

**Clinical Trials Administration Committee (CTAC)**

**Meeting Minutes**

**March 4, 2020**

**12:00 – 1:00 pm**

**Faculty Office Tower, 12<sup>th</sup> Floor, Large Conference Room**

In attendance:	Busby (OCCC)	Marchant (CTAO)
	Cotten (OVPR/OSP)	McClintock (IRB)
	Croker (CCTS)	Miller (OVPR)
	Farough (Health System)	Motl (SHP)
	Fitz-Gerald (CCTS)	Nichols (SOO, OVPR)
	Gordon (HSIS)	Redden (SOPH)
	Horn (OVPR)	Sandefur (OnCore)
	Kimberly (SOM/CCTS)	Schwebel (CAS)
	Mack (SOM)	
Unable to attend:	Bates (Health System Compliance)	Ladores (SON)
	Bertram (OCCC)	Nabors (SOM/CCTS)
	Dransfield (SOM)	Rizk (CTAO/CCTS)
	Gilbert (SOD)	Roberson (UAB Compliance)
	Joiner (SOM)	Wasko (SOB)

1. **Review of CTAC minutes from February 5<sup>th</sup> meeting:** The minutes were reviewed and approved as written.

2. **Updates**

a. **OnCore Reporting** (Sandefur): The financials implementation continues with the Department of Surgery and several other areas across the School of Medicine scheduled in the coming weeks. To aid in these efforts, a Financial Analyst was hired in December. The system's upgrade is scheduled for the weekend of April 4<sup>th</sup>, and testing is already underway. The next major upgrade will occur this fall with Version 16. The majority of the OnCore team moved to a newly renovated space in Jefferson Tower, 16<sup>th</sup> floor. A few team members are still in other buildings across campus. Assessment and development of more robust reporting mechanisms by Mr. Sandefur continues. To aid in reporting, the institution is looking at various products including one by Forte called Insights. A demonstration of this tool is scheduled on April 10<sup>th</sup> via webinar.

**Actions:**

1. Continued training and implementation in OnCore Financials
2. Insights demonstration for reporting purposes by Forte (4/10/20)
3. Development of a training module for Reporting
4. Prepare for the expansion beyond trials with clinical billables
5. OnCore v16 upgrade in Q3 2020

b. **Tango eCards** (Marchant): Financial Affairs informed Dr. Gilbert's team last month that Tango has been approved only for payments to international participants and not to those within the continental U.S. Further clarification of this position and its relationship to the

lack of 1099 reporting capabilities by the system/vendor is being sought. Currently only Greenphire and University-issued checks are approved for payments to research participants. Mr. Marchant, with Dr. Gilbert, will determine if there are other eCard vendors who can meet the needs of the University including 1099 reporting.

**Action:**

1. Clarification from Ms. Mullins on the situation with Tango.
2. Mr. Marchant to explore other vendors with Dr. Gilbert.

- c. **Clinical Research Career Ladder** (Marchant): Go-live is scheduled for April 1<sup>st</sup>. Phase VIII data collection is underway. Of the staff originally mapped through Phase VII, approximately 10% had their titles appealed by unit leadership across campus, and responses were returned to units earlier this week. The final mapping, including official letters signed by Central HR, will be distributed to unit leadership on March 5<sup>th</sup> for dissemination to staff. New titles on the Ladder will be available for posting on March 9<sup>th</sup>. Efforts are underway by HR to ensure a smooth transition leading up to April 1<sup>st</sup> and beyond as we begin to utilize the Ladder for hiring and training purposes going forward.

**Actions:**

1. Collect final cohort of staff (Phase VIII) not mapped to date to take through the review process.
2. Distribute documentation for transitioning staff from current to proposed titles.

3. **Time to Activation: IRB-Industry trials** (McClintock): The IRB has been conducting a pilot project with the O'Neal Comprehensive Cancer Center (OCCC) to reduce overall IRB processing and review times for industry-sponsored trials using the Western Institutional Review Board (WIRB). Data from that pilot have shown a significant decrease in time with the IRB (from ~8 weeks to ~5-6 weeks) by having the OIRB submit the protocol to WIRB after pre-review rather than returning it to the investigator to submit to WIRB. The pilot will be expanded immediately to include all trials managed by the OCCC with plans to further expand across the institution in the coming months. The overarching goal is to reduce the median time to activation for industry sponsored clinical trials (OIRB/WIRB) to 30 days total.

