

Clinical Trials Administration Committee (CTAC)

Meeting Minutes

June 12, 2019

12:00 – 1:00 pm

Wallace Tumor Institute 101

In attendance: Bertram (CCC) Kimberly (SOM/CCTS)
Cotten (OVPR/OSP) Marchant (CTAO)
Croker (CCTS) McClintock (IRB)
Fitz-Gerald (CCTS) Miller (OVPR)
Gilbert (SOD) Motl (SHP)
Gordon (HSIS) Redden (SOPH)
Horn (OVPR) Sandefur (OnCore)
Joiner (DOM) Schwebel (CAS)

Guests: Turner (HSIS)

Unable to attend: Bates (Health System Compliance) Mack (SOM)
Bragg (UAB Compliance) Nabors (SOM/CCTS)
Dransfield (SOM) Nichols (SOO, OVPR)
Farough (Health System) Saleh (SOM/CCC)
Ladores (SON) Wasko (SOB)

1. **Review of CTAC minutes from May 1st meeting:** Minutes were reviewed with no additional comments. They were approved as outlined.

2. **Updates**

a. **OnCore** (Sandefur): OnCore version 15.4 upgrade went live on June 3rd. There were only a few minor user issues that were easily resolved in the transition. The Financials Pilot is scheduled to begin in late July 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 2019.
2. Completion of phased roll-out by December 2019.

b. **Clinical Research Career Ladder** (Marchant): The CCC Pilot is expected to be completed this month when Central HR returns the Ladder titles to CCC leadership for review. The implementation of Phase I has begun with the identification of ~50 staff across 8 orgs within the School of Medicine. Data collection is underway with mapping to be conducted in July. The initial communications across campus, which began in earnest in February, were completed in May with a presentation to the Staff Council. A question was relayed from Tuesday's PI Subcommittee meeting about the anticipated timeline of the full implementation. Mr. Marchant shared information gleaned from the Pilot and how Phase I is expected to set the course relative to the timeline but it is already known that under the current process, it will be mid-2020 before all

employees are mapped, which numbers between 600-700. The desire to expedite the process was expressed and will be explored to determine if it is feasible.

Action:

1. Begin mapping Phase I staff.
2. Explore ways to expedite the process to complete it prior to mid-2020.

- c. **PowerTrials Research Summaries** (Marchant): Current data from May 31st reflects a 93% utilization rate in terms of trials registered in Cerner as having Research Summaries. The lone outlying Department has not yet engaged, and that Department will be approached through another venue.

Action:

1. Get final Department engaged in the initiative.

3. **Access to IMPACT and Signature Authority for Orders** (Bates, unable to attend): Mr. Bates will distribute the guidance document for review on Friday June 14th as identified as an Action Item from May's meeting.

Action:

1. Mr. Bates will distribute a guidance document for privileges within IMPACT to help manage clinical trial participant activities in the record.

4. **Subcommittee Reports**

- a. **Screening & End of Study Position Statement** (Marchant): A specific exception to the general position that screening activities are charged to the research account was discussed. In the circumstance whereby a patient presents to the ED with an acute event that is managed according to standard of care protocol, the activities necessary for appropriate treatment and billed to the patient's insurance might also fulfill the purposes of the clinical trial protocol's screening procedures. In such an instance, these activities would not be billed to the research account and double billing would be avoided.
- b. **TTA: IRB Metrics** (McClintock): Mr. McClintock led a discussion of areas in which he has identified within the Office of the Institutional Review Board (IRB) where improvements can be made to reduce the 'throughput' time for reviews. These included the following:
- i. E-Forms for 'personnel only' changes are to be implemented quickly, and should be ready for beta testing within the next couple of weeks. The eForms for the rest of the IRB submissions documents are being developed concurrently with the personnel eForm and will be rolled out in steps.
 - ii. An issue has been identified relative to data access within IRAP. They are exploring ways to better extract the data in a reportable format to understand trends to identify bottlenecks which may be addressed in streamlining processes.
 - iii. They have begun fast-tracking certain types of amendments which require less scrutiny.

- iv. They are identifying various 'pathways' so that staff are reviewing submissions in a more balanced and focused manner instead of taking a 'first in, first out' approach.
- v. They are working to build infrastructure to support new and ongoing commitments based on the Single IRB model and the regulatory requirements for single IRB review for cooperative trials.
- vi. Given recent staffing departures, training and development of staff will be increased to ensure adequate coverage in the event of future changes to avoid drop-off in regulatory and institutional knowledge.
- vii. An advisory group, the Human Research Advisory Committee, to advise the VPR on identifying and prioritizing policy updates, procedural changes, and opportunities for improvement. Membership will be sought from the Schools / College and will be proportionally representative of the human subject's research community.

There was a discussion about a recent study from Johns Hopkins about conducting real-time reviews which led to decreased overall review time. This has been done intermittently at UAB in the past, acknowledging the limitations identified by the authors of the study. The importance of assigning timelines to each area of improvement was stressed as well so that expectations can be set across campus for how the IRB plans to move these items forward and the CTAC can assist in those efforts.

Action:

- 1. Assign timelines for the various areas of improvement to be carried out.
- 2. Provide monthly reports on those efforts to CTAC so that it may assist in communicating those improvements across campus.

5. Additional Topics

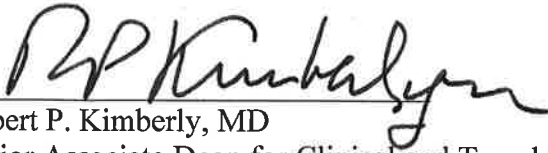
- a. **Effort on Clinical Trials-Operating Accounts** (Kimberly): Dr. Kimberly reported that there are efforts underway to ensure appropriate PI effort is applied to clinical trial accounts in the event that an Operating Account is not in use. Continued communication with departmental leadership and clinical investigators is planned.
- b. **Clinical Investigator Training Program (CITP) and Continual Training Updates** (Kimberly): Dr. Kimberly announced that Dr. Saleh will be leaving UAB to take a position at Aga Khan University in Nairobi, Kenya. With his impending departure, the Clinical Investigator Training Program that he has led in recent years with the active participation of others is being evaluated to determine how to best continue its operation to ensure investigators are getting the proper training needed to be successful in their role conducting clinical trials. Leadership transition for the CITP will occur during the summer months.

Action:

- 1. Submit your ideas for the training program to Drs. Kimberly and Joiner and the re-formatting of CITP will be discussed more in depth at the July meeting.

6. **Next meeting:**

- a. July 10th, Noon. FOT 12 Large Conference Room

A handwritten signature in black ink, appearing to read 'R.P. Kimberly', written over a horizontal line.

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