Clinical Trials Administration Committee (CTAC)
Meeting Minutes
September 2, 2020
12:00 – 1:00 pm
Zoom Conference Call

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

1. **Review of CTAC minutes from July 1st meeting:** The minutes were reviewed and approved.

2. **OCCC-Huron Feedback** (Sleckman): Dr. Kimberly introduced Dr. Sleckman who began his tenure at UAB as the Director of the O'Neal Comprehensive Cancer Center (OCCC) in January 2020. Dr. Sleckman emphasized that clinical trials are a major point of emphasis in the overall mission of the OCCC. The OCCC is expected to place ~10% of its patients at a minimum on clinical trials. With about 4,000 patients per year, that bnchmark translates to ~400 accruals with the goal of up to 20% (~800). Dr. Sleckman presented trend data which reflected a decline in trial accruals over the past few years reflecting <10% so improving accruals is a point of emphasis for all faculty within Oncology. Dr. Kimberly reminded the Committee that the NIH/NCATS also looks at clinical trial accruals when reviewing the CCTS in its annual reports and competitive renewals. The importance of advancing knowledge through a vigorous clinical trials portfolio is one shared across the institution. Based on information gathered earlier this year as part of the Huron engagement (surveying the 70+ faculty and 50+ staff but also personal interviews with over 60 people across the research enterprise on campus), initial feedback on August 10th denoted 2 primary points of interest to improve clinical trial operations. Huron noted that UAB's TTA for oncology studies showed 215 days to activate a trial with the gold standard being <100 days. Dr. Sleckman presented data from Huron with a graph which demonstrated performance by several other CCC's which was closer to, if not better, than the

standard benchmark. He noted that a serial approach to the steps of trial activation was likely less efficient that a parallel process, and conversations with institutional leadership to address this issue are underway. The second primary issue noted by Huron pertained to the electronic administrative research system (IRAP). Discussions with InfoEd, the IRAP vendor, have been underway for some time, but have been slowed by COVID's arrival. Dr. Sleckman stated that a detailed report is expected from Huron soon and he will distribute it to any wishing to see, as we work together to improve operations relative to clinical trial activation.

Actions:

1. Continued discussion of process improvements in various administrative offices to drastically shorten TTA.
2. Dr. Sleckman to distribute Huron report upon receipt.

3. **CITP-on-the-Go** (Rizk): Dr. Rizk discussed the continued efforts to train investigators across campus through the Clinical Investigator Training Program (CITP). The twice a year (Spring & Fall) schedule has been disrupted by Dr. Saleh's departure for a new role in Kenya at Aga Khan University and by the change in business operations due to COVID. In response, a series of podcasts have created to help bridge the gap in information. Dr. Rizk shared a clip from one of them about the informed consent process. After each podcast, a survey may be completed to provide feedback on its utility in meeting learning objectives. As previously done, applications for the Fall CITP, planned for a virtual format starting in October, will require a letter of support from his/her Division Director or Department Chair (see attached agenda). The virtual platform will allow the program to expand attendees to 25 with the 16 from the Spring being included. Going forward, Dr. Rizk also noted that the timing of each program will be alternated so that all classes will occur in the morning during one seasonal session and evening the next to aid in meeting clinicians' schedule needs.

   Actions:

   1. Continue to promote the opportunity to take part in CITP going forward.

4. **R2Ops-Clinical Trials** (Kimberly): Dr. Kimberly opened the discussion by presenting a slide which depicted hospital discharge data from the UAB Health System. The graph displayed a dip in April caused by COVID as the hospital reduced operations temporarily to 'flatten the curve' and implement new safety measures. Discharges quickly rebounded as operations were reopened and have been steadily maintained near pre-COVID volumes. He then displayed OnCore visit data which showed a similar dip in activity in the Spring due to COVID but without a rebound as operations reopened in early summer. Discussion centered around measures that can be pursued to support R2Ops-HSR. Dr. Rizk shared her experience with Sponsors not wanting to reopen recruitment at UAB due to the state's continued issues in curtailing the community spread of the disease. Dr. Motl then shared his experience with participants not desiring to come on campus for research opportunities where ~25% have expressed concerns toward this end. He indicated that their efforts to engage participants remotely continues at a robust pace with little to no hindrance by the pandemic.

   Actions:

   1. Send additional ideas via eamil on how to assist with returning recruitment and ongoing retention efforts to pre-COVID levels to Dr. Kimberly and Mr. Marchant.

5. **Updates**
    a. **OnCore** (Sandefur): The implementation of OnCore, Phase 2, continues with the addition of clinical trials without billables to the health system. This implementation applies only to new trials. The OnCore team has distributed a survey to Departments to gain a sense of the volume in the coming year. Expectations are that up to 400 new trials may be added. In response to a question by Dr. Schwebel, Mr. Sandefur stated that once all current clinical trial teams have their trials without health system billables added, the OnCore team will then begin engaging units across campus not currently utilizing the system. Financials training continues with virtual overview courses. Mr. Sandefur shared a table which reflected those units that have already been trained as well as those who are upcoming. Dr. Rizk noted that note all units have been scheduled for training as yet.
    Actions:
        1. Continue Phase 2 of implementation for clinical trials without billables.
        2. Continue the Financials implementation to enable the use of OnCore for budgeting/invoicing within trials.

    b. **IRB/WIRB Process Extension** (McClintock): Mr. McClintock reported that, as part of the continuing pilot study, IRB staff submitted 5 submitted trials directly to WIRB via Connexus. University-wide implementation of this process change was scheduled for September but a change in IRB staffing has delayed the start by ~6 weeks. Mr. McClintock has worked with Mr. Marchant to devise an implementation plan, based on WIRB submission data, which constitutes 3 phases through the Fall. Additionally, Mr. McClintock discussed other efforts by the IRB to improve processes within the office as part of ongoing TTA efforts including the newly launched IRB eForm and integration of current systems such as IRAP and Connexus. Mr. McClintock pointed out that the change to the new eForm alone has allowed the office to move 2 FTEs to other duties creating greater efficiency in their operations.
    Actions:
        1. Following restaffing positions related to the WIRB submission process, Mr. McClintock and Mr. Marchant to implement direct submission from IRB to WIRB on a University-wide basis.
        2. Continue providing regular updates to CTAC on IRB approval data to understand trends over time so adjustments may be made as needed.

    c. **Communications-Trending in Trials (TnT)** (Kimberly): Dr. Kimberly reminded the Committee of efforts discussed early in the year to begin a new communication channel from the CCTS specifically to PIs. Following various efforts relative to content and timing since the initial launch of TnT, the plan is to provide a few terse points twice monthly via email. To ensure an appropriate and up-to-date distribution list of active PIs on campus, the CCTS is working with the CTAO to harmonize data. Dr. Croker showed the most recent TnT distributed and, along with Ms. Bradford, asked the Committee for ideas on content which will benefit the PIs' knowledge base.
    Actions:
        1. Send content ideas for inclusion in *Trending in Trials* to Ms. Bradford.

6. **New Business/Open Floor** (all): Dr. Kimberly reminded the Committee of the upcoming 'Lunch & Learn' scheduled virtually for Tuesday September 8th and that all are invited to attend.

7. **Next meeting:**
    a. October 7th at Noon. Zoom Conference Call (to be provided)

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