Clinical Trials Administration Committee (CTAC)
Meeting Minutes
October 7, 2020
12:00 – 1:00 pm
Zoom Conference Call

In attendance:

Bertram (OCCC)
Busby (OCCC)
Cotten (OVPR/OSP)
Croker (CCTS)
Farough (Health System)
Fitz-Gerald (CCTS)
Gilbert (SOD)
Gordon (HSIS)
Horn (OVPR)
Joiner (DOM)
Kimberly (SOM/CCTS)
Ladores (SON)
Marchant (CTAO)
McClintock (IRB)
Miller (OVPR)
Motl (SHP)
Nichols (SOO, OVPR)
Redden (SOPH)
Rizk (CTAO/CCTS)
Roberson (UAB Compliance)
Sandefur (OnCore)

Unable to attend:

Bates (Health System Compliance)
Dransfield (DOM)
Mack (SOM)
Nabors (DON/CCTS)
Schwebel (CAS)
Wasko (SOB)

Guests:

Bradford (CCTS)
Brown (OVPR)

1. **Review of CTAC minutes from September 2nd meeting:** The minutes were reviewed and approved.

2. **Research Administration Improvement Process** (Brown): Dr. Kimberly opened comments by reminding the Committee of Dr. Sleckman's discussion last month on the Huron visit and findings relative to institutional infrastructure which led him to introduce Dr. Brown as a guest attender to go over the various components of an evolving improvement process by the Office of the Vice President for Research. Dr. Brown began his comments by mentioning that his office receives feedback from a number of paths including the RANG and HRAC in addition to CTAC. He is actively compiling this feedback into an 'organic' report which includes each issue along with respective goals, progress to date, and further actions. Due to time constraints, he briefly went through a list of 9 items which included the following:
    i. Policy 005: This describes expectations surrounding sponsored projects which previously prohibited parallel processing during start-up activities. This especially impacted contract negotiations. The Policy was recently revised and approved with an effective date of October 1st. While awareness must be made at the System level, they are not awaiting an official approval by the Board.

ii. IRAP: A process was initiated several months ago to release a 'Request for Quotes' (RFQ) to vendors to find a suitable way forward in terms of a research administration system that meets the needs of the institution, but it was stalled due to COVID in March. Both Mr. Allen Bolton (Financial Affairs) and Dr. Curt Carver (Information Techology) have recently given approval to move forward with the RFQ and the plan is to do so this month.

iii. Central Office Personnel: Dr. Brown mentioned one metric that reflects 43% growth in research dollars over the past 5 years. In contrast to that, the staffing levels of central offices that support the infrastructure have not increased at nearly the same level. He acknowledged that while added resources will not solve all issues related to 'Time to Activation' (TTA), increased staffing will be part of the solution. They are currently assessing FTE levels and as a part of that exercise, recently assigned an OSP officer to the O'Neal Comprehensive Cancer Center full-time. He added that other assignments may be made in the future to similar areas where large volumes of research is conducted and that this is an ongoing evaluation as to its effectiveness. Another item relative to personnel is the ongoing turnover experienced among central offices. To help in this, they are working with Human Resources to conduct market analyses to ensure staff are compensated at fair market value to help reduce departures where compensation may be a driving force. Ms. Cotten also mentioned past temporary decreases in staffing such as maternity leaves which caused an increased workload on remaining staff where getting additional staff trained to manage the load was inefficient due to the temporality of the shortage and the time it takes to train staff. Mr. Marchant asked if outsourcing on a temporary basis to a group of trained professionals would be appropriate in such a circumstance to which Ms. Cotten replied that the inconsistent positions on certain institutional topics like indemnification made that option untenable for now but that could be a consideration in the future once resolved.

iv. Contract/Legal Review: There is an assessment underway to determine the institution's appetite for risk within the legal realm as a handful of sections in contract negotiations are routine sticking points such as indemnification and subject medical injury. It is thought that having standard guidance around these and other items for the OSP officers to enable triaging by complexity would assist greatly in reducing TTA. Discussions are currently underway with Huron to develop a UAB-specific toolkit to aid in this process.

v. IRB Submission: The ePortfolio suite was released in August which enabled the consolidation of 17 IRB documents into 1 'living' document. The upcoming University-wide introduction of a revised process for WIRB submissions was also mentioned with additional details coming later in the meeting (6b).

vi. Consent Language: Work is currently underway with Legal to better define standard language relative to Subject Medical Injury, use of specimens, and other items to increase speed in reviews.

vii. Reliance Agreements: They are currently working to ensure appropriate agreements in place with external IRBs such as Advarra to enable swifter processes during multi-site trial initiation.

viii. They are reviewing lists across offices to ensure Principal Investigators are identified to reduce redundancies.

ix. Training: OSP has released a series of modules to address common issues identified across Departments to increase knowledge by submitters. IRB recently hired a Trainer as well and is anticipated to release a similar series for regulatory submitters. Ms. Cotten began holding office hours at Faculty Office Tower in 2019 to assist investigators with their issues. This had great attenance for about 6 weeks. Due to COVID, these have not been taking place but the thought is to reintroduce it virtually via Zoom and to advertise through venues such as *Trending in Trials* and *Research Matters* to raise awareness by the investigator community.

