

## Clinical Trials Administration Committee (CTAC)

### Meeting Minutes

December 1, 2021

12:00 – 1:00 pm

### Zoom Conference Call

In attendance:

Bertram (OCCC)	Kimberly (SOM/CCTS)
Boles (SOM)	Lee (DOM)
Cotten (OVPR/OSP)	Logan (University Compliance)
Farough (Health System)	Marchant (CTAO)
Fitz-Gerald (CCTS)	McClintock (OVPR/IRB)
Gilbert (SOD)	Miller (OVPR)
Gordon (HSIS/CCTS)	Nichols (SOO, OVPR)
Goss (SHP)	Rizk (CTAO)
Horn (OVPR)	Sandefur (OnCore)
Joiner (DOM)	Schwebel (CAS, OVPR)

Unable to attend:

Bates (Health System Compliance)	Gutierrez (CCTS)
Busby (OCCC)	Redden (SOPH)
Croker (CCTS)	Smith (SON)
Dransfield (DOM)	Wasko (SOB)

Guests: Bradford (CCTS)

1. **Review of CTAC minutes from November 3<sup>rd</sup> meeting:** The minutes were reviewed and approved.
2. **Introductions** (Kimberly): Dr. Kimberly opened the meeting by introducing Dr. Amy Goss from the School of Health Professions as its new representative following Dr. Motl's departure. Dr. Goss stated that she appreciates the opportunity to work with the committee and that her primary research focus is in conditions related to nutrition such as Type 2 Diabetes and Non-alcoholic Fatty Liver Disease.
3. **Updates**
  - a. **OnCore** (Sandefur): Mr. Sandefur stated that the previously discussed process change which consolidated submissions to the CCTS, Clinical Billing Review, and the OnCore Calendar Service went live on November 15<sup>th</sup>. He also mentioned that testing has been completed on the latest version of OnCore with the upgrade slated to go-live on Monday December 13<sup>th</sup>. Following updates, Dr. Kimberly announced that Mr. Sandefur would be retiring at the end of the month and thanked him for all his efforts in bringing OnCore Enterprise to fruition. Mr. Gordon and Dr. Bertram echoed those comments as Dr. Bertram reminded the committee that Mr. Sandefur was also responsible for implementing OnCore at the OCCC back in 2009. Everyone wishes Mr. Sandefur the best of luck with his future pursuits.

#### **Actions:**

1. Finalize the annual upgrade of the software this month.
  2. Continue with accrual initiative.
- b. **IRB-Advarra Engagement** (McClintock): Mr. McClintock shared slides (attached) that were recently presented to the Faculty Senate which displayed activities pursuant to improving operations with the OIRB. In terms of staffing, they have now filled all but 2 positions and are continuing to recruit. The backlog of HSPs pending review has been essentially eliminated with the assistance from Advarra. Even with the 2 vacancies, the OIRB is holding a steady state relative to its review times as reflected by data that was shared. Given the recent improvements enacted in processes that were initiated by Mr. McClintock and supported by Advarra, the IRB expects to maintain efficient

through-put rates that are in alignment with UAB's expectations on 'time to activation'. Dr. Gilbert congratulated Mr. McClintock on the heroic efforts to improve operations during his time at OIRB with Mr. Miller seconding those comments.

**Actions:**

1. Complete elimination of review backlog through Advarra's effort until contract completion.
2. Maintain work-flow process improvements and accelerated through-put rates relative to TTA to ensure efficient operations.

- c. **myUABresearch** (Cotten): Ms. Cotten stated that the Scope of Work (SOW) is still being refined with the vendor InfoEd which will outline the implementation of the eRA system. The staged approach will begin with the Conflict of Interest (CIRB) module. She also noted that the plan is to migrate 7 years worth of data from the existing system with the remainder going into an archive file. Ms. Cotten also reminded the committee that the Research Administration Forum (RAF) is being held later in the day at 3:00pm and that everyone is invited to attend with registration required. There have been ~400 registrants with 25-30% of those being faculty. Following the presentations, the VPR website will house information from the RAF including slides, supplements, surveys, etc. with further information available in *Research Matters*.

**Action:**

1. Monthly reports to continue until completion of implementation across all modules.

- d. **Lunch & Learn (12/14) Topics** (Fitz-Gerald): Ms. Fitz-Gerald announced that the next quarterly CCTS Lunch & Learn will be held on Tuesday December 14<sup>th</sup> at 11:30am. Updates will be provided by a number of institutional offices such as the IRB, CTAO, OSP, RIO, OnCore, PowerTrials, etc.

**Action:**

1. Send any potential topics for discussion on the 14<sup>th</sup> to [Ms. Fitz-Gerald](#) for inclusion.

4. **Accrual Initiative** (Kimberly): Dr. Kimberly reported that the workgroup continues its regular discussions which most recently have focused on accrual reports, development of recruitment plans and data mining of the EMR. The initial draft of the accrual report based on OnCore data is available for individual studies to be reviewed by the respective PI and study team. An additional report, which will display all accruing studies in a given therapeutic area with current state of recruitment relative to the planned goal for comparison, is in development. Secondly, the engagement of a recruitment specialist within CRSP who can assist with recruitment plan development will start in January. Contact information will be available at the next meeting. Thirdly, Dr. Rizk outlined recent discussions with a vendor named [IllumiCare](#) to improve data mining capabilities within the EMR. A pilot study of the use of the IllumiCare product in a few clinics to assess its capabilities and potential value to the recruitment process is planned.

**Action:**

1. Disseminate messaging relative to recruitment specialist availability to colleagues in your area.

5. **Guidance for Data Coordinating Centers** (Nichols): Dr. Nichols noted that the workgroup is currently meeting to identify the activities which include, but is not limited to, Legal, Financial Affairs, and Regulatory. The roles and responsibilities across these areas pertain to the challenges with getting these types of centers initiated. The working group is looking at 'use cases' to better understand not only the challenges lie but also the potential opportunities for improvement. Dr. Kimberly acknowledged the gap in understanding across the institution about some of the concepts terms involved.

6. **New Business/Open Floor:** Dr. Kimberly announced that with Mr. Sandefur's impending retirement, a position has been posted. Any interested parties should be directed to apply [here](#).

7. **Next meeting:** January 5<sup>th</sup> (Zoom meeting)



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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