpertTrials: Evaluation of both tools, which enable potential participants and providers looking for clinical trials at UAB to find up-to-date and reliable information, is underway. The Cancer Center currently uses the OnCore based search tool developed by Forte. Discussions about continuing to work with XpertDox have been initiated.
- c. ThreeWire: The subsidiary of WCG was previously on campus in late July to meet with Jonathan, Leslie, and Mark to discuss their ability to provide personnel at no cost to the site to assist in recruitment and retention of participants. UAB has a 2016 BAA in place, used by Orthopedics in a Pfizer trial. A conference call for further discussion is scheduled for October 24th.

7. **Next meeting:**

- a. November 7th 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