Clinical Trials Administration Committee (CTAC)
Meeting Minutes
January 11, 2023
12:30 – 1:00 pm
Zoom Conference Call

In attendance:	Bertram (O'Neal)	Kimberly (SOM/CCTS)
	Boles (SOM)	Lee (DOM)
	Brown (Health System)	Marchant (CTAO)
	Croker (CCTS)	Mike Matthews (OVPR)
	McClintock (IRB)	Miller (OVPR)
	Fitz-Gerald (CCTS)	Nichols (SOO, OVPR)
	Gilbert (SOD)	Pitts (Health System)
	Gordon (HSIS/CCTS)	Schwebel (OVPR)
	Horn (OVPR)	Smith (SON)
	Joiner (DOM)	
Unable to attend:	Goss (SHP)	Rizk (CTAO)
	Jackson (Health System Compliance)	Specht (OnCore)
	Logan (University Compliance)	Wasko (SOB)
Guests:	Katie Bradford (CCTS)	
	Mark Bolding (Radiology)	

1. **Review of CTAC minutes from November 16th meeting:** The minutes were reviewed and approved.

2. **Updates**

   a. **OnCore** (Gordon): Mr. Gordon announced that the new Clinical Trial Billing Notice (CTBN) platform titled *CTBN Central* launched on Monday January 9th with the intent to improve not only the prior site that was outdated, but to also enable both back-end (Billing offices) and front-end (Departments) users to have access to shared information. Orientation on the new tool is underway. As a reminder, the CTBNs are used to convey billing designation information for the activities conducted within the Health System for clinical trials. This ensures appropriate payors are billed for these activities.
   Actions:
   1. Continue weekly OnCore Q/A sessions to provide ongoing training to the clinical research community.
   2. Identify the manageable target percentage of late 'occurred' visit entries and strategies for reducing delayed CTBN submissions.
   3. Include Accrual Reports on the February CTAC agenda for further discussion.

   b. **IRB Metrics & Process** (McClintock): Mr. McClintock noted that review time for submissions remains steady. Investigation has been conducted to determine the reason behind the 'plateau' effect and what interventions may occur to continue improvements in timing. A potential reason was outlined pertaining to ongoing training for onboarding new staff as well as existing staff in new roles. Mr. McClintock expects to see the training lessen as they move forward which will enable faster processing. Additionally, he outlined that 2 new positions have been requested. A Protocol Analyst II has been approved and recruitment is underway. An Assistant Director role is still under review. Both of these positions would expect to aid in review time as work continues to be

dispersed more widely. Lastly, Mr. McClintock touched on recent efforts surrounding guidance documents being drafted and reviewed for eSignature and Phone Scripts. These are circulated with the Minutes for committee feedback.

Actions:

1. Continue efforts to improve IRB throughput rates and enact process changes to enable such improvement.
2. Committee members encouraged to provide feedback to the IRB for ways to improve the submission forms/process by reaching out to Mr. McClintock.
3. Committee members asked to provide feedback to Mr. McClintock on guidance documents.

3. **Radiology Over-Reads** (Bolding): Dr. Bolding returned to give an update to the committee on progress made since his last report in September on the process for reporting incidental findings identified in radiographic images conducted in the context of clinical research studies. A detailed memo is included with the Minutes. In summary, Stage 1 has been completed to outline a process and identify next steps which brings the group to Stage 2 that will occur throughout 2023 with the expectation that modifications will be made in January 2024 based on what they learn. Additonal stakeholders will be engaged as they move forward, such as the IRB.

Action:

1. Dr. Bolding and the committee will move forward with drafted workflows and monitor process throughout 2023 and report back to CTAC later this year with an update of progress.

4. **Quick Notes** (multiple):
   a. **OSP National Search** (Schwebel): Dr. Schwebel, who chairs the search committee, reported that the search is underway to replace Ms. Melinda Cotten who retired in November. The University is working with the search firm LeadExec as a part of the process, which is looking nationally for a new leader in the role of Associate Vice President of Research and Executive Director of the Office of Sponsored Programs (OSP). Dr. Schwebel referenced the website for details on the process and search committee membership. February 9th was cited as the deadline for applications. After that, the committee will conduct online interviews with the top applicants and then whittle the list down to 3-4 for onsite interviews with an expected finalist by mid April. He expected the finalist to be in the role this summer at the earliest.
   b. **Project eRA** (Matthews): Mr. Matthews reported that the current research administration system (IRAP) no longer meets the needs of the University and will be replaced. Several ways to address this need have been discussed and multiple options are on the table for consideration at this point, such as acquiring a single system or going with multiple systems for a 'best in class' approach. As a reminder, this effort is in support of President Watts' institutional goal of obtaining $1 Billion in annual research funding within 5-7 years. A change in goal setting and priorities to better align with industry trial metrics is a part of this initiative, which means that better transparency through reporting is at the forefront of decision makers' minds. Mr. Matthews also mentioned that leadership expects to likely move forward with an accelerated, limited review process rather than full procurement in order to save time through the use of a resaler. The projected timeline for full implementation at this juncture is 2-3 years.
   c. **Accrual Project** (Kimberly)**:** Dr. Kimberly revisited several prior discussions in recent meetings that point to the need for better recruitment and retention of clinical trial participants. Some of these included Digital Media use, Recruitment Plans, and OnCore Accrual Reports. Several of these efforts can be found on the Clinical Trials Kiosk. Dr. Bertram inquired about the potential acquisition of an EMR-mining tool that uses AI or NLP for better cohort building to which Dr. Kimberly replied about ongoing vetting efforts by the University with several different vendors who have reached out over the past few years with solutions for sale. Dr. Bertram also reminded the group about the need to conduct rare disease studies to which special consideration must be given. Mr. Gordon replied that he will meet with Dr. Bertram offline to discuss ways to flag these studies in OnCore so they are more easily identifiable. Dr. Kimberly closed the topic by asking Ms. Fitz-

Gerald to remind the committee of the availability of study recruitment plans and feasibility assessment. For further questions or counsel, you may reach her at mfitzgerald@uabmc.edu.

5. **New Business/Open Floor** (All)**:** No additional items identified at this time.

6. **Next meeting:** February 1, 2023

Robert P. Kimberly, MD
Senior Associate Dean for Clinical and Translational Research
Chair, Clinical Trials Administration Committee

CC: Chris Brown, PhD, VP-Research
Anupam Agarwal, MD, Interim SVP for Medicine and Dean-Heersink SOM