

Clinical Trials Administration Committee (CTAC)
Meeting Minutes
December 4, 2019
12:00 – 1:00 pm
Faculty Office Tower, 12th Floor, Large Conference Room

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

1. **Review of CTAC minutes from November 6th meeting:** The minutes were reviewed and approved as written.

2. **Updates**

a. **OnCore Financials/Expansion** (Sandefur): Implementation of the Financials module continues in the Department of Medicine with Dr. Ken Saag's group (Rheumatology). Nephrology will begin in January, followed by Neurology. The goal is to implement 2 groups per month. Staff training on appropriate practices supporting the financial management of trials continues to be a time-consuming challenge. Dr. Rizk suggested that we evaluate staffing models to aid study teams with the mechanics of financial management. Having specialized financial teams is a practice adopted by many Academic Medical Centers (AMCs). Mr. Sandefur notified the committee that the upgrade to OnCore v16 is anticipated in 2020.

Actions:

1. Continued training and implementation in OnCore financials
2. Evaluation of more specialized staffing models, including financial management
3. OnCore v16 upgrade in mid-2020

b. **Tango eCards** (Marchant): The review of the vendor rests with Stephanie Mullins in Central Administration. Ms. Mack has reached out for an update and an expected timeline for action.

Action:

1. Reminder to Ms. Mullins in Central Administration to complete the review process.
- c. **Clinical Research Career Ladder** (Marchant): Stage 1 mapping of teams is complete through Phase V. Stage 2 mapping by Central HR is complete through Phase III. Finalizing the implementation process is under way with an expected go-live in early 2020 at the conclusion of mapping. Communication across campus to stakeholders continues with recent presentations given to the Faculty Senate, SOM Department Chairs, and Staff Council. Meetings to discuss results of the mapping process across campus are being scheduled.

Currently, “certification” is listed as a preference in the senior level positions on the Ladder. Central HR supports making it a firm requirement. While CTAC discussion supported required training during the first ~3-6 months in a clinical research position (eg, probationary period), there was a range of opinions about a “certification” requirement. Among the questions to be addressed prior to implementation of “certification”:

- i. Who provides the certification (internal v external)?
- ii. At what level (entry, intermediate, senior) would certification be required as opposed to preferred or not required at all?
- iii. Who pays for the certification (institution v individual)?

Overall, there was consensus that a greater emphasis must be placed on proper training at all levels of the career arc for both staff and investigators to ensure the appropriate skills are present across the research community. Ms. Fitz-Gerald pointed out the value of a mentorship (preceptorship) model.

Action:

1. Mapping of staff in the Catch-up Phase will occur the first week of January.

3. **Single Identifier / SinglePortal** (Nichols/Marchant). Dr. Nichols reminded the group of last month’s discussion on the Single Identifier efforts underway which includes a Pilot in the O’Neal Comprehensive Cancer Center (OCCC). This will enable researchers across campus to use a single number (IRB) to identify a trial when searching various systems for information pertaining to it.

A “single portal” concept which would enable study teams to upload all the relevant documents for trial review and initiation through a single site in order to reduce duplicate efforts and provide a dashboard to enable tracking transparency in the process was discussed. Ms. Cotten noted that development of the RFA for a new research administration system, including performance specifications, was in process and that an Advisory Committee would be formed. The initial goal for review and a decision about the path forward is the Summer of 2020.

Actions:

1. Development of the technical and performance specifications for the research administration system and creation of the Advisory Committee to include IT professionals for OnCore Enterprise (Gordon, Sandefur).

4. **TTA: IRB Workflow** (McClintock): Mr. McClintock identified several reasons why industry trial submissions get delayed prior to sending them to Western IRB (WIRB) for review: (1) incomplete submissions by study teams, perhaps due to lack of staff specialization, and (2) internal legal review. Discussions are ongoing to determine if the institution can move toward a model that many other AMCs have adopted which is to take a 'take it or leave it' stance surrounding Subject Medical Injury language in the Informed Consent document. The pilot study in the OCCC has demonstrated that having more experienced and specialized staff who manage the regulatory documents is more efficient and that submissions prepared by them move through the process more quickly than those prepared by less experienced staff. A 'fast track' for units with an established record of submissions with few, if any, needed corrections is under consideration.

Action:

1. IRB to increase personnel to reduce backlog of RPLs which slow down the UAB pre-review.
2. UAB IRB to start submitting the WIRB applications upon completion of the pre-review based on the pilot experience with the OCCC (which reduced the overall UAB/WIRB time by ~14 days).
3. IRB to identify ways to streamline the pre-review process for WIRB submissions to ensure a 'turn around' time of less than 10 days (currently 14 days from initial submission until returned to PI/study team with initial queries).

5. **Clinical Trials Newsletter** (Kimberly): Dr. Kimberly distributed an example of the new newsletter that has been developed within the CCTS and will be distributed this week across campus. He requested that members review it and provide comments to him.

Action:

1. Send comments and suggestions for future content to Dr. Kimberly after reviewing the prototype of the newsletter.

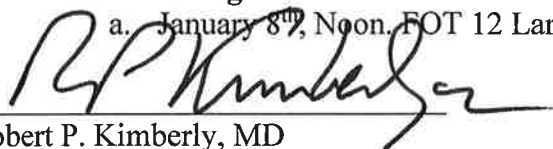
6. **New Business/Open Floor:** No new business offered for discussion.

7. **Reminder:**

- a. CCTS Lunch & Learn: December 10th at 11:30am in Spain Auditorium
- b. The January CTAC meeting has been moved to January 8th in observance of the New Year's holiday on January 1st.

8. **Next meeting:**

- a. January 8th, 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