

**Clinical Trials Administration Committee (CTAC)**  
**Meeting Minutes**  
**October 4, 2023**  
**12:00 – 1:00 pm**  
**Zoom Conference Call**

In attendance:

Bertram (O’Neal)	Joiner (DOM)
Croker (CCTS)	Kimberly (HSOM/CCTS)
Fitz-Gerald (CCTS)	Marchant (CTAO)
Gilbert (SOD)	McClintock (IRB)
Gordon (HSIS/CCTS)	Nichols (SOO/OVPR)
Goss (SHP)	Rizk (CCTS/CTAO)
Horn (OVPR)	Schwebel (OVPR)
Irvin (SOPH)	Specht (OnCore)
Jackson (Health System Compliance)	

Unable to attend:

Boles (HSOM)	Miller (OVPR)
Brown (Health System)	Pitts (Health System)
Lee (DOM)	Smith (SON)
Logan (University Compliance)	Wasko (SOB)
Matthews (OSP)	

1. **Review of CTAC minutes from September 6<sup>th</sup> meeting:** The minutes were reviewed and approved.

2. **Updates:**

- a. **OnCore (Specht):** Ms. Specht started the discussion by announcing that the system upgrade will take place on October 13-14<sup>th</sup>. She noted that the Financials module implementation continues and is currently working with Nephrology. Ms. Specht also mentioned that the new Q/A Analyst began this past week. Since this person was an internal hire from the team, a new calendar builder must be hired to fill that newly created vacancy. Ms. Specht reminded the committee that the OnCore team will be joining the CBR analysts in their annual departmental trainings along with Health System Compliance and CCTS. Rather than having individual trainings this year with each Department, a new consolidated approach will be taken with several sessions to be held and with all Department reps expected to attend one of them. These sessions will be recorded and cataloged on the Clinical Trials Kiosk for reference. Dr. Kimberly inquired about the OnCore Financials implementation initiative. Ms. Specht indicated it is progressing. This is but one piece of a multi-pronged approach to improve the financial management of clinical trials.

**Actions:**

1. Conduct the annual system upgrade on October 13-14<sup>th</sup>.
2. Continue implementation of the use of the Financials module across campus.
3. Assist in the completion of the annual CBR trainings with Departments in conjunction with Health System Compliance and CCTS.

- b. **IRB Metrics & Process (McClintock):** Mr. McClintock began by stating that the Telephone Recruitment Script project is continuing to move along. The LMS training has been finalized and he is currently working with the IRB staff to ensure everyone is properly educated within the office first, prior to rolling out across the University. He anticipates a formal announcement

about it to be circulated within the next two weeks. Relative to commercial IRB engagements, Mr. McClintock stated that the data look good in terms of timelines for turn-around of reviews. He indicated that the IRB is about to be fully staffed for the first time in several months with the last two openings being filled. Dr. Kimberly inquired about Dr. Basu's comments last month about outsourcing industry reviews to commercial IRBs, which UAB has done for the past 20 years. Mr. McClintock replied that some initial discussions have occurred but that a more substantial assessment and report back can be expected at the November meeting. Mr. McClintock also mentioned that the FDA has issued a notice of proposed rulemaking that includes changes to FDA regulations, which would require the use of a single IRB for multisite, FDA regulated studies. The anticipation is that pharmaceutical sponsors will largely designate commercial IRBs as the reviewing IRB.

**Actions:**

1. Continue efforts to improve IRB throughput rates and enact process changes to enable such improvement.
2. Complete the phone script dissemination across campus.
3. Further discussion about use commercial IRBs for industry-sponsored trials and report on the assessment at November's meeting.

c. **OSP Updates (Matthews):** Mr. Matthews was unable to attend, and the topic was deferred.

d. **AVP Search (Schwebel):** Dr. Schwebel noted that the 4 finalists for the position were on campus for in-person meetings and presentations over the past two weeks. Feedback was requested and is currently with Dr. Brown for review and determination of the top candidate. Dr. Brown will then commence with making and negotiating terms of an offer. The hope is to have someone in the role by early 2024.

e. **Clinical Trial Fees (Nichols, Kimberly):** Dr. Nichols shared an overview of the application of institutional fees to industry-funded clinical trials over the past several years. These fees are used to offset costs for various functions such as CIRB, CBR, CTMS, and IRB. He reminded the committee that the original plan was to have an annual review and adjustment as needed, but that following the financial uncertainty caused by the COVID-19 pandemic, such review had been tabled for the past few years. He also reminded the committee that the application of the fees to industry trials only is due in large part to the difference in Indirect Costs between Federal and Industry trials and that the Indirect Cost rate for Industry trials has not changed since 2016. Both internal and external data were reviewed to determine the need for a modest increase beginning in FY24. Communication about anticipated fee changes for budgeting purposes will continue with potential initiation in December of this year. The adjusted fees will be applied to new studies going forward. Dr. Kimberly asked Dr. Joiner and Ms. Fitz-Gerald to review the Sponsor-facing documentation which is currently under review within the HSOM Dean's and VPR's offices.

**Actions:**

1. Dr. Kimberly to send draft memo for Sponsors to Dr. Joiner and Ms. Fitz-Gerald for review and suggested wording.
2. Communicate to Chairs, PIs, financial officers and clinical research professionals across campus about upcoming change in institutional fees.

3. **Budget Tool Update (Fitz-Gerald):** Ms. Fitz-Gerald noted that since the Budget Workshop in June, a workgroup has been reviewing a tool to help enable better budget processes. Testing continues as new trials are received to determine what works well and what may be omitted in order to simplify the process. Following testing, the plan is to train staff with financial responsibilities on its use. Dr.

Kimberly mentioned that he would like to have it ready expeditiously to align with other financial initiatives discussed during the meeting.

**Action:**

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

4. **Industry-Sponsored Research ChargeMaster (Marchant):** Mr. Marchant shared that the work to create a 2-tiered Research ChargeMaster will enable the application of a 150% Medicare rate for industry trials and 100% Medicare rate for all others. He continued by saying that the new rate for industry trials will be for new studies only received after the go-live date for budget building and that amendments for existing studies will continue at 100% for consistency. The communication and training for budget building with Departments will begin in the coming weeks.

**Action:**

1. Development of the communications for the new Industry Research ChargeMaster to enable budget building dependent upon Sponsor type.

**5. New Business:**

- a. **In-State Travel Reimbursement (Gilbert):** Dr. Gilbert raised a concern with implementation of the new policy discussed at last month's meeting. He stated that he is now required to provide receipts for meals for reimbursement, which is not in alignment with his experience for out-of-state travel. Drs. Croker and Schwebel shared that they have historically provided receipts for reimbursement of meals for out-of-state travel. Dr. Gilbert acknowledged that there may be differences in School-based interpretation of the requirement which led SOD to do things differently from other Schools like HSOM and CAS in the past. He was to speak further to his administration.
- b. **eLAS and Oracle Travel (Gilbert):** Dr. Gilbert also shared that he finds it redundant that one is required to enter the same information for professional travel into both eLAS and a pre-approved travel form that became a requirement following the COVID-19 pandemic. Mr. Marchant noted that he was previously told by Financial Affairs that the travel form was instituted by the UA System office and was not a UAB-centric requirement. Dr. Bertram added that each represents different institutional office processes (Human Resources v Financial Affairs) in terms of who receives and reviews the information.

7. **Next meeting:** Wednesday, November 1<sup>st</sup> at Noon.



**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