Clinical Trials Administration Committee (CTAC)
Meeting Minutes
September 6, 2023
12:00 – 1:00 pm
Zoom Conference Call

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

1. **Review of CTAC minutes from July 19th meeting:** The minutes were reviewed and approved.

2. **Introduction of Dr. Rita Basu (Kimberly):** Dr. Kimberly opened the discussion by introducing Dr. Rita Basu, who recently came to UAB from the University of Virginia. Dr. Basu will serve as the new Medical Director of the IRB in addition to her duties as a Diabetes researcher in the Division of Endocrinology, Diabetes, & Metabolism. Dr. Basu has extensive experience in IRB operations going back to her days at the Mayo Clinic and is really looking forward to working with Mr. McClintock and his team.

3. **Updates:**

    a. **OnCore (Specht):** Ms. Specht began by commenting on the new version upgrade which continues to date. Work also continues on the Financials module through scheduled trainings with Departments, most recently Neurology, which went very well per Ms. Specht. The next training is scheduled with Nephrology in a few weeks. Ms. Specht continued by saying a finalist has been identified for the Q/A Analyst position, which will serve as the 'front-door' to the calendar request process in addition to assorted quality control efforts.
    Actions:
    1. Work with Advarra to identify and resolve technical issues with the software that preclude the annual upgrade.
    2. Continue efforts to expand on the use of the Financials module across campus.

    b. **IRB Metrics & Process (McClintock):** Mr. McClintock stated that the previously discussed phone scripts that have been under development continue to have their launch date pushed back for ongoing development of the educational materials needed to support the implementation. The

required education must be available for IRB staff to check in IRAP, and this has been delayed. He noted that there will be an IRAP system update on September 22nd that will include this change. The OIRB will work on an aggressive implementation of the scripts3 after this system update. Efforts continue in modifying some procedures between UAB IRB and commercial IRBs with whom we work. Just in the past quarter, there has been a 9-day improvement in processing time. Mr. McClintock shared that HIPAA language was recently updated in the consent template. Dr. Basu inquired about the history of using commercial IRBs for industry-sponsored clinical trials, which is a practice that goes back 20 years at UAB when it entered into an agreement with WIRB to serve as an IRB of record for industry-funded, industry-initiated clinical trials implemented at the institution. Mr. McClintock is going to follow-up with leadership on the topic.

Actions:

1. Continue efforts to improve IRB throughput rates and enact process changes to enable such improvement.
2. Complete the phone script dissemination.
3. Finalize the agreement with Advarra to standardize expectations with the other primary commercial IRB (WIRB).
4. Discuss with leadership the necessity of continuing to use commercial IRBs for industry-sponsored trials.

c. **OSP Updates (Matthews):** Mr. Matthews reminded the committee that virtual office hours are held the first Thursday of each month from 2:00-3:00pm. Additionally, he shared that *Research Matters* is distributed weekly on Wednesdays. Mr. Matthews continued by outlining a number of training opportunities that Office of Research is making available through its Training Hub. Dr. Gilbert inquired about timelines pertaining to federal sub-awards to which Mr. Matthews replied that the team responsible for those is currently short-staffed, but that if there are pressing items needing attention, reach out to him directly for intervention. Dr. Schwebel then shared that the search continues for a new AVP for Sponsor Programs with two candidates currently being scheduled for onsite visits the last two weeks of September. There is an additional candidate or two that are currently being considered as well for potential visits in October. Given the current timeline, Dr. Schwebel anticipates a start date for a new leader in early 2024.

Actions:

1. Continue providing robust training opportunities for the research community to improve the quality of submissions which aids 'time to activation'.
2. Identify a finalist for the AVP position to oversee Sponsored Program operations.