Following the review of the items by Dr. Brown, Dr. Kimberly asked if the metrics relative to TTA going forward could be made available to maintain transparency of progress to which Dr. Brown agreed.

Actions:

1. Dr. Brown to circulate the Research Adminstration Process Improvement document (current updated version attached).
2. Dr. Brown to regularly release the TTA data to keep the research community apprised of progress.
3. Ms. Cotton to re-establish 'office hours' to enable investigators to meet to discuss contract issues.

3. **R2Ops-HSR** (Nichols): Dr. Nichols reported that the latest update to the R2Ops Guidance was released on September 25th. A key item of note is that pre-approval is no longer required for in-person monitoring visits though remote visits are still the recommended method (issued 9/25/2020). A second update relates to the issue of research participants' exposure to COVID-19 through their involvement in on-site/in-person research activities. Updated R2Ops HSR guidance will be issued within a week of the CTAC meeting to address the latter scenario.

   Actions:

   1. Continue to monitor the University's R2Ops Guidance page for updates.

4. **Trending in Trials (TNT) Storyboard** (Bradford): Dr. Kimberly reminded the Committee of recent changes to TNT based on comments by investigators to provide a more pithy overview of updates of which they need to be aware. Ms. Katie Bradford who oversees its creation and distribution presented a biweekly publishing schedule which covered the next several months. Each edition included 3 items that were color-coded by theme with a rotating schedule (see attached); suggestions from the Committee on additional topics are welcome. Dr. Nichols asked if recruitment information could be included, and she would reach out to him directly for details.

   Actions:

   1. Send additional ideas for inclusion in TNT via email to Ms. Bradford at ksbrad@uab.edu.

5. **CIRTification for Community-based Investigators** (Kimberly): The CTSA program continues to provide resources to instituions to aid in their clinical and translational research initiatives. The website shared by Dr. Kimberly includes Best Practices and is managed by the University of Illinois in Chicago.

6. **Updates**
    a. **OnCore** (Sandefur): Mr. Sandefur reported that 19 units have been trained so far through the Financials implementation. Dr. Nichols asked for the definition of a 'unit' to which Mr. Sandefur reported that it may represent a Department or Division within our organization. Within OnCore a "unit" signifies a Management Group, of which there are 28. Phase 2 of implementation (clinical trials without Health System billables) will begin in early December with piloting underway in Infectious Diease and Nephrology-CTG. Dr. Kimberly asked if there had been any impact on OnCore operations due to COVID to which Mr. Sandefur replied that given the nature of IT work, the transition to remote operations (working from home) has been seemless and that they regularly track activity through daily reporting and weekly meetings. The OnCore team is also currently working with Ms. Busby and the O'Neal CCC staff to clean-up old data in the Oncology Library and to harmonize processes across Enterprise and Oncology.
    Actions:
        1. Continue Phase 2 of implementation for industry-sponsored clinical trials without Health System clinical 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 there has been a total of 6 trials submitted directly by IRB staff to WIRB via Connexus. University-wide implementation of this process change will begin on November 16th due to a 2-week delay given an AAHRPP site visit on November 12/13th. An introductory Zoom presentation will be held in early November with the organizational groups on campus initially implementing this process.
    Actions:
        1. Initiation of Phase 1to begin on November 16th.
        2. Continue providing regular updates to CTAC on IRB approval data to understand trends over time so adjustments may be made as needed.

    c. **Lunch & Learn** (Fitz-Gerald): Ms. Fitz-Gerald reported that the next CCTS Lunch & Learn will be held at 11:30am on December 8th. Attendance during remote operations caused by COVID has continued to be good with 252 in attendance at the April presentation. Ms. Fitz-Gerald noted that she will include recent Agendas for distribution with the Minutes and that suggestions are welcome for additional topics on December 8th.
    Actions:
        1. Send topic ideas for inclusion at next Lunch & Learn to Ms. Fitz-Gerald at mfitzgerald@uabmc.edu.

7. **New Business/Open Floor** (all): Ms. Cotten mentioned recent queries by non-medical researchers about alternative ways to pay participants to the Greenphire ClinCard system. Mr. Marchant responded by stating that there has been ongoing discussion since Dr. Gilbert raised the point at a CTAC meeting in September 2019, that other options have been considered by the University but that none have currently met all the legal and financial needs which led to the implementation of Greenphire initially. Greenphire has announced that due to COVID, an

increased demand has presented itself due to remote visits during the pandemic and that in response they are working on an eCard solution to go along with ClinCards. Mr. Marchant has volunteered the University to serve as a pilot if needed due to its robust utilization of the system, and reported that the latest update from Greenphire indicated that an eCard option may be ready before 2021.

8. **Next meeting:**
    a. November 4th 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