

**Clinical Trials Administration Committee (CTAC)**  
**Meeting Minutes**  
**July 10, 2019**  
**12:00 – 1:00 pm**  
**FOT 12 Large Conference Room**

In attendance:

Bertram (CCC)	Kimberly (SOM/CCTS)
Bragg (UAB Compliance)	Mack (SOM)
Cotten (OVPR/OSP)	Marchant (CTAO)
Croker (CCTS)	McClintock (IRB)
Fitz-Gerald (CCTS)	Miller (OVPR)
Gilbert (SOD)	Nichols (SOO, OVPR)
Gordon (HSIS)	Redden (SOPH)
Horn (OVPR)	Sandefur (OnCore)
	Saleh (SOM/CCC)

Guests: Turner (HSIS)

Unable to attend:

Bates (Health System Compliance)	Motl (SHP)
Dransfield (SOM)	Nabors (SOM/CCTS)
Farough (Health System)	Schwebel (CAS)
Ladores (SON)	Wasko (SOB)

1. **Review of CTAC minutes from June 12<sup>th</sup> meeting:** Minutes were reviewed with no additional comments. They were approved as outlined.

2. **Updates**

a. **OnCore** (Sandefur): The Financials Pilot is scheduled to begin on July 29<sup>th</sup> with a group within Department of Medicine. There will be a phased roll-out across the remaining users with an anticipated completion by the end of 2019.

**Action:**

1. Financials pilot with DOM, starting July 29<sup>th</sup>.
2. Completion of 'all trials' implementation by Q1 2020.

b. **Clinical Research Career Ladder-Timeline** (Marchant): The current data about impacted staff has been reviewed with the implementation team, and the initial mapping of current employees may be completed by December 2019, barring any unforeseen issues. Following the completion of the mapping, all impacted staff will be provided an institutional letter from HR that provides the new title and status. This is scheduled to occur in early January, 2020.

**Action:**

1. Completion of the mapping of staff in the initial wave of units (Phase I) in July.
2. Initiation of the second wave of mapping to be complete in August.

c. **Access to IMPACT and Signature Authority for Orders** (Bates, [unable to attend]; attachment): Mr. Bates distributed a draft guidance document for review

in June. A revised, updated version was circulated during the meeting for any additional comment.

**Action:**

1. CTAC members are asked to review the revised Guidance document and to provide any further comment to Mr. Bates with copy to Dr. Kimberly for finalization of the document.

- d. **Pending Accounts and PI/Staff Effort** (Mack/Marchant): A committee had been tasked by the President's Risk Cabinet earlier this year to identify a method by which to ensure appropriate effort is expensed to Pending Accounts for clinical trials in the event an Operating Account is not in use by the corresponding Department/Division. Following up on the recommendations of both the Clinical Investigator Working Group Subcommittee and CTAC, it was determined that of the options presented the holding contracts for the applicable PI would be done by the Office of Sponsored Programs. This process will be monitored and initiated by the Clinical Trials Administrative Office through communications with not only the PI, but also the appropriate Department Chair, Account Manager, and Departmental Effort Officer. Refinement of that workflow for SOM in industry-sponsored/funded clinical trials is currently underway by Ms. Mack, Mr. Marchant, and Ms. Cotten. Upon finalizing the workflow, it will be presented in August to CTAC.

**Action:**

1. Finalize workflow to insure effort allocation, including when to hold contacts when appropriate at OSP.
  2. Members of CTAC representing other schools are tasked with determining who the appropriate officials are in their respective Schools to work with Mr. Marchant to standardize workflow across all Schools at UAB.
3. **Medical Director RFA** (Kimberly; attachment): Congratulations to Dr. Saleh on the fulfillment of a lifelong dream to lead the Oncology Division at Aga Khan University in Nairobi, Kenya to ensure excellent care is provided to cancer patients in that region of the world. With his pending departure, it is necessary to fill a void left in the Medical Director role of the CTAO. An RFA was circulated for comment and feedback prior to broad circulation. It will provide 20% effort from the CCTS. It is desired to have a candidate identified prior to September 2<sup>nd</sup> (Labor Day) in order to ensure time for training by Dr. Saleh prior to his departure.
4. **Clinical Trials Initiative/CTAC** (Kimberly; attachment): Dr. Kimberly circulated a handout which outlined the breadth of the Clinical Trials Initiative as a reminder to CTAC of all the activities currently underway. It was also noted that going forward, CTAC will address a broader scope beyond tools or processes. Suggested additions included IND/IDE Process, Conflict of Interest Review, CT.Gov process for IITs, and informatics tools such as i2b2 for participant recruitment.

**Action:**

1. Update the handout to use to inform senior leadership across the institution as well as track high-level progress for communicating to CTAC.

5. **SHARE/TIN (Horn):** Ms. Horn provided a presentation to inform CTAC of ongoing efforts across both the region (Southeast Health Alliance for Research) and nationally (Trial Innovation Network) to provide resources to investigators conducting multisite clinical trials. This included not only the governance of the 2 initiatives but also the related activities provided at no cost. Additionally, the importance of timing for requesting these resources was stressed (i.e. early in the study development process). She also asked that CTAC help in disseminating information about these resources and asking anyone desiring assistance to contact her. She is also available to help 'spread the word' by attending meetings across campus to ensure knowledge of these resources that are available, again at no cost.

**Action:**

1. CTAC members are asked to share with investigators the availability of resources through SHARE or TIN.
  2. Mr. Sandefur volunteered to query data in OnCore to ascertain IITs identified in the system to share with Dr. Nichols.
6. **Upcoming Events (Kimberly):** Dr. Kimberly identified a number of events upcoming in the clinical trials space starting today (IIT presentation by Dr. Nichols) and running through the fall with the initiation of CITP 6.0.
7. **New Business/Open Floor:** Several items were mentioned at the close of the meeting which included the following:
- a. IRAP Survey: Ms. Cotten announced the release of a survey to all faculty and staff to help guide a report to be given to President Watts and Vice-President for Research Chris Brown this fall. Broad distribution through any channels available will be made. It is expected to take 7 minutes to complete.
  - b. Research Summaries: Dr. Kimberly notified CTAC of a discussion at the Clinical Investigator Working Group Subcommittee and their recommendation to ensure that all Departments were inputting Research Summaries due to its importance for patient safety.
  - c. Power Plans: Dr. Kimberly also let members know that the Clinical Investigator Working Group stressed the importance of research teams working with Power Plan builders in HSIS in a timely fashion to enable appropriate builds of Power Plans due to their importance in the service ordering and billing processes for the Health System.
  - d. Clinical Investigator Training Program (CITP): Dr. Saleh commented about the upcoming version 6.0 of CITP. This will bring the overall cohort of investigators trained to 90 (15 per cohort). The important progress made over the past few years will be highlighted in an upcoming manuscript. It is expected that the next cohort will begin this fall.
  - e. Research Administrator Forum: Ms. Cotten announced that a Forum will be held at Spain Auditorium on September 20<sup>th</sup> at 2:00 pm.
  - f. Personnel eForm: As a follow-up to the June meeting, Mr. McClintock announced that an email was distributed today to the research community that the new Personnel eForm which will enable changes to personnel listings at the IRB will begin on July 31<sup>st</sup>.

**8. Next meeting:**

- a. August 14<sup>th</sup>, Noon. FOT 12 Large Conference Room

A handwritten signature in black ink, appearing to read "RP Kimberly", with a long horizontal flourish extending to the right.

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