

Clinical Trials Administration Committee (CTAC)
Meeting Minutes
May 6, 2020
12:00 – 1:00 pm
Zoom Meeting

In attendance:

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

Unable to attend:

- Bates (Health System Compliance)
- Mack (SOM)
- Nabors (SOM/CCTS)
- Wasko (SOB)

1. **Review of CTAC minutes from March 4th meeting:** The minutes were reviewed and approved as written.

2. **Updates**

a. **OnCore Reporting** (Sandefur): OnCore operations have continued as expected during the Limited Business Operations period since March 16th. The data clean-up initiative continues as does the OnCore Expansion and Financials projects. Training has moved to Zoom calls as necessitated by COVID-19. Discussions continue about finding a more robust reporting solution. Dr. Rizk discussed efforts to assemble a small group of engaged PIs to serve as champions for OnCore to ensure investigators across campus grow in their understanding of the system and how to not only maintain clean data going in but also understand that such effort leads to more informed decision-making based on the output it enables. She is working with Dr. Orlando Gutierrez on this effort, with her primary background in the industry space and his in NIH trials.

Actions:

1. Continued training and implementation in OnCore Financials
2. Development of a training module for Reporting
3. Prepare for the expansion beyond trials with clinical billables
4. OnCore v16 upgrade in Q3 2020

b. **Tango eCards** (Marchant): Based on further discussions with Dr. Gilbert and his team within the School of Dentistry as well as Financial Affairs, it appears that Tango will not

meet the needs of all parties across the institution for domestic payments. It has been approved, as reported at the March CTAC meeting, for use in international studies though. We were informed in a recent call with Greenphire that they are currently working on an eCard solution as a supplement to ClinCards. Mr. Marchant has volunteered UAB to serve as an advisor to ensure it meets the needs of the institution going forward. While a firm timeline has not been outlined, we know that it will not be ready for piloting in 2020.

Actions:

1. Mr. Marchant to continue discussions with Greenphire on the development of their eCard product.

- c. **Clinical Research Career Ladder** (Marchant): The Go-live occurred on April 1st as planned. Recent efforts have involved ‘clean-up’ for Orgs across campus who have identified additional staff for mapping since the last Phase (VIII) that occurred in March. The Job Descriptions and related information have been posted on the UAB HR website for use going forward.

Actions:

1. Finalize mapping any remaining staff who were hired post-Phase VIII.
2. Assist Orgs with identifying appropriate titles on Ladder for new hires going forward.

- d. **Time to Activation: IRB-Industry trials** (McClintock): Dr. Kimberly opened the comments by praising the work that Mr. McClintock and the IRB have done in recent weeks during the COVID-19 pandemic. These comments were echoed by several other members of CTAC. 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 showed a significant decrease in time with the IRB by having the OIRB submit the protocol to WIRB after pre-review rather than returning it to the investigator to submit to WIRB. Given recent developments with COVID-19, activities have been paused for the past six weeks but are expected to pick-up as discussions move toward ‘re-opening’ operations as discussed later in the meeting. 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 OCCC and CTAO personnel to discuss expansion efforts.
2. Mr. McClintock to outline a plan for a University-wide implementation of the revised process to achieve greater reductions in TTA.

- e. **Pilot: Single Identifier** (Nichols): No update available at this time.

Actions:

1. Provide guidance to CTAC on the state of the Single Identifier Pilot and potential plans for expansion across campus.

3. **Re-opening for Clinical Research** (Nichols/Kimberly): Drs. Nichols and Keyser are leading a committee (Return to Research Operations (R2Ops)) of about 25 representatives from across campus to create a guidance document on how to re-open research operations across campus. The document is nearing completion and is expected to be released soon. It will outline a phased approach by which various milestones must be met in terms of COVID-19 activity based on reports from health officials and how that corresponds to appropriate precautionary measures to be taken by research personnel. There are 4 levels (Red, Orange, Yellow, Green) that identify the state of operations. We are currently in the Orange phase (essential operations). The goal is to move to Yellow (modified operations) later this month. Operational plans for meeting the outlined requirements by the guidance will have to be created by the Investigators which will include items like social distancing, sanitizing areas, masking, hand washing, and participant screening and testing. Monitoring and enforcement will be conducted at the unit level. A question was raised concerning access to masks with an ensuing discussion that included remarks about recent communications by both the University (HR) and the Health System about masking requirements (including a city-wide mandate) and provision to meet those requirements.

Actions:

1. Finalization of the guidance document and distribution for action by research personnel.

4. **Research Models and Institutional Practices** (Kimberly/Nichols): Dr. Kimberly asked the Committee for comments on ways that they have seen the Limited Business Model brought about by COVID-19 lead to innovative methods of working and collaborating across campus. Dr. Rizk expressed that the expansion of Zoom has enabled her to participate in meetings during times that she would not necessarily have been able in the past. Dr. Croker mentioned being able to collaborate on projects with people across campus that has previously not been possible. Dr. Joiner referenced the openness by institutional leadership to 'phone consenting'. Ms. Cotten commented that despite the limited operations, UAB's research portfolio is tracking \$35M above where it was this time last year, which was cited as a banner year at the time. Dr. Kimberly asked for additional lessons learned to be sent via email. Dr. Kimberly then asked if it would be helpful to hold a Town Hall (or series of meetings) with research faculty and staff in the coming days to discuss relative topics of interest surrounding resuming operations amidst COVID-19. The overwhelming response was 'yes' with the caveat that the guidance by the R2Ops Committee would need to be released first.

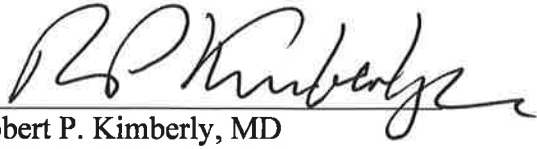
Actions:

1. Send 'lessons learned' to Dr. Kimberly and Mr. Marchant.
2. Plan and execute Town Hall(s) following the release of the R2Ops guidance document.

5. **New Business/Open Floor** (all): No additional comments.

6. **Next meeting:**

- a. June 3rd, 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