Clinical Trials Administration Committee (CTAC)
Meeting Minutes
March 6, 2024
12:00 – 1:00 pm
Zoom Conference Call

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

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

2. **Updates:**

   a. **OSP Operations (Hedberg):** Dr. Kimberly opened the meeting by asking Mr. Matthews to introduce Ms. Gina Hedberg who began in her role as Associate Vice President and Executive Director of the Office of Sponsor Programs in January. Following a few comments by Mr. Matthews, Ms. Hedberg thanked Mr. Matthews for his outstanding leadership during the interim period while a national search was conducted. Ms. Hedberg notes that coming to UAB after a lengthy career at the University of South Alabama is the pinnacle of her career. She commented that she is currently reviewing processes to understand where there may be opportunities to continue to build upon recent strides to improve efficiency along with transparency, starting with the federal awards team. She continued that the new eRA system, which is currently being sought, will change many processes in the future. Moving on to the industry side of operations, Ms. Hedberg noted that time to activation (TTA) is always at the forefront of people's minds and the top priority for that team. The goal will be to reduce the time in the areas where UAB has control as much as possible, while also encouraging Sponsors to do their part in turning contracts around without delay as well. Ms. Hedberg closed by asking if additional questions or concerns arise at any time by CTAC members, please reach out directly as she'd be glad to talk.

Actions:

1. Continue discussions to make meaningful revisions to standard industry contract language to aid in negotiation timelines.
2. Continue review of processes to understand where meaningful changes may be made to save time in executing, while increasing transparency with Departments.
3. Update the committee on the state of the RFA for a new eRA system.

b. **IRB Metrics & Process (McClintock):** Mr. McClintock started by stating that performance metrics are holding steady for the IRB at the moment. He continued by saying that given the tumultuous past few weeks though with staffing fluxuations, he expected a slight dip relatively soon but did not think it would last long. Mr. McClintock mentioned that staffing for local IRB meetings is still a 'works in progress' with the conversion to be completed by this summer. As a follow-up to a query by Dr. Gilbert last month, Mr. McClintock informed the committee that the IRB is taking a more proactive position at addressing questions/issues related to locally-reviewed submissions by following up with the PI prior to the actual Board meeting in order to reduce the amount of time and dialogue after the meetings so that they are approved more quickly. He noted that a tool called an Institutional Memory Bank that was recently developed by Dana Farber is under consideration for use here. It is believed to use REDCap technology, but additional information is needed so Mr. McClintock has reached out to leadership there to find out more. Dr. Kimberly inquired about last month's WCG visit, to which Mr. McClintock replied that nothing extraordinary surfaced from the discussions. Dr. Kimberly followed with a question about accrual data and whether the UAB IRB has receives industry trial accrual data from Departments when WIRB is the IRB record. Mr. McClintock replied that the UAB IRB neither requests nor receives these data so a short discussion about the desirability of having such data to cross-validate accrual reports with OnCore ensued. Dr. Kimberly then inquired about the NYU outreach about tool(s) for sIRB activities. Mr. McClintock replied that discussions were ongoing but that little may be done by UAB at this time given the upcoming transition in eRA systems, which must be stable to take part in the project funded by NCATS.

Actions:

1. Continue to develop additional training opportunities for OIRB staff.
2. Identify ways to improve efficiencies in both internal operations as well as departmental submissions to improve Time to Activation (TTA).
3. Mr. McClintock to contact WCG about a potential integration between their system and UAB's OnCore team to regularly transmit our accrual/demographic data for industry trials reviewed by WIRB.
4. NYU project to remain in the 'parking lot' for now, but to be revisited at a later time once eRA environment transitioned.

c. **OnCore Operations (Specht):** Ms. Specht stated that the team is in the process of upgrading the system to version 2023 R3. She continued by saying that the Financials project remains underway with two teams still requiring initial training, while customized training continues for the others. Ms. Specht noted that a primary point of emphasis is that study teams must keep their visits in OnCore immediately following their occurrence in order for information to flow as it should. The OnCore team is continuing to monitor industry-sponsored clinical trials to ensure they are entered into the system pursuant to the institutional requirement. Mr. McClintock inquired about an OnCore integration with WCG to receive accrual data for industry trials reviewed by WIRB.

Actions:

1. Continue implementation of the use of the Financials module across campus.
2. Continue monitoring new industry-sponsored clinical trials to ensure they are being entered into OnCore as required.

d. Accruals to Trials (Rizk): Dr. Rizk began by stating that Accrual Reports are distributed to PIs and their teams on a monthly basis. Recent discussions have occurred to explore ways to highlight the reports for PIs in their Outlook inboxes. Dr. Rizk mentioned the nuance between typical accrual metrics which simply state the number of participants on trials and what the Accrual Report actually outlines, which includes the number in relation to time the trial has been open to accrual along with the number expected to be accrued overall. Dr. Rizk asked Ms. Fitz-Gerald if there had been any recent requests to CRSP for Recruitment Plan assistance, to which Ms. Fitz-Gerald replied that there have not been. Ms. Horn then mentioned that the UAB Digital Media team continues to field queries for assistance and that they are slated to speak at next month's *CCTS Lunch & Learn* which is scheduled for April 9th. The RIC Community of Practice was highlighted as a place for study team members including investigators to crowd source ideas to address issues they may face in recruitment.

Action:

1. Dr. Rizk will continue to follow-up with PIs to increase awareness of monthly Accrual Reports and to identify any who are not receiving Accrual Reports as planned.

e. Budget Harmonization (Fitz-Gerald): Ms. Fitz-Gerald stated that the development of the budget tool is complete and that the workgroup is currently finalizing the prototype justification document. Departments will be able to customize the documentation, as they have in the past, to best fit their clinical research portfolio needs. Initial distribution will be through Clinical Department Chairs and a series of trainings will be conducted to aid in their uptake across campus

Action:

1. Finalize and distribute the prototype justification document and train the community of clinical research professionals on its use as part of the budget tool.

3. **New Business:** None proposed at this time.

4. **Next meeting:** April 3rd (to be confirmed)

Robert P. Kimberly, MD
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Chair, Clinical Trials Administration Committee

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

Christopher Brown, PhD
VP-Research