Clinical Trials Administration Committee (CTAC)
Meeting Minutes
July 19, 2023
12:00 – 1:00 pm
Zoom Conference Call

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

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

2. **Updates:**

   a. **OnCore (Specht):** Ms. Specht kicked off the discussion by commenting on the recently updated security patch for the system, which she noted went well. The new version upgrade is a 'work in progress' as discussions with the vendor Advarra continue due to their ongoing technical issues. Work continues on the Financials module through the development of implementation workflows.
   Lastly, Ms. Specht and Dr. Kimberly noted the recent approval by Dean Agarwal of a second Research ChargeMaster for clinical billables in industry sponsored studies. Health system clinical billables for industry studies will be charged at a rate of 150% of Medicare while the clinical billables for federal, foundation and investigator-initiated studies will continue at the current 100% Medicare rate. Both ChargeMasters have been updated for 2023 and both will be housed in OnCore. The industry ChargeMaster has a target go-live date of October 1st to coincide with the new fiscal year.
   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.
   3. Research ChargeMaster expected to be updated to reflect both an Industry and Non-Industry rate for billable activities with an October 1st goal for go-live.

   b. **IRB Metrics & Process (McClintock):** Mr. McClintock stated that the previously discussed phone script for potential participant recruitment has had its launch date pushed back to enable more time for the development and implementation of educational materials needed to support

the process. He currently anticipates a mid-August launch. To expedite information flow, efforts continue in modifying some processes between UAB IRB and commercial IRBs with whom we work (primarily WCG). Over the past couple of quarters, this work has resulted in a 26% reduction in processing time. Mr. McClintock noted the efforts to send reminders to PIs when they are responsible for an activity. Dr. Rizk inquired if these reminders went only to the PI, to which Mr. Miller replied that they went to not only the PI but also to any delegates associated in IRAP. Mr. Marchant inquired about the expansion of commercial IRBs over time beyond WIRB, with whom UAB has had a working relationship since 2003. Mr. McClintock responded that while WIRB still holds the majority of the industry work, Advarra has developed a much stronger presence due to Sponsor requests for specific studies. Others like Sterling have a small portion of the portfolio. Dr. Kimberly closed comments in this area by mentioning that the revised eConsent platform for biorepository efforts that went live last month.

Actions:

1. Continue efforts to improve IRB throughput rates and enact process changes to enable such improvement.
2. Complete the phone script dissemination in August.
3. Finalize the agreement with Advarra to standardize expectations with the other primary commercial IRB (WIRB).

3. **Budget Workshop Recap (Fitz-Gerald):** Ms. Fitz-Gerald updated the committee on the workshop that was held on June 7th and 8th for clinical researchers at UAB and across the CCTS Partner Network. Attendees engaged both in-person as well as Zoom attendees with 80 in attendance for Day 1 and 62 for Day 2. During the sessions, attendees were polled on various practices with those responses helping to inform decision making on potential modifications to the institutional fees discussed in item 5b below. One item of particular interest noted by Ms. Fitz-Gerald is the lack of systematic post-study budget review by all clinical trial units and departments. This will be a point of focus in upcoming training. Ms. Fitz-Gerald asked the committee to send her practices and tools currently being used in this space to aid in creating best practices and training clinical research teams.

   Actions:

   1. Committee members asked to send Ms. Fitz-Gerald information on practices and tools they use to evaluate budgets post-study to assist in ongoing development and improvements in the budgeting process.
   2. A budget review workgroup to be created by Ms. Fitz-Gerald to conduct ongoing reviews of completed trial budgets to garner lessons learned to help inform future budget efforts.

4. **IllumiCare Pilot (Marchant, Rizk, Gordon):** Mr. Marchant notified the committee of the recent contract extension between HSIS and the vendor that will enable the pilot to move forward through the end of the calendar year. Work is underway to monitor referrals from providers at the point of care to the researchers for the studies involved in the pilot. Dr. Rizk reminded the committee that the process involves cohorts of patients being built within the electronic medical record (EMR) based on inclusion/exclusion criteria that will flag eligible patients in the EMR when they appear for a visit with a UAB Medicine provider that is a part of the pilot. There are 5 therapeutic areas involved so far which include Cardiology, Rheumatology, Nephrology, Gastroenterology, and Family Medicine. Several metrics will be tracked during the pilot to determine the effectiveness of the application to aid in recruitment. Feedback from both providers and researchers will be sought throughout to help the vendor modify the application in real-time to improve its effectiveness.

   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. **Quick Notes:**

   a. **Huron Update (Kimberly, Khadka):** Dr. Kimberly welcomed Ms. Khadka who was recently hired by President Watts to manage special projects, including the upcoming strategic assessment for growing the research portfolio at UAB. Ms. Khadka discussed the recent announcement that was circulated last week outlining the engagement with Huron Consulting whereby they will be collecting information through both asynchronous requests via email and onsite multi-day visits where interviews will be conducted. The interviews will commence on August 9th and run through the 17th. This will kick-off a 21-week engagement with Huron that will culminate in a report containing what they have learned and recommendations on ways to assist the institution reach its $1 Billion goal for research. As a point of reference, UAB most recently announced a $713 Million research portfolio. The review by Huron will be very comprehensive, covering everything from space and processes to technology and human resource, as well as future trends in research funding and untapped opportunities. Internally, these efforts will be led by a 15-member Research Design Working Group that includes President Watts. In addition to the targeted interviews being conducted with 100+ UAB stakeholders, surveys will be distributed to all faculty and staff for completion to ensure a broad representation is captured during the information collection phase.

   b. **Clinical Trial Fees (Nichols, Kimberly):** Dr. Nichols noted that institutional fees have been used as a source of additional income to offset costs in covering University-wide operational expenses for research administration. He noted that the Study Management Fee had remained constant since last revised in the fall of 2019. Due to costs continuing to increase over that time, a review has recently been undertaken to understand where those institutional fees currently stand in relationship to both the internal and external landscape. Based on the information received and reviewed so far, a modest increase is expected if approved by Drs. Brown and Agarwal, with a potential go-live date of October 1st. More information is anticipated at the time of the September meeting. Dr. Schwebel closed comments by stating that he felt an increase would be in order given the time since the last change and that PIs expect costs to rise gradually over time in all aspects of research.

6. **New Business/Open Floor (Kimberly):** Dr. Kimberly closed the meeting with a reminder that the July discussion was a modified session combining both the July and August meetings due to summer travel and that the next meeting is anticipated to return to the normal cadence for the first Wednesday of September.

9. **Next meeting:** September 6th

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