Clinical Trials Administration Committee (CTAC)
Meeting Minutes
October 2, 2024
12:00 – 1:00 pm
Zoom Conference Call

In attendance:	Bertram (OCCC)	Kimberly (HSOM/CCTS)
	Croker (CCTS)	Logan (University Compliance)
	Fitz-Gerald (CCTS)	Marchant (CTAO)
	Gordon (HSIS)	McClintock (IRB/OVPR)
	Goss (SHP)	Miller (OVPR)
	Irvin (SOPH)	Rizk (CTAO/CCTS)
	Joiner (DOM)	Smith (SON)
		Specht (OnCore)
Absent:	Boles (HSOM)	Matthews (OVPR)
	Brown (Health System)	Nichols (SOO/OVPR)
	Gilbert (SOD)	Pitts (Health System)
	Hedberg (OSP/OVPR)	Schwebel (OVPR)
	Horn (OVPR)	Wasko (SOB)
	Jackson (Health System Compliance)	Wells (DOM)
	Lee (DOM)	
Guests:	Harris (Pulmonary)	
	Moon (CCTS)	

1. **Review of CTAC minutes from September 11th meeting:** The minutes were reviewed and approved.

2. **Updates:**

   a. **IRB Metrics & Process (McClintock):** Mr. McClintock opened by announcing that the OIRB has recently hired 3 new staff, while continuing with 1 vacancy at the moment. The engagement with Advarra Consulting has begun and will continue for roughly the next 6 months with a 0.75 FTE assigned to assist with Expedited IRB Reviews and determinations of exemption from IRB review. Mr. McClintock closed by addressing a question from Dr. Kimberly about training for investigators and staff members submitting HSPs. He replied that while the quality is holding steady, there remain opportunities for improvement in submission quality.
   Action:
   1. Identify new ways to improve efficiencies in both internal operations as well as departmental submissions and enact the changes.

   b. **OSP Operations (Hedberg):** Topic deferred due to Ms. Hedberg's absence.
   Action:
   1. OSP update to be provided at the next CTAC meeting.

c. **OnCore Operations (Specht/Gordon):** Ms. Specht began by stating that the Advarra HealthCheck discussion continues with the vendor in order to articulate the scope and cost of the effort prior to beginning. The Financials project is ongoing through the onboarding of new industry-sponsored clinical trials as they are identified. Ms. Specht shared that a team consisting of Dr. Rizk, Mr. Marchant, Ms. Bruer, and herself has conducted 31 presentations over the past 2 months with study teams to outline efforts surrounding visit management, which includes both unmanaged and delinquent visits. Ms. Specht thanked the committee for their suggestions last month surrounding a new email address for report distribution. The 'winning' suggestion was MyOnCoreData@uabmc.edu. She invited members to inform their areas that if there are any issues with OnCore calendars that need addressing, please send them her way.

Dr. Kimberly inquired about the goal for conducting the HealthCheck. Ms. Specht and Mr. Gordon included items such as ensuring the system is fully utilized and understanding best practices. Ms. Specht welcomed committee members to share their own perspectives and goals.

Dr. Kimberly invited discussion of the upcoming acquisition of St. Vincent's and how their research portfolio will impact our operations. Mr. Gordon noted the complexity of logistics in bringing the 2 organizations into 1 research enterprise. Dr. Joiner noted that she is setting expectations such that involvement of a research component is not expected to happen immediately to ensure that expectations are realistic at all levels for this lengthy transition.

Finally, Mr. Gordon commented on the effort to operationalize OnCore's Study Information Portal (SIP) for OCCC studies which will be made available to providers for recruitment purposes. While SIP is utilized by some institutions as a patient-facing platform to inform them about recruiting trial opportunities, UAB is not moving forward with that functionality at this time.

Actions:

1. Continue implementation of the Financials module across campus and track performance improvement by the Departments.
2. Committee asked to inform their respective areas that if they have OnCore calendars that requiring 'cleaning up' to please contact Ms. Specht.
3. Committee invited to send any potential goals for the HealthCheck to Ms. Specht to consider as a part of the engagement with Advarra.

3. LLMs & HSPs (Croker): Dr. Croker shared that Dr. Ryan Melvin in Anesthesiology has been crafting informatics tools that use Large Language Models (LLMs) to aid investigators in preparing documentation for HSP submissions. She demonstrated a website that illustrated the various tools including those for Human Subject Protocol and Consent Form development. The goal for such efforts would be to save time, especially for those engaged in Investigator Initiated Trials (IITs) and trainee projects. Dr. Croker noted that she is working with the IRB and with CRSP to evaluate the suitability of the HSP tool, and she encouraged CTAC members to contact her for further discussion as desired. Mr. Logan provided a link to institutional guidelines regarding the use of generative AI.

Action:

1. Evaluation of the suitability of the HSP tools (Drs. Croker and Melvin working with CRSP).

4. New Business/Open Floor: None proposed at this time.

5. **Next meeting:** TBD; CTAC on pause per Drs. Brown and Agarwal.

Robert P. Kimberly, MD
Senior Associate Dean for Strategic Initiatives
Chair, Clinical Trials Administration Committee

CC: **Anupam Agarwal, MD**
SVP for Medicine and Dean,
UAB Heersink SOM

Christopher Brown, PhD
VP-Research