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

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

1. Review of CTAC minutes from October 4th meeting: The minutes were reviewed and approved.

- 2. Updates:
 - a. OnCore (Specht): Ms. Specht began her comments by stating that the OnCore upgrade was completed the weekend of October 13th and went well. She confirmed that they had identified a candidate for the open Calendar Builder position and that an offer would be made soon. The Financials project work continues with the recent meetings with Neurology and Nephrology. A recent *Lunch & Learn* was conducted with Investigators with a follow-up request for discussions to continue at routine faculty meetings. Those meetings are being scheduled. Following the meetings with Neurology and Nephrology, through which additional feedback was gleaned, the development of more formalized training materials is underway. Dr. Kimberly then mentioned that a Memo announcing the required use of the OnCore Financials module has been drafted for the President's Clinical Trials Oversight Committee.
 - 1. Continue implementation of the use of the Financials module across campus.
 - **b. IRB Metrics & Process (McClintock):** Mr. McClintock stated that there was no additional insights yet on switching industry trial reviews from commercial IRBs to the UAB IRB. He will speak with Dr. Basu soon, once she returns to campus. Mr. McClintock said that staff training on the recruitment script effort will be completed next week with several announcements coming in December starting with the *Lunch & Learn* on December 12th. He then stated that the IRB's through-put metrics continue to remain steadily positive. They will look for new areas to focus improvement moving forward.

Actions:

1. Continue efforts to improve IRB through-put rates and enact process changes to enable such improvement.

- 2. Complete the phone script dissemination across campus.
- **3.** Further discussion about use of commercial IRBs for industry-sponsored trials and report on the final assessment at December's meeting.
- c. OSP Updates (Matthews): Mr. Matthews opened by stating that OSP will be impacted by the Joomla 4 platform updates. This is not expected though to have an effect during normal business hours. He proceeded to update the Committee on recent metric efforts. This included 97 calendar days for industry sponsored clinical trials contract review, which surpasses the initial 100-day goal. The next iterative goal is a 90-day average review time. OSP is currently working with Office of Counsel to address language that has a perceivable 'bottleneck' effect on review times. The OSP webpage will be updated to reflect these changes to help keep the campus informed as these are addressed. Mr. Matthews reminded the Committee that monthly virtual office hours continue from 2-3pm on the 1st Thursday of each month. He continued by discussing the widget available in IRAP that allows PIs to have a dashboard that displays industry agreements under review. Plans are under way to develop a training course for both this tool and eReports available in the system for ad hoc use. Mr. Matthews then closed by mentioning the recent <u>DUA</u> process update that was announced in <u>Research Matters</u>.
- d. AVP Search (Matthews): Mr. Matthews echoed the recent announcement that <u>Virginia</u> <u>Hedberg</u> has accepted the position of Associate Vice President for Research which includes oversight of the Office of Sponsored Programs. She comes to UAB from the University of South Alabama where she has worked since 1988. She will start her new role here on January 15th.
- e. Clinical Trial Fees (Kimberly): Dr. Kimberly opened by stating that following feedback from Committee members and others after last month's CTAC meeting, the formal Memo announcing the new Fee structure is finalized and awaiting the last of the signatures to enable dissemination. Dr. Agarwal has sent communication to the HSOM Department Chairs. Other announcements are forthcoming to PIs, staff, and additional impacted leaders across campus. Dr. Kimberly encouraged representatives on CTAC across other Schools to spread the word to their colleagues. The official go-live is January 1st which means that all contracts received in OSP associated with industry-funded clinical trials will fall under the new Fee schedule after that date going forward. Action:

1. Continue communication to impacted UAB personnel across campus about upcoming change in institutional Fees.

3. Budget Harmonization Initiative (Fitz-Gerald): Ms. Fitz-Gerald stated that a workgroup continues the review and development of a tool to help enable better budget building across campus. This effort coincides with previously mentioned efforts for OnCore Financials and the dissemination of the new Fee and Research ChargeMaster structures.

Action:

1. Continue refinement of the budget tool and prepare training for its use to enable better financial management of trials.

4. New Business:

a. Radiology Over-Reads (Kimberly): Dr. Kimberly reminded the Committee of the discussion on this topic back in the spring. Dr. Bolding will present at December's meeting to provide a formal update.

December Meeting (Marchant/Kimberly): Mr. Marchant inquired about the desire to have an in-person meeting for December. An informal poll of the members found other meetings

immediately prior to or following the normal hour-long Zoom format on the first Wednesday. It was agreed that Committee members would send their availability for either Wednesday December 6th or 13th to Mr. Marchant by Thursday November 2nd. **Action:**

- 1. Committee members to send their availability for the December CTAC meeting by Thursday November 2nd to <u>marchant@uab.edu</u>.
- 2. Note: based on feedback provided, the regularly scheduled time/format was best suited for the December meeting.
- 5. Next meeting: Wednesday December 6th at Noon via Zoom

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

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

Christopher Brown, PhD VP-Research