Clinical Trials Administration Committee (CTAC)
Meeting Minutes
March 8, 2023
12:00 – 1:00 pm
Zoom Conference Call

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

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

2. **Updates**

   a. **OnCore** (Specht/Gordon): Ms. Specht opened comments by discussing efforts surrounding 'late CTBNs'. Clinical Trial Billing Notices (CTBNs) are the mechanism by which information related to clinical trial activities conducted by the Health System are communicated to the billing office to ensure appropriate processing to payers. She described the process by which a member of the OnCore team generates and reviews a weekly report to understand when 5 or more CTBNs have not been sent to the billing office within 7 days following a study visit (CTBNs are generated when the study team marks a visit in OnCore as "occurred"). Over the past 6 months, that number of late CTBNs has been reduced from ~120 to 4. As a second topic, she noted that engagement in the regular Q/A sessions held by the OnCore team has diminished recently with no attendees at the last few sessions. Ms. Specht asked the committee to share ideas for encouraging participation by OnCore users. As a part of these sessions, she reminded the committee that micro-tutorials are offered on various components of OnCore, such as Financials. She closed her portion of the comments by reminding the committee that several members of the OnCore team would be at the OnSemble conference next week conducted by the vendor Advarra. Mr. Gordon mentioned that the version upgrade continues for the system, which includes working through some items with Advarra. Additionally, he mentioned that work has recommenced on the IllumiCare pilot to assist with recruitment in outpatient clinics.
   Actions:
      1. Continue weekly OnCore Q/A sessions to provide assistance and ongoing training to the clinical research community.
      2. Committee members asked to send ideas to Ms. Specht to increase awareness of the Q/A sessions among the user base.
      3. Identify the manageable target percentage of late 'occurred' visit entries and report at the April meeting.

b. **IRB Guidance & HSP 'Top 10'** (McClintock): Mr. McClintock announced that three guidance documents will be launching relatively soon. Those include topics related to *E-Signatures*, *Social Media*, and *Direct-to-Participant Engagement by Phone*. Training and communication strategies are being drafted presently for dissemination. He shared the 'Top 10' list of areas for improvement (attached) for distribution to study teams across the University with the goal of reducing the IRB review time metrics. A variety of ways was discussed for socializing this material, including podcasts. Ideas for methods to improve its dissemination are welcome from the committee.

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 Mr. McClintock for ways to distribute the 'Top 10' list in order to maximize its impact on review times by helping Departments reduce common errors in their submissions.

c. **Pediatrics IRB Pilot** (McClintock/Kimberly): The IRB is partnering with the CCTS to compile and analyze data for Human Subjects Protocol (HSP) submissions to determine if the experiences reflected in comments from Pediatric investigators are supported by IRB approval times. The Clinical Research Support Program (CRSP) is currently providing regulatory services expertise for several divisions in the Department which is thought to reflect a more expedient process for getting studies submitted and approved. The IRB plans to review timelines for studies submitted prior to the Pilot compared to those during it.

Action:

1. The IRB to document review times for a select group of studies to determine whether efficiencies have been gained by the effort.

3. **Quick Notes**

a. **OSP National Search** (Schwebel): Dr. Schwebel updated the committee by stating a diverse group of applicants was received for the position and that online interviews would commence with the confidential pool next week. The list will then be trimmed to a final group of four who will be invited to campus for an additional round of in-person interviews and presentations that will take place between March 30th and April 14th. Based on this timeline, it is felt the final candidate should be able to start by this summer.

b. **Project eRA** (Matthews): Mr. Matthews was unable to attend but conveyed to Dr. Kimberly in advance that no new information was available compared to last month's report.

c. **CTAC/Accrual Project** (Rizk/Kimberly)**:** Dr. Rizk reminded the committee of the OnCore accrual reports that have been discussed in recent meetings and how they are being used to gauge where additional guidance and intervention is being focused to continually improve efforts to recruit and retain participants. Assistance in the development of Recruitment Plans continues to be offered by CRSP at no cost with outreach being conducted at both early onset and mid-trial to ensure every opportunity is available to study teams.

4. **Clinical Trials Initiative** (Kimberly): Dr. Kimberly mentioned recent comments expressed by President Watts in relation to growing the research enterprise across campus, which includes clinical trials. This is a part of the University's efforts to continue to expand upon its economic impact across the city, state, and region. He also reminded the committee that all of the activities discussed in each CTAC meeting were threads in the overarching fabric that constitutes the Initiative as a whole.

5. **New Business/Open Floor** (All)**:** Dr. Croker reminded the committee that Clinical Trials Day will be taking place on May 18th from 7:30-9:30am in the lobby of Wallace Tumor Institute. In addition to

comments being shared by President Watts, Dean Agarwal, Dr. Kimberly, and Dr. Sleckman, information clinical trial resources and processes will be available, along with breakfast biscuits for all attendees.

6. **Next meeting:** April 5, 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, SVP for Medicine and Dean-Heersink SOM