4. **IllumiCare Pilot (Marchant, Gordon):** Mr. Marchant noted that the Pilot is fully operational now after some delays over the past year. He mentioned that the five areas (Family Medicine, Nephrology, Rheumatology, Gastroenterology, and Cardiology) have been re-engaged through a series of refresher presentations to remind providers of the application's capabilities and how to interact with it at the point of care in the EMR. Statistics are being shared which identify how many notifications are being distributed, times the application is opened, and number of referrals sent to researchers. Feedback is actively being sought from providers and researchers as well and being incorporated into the application when feasible. Lastly, the committee was reminded that the Pilot is only slated to go through the end of the calendar year and that 'measures of success' are actively being discussed to determine if the application proves fruitful in its goal to improve recruitment to trials in the outpatient setting.

Action:

1. Continue the developmental pilot with the specified groups to determine the feasibility, usability and value-add of the app in recruiting patients for studies at the point of care.

5. **Industry-Sponsored Research ChargeMaster (Kimberly, Marchant):** Mr. Marchant shared that the work to create a 2-tiered Research ChargeMaster as discussed at the July CTAC meeting continues. He reminded the committee that historically we have had a single price list for all clinical trials, regardless of sponsor type, that was set at 100% of the Medicare rate. Going forward, the plan will be to have a second tier for all industry-sponsored trials that is set at 150% of the Medicare rate with all other trials' activities continuing at the current 100% rate. Mr. Marchant stated that the two lists have been provided by PFS and MSO to the OnCore team where they will be uploaded into its ChargeMaster. The current goal is to make the new industry rates available to study teams for budget negotiations starting in early October. The timeline for when those rates will actually be charged is not yet determined due to a number of factors being discussed internally within the Health System. Those timelines will be an ongoing topic in future CTAC meetings to keep everyone apprised of progress.

   Action:

   1. Continue work to develop the 2-tiered Research ChargeMaster and outline the processes to enable billing dependent upon Sponsor type.

6. **Quick Notes:**

   a. **Budget Workshop Follow-up (Fitz-Gerald):** Ms. Fitz-Gerald referenced the workshop that was conducted on June 7th and 8th for participants across the CCTS partner network. Since that time, a number of smaller discussions have been held to determine ways to standardize a variety of budget practices and tools to ensure all Departments are creating and negotiating the most viable budgets possible. She then notified the committee that the next *CCTS Lunch & Learn* is being held Tuesday September 12th at 11:30am via Zoom.

   b. **Clinical Trial Fees (Kimberly):** Dr. Kimberly noted that an internal review has been conducted that led to the determination that institutional fees would need to be raised in the coming fiscal year. These fees (Study Management, Study Maintenance, & Close-out) have remained consistent over the past 4 years. While exact amounts have not yet been determined, Dr. Kimberly expects this to be known within the next 4-6 weeks. Further communication will be distributed once finalized to enable Departments to begin including the new amounts in their budgets going forward.

   c. **Travel Reimbursement (Marchant):** Mr. Marchant shared the recent announcement from Financial Affairs that beginning October 1st, in-state travel will be reimbursable with prior approval by the University at full cost as opposed to a 'per diem' amount which has been the State's practice historically. This was significant given Dr. Gilbert initially raising the issue last January to the committee, which was then articulated to Financial Affairs leadership by way of a memorandum from Dr. Kimberly and Mr. Marchant outlining specific examples of how researchers were losing money by conducting business within the State's borders based on the reimbursement policy and encouraging Financial Affairs to address the issue with our government relations team who are charged to work with our State's legislative delegates on proposing and passing bills. Special thanks was extended to all the committee members who helped outline examples for inclusion in the memo to highlight the need for this important change. At the conclusion of this discussion, Dr. Wasko notified the committee of a recent issue whereby visitors from the NIH were forced to stay at a more distant hotel from campus due to a nearby hotel not extending a government rate to the visitors. She inquired if there is a way to ensure the government rate is available in this circumstance going forward.

      Action:

      1. Mr. Marchant to follow-up with local hotel to inquire about availability of government rate for future visits.

6. **New Business/Open Floor (Kimberly):** No new items were raised for discussion.

7. **Next meeting:** October 4th

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