

Clinical Trials Administration Committee (CTAC)

Meeting Minutes

May 2, 2018

12:00 – 1:00 pm

FOT 12 Large Conference Room

In attendance: Kimberly (SOM/CCTS), Schwebel (CAS), Redden (SOPH), Ladores (SON), Nichols (SOO/OVPR), Gilbert (SOD) Mack (SOM), Joiner (SOM), Marchant (CTAO), Farough (Health System), Gordon (CCTS/HSIS), Sandefur (OnCore), Fitzgerald (CCTS), Gerrity (OVPR)

Unable to attend: Dransfield (SOM), Mugavero (SOM), Bragg (UAB Compliance), Bates (Health System Compliance), Nabors (SOM), Motl (SHP), Saleh (SOM, CTAO), Agarwal (SOM)

(1) OnCore

- a. John Sandefur provided a brief update on OnCore implementation (Attachment), including the goal of completing the OnCore financials project in October-December 2018 time frame.

(2) Pending Accounts

- a. LaKisha Mack reviewed the rationale for and importance of using pending accounts for clinical trial expenses. Posting of investigator (PI) effort in clinical trials is important. Mark Marchant noted that 61% of accounts are being used, at least in part. The Calendar 2018 goal is $\geq 85\%$ utilization.
- b. Current strategies for increasing utilization were discussed, and monthly updates on utilization will be provided to CTAC.

(3) Time to Activation

- a. Bob Kimberly provided an overview of the components of the clinical trials initiative since 2Q 2016, including efforts to decrease the time to activation (Attachment)
- b. Jason Nichols discussed the four major task groups in TTA (Attachment); the group asked that he identify the start & end points by which TTA is to be measured and how CCC contributes to TTA prior to SRC.
- c. David Schwebel asked that monthly status reports for Clinical Billing Review, OnCore (calendar builds), OSP and IRB be provided to CTAC. This request was supported by consensus.

(4) CTAC Charter and Requirements

- a. Based on discussion with Teresa Bragg and Katie Crenshaw since the April CTAC meeting, many of the critical parameters and activities in clinical trials will be considered requirements, not policies *per se*. Thus, relative to the CTAC charter:
 - i. The full CTAC is broad and inclusive in membership to provide avenues for communication with constituencies involved in clinical trials.

- ii. The specific work of the CTAC may be performed by sub-committees which then report to the full group.
- iii. To fulfill its mission as outlined in the Charter, CTAC will make recommendations, as needed, regarding UAB requirements to the President and the President's Risk Cabinet for approval.

(5) CBR review process: requirement and streamlining process (modified review)

- a. All clinical trials must undergo a clinical billing review.
- b. As part of the Time-to-Activation (TTA) improvement process, the throughput of the Clinical Billing Review unit has been assessed. Because of the extensive backlog of protocols awaiting review, a streamlining of the review process into tiers of intensity according to the probability of change in SOC designation to Research designation has been reviewed by Compliance (Teresa Bragg, Brian Bates) and agreed upon.
- c. Streamlining will reduce the backlog 60% by June 30th (Attachment).
- d. Back-end quality control procedures will be implemented as well as routine individualized educational briefings with all Departments.

(6) Research summaries: requirement

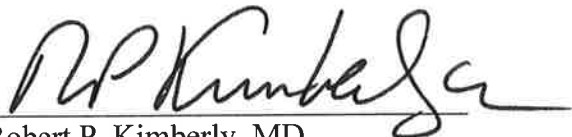
- a. All clinical interventional studies must have a research summary in the electronic medical record.
- b. The PI is responsible for writing / approving the research summary using the template developed by the ED physicians
- c. The value of each participant having a copy of the summary for the study in which he/she is participating was recognized and set as a future goal.

(7) New Business

- a. None added to the agenda.

(8) Next meeting:

- a. June 6th at Noon in FOT



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