Clinical Trials Administration Committee (CTAC)
Meeting Minutes
December 9, 2020
12:00 – 1:00 pm
Zoom Conference Call

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

1. **Review of CTAC minutes from November 4th meeting:** The minutes were reviewed and approved.

2. **OnCore Phase 2** (Sandefur): Mr. Sandefur reported that Phase 2 of OnCore Enterprise implementation for industry-sponsored trials without clinical billables through the UAB Health System has begun. Based on survey data, it is expected that the utilization of the OnCore CTMS will grow substantially in the coming year. Dr. Gilbert asked for clarification of the clinical trials requirement for upload into ClinicalTrials.gov which in turn drives upload into OnCore. Dr. Motl expressed interest in using OnCore for clinical studies that might not met the formal definition of a clinical trial.
   Actions:
   1. Continue Phase 2 of implementation for industry-sponsored clinical trials without billables.
   2. OnCore team follow-up with Dr. Motl regarding the benefits of using OnCore for all studies.
   3. Continued Financials implementation to enable the use of OnCore for budgeting/invoicing within trials.

3. **Research Administration Process Improvement (RAPID) Metrics: OSP** (Cotten):
   Ms. Cotten announced that Dr. Motl will serve as the Chair for the Research Administration Network Group (RANG). She reviewed a list of proposed metrics being considered for OSP and emphasized the importance of industry-sponsored clinical trials. She noted the importance of ensuring that what is intended as a metric is actually obtained going forward. She also introduced the concept of "premium services" through which units wanting dedicated OSP officers to facilitate review could provide funds to support that officer. Ms. Mack noted that the SOM has initiated a 'shared services' model for research administration within the School across Departments and suggested that further discussion of both models would be helpful. The issue of different performance standards for regular and "premium" services was raised for further discussion.

Ms. Cotton noted that the RFP process for a new research administration system that would upgrade or replace the current InfoEd IRAP system was underway.

Actions:

1. The metric subcommittee to meet virtually for review of defined metrics and establish benchmarks against which they will be measured for success. Volunteers in November included Ms. Horn, Dr. Croker, Mr. Miller, Mr. McClintock, Dr. Rizk, Dr. Gilbert, Mr. Marchant, and Ms. Busby.
2. OSP to track metrics with regular updates to CTAC on progress made throughout the coming year.
3. RAPID Task Force, chaired by Dr. Vickers and Brown, to meet regularly to assess progress.

4. **Research Administration Process Improvement (RAPID) Metrics: IRB** (McClintock):
Mr. McClintock discussed ongoing efforts in the IRB with input from HRAC. Mr. McClintock mentioned two metrics of primary interest: 1) pre-review time, and 2) overall time to IRB approval.

   Mr. McClintock also reported on a meeting with WCG, the host company for the WIRB. WCG has apparently revised its software platform which will not allow the IRB to directly upload protocols for WIRB review. Recognizing that this change runs counter to the pilot program with the O'Neal CCC, Mr. McClintock is assessing options with WCG to retain the efficiencies realized by direct upload by the IRB. Mr. McClintock also noted the with the introduction of eForms has enable deployment of several staff members to tasks other than keyboard entry, which has helped to facilitate IRB efficiency.

   Mr. McClintock reported that several members of the CTAC met with WCG to review performance metrics provided by WCG, noting that for initial expeditied reviews, protocols the average approval period for WIRB was 21 calendar days in total. Of the 21 days, 5 days were with WIRB and 16 days were with UAB study teams either revising original submissions OR responding to WIRB reviews. It was noted that compared to 4 other peer institutions, this 16 day time period at UAB was 2-3 times longer than comparator institutions. WCG will send UAB these data and also committed to reporting these metrics to UAB at least quarterly. Dr. Kimberly thanked Mr. McClintock for the IRB's work and reminded CTAC that, from a sponsor's perspective, the integrated total Time-to-Activation is the most important metric.

   Actions:
   1. Mr. McClintock to continue to work with WCG on digitally enabled efficiencies in the WIRB review process.
   2. Mr. McClintock to track metrics as presented with regular updates to CTAC on progress made throughout the coming year.
   3. Mr. McClintock and others to track WCG metrics reporting quarterly and to share data with CTAC and other relevant committees.

5. **New Business/Open Floor** (all): None.

6. **Next meeting:** Date in January to be determined (Zoom meeting).

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