Clinical Trials Administration Committee (CTAC)
Meeting Minutes
March 13, 2019
12:00 – 1:00 pm
North Pavilion 2532

In attendance:	Bertram (CCC)	Marchant (CTAO)
	Cotten (OVPR/OSP)	Mack (SOM)
	Croker (CCTS)	McClintock (IRB)
	Farough (Health System)	Miller (OVPR)
	Fitz-Gerald (CCTS)	Nichols (SOO, OVPR)
	Gerrity (OVPR)	Redden (SOPH)
	Gordon (HSIS)	Saleh (SOM/CCC)
	Kimberly (SOM/CCTS)	Sandefur (OnCore)
	Ladores (SON)	Schwebel (CAS)
Unable to attend:	Bates (Health System Compliance)	Joiner (DOM)
	Bragg (UAB Compliance)	Motl (SHP)
	Dransfield (SOM)	Mugavero (SOM)
	Gilbert (SOD)	Nabors (SOM/CCTS)
	Horn (OVPR)	Wasko (SO)

1. **Review of CTAC minutes from February 6th meeting:** Minutes were reviewed with no additional comments. They were approved as outlined.

2. **Updates**
   a. **OnCore** (Sandefur): OnCore version 15.4 upgrade is planned for June 3rd due to some personnel changes. Work continues with the billing office in development of the consolidated Research ChargeMaster which is nearing completion after receipt of the price list from Patient Financial Services (PFS). It was announced that UAB was selected by Forte for the Top Performance Award based on various operational metrics extrapolated from the system. The award is presented twice a year at its Onsemble Conference. This is the 2nd spring in a row that UAB has achieved this honor. Forte noted in its announcement UAB's exceptional timeline for navigating protocols through the scientific review process.
      Actions:
      (1) Recruitment of a financial analyst
      (2) Recruitment of training personnel within CRSP.
      (3) Modeling of financials work-flow with calendar builds.

   b. **Operating Accounts** (Mack): Ms. Mack reported that Operating Accounts are available for use now, and training through LMS before an account will be provided will be required by the SOM for its faculty. Each School can set its own guidelines. These accounts allow an investigator to apply all applicable effort for industry-sponsored trials to one location for not only initial financial management but also reporting purposes, thereby allowing an Investigator to denote a single source for effort on industry-sponsored clinical trials. The associated expenses are expected to be moved from the Operating Account to the applicable project

account no less than quarterly. SOM Dean's office will be conducting random audits for its faculty to ensure the accounts are managed appropriately. Dr. Schwebel asked about the availability of the accounts for non-trial use, and while this is a possibility for future consideration, current plans focus on industry-sponsored trials.

Actions:

(1) Completion of the LMS training module for operating acc'ts.
(2) Develop Operating Account audit strategy.
(3) Continue communications to stakeholders across campus.

c. **Clinical Research Career Ladder** (Marchant): Mr. Marchant gave an update on recent activities including follow-up on action items from the February meeting. These include presentations across campus to various stakeholders (Deans, Chairs, Faculty, Staff) in the 7 impacted Schools as well as senior leadership at the institution. Preliminary steps for the CCC Pilot were completed in February with the document retrieval. The REDCap Assessment was distributed to the 86 staff members on Monday the 11th. The Assessment will be completed over the next 2 business weeks before documentation will continue through the process for mapping. Mr. Marchant described the mapping process and the anticipated timeframe for completion which is end of Q2. Dr. Bertram reminded the group that given this is a pilot and that it's never been conducted on campus, we should remain flexible in the timeline while we work through potential unanticipated issues. Mr. Marchant also apprised the Committee that discussions are ongoing with Compensation to create a flexible model for the CRSP unit given their unique practice of serving the entire institution on an 'as needed' basis similar to Float Pool nurses in the hospital.

Actions: (1) Continue working with Compensation to consider the float pool model for CRSP personnel.
(2) Continue the mapping process for the CCC Pilot.
(3) Continue communications to stakeholders across campus.

3. **Subcommittee Reports**
   a. **Standard Budget Fees** (Kimberly): Dr. Kimberly distributed a couple of different versions of the Standard Budget Fee Schedule to garner feedback from the Committee. The difference between the Schedules being the use of a 'tiered' approach for Study Start-up in one and a 'standard' fee on the other. The premise in both situations is that the listed fees be used as a 'floor' for budget negotiations and not a 'ceiling'. Mr. Farough stated that he felt the standard rate of $12,000 was low. Information gathered by the working group (Horn, Kimberly, Mack, Marchant, Nichols) from more than 20 phone interviews and 20 web searches of peer institutions was shared and showed that $12,000 is a general average. Internal data reflected an average of roughly $8,000 which shows opportunity for improvement across the institution. A request was made for additional suggestions be sent to Mr. Marchant as we work to finalize the document for distribution to the institution in the coming days. A reminder was provided that in situations where an Investigator intends to do a trial where the budget provided by the Sponsor does not cover all costs, a source of revenue within the relevant

Department should be identified by the Investigator prior to the trial being conducted to cover the deficit.

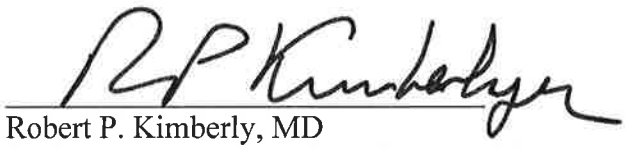
Actions: (1) Send all suggestions to Mr. Marchant for edits to the Fee Schedule by Friday March 15th.

b. **ClinicalTrials.Gov Registration** (Miller): Mr. Miller provided a draft flowchart outlining 'Clinical Trial Registration, Results Reporting, and Consent Form Posting Requirements'. He is working with Denise McKenzie on its creation. The document, once finalized, will be posted on the CTAO website for access in addition to being discussed in various venues around campus.

Actions: (1) Finalize documentation and distribute in various forums around campus.

4. **New Business**
   a. Digitally Federated Biorepository (Kimberly): Dr. Kimberly discussed work with Surgery, IRB, and Health System Compliance to create consent language enabling archiving of remnant tissue collected during clinical procedures for future use outlined in future IRB-approved protocols. The roll-out for this initiative will begin at 5:00pm today (March 13th) in the Department of Surgery.

5. **Next meeting:**
   a. April 3rd, Noon. FOT 12 Large Conference Room



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