

Clinical Trials Administration Committee (CTAC)
Meeting Minutes
February 5, 2020
12:00 – 1:00 pm
Faculty Office Tower, 12th Floor, Large Conference Room

In attendance:

Bragg (UAB Compliance)	Marchant (CTAO)
Busby (OCCC)	McClintock (IRB)
Cotten (OVPR/OSP)	Motl (SHP)
Farough (Health System)	Nichols (SOO, OVPR)
Fitz-Gerald (CCTS)	Redden (SOPH)
Gilbert (SOD)	Rizk (CTAO/CCTS)
Gordon (HSIS)	Sandefur (OnCore)
Kimberly (SOM/CCTS)	Wasko (SOB)
Mack (SOM)	

Unable to attend:

Bates (Health System Compliance)	Joiner (SOM)
Bertram (OCCC)	Ladores (SON)
Croker (CCTS)	Miller (OVPR)
Dransfield (SOM)	Nabors (SOM/CCTS)
Horn (OVPR)	Schwebel (CAS)

Guest: Michael Matthews (OVPR)

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

2. **Updates**

- a. **OnCore Enterprise implementation: Financials/Expansion** (Sandefur): Overall, onboarding continues for new users with the total active users now above 400. With the hiring of a financial analyst in December the ongoing implementation of the Financials module is moving forward. Training across Departments and Divisions is intensive and includes three 4-hour sessions. Mr. Sandefur is currently developing a training for Reporting as well. The expansion of OnCore is expected to take place in Q3/Q4 of 2020.

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 mid-2020
- b. **Tango eCards** (Marchant): Financial Affairs is working with the vendor to determine if 1099 reporting is available. It was originally believed from the vendor that such reporting would be available, but messaging changed during the contracting process which has caused pause by UAB. If the vendor can provide 1099 reporting, the contract will move forward. If not, the institution will have to determine if an alternative means of collection

and storage of SSNs is viable for the product. Ms. Bragg reminded the Committee of the risk associated with the collection and storage of SSNs.

Action:

1. Update from Ms. Mullins on the progress with Tango and discussion of alternative strategies.

- c. **Clinical Research Career Ladder** (Marchant): Discussions with organizational units across campus notifying them of the mapping results began on January 29th and will continue through February 17th. Ms. Mack mentioned that Departments agree with the majority of mapping results to the new titles in the Ladder. Phase VII recently completed stage 1 of mapping. The go-live has been scheduled for April 1st, and the new titles will be available for posting on March 9th. There will be ~550 people mapped to the Ladder. Discussions are underway for operational processes following go-live.

Actions:

1. Collect final cohort of staff (Phase VIII) not mapped to date to take through the process.
2. Finalize documentation for transitioning staff from current to proposed titles.
3. Complete results discussions with campus-wide organizational units.

3. **Single Identifier / Single Portal** (Nichols/Matthews). The pilot for the use of the IRB number as the single identifier continues with the O'Neal Comprehensive Cancer Center (OCCC). This initiative will enable researchers across campus to use a single number (IRB) to identify a trial when searching various systems for information. The pilot has identified a few issues that will require modification prior to rolling out campus-wide.

Actions:

1. Continue testing of the Single Identifier at OCCC. (Matthews/Busby)
2. Begin a second round of pilot implementation of the single identifier with another unit; consider the timing of the enterprise-wide roll-out.

4. **IRAP replacement project** (Matthews/Cotten). Mr. Matthews reported that Central Administration is currently working on a Request for Proposals (RFP) for an IRAP replacement. A group has been convened to assist in this endeavor which has met once.

Actions:

1. Formalization of the RFP for an electronic Research Administration system (IRAP replacement) for distribution and collection of responses. (Cotten)

5. **Time to Activation (TTA) for Clinical Trials** (Nichols): Dr. Nichols presented time to activation (TTA) data collected from various units within central administration since 2014 and analyzed by Dr. Redden. The data represent industry clinical trials that have OSP executed clinical trials agreements between June-October each year over a 4-year period (2014, 2016, 2018, 2019) and also have gone through both Medicare Coverage Analysis with CBR and IRB review (ie, the most complicated clinical trials from an administrative and regulatory standpoint). Dr. Kimberly reminded CTAC members that this type of data is required by the National Institutes of Health (NIH) to report through the CTSA Common Metrics initiative, in addition to

being required in NCATS CTSA competitive review submissions. The overall trend reflects an increase in review time for the Offices of the Institutional Review Board (IRB, increase in 16 days, median time in calendar days) and Sponsored Programs (OSP, increase of 25 days, median time in calendar days) with a decrease exhibited by the Clinical Billing Review office (CBR, decrease of 38 days, median time in calendar days). **See attached for reference.** Factors such as volume of submissions received compared against staffing levels was not known although Ms. Cotten did explain that there was a sizeable staff shortage in OSP in 2019 (43%) due to FMLA leave for births. One notable statistic pointed out by Dr. Nichols was the marked increase in lag time between first submission to last submission across the offices which essentially doubled from 31 days to 61 between 2018 and 2019. This observation speaks to the opportunity that the Single Portal initiative will help to address. Also discussed was the UAB Clinical Trials Study Management Fee (\$5,500) that is billed to industry-funded clinical trials when the OSP checklist is submitted (rather than when the IRB documents are submitted as has been in the past). The goals of moving the fee forward were in part to help align these parallel processes. As discussed, if a clinical trial were to not be executed (for whatever reason), only 50% of the fee would be assessed.

Actions:

1. Determine ways to reduce review times across all central offices to enable the institution to remain competitive for industry-sponsored clinical trials
2. Follow-up on December 4, 2019 CTAC/OIRB/WIRB initiatives to reduce TTA for IRB (McClintock)

6. **Research Resolution Council (RRC, Cotten):** A copy of the charter was provided by Ms. Cotten for review. The purpose of the Council is to reach a resolution on how to move problematic research agreements forward. Members include several senior leaders across both central administration and the School of Medicine, including Drs. Kimberly, Nichols and Ms. Cotten from the CTAC. The most common issues identified typically include Subject Medical Injury, Indemnification, and Intellectual Property. Recent data shows a decline in the number of items brought before the Council between 2018 (23) and 2019 (10).

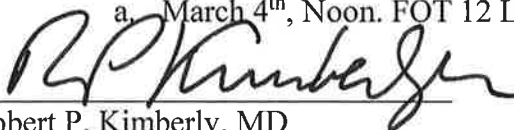
Actions:

1. CTAC members to disseminate information about the Council's presence and function in helping to provide resolution in problematic research agreements.

7. **New Business/Open Floor:** No new business offered for discussion.

8. **Next meeting:**

- a. March 4th, 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