Clinical Trials Administration Committee (CTAC)
Meeting Minutes
November 4, 2020
12:00 – 1:00 pm
Zoom Conference Call

In attendance:	Bertram (OCCC)	Ladores (SON)
	Busby (OCCC)	Marchant (CTAO)
	Cotten (OVPR/OSP)	McClintock (IRB)
	Croker (CCTS)	Miller (OVPR)
	Farough (Health System)	Nichols (SOO, OVPR)
	Fitz-Gerald (CCTS)	Redden (SOPH)
	Gilbert (SOD)	Rizk (CTAO/CCTS)
	Horn (OVPR)	Sandefur (OnCore)
	Joiner (DOM)	Schwebel (CAS)
	Kimberly (SOM/CCTS)	
Unable to attend:	Bates (Health System Compliance)	
	Dransfield (DOM)	
	Gordon (HSIS)	
	Mack (SOM)	
	Motl (SHP)	
	Nabors (DON/CCTS)	
	Roberson (UAB Compliance)	
	Wasko (SOB)	
Guests:	Matthews (OVPR)	

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

2. **OVPR Request for Research Administration Process Improvement (RAPI) Metrics** (Kimberly): Dr. Kimberly reminded the Committee of Dr. Brown's presentation last month about research administration process improvement (RAPI) efforts and his request that CTAC suggest metrics to help guide RAPI efforts.

   Ms. Cotten mentioned that she was seeking additional faculty to serve on the Research Administration Network Group (RANG), including a faculty member to Chair it. Dr. Kimberly emphasized the importance of everyone understanding the focus for each group (such as RANG and HRAC) and how these groups are coordinating their efforts. Dr. Kimberly clarified the need not only for metrics (what is to be measured) but also the performance benchmarks against which our comparative performance is measured.

   Mr. McClintock discussed ongoing efforts in the IRB with input from HRAC. Mr. McClintock mentioned two metrics of primary interest: 1) pre-review time, and 2) overall time to IRB approval. Mr. McClintock outlined current performance times for various review types along

with the benchmark goals in calendar days, reflecting AAHRPP national standards, for the end of 2021 (Table attached). He also presented stepwise goals for each quarter. After brief discussion, Dr. Redden stated that one could include not only the Median but also the Mean, Min, Max, and Standard Deviation as well. Mr. McClintock also clarified that the pre-review time displayed was a subset of the overall time. In response to questions about IRB protocol amendments, Mr. McClintock indicated that the time is typically short (2-5 days), and CTAC members suggested that successful performance for those metrics be announced and celebrated. Dr. Kimberly thanked Mr. McClintock for the IRB's work and reminded CTAC that, from a sponsor's perspective, the integrated total Time-to-Activation is the most important metric.

Ms. Cotten reviewed the list of proposed metrics for OSP which had been distributed prior to the meeting (attached). She noted the importance of ensuring that what is intended to be measured is actually obtained going forward. She also noted that Consultant agreements are not handled by her office.

(1) pertaining to Master Agreements (link shown in Action Items), Ms. Cotten reported that there are currently 75 agreements with pharma companies including 36 which are evergreen (meaning no expiration date). We have 36 master agreements which have expired and there may or may not be a need to renegotiate another if we do not have any projects submitted by UAB faculty. Mr. Marchant asked about OSP's ability to successfully utilize Master Agreements, even when CROs are involved, to which Ms.Cotten stated that CROs make it very difficult for master agreements to be used because they want to use the same contract template (not a master agreement) across all sites. Mr. Marchant mentioned that other sites often have successful use of ACTA language in their negotiations and wondered if UAB's experience has proven successful as well. Ms. Cotten responded that the use of ACTA lanaguge is not tracked so it would not be possible to know from UAB's perspective if efficiency is gained through its use. OSP does offer the ACTA contract template when a company does not have its own.

(2) Dr. Gilbert asked about timelines surrounding sub-awards and specifically about the time it takes to get them returned to PIs for review. Ms. Cotten replied that their data shows about 6-7 weeks currently to return sub-awards to PIs for review. Ms. Cotten expanded by stating that the staff team that manages these agreements was down 1 person and that all of them had been in their positions for less than 2 years.

(3) Ms. Cotten went on to discuss comparative data relative to executing agreements between FY19 to FY20 which shows a 12% reduction in time for OSP to finalize agreement terms with sponsors (down from 76 days in FY19 to 67 days in FY20) and a 24% reduction from 113 to 86 calendar days for OSP to execute agreements (from submission to OSP to execution).

