Clinical Trials Administration Committee (CTAC)
Meeting Minutes
April 7, 2021
12:00 – 1:00 pm
Zoom Conference Call

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

1. **Review of CTAC minutes from March 3rd meeting:** The minutes were reviewed and approved.

2. **Updates**

   a. **RAPID Taskforce** (Brown): Dr. Brown discussed the RAPID (Research Administration Process Improvement & Design) initiative and its website (found here.). The Taskforce's goals and recent activity include Policy 005, Project eRA, IRB ePortfolio, and various performance metrics. Dr. Gilbert asked about discussions with Financial Affairs regarding an eCard method of payment to research participants. Dr. Bertram asked whether the metrics displayed for RAPID aligned with the RCM service level standards; Ms. Cotten and Mr. Miller confirmed that they would be.

   Actions:
   1. Dr. Brown to follow-up on Dr. Gilbert's query with Financial Affairs on eCard payment mechanisms and its relationship to the University's interpretation of federal regulations.

   b. **Project eRA** (Cotten): The advisory group to Project eRA, which is the effort to identify and implement a new Research Administration system, met last week. The Project is overseen by an Executive Steering Committee, Advisory Group, a Core Team, and an Implementation Task Force. Work with Procurement has enabled vendor identification through a reseller process as opposed to a typical bid process in order to save time and avoid having to award the project to the lowest bidder, which may not be conducive to best meeting the needs of the institution. The vetting process with vendors is expected to be completed by this summer and the total timeline for implementation is to take 1-2 years for all modules. Monthly updates will be provided to the Committee to keep everyone apprised of progress.

   Actions:
   1. Identify a vendor with whom to partner in implementing the new eRA system.
   2. Provide monthly updates to CTAC on progress toward full implementation of all modules.

c. **IRB Update** (McClintock): Mr. McClintock apprised the Committee that the IRB is moving forward with updating consent templates in conjunction with WIRB and Advarra to bring greater efficiency in study start-up with an exected completion later this month.

Actions:

1. Consent language discussions to be completed in April with WIRB and Advarra.
2. Continue reviewing internal processes to further enable efficiencies in operations.

d. **OnCore** (Sandefur): OnCore Financials training continues with Departments, Divisions and clinical study units; the target for completion is July 1st. Wave 2 of Phase 2 of OnCore Enterprise implementation for industry-sponsored trials without clinical billables through the UAB Health System is scheduled for a May 1st go-live with 5 research units. Wave 3 will come next on August 1st with 11 units. Mr. Sandefur discussed the ongoing collaboration with representatives from PowerTrials, Clinical Billing Review, and the Billing Office to re-engineer processes to create a more streamlined approach for information flow during trial initiation and management surrounding billable procedures through the Health System. This effort will be discussed at the April 13th CCTS Lunch & Learn by Emily Bruer (OCR) and Ashley Specht (CBR). The updated Oncore ChargeMaster awaits finalization of hospital pricing. This effort has an annual update target of March 1st. Mr. Sandefur noted that the OnCore team will assist in an upcoming Cerner update given the interface between the 2 systems for things such as the Master Patient Index and PowerTrials.

Actions:

1. Continue Phase 2 of implementation for industry-sponsored clinical trials without Health System billables.
2. Continue Financials implementation to enable the full use of OnCore for budgeting/invoicing within trials.
3. Finalize process re-engineering for information flow relative to billable services through the Health System.
4. Complete the annual ChargeMaster update upon receipt of pricing from University Hospital.

3. **Procedural eConsent/Remnant Tissue** (Bates): The eConsent for procedures and for remnant tissue available following SOC procedures went live on April 2nd. The new process utilizes iPads to provide the pertinent information and document the patients' consent to the procedure. Additional units such as the Emergency Room will be incorporated into the process going forward over time. The documentation is stored in the electronic medical record (EMR). Discussions are underway with Callahan Eye Hospital on how to integrate their NextGen EMR into the process.

Actions:

1. Work with Callahan HIM to ensure a seamless electronic process for capturing consent for securing remnant tissue in medical procedures and storing it in the EMR.

4. **Trial Accrual: Strategies for Improvement** (Kimberly): Dr. Kimberly reiterated the importance of adequate accrual as discussed in last month's CTAC meeting by stressing the importance of avoiding non-informative trials. He asked several CTAC members to provide brief updates on various discussions that have been held on different components of the recruitment / accrual to trials process:

a. **Population-based Recruitment Platform** (Nichols): Dr. Nichols discussed a digital platform (EDICT: Enhancing Diversity In Clinical Trials) developed by Acclinate, a start-up based in Birmingham. The electronic platform engages under-represented groups and communities regarding health and disease, including clinical study opportunities. Discussions are underway to better understand the benefits of the platform in enhancing recruitment and enrollment to UAB's population-based clinical research. Dr. Bertram mentioned that Dr. Monica Baskin may be interested in learning about Acclinate given her role in Community Engagement. Dr. Schwebel mentioned the success that the Department of Psychology in the College of Arts & Sciences (CAS) has had in using social media (specfically Facebook and Instagram) to recruit minority participants

to their studies. Recently CAS has partnered with a vendor called Splash Clinical to assist in these efforts.

b. **Participant-initiated Contact** (Kimberly): Dr. Kimberly discussed the ongoing collaboration with XpertTrials and how it is being utilized by UAB to direct patients to trial opportunities registered in ClinicalTrials.gov. UAB Medicine, CTAO and CCTS websites include links to the search portal (found here).

c. **Patient-based EMR Mining** (Rizk): Dr. Rizk reviewed discussions with multiple vendors to learn more about their ability to use natural language processing (NLP) to search EMR data (structured and unstructured) for patients meeting inclusion/exclusion criteria associated with specific protocols; real-time alerts at the POC for clinical providers would be possible. Actual functionality needs to be explored as well as issues related to access to protected Health System data, potential costs, and workflow adoption.

d. **Embedded Recruiters/Navigators in Clinics** (Busby): Ms. Busby discussed collaborative efforts with the Cancer Service Line in University Hospital to assist in identifying patients who may be likely candidates for clinical trials in the O'Neal Comprehensive Cancer Center. By engaging with nurses and navigators in the Hospital, the researchers in the OCCC are expected to have greater success in meeting one of their NCI-driven goals of more effective accrual of patients to trials.

e. **Recruitment Plans** (Kimberly): The creation of recruitment plans is expected to be included in upcoming discusions.

Actions:

1. Dr. Kimberly and Mr. Marchant to coordinate a subcommittee in the near future for review of efforts in improving trial accrual and formulating a plan of action assisted by the new accrual reports being created in OnCore.

5. **New Business/Open Floor** (all):
   - Dr. Nichols spoke to Financial Affairs about the prospect of increasing in-state travel reimbursement, which was a topic originally raised by Dr. Gilbert in January. A PI may contact Ron Collins or Stephanie Mullins to discuss direct-billing of in-state hotel expenses expected to be utilized for multiple nights by the employees in their University-required travel.
   - Mr. Marchant noted that the consent form(s) for the use of Uber in providing transportation for research study subjects are being discussed internally with Legal. Updated information will be circulated via the Trending in Trials newsletter as well as the upcoming CCTS Lunch & Learn on April 13th.

6. **Next meeting:** May 5th (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