

Clinical Trials Administration Committee (CTAC)

Meeting Minutes

September 05, 2018

12:00 – 1:00 pm

FOT 12 Large Conference Room

In attendance:

|                         |                     |
|-------------------------|---------------------|
| Bragg (UAB Compliance)  | Horn (OVPR)         |
| Bertram (CCC)           | Kimberly (SOM/CCTS) |
| Croker (CCTS)           | Ladores (SON)       |
| Cotten (OSP)            | Nabors (SOM)        |
| Gerrity (OVPR)          | Nichols (SOO, OVPR) |
| Farough (Health System) | Redden (SOPH)       |
| Fitz-Gerald (CCTS)      | Sandefur (OnCore)   |
| Gordon (CCTS/HSIS)      | Schwebel (CAS)      |
|                         | Wasko (SOB)         |

Unable to attend:

|                                  |                 |
|----------------------------------|-----------------|
| Bates (Health System Compliance) | Marchant (CTAO) |
| Dransfield (SOM)                 | Miller (OVPR)   |
| Gilbert (SOD)                    | Motl (SHP)      |
| Joiner (SOM)                     | Mugavero (SOM)  |
| Mack (SOM)                       | Saleh (SOM)     |

1. Review of CTAC minutes from August 1<sup>st</sup> meeting:
  - a. Approved as read without further modification
2. New Committee Members
  - a. Melinda Cotten (OSP)
  - b. Jonathan Miller (IRB)
3. Updates / Reports
  - a. **OnCore** (Sandefur): Wave 3 implementation and the Financial subproject discussed;  
**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** (Bragg/Kimberly for 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 departments. Current utilization is “stalled” at about 60%. The target date for full utilization is October 1<sup>st</sup>. David Schwebel suggested that the ability to implement sub-awards tied to pending accounts would be very helpful and might accelerate the utilization of pending accounts.  
**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.

- (4) Bragg to investigate sub-awards and pending accounts with Financial Affairs to determine if pending accounts can be used to establish sub-awards.
  - c. **Clinical Billing Review** (Kimberly for Marchant): Mean wait time is now 11 days.
    - Actions:** (1) The educational component of the re-engineered triage and review process study teams to ensure best practice began the week of September 3<sup>rd</sup>.
    - (2) Operationalize quarterly Quality Control procedure of comprehensive review of a standardized sampling of protocols.
  - d. **OSP and IRB developments** (Cotten, Nichols).
    - a. The draft report from the Society of Research Administrators (SRA) review of process for both the Institutional Review Board (IRB) and Office of Sponsored Programs (OSP) is being considered by the Office of the VP for Research
      - Action:** (1) Formal search reactivated for new IRB Director (Denise Ball serving as interim)
      - (2) Plans to create an OSP Research Optimization Committee (may consider merging with a similar advisory board for the IRB since the membership may be very similar)
      - (3) OSP and IRB working with University Relations on an upgraded communications strategy
      - (4) 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.
- 4. **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 identified; device trials will be incorporated into the TTA process.
    - Action:** (1) The PTAT (Procedures and Technology Assessment Team) group will discuss how the Hospital LOA process can be expedited;
    - (2) Further discussions with Edwards Life Science to understand and expedite the Master Contract process are underway.
  - b. **Greenphire** (Marchant). Tabled.
- 5. **Clinical Research Career Ladder** (Kimberly for Marchant). The working group for the career ladder has met Kent Keyser to draw on the experience with the Researcher and Scientist ladders. Additionally, Mark has met with Alesia Jones to gain further perspective on prior institutional efforts.
  - Actions:** (1) Mapping of current UAB titles to a newly proposed 6-step ladder
  - (2) Phase in through natural turn-over and systematic migration
- 6. **Clinical Trial Budget Standards** (Kimberly). Meetings with each SOM Department conducting clinical trials as well as Departments in other Schools to discuss the initiative

to set a standard floor for fees associated with direct costs for clinical trials continue. The fee schedule is set to go 'live' this fall.

**Action:** (1) Meetings with Central Administration are scheduled.

(2) Full implementation of the Charge Master for Health System Charges will occur as part of the 'financials' project

7. **New Business:** none proposed

8. **Next meeting:**

a. October 3<sup>rd</sup> 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