

**Clinical Trials Administration Committee (CTAC)**  
**Meeting Minutes**  
**August 14, 2019**  
**12:00 – 1:00 pm**  
**FOT 12 Large Conference Room**

In attendance:	Bertram (CCC)	Kimberly (SOM/CCTS)
	Bragg (UAB Compliance)	Mack (SOM)
	Croker (CCTS)	Marchant (CTAO)
	Farough (Health System)	McClintock (IRB)
	Fitz-Gerald (CCTS)	Miller (OVPR)
	Gilbert (SOD)	Nichols (SOO, OVPR)
	Gordon (HSIS)	Redden (SOPH)
	Horn (OVPR)	Sandefur (OnCore)
	Joiner (SOM)	Schwebel (CAS)

Unable to attend:	Bates (Health System Compliance)	Motl (SHP)
	Cotten (OVPR/OSP)	Nabors (SOM/CCTS)
	Dransfield (SOM)	Saleh (SOM/CCC)
	Ladores (SON)	Wasko (SOB)

1. **Review of CTAC minutes from July 10<sup>th</sup> meeting:** Dr. Kimberly relayed a conversation with Mr. Bates earlier relative to the Guidance Document distributed at the prior meeting and that no further comments were received. Minutes were reviewed with no additional comments. They were approved as outlined.
2. **Updates**
  - a. **OnCore** (Sandefur): The Financials Pilot began on July 29<sup>th</sup> with Cardiology and followed by Lung Health Center last week. The final pilot group from DOM will be implemented within the next two weeks. There will be a phased roll-out across the remaining users with an anticipated completion by the end of 2019. Mr. Sandefur confirmed that the implementation of OnCore to include all trials regardless of clinical billables is slated to begin this Fall with completion anticipated by Q1 2020.  
**Action:**
    1. Financials pilot currently underway; feedback welcome.
  - b. **Clinical Research Career Ladder-Timeline** (Marchant): Phase I was completed last month and data collection for Phase II ended this week with mapping expected to take place the week of August 26<sup>th</sup>. Phase III was initiated this week for the Schools outside of Medicine. Based on currently timelines, it is still expected to have all applicable staff mapped by the end of 2019.  
**Action:**
    1. Mapping Phase II staff in August.
    2. Discussions with Phase III Orgs to be completed in September.

- c. **Pending Accounts and PI/Staff Effort** (Kimberly/Mack/Marchant): Dr. Kimberly presented a slide deck that illustrated in schematic form the process for getting and utilizing a Pending Account. It also illustrated the ramifications if that Pending Account is not used in absence of an Operating Account. This includes having one's contract held for signature until appropriate expenses are applied. Dr. Joiner noted that some investigators want to 'keep it simple'; others want more detail. Members of CTAC will work to deliver a focused message to all stakeholders to ensure appropriate understanding at the level needed in order to insure adherence to the requirement which reflects best practice for the institution. Additionally, a retrospective review of Pending Account usage, conducted by University Compliance for the period of January 2017 through December 2018, was discussed; that analysis is to be complete in September.

**Action:**

1. Finalize various messages for all stakeholders to fit the diverse needs.
2. University Compliance to complete their analysis with the results provided to Schools/Departments for follow-up with investigators for the 2017-18 period.

- d. **Medical Director Update** (Kimberly): With Dr. Saleh's pending departure for Aga Khan University in Nairobi, Kenya, a search is underway to identify a replacement. Applications have been received and will be reviewed in August with an anticipated start date in early September for the new Medical Director.

3. **Clinical Trials Initiative** (Kimberly): Dr. Kimberly reminded the group of the handout circulated in July which outlines the breadth of the Clinical Trials Initiative. CTAC meetings will include these broader initiatives.

**Action:**

1. Recirculate the handout outlining the elements of the Clinical Trials Initiative.

4. **CITP Recommendations** (Kimberly): Dr. Kimberly asked for suggestions regarding content elements that should be included in the Clinical Investigator Training Program. Dr. Joiner suggested differentiating between new (young) investigators and more senior investigators who may need a refresher in various items or updating on new processes or initiatives. Clinical trial-focused webinars including the Duke-sponsored weekly seminar (streamed at Noon on Friday) were discussed. Additionally, after brief discussion, a proposal to postpone the start of the fall cohort of CITP until the new Medical Director is identified and on-boarded was adopted.

**Action:**

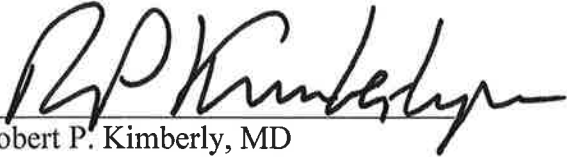
1. Engage new Medical Director once identified about ways to improve efforts in training of investigators.

5. **Upcoming Events** (Kimberly): Ms. Fitz-Gerald reminded everyone that the quarterly CCTS Lunch & Learn will take place on September 17<sup>th</sup>. She also asked that anyone with additional topics is welcome to submit them for inclusion.

6. **New Business/Open Floor:** No items identified at this time.

**7. Next meeting:**

- a. September 4<sup>th</sup>, Noon. FOT 12 Large Conference Room

A handwritten signature in black ink, appearing to read "R.P. Kimberly". The signature is written in a cursive, flowing style with a horizontal line underneath it.

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