(4) Dr. Kimberly asked CTAC about Data Use Agreements (DUAs) and Confidentiality Disclosure Agreements (CDAs). While Committee members felt that these agreement were typically not rate-limiting, the approval times should be tracked to ensure timely processing. Dr. Kimberly then inquired about engaging a group of volunteers to look at metric definitions and benchmarks in order to collaborate with HRAC and RANG, ensuring specific inclusion by faculty. Volunteers included Ms. Horn, Dr. Croker, Ms. Cotten, Mr. Miller, Mr. McClintock, Dr. Rizk, Dr. Gilbert, Mr. Marchant, and Ms. Busby.

Actions:

1. Mr. McClintock to track metrics as presented with regular updates to the Committee on progress made throughout the coming year.

2. The metric subcommittee to meet virtually for review of defined metrics and establish benchmarks against which they will be measured for success.
3. https://www.uab.edu/research/home/osp-industry-projects/ind-other/project-master-agreements

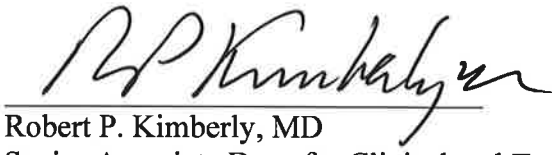
3. **Staff Recruitment** (Marchant): Mr. Marchant discussed efforts over the past couple of years to increase awareness among both upper-level college and high school students about career opportunities in Clinical Research. These efforts include engaging, through both presentations and 'shadow day' opportunities, senior honors program students in the UAB School of Nursing (SON), which were formerly led by Committee member Dr. Ladores. Additional efforts within UAB include working with faculty and Career Services to engage undergraduate students in the Departments of Biology and Psychology in the College of Arts and Sciences (CAS). More broadly, Mr. Marchant has worked with faculty at CCTS partner institutions (University of Alabama and Auburn University) to engage both undergraduate and graduate students in their respective Schools of Nursing as well as UA's Community Health Sciences through in-person (pre-COVID) and online presentations (post-COVID). The 'shadow days' program is expected to resume in the near future. Lastly, an opportunity to partner with the UAB School of Education's federally-funded project 'GEAR UP Alabama' has enabled the ability to connect with high school upper classmen and discusions were held this past summer with area coordinators at Carver High School in Birmingham and 4 Black Belt counties in West Alabama to increase awareness of new job opportunities specifically at UAB. The Clinical Research Career Ladder has instituted 4 positions requiring only a high school diploma for eligibility. Applicants who are able to obtain one of these positions would then be eligible for tuition assistance through employee benefits following 6 months to pursue additional education at little cost. This approach has the added benefit to bring strong candidates from traditionally underserved areas which may have the trickle-down effect of assisting recruitment of more diverse participants to clinical research.
Actions:
    1. Continue to distribute information about career opportunities to students soon to be joining the job market to foster growth in the applicant pool at UAB in Clinical Research and abroad.

4. **Updates**
    a. **OnCore** (Sandefur): Mr. Sandefur reported that the Financial roll-out continues with 20 units having been trained so far. Relative to Phase 2 of OnCore Enterprise implementation, the team is expected to start in December with 2 units inserting their industry-sponsored trials without clinical billables through the UAB Health System into OnCore. Based on recent survey data gathered from Departments, it is expected that the utilization of the OnCore CTMS will grow substantially in the coming year.
    Actions:
        1. Continue Phase 2 of implementation for industry-sponsored clinical trials without billables.
        2. Continue the Financials implementation to enable the use of OnCore for budgeting/invoicing within trials.

b. **Policy 005 Approval** (Cotten): Ms. Cotten stated that Policy 005 has been approved which enables execution of contracts prior to IRB approval but emphasized that human subjects research cannot begin until IRB approval is obtained. This may help to reduce the overall TTA of clinical trials. She continued by clarifying that it will have no effect on the process regarding sub-awards.
Actions:
    1. Assess the impact of Policy 005 changes on the reduction of overall approval times in OSP.

5. **New Business/Open Floor** (all): None.

6. **Next meeting:**
    a. December 2nd at Noon (Zoom meeting).



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

CC: Chris Brown, PhD, VP-Research
Selwyn Vickers, MD, Senior VP-Medicine and Dean-SOM