**Actions:**

1. Mr. McClintock to meet with Ginger Reeves the Regulatory Manager within OCCC on Friday, 03/06 to discuss the expected volume increase associated expansion efforts. This will inform how expansion efforts will be rolled out.
2. Mr. McClintock to outline a plan for a University-wide implementation of the revised process to achieve greater reductions in TTA.

**Addendum:**

1. The Clinical Trials Investigator Working group supports expeditious expansion of the revised process with WIRB (03/10/20 meeting)

4. **Training Updates**

- a. OCCC/CCTS (Fitz-Gerald/Busby): Given the recruitment of new faculty investigators in Hematology/Oncology since last summer, a condensed training session for all newer investigators on campus for conducting clinical trials will be held today (March 4<sup>th</sup>) at

4:00 pm in the Pittman Center for Advanced Medical Studies (PCAMS). This session will serve as a refresher and Q/A opportunity for more seasoned PIs.

**Actions:**

1. Review attendance by PIs and study team members and determine what other efforts may be made to engage investigators across campus in training and informational sessions.
- b. Clinical Investigator Training Program (Fitz-Gerald): The 16 attendees have been selected for the upcoming training program which starts on April 6<sup>th</sup>. There will be 4 sessions held every other week through May 18<sup>th</sup>. Invitations have been extended to speakers who will present during the sessions.

**Actions:**

1. Conduct Spring 2020 session of CITP and glean feedback on ways to continue broadening both the breadth and depth of offerings to improve the overall competencies of our faculty investigators on campus.

## 5. Communications

- a. Trending in Trials newsletter (Crocker): The inaugural edition of the newsletter was distributed in December and the second edition is in draft form. While intended for PIs as the target audience, it is distributed to both faculty and staff on a quarterly schedule as recommended by CTAC. The goal is to provide key information and updates to researchers while creating a stronger sense of community among investigators. Among the suggestions and questions posed by CTAC include the following:
- i. Consider/evaluate the optimum frequency of the newsletter (monthly, bimonthly, quarterly);
  - ii. Consider/evaluate how best to leverage the mechanism of communication for widespread uptake of information;
  - iii. Include new policies at both a local or national level.

Mr. Farough suggested a regular conference call as another consideration to communicate to investigators. Dr. Nichols added that including data in the newsletter would create greater transparency from a metrics perspective on how we are doing at various levels (University, School, Department, etc.). Ms. Cotten noted, based on some national web metrics, that Wednesday at 3:00 pm may be the optimum time to distribute information via email maximize opening and 'click rates'. Such observations were the basis for distributing *Research Matters* from the Office of Research at that time.

**Actions:**

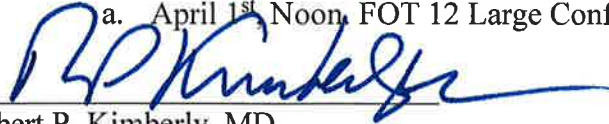
1. Dr. Rizk and Dr. K. Saag have agreed to serve as Editors and content developers for Trending in Trials

6. **New Business/Open Floor** (all): Dr. Kimberly notified the committee that a recent National Academy of Medicine report on site standardization has been distributed to CTSA National Steering Committee. Given this distribution, it is likely that site standardization will be a point of emphasis in 2020 for the NIH, and he recommended that CTAC think about how to ensure that UAB is positioned to excel in these standards. Dr. Kimberly also reminded the committee of the upcoming visit by the Director of the NIH, Dr. Francis Collins who will discuss *Exceptional*

*Opportunities in Biomedical Research* at 8:00am on Friday March 6<sup>th</sup> in Spain Auditorium with the entire campus invited to attend.

**7. Next meeting:**

a. April 1<sup>st</sup> 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