

Clinical Trials Administration Committee (CTAC)

Meeting Minutes

May 1, 2019

12:00 – 1:00 pm

FOT 12th Floor Conference Room

In attendance: Bates (Health System Compliance) Marchant (CTAO)
 Bertram (CCC) Mack (SOM)
 Cotten (OVPR/OSP) McClintock (IRB)
 Croker (CCTS) Miller (OVPR)
 Farough (Health System) Motl (SHP)
 Fitz-Gerald (CCTS) Nichols (SOO, OVPR)
 Gilbert (SOD) Redden (SOPH)
 Gordon (HSIS) Schwebel (CAS)
 Joiner (DOM) Wasko (SOB)
 Kimberly (SOM/CCTS) Roberson (for Bragg)

Guests: Stair (Health System)

Unable to attend: Bragg (UAB Compliance) Nabors (SOM/CCTS)
 Dransfield (SOM) Saleh (SOM/CCC)
 Horn (OVPR) Sandefur (OnCore)
 Ladores (SON)

1. **Review of CTAC minutes from April 3rd meeting:** Minutes were reviewed with no additional comments. They were approved as outlined.

2. **Updates**

a. **OnCore** (Gordon): OnCore version 15.4 upgrade go live is planned for June 3rd. Work continues in development of the consolidated Research ChargeMaster. Mr. Gordon thanked those who were able to attend the celebration of the recent Excellence in Clinical Research Operations award provided by Forte to UAB at its biannual Onsemble Conference based on data in the OnCore CTMS.

b. **Clinical Research Career Ladder** (Marchant): The implementation team continues to carry out the Pilot within the CCC which included recently mapping each of the ~80 staff members to a new title on the Ladder, where applicable. These recommended titles will now go to Central HR for an additional review for confirmation. Following that, the information will be provided back to the CCC leadership and finally the staff. Planning is underway to outline the potential implementation schedule beyond the Pilot. The initial communications phase is wrapping up in May with a presentation to the Staff Council. The team is currently reviewing processes to determine areas for improvement as the process goes forward.

Action:

1. Continue the mapping process for the CCC Pilot.
2. Continue communications to stakeholders across campus.

- c. **PowerTrials Research Summaries** (Marchant): Current data from April 30th reflects a 93% utilization rate in terms of trials registered in Cerner as having Research Summaries. This metric is maintaining level through 2019. One department remains unengaged in the process.

Action:

- 1. Dr. Kimberly to follow-up with Department Chair for remaining unit to engage in Research Summaries.

- 3. **Signature Authority for Orders** (Bates): Mr. Bates discussed both access to the electronic health record (Impact) and authority to propose and sign orders. Based on conversations with peer institutions, our requirements for access may be more stringent than some. Discussions have included tying Impact access to one's title in the new Career Ladder which will more closely identify people who are 'patient interacting'. Signature authority for orders aligns with state licensing provisions.

Action:

- 1. Mr. Bates will create a guidance document for privileges within Impact to help manage clinical trial participant activities in the record to report at the June CTAC meeting.

4. Subcommittee Reports

- a. **Screening & End of Study Position Statement** (Marchant): An update was provided by Mr. Marchant around the institutional position, created and reviewed last spring, providing clarity around how activities should be billed in clinical trials at the Screening and End of Treatment visits. This position was established to support prior guidance that requires all participants to be billed consistently across visits within a given trial. This position helps prevent participants from potentially being billed for an activity due to their inclusion in a trial. A few industry sponsors have pushed back. Nationally, an increasing number of institutions are taking this position.

- b. **Clinical Trials Principal Investigator Group** (Joiner): A Clinical Trial PI group, constituted to provide a forum for PIs to express their perspectives for consideration by CTAC, consists of representatives from Departments of Medicine and Pediatrics and from OCCC, with plans to expand in the future.

Action:

- 1. The first meeting of the full group is scheduled for May 10th.

- c. **TTA: IRB Metrics** (McClintock): Data on IRB approval times, required by NIH / NCATS as a part of the CTSA Common Metrics initiative, were reviewed. The question posed is 'how can CTAC help in the endeavor to improve the review times illustrated in the data?' The data reflect opportunity to improve processes by both the IRB and the submitting investigators and investigative teams. Dr. Motl noted that during his time as IRB Chair at the University of Illinois, the IRB initiated an improvement process using specific panels for different study types which enabled them to develop content expertise and reduce their timelines for feedback and approval significantly. A discussion of such 'pathways'/special

panels ensued with recognition that specific panels might enhance consistency in responses as well.

Action:

1. Consider potential touchpoints where processes may be changed to enable a more efficient flow of information from IRB entry to review and approval to report at June's meeting.
2. Consider educational offerings to assist investigators in submitting better applications to reduce returns for revision.

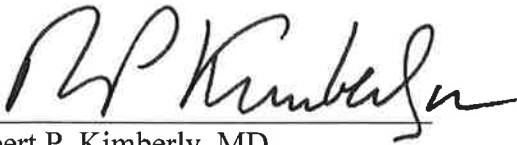
d. **TTA: Common Portal** (Kimberly): This topic was tabled due to lack of time for discussion.

5. New Business

- a. Ms. Cotten announced that a new position is being enacted whereby OSP will no longer be required to hold contract execution until IRB approval is in place.

6. Next meeting:

- a. June 5th, Noon. FOT 12 Large Conference Room



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