Clinical Trials Administration Committee (CTAC)
Meeting Minutes
May 5, 2021
12:00 – 1:00 pm
Zoom Conference Call

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

1. **Review of CTAC minutes from April 7th meeting:** The minutes were reviewed and approved.

2. **Updates**

   a. **Project eRA** (Cotten): Ms. Cotten reported that the Request for Information (RFI) went out to seven vendors on April 15th. Responses have been received from all but one so far. The vendors will present two-hour demos in June, at which time they will outline responses to specific questions by the University in addition to allocated time to delve into other areas of their capabilities that they wish to highlight. In preparation for this, there will be a meeting with the core team next week.

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

   b. **IRB Update** (McClintock): Mr. McClintock updated the Committee on the progress with updating consent templates in conjunction with WIRB and Advarra. Due to a large number of informational requests by Advarra, the IRB has decided to separate the release of the 2 templates and move forward with WIRB independently to avoid its delayed release, which is scheduled for later this month. The IRB will continue working with Advarra to address their questions. Relative to ongoing improvements in operational efficiency, Mr. McClintock outlined 3 areas based on feedback received from the research community related to eForms:

   i) Intake Process
   ii) 'Section 5' of the eForm that opens up the appropriate application pathways (exempt, expedited, etc.)

iii) Uploading documents within the eForm

Based on feedback received so far, it was determined that more robust guidance is needed for eForm completion, and would benefit less experienced submitters. Dr. Kimberly suggested that CTAC members serve as advisors to ongoing efforts, which Mr. McClintock welcomed.

Actions:

1. Consent language discussions to be completed in May with WIRB.
2. Consent language discussions to continue with Advarra until resolution.
3. Continue reviewing internal processes to further enable efficiencies in operations with CTAC members providing counsel on efforts as needed.

c. **OnCore** (Sandefur): OnCore Financials training continues across campus with July 1st as the target for completion. Wave 2 of Phase 2 of OnCore Enterprise implementation for industry-sponsored trials without clinical billables through the UAB Health System went 'live' on May 1st in 13 Management Groups. Mr. Sandefur mentioned that the ongoing collaborative efforts among 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 continues with a Pilot in 2 Departments (Dermatology & Urology). The updated Oncore ChargeMaster, which is a consolidated list of research prices, continues refinement with ongoing compilation of information from areas such as Hosptial Finance and the Cancer Center. Per Mr. Gordon, the tentative date for completion is July 1st.

Actions:

1. Continue Financials implementation to enable the full use of OnCore for budgeting/invoicing within trials.
2. Finalize process re-engineering for information flow relative to billable services through the Health System.
3. Complete the annual ChargeMaster update.

3. **Procedural eConsent/Remnant Tissue** (Al Diffalha): Dr. Kimberly reminded the Committee of last month's presentation about eConsent by Mr. Bates and its importance. He then introduced Dr. Sameer Al Diffalha from Pathology to provide an overview of the process (see attached slides). Dr. Al Diffalha started by outlining the Mission and Rationale for the UAB Tissue Biorepository (TBR) which included optimizing patient care, meeting NIH expections, and integrating digital platforms within the institution. He continued by providing some history on tissue banking at UAB before discussing the process for faculty investigators to both request and store tissue with TBR which included not only the workflow, but also the appropriate approvals needed to do so. To aid in this effort, a new website has been created which includes a Service Request Form.

   Action:

   1. Communicate to Investigators across campus the capabilities of TBR to raise awareness.

4. **Training Strategies & Expectations** (Fitz-Gerald): Ms. Fitz-Gerald outlined the various components and timing of trainings in the Clinical Research space for faculty and staff throughout their careers (slides attached). She then elaborated by providing more details on what each conveys to deepen one's understanding, given their knowledge base. Ms. Fitz-Gerald then gave the Committee a tour of the revised training page within the CCTS website where these offerings may be found and highlighted the growing number of videos that are being generated to assist employees in accessing on-demand learning, which has become paramount with remote operations due to COVID. She also shared the Clinical Trials Kiosk, an online menu of tools and guidance to support clinical studies. Following this overview, Dr. Kimberly asked whether these trainings were 'required' learning by the Clinical Research community to which Ms. Fitz-Gerald replied that they were not, but rather only 'recommended' at this time. A discussion then ensued on how to incent clinical researchers to take part in trainings. A workgroup will be comprised to address the issue. Additionally, Ms. Fitz-Gerald mentioned that suggestions for ways to improve knowledge gaps are also welcome.

Action:

1. Dr. Kimberly and Ms. Fitz-Gerald to coordinate a workgroup to determine how to improve participation in training opportunities in clinical research as well as identify additional knowledge areas for training. All CTAC members interested in participating should email them to opt-in.

5. **Trial Accrual Strategies** (Kimberly): Dr. Kimberly reminded the Committee of the ongoing effort to improve trial accrual as discussed at the last couple of meetings. A workgroup will provide recommendations based on the presented preliminary work conducted in recent weeks.

6. **New Business/Open Floor** (all): No new business offered at this time.

7. **Next meeting:** June 2nd (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