Clinical Trials Administration Committee (CTAC)

Meeting Minutes March 7, 2018 12:00 – 1:00 pm FOT 803

In attendance:

Schwebel (CAS), Redden (SOPH), Ladores (SON), Nichols (SOO), Saleh

(SOM CTAO), Nabors (SOM), Joiner (SOM), Marchant (CTAO),

Farough (Health System), Gordon (CCTS/OnCore), Sandefur (OnCore),

Fitzgerald (CCTS), Gerrity (OVPR)

Unable to attend:

Dransfield (SOM), Mugavero (SOM), Agarwal (SOM), Bragg (UAB Compliance), Bates (Health System Compliance), Mack (SOM), Gilbert

(SOD), SHP representative

(1) Greenphire

- a. A quick summary of the initiative was given for the new CTAC members.
 - i. Web-based system utilized to pay participants in research studies.
 - ii. Replaces checks, petty cash, pre-loaded debit cards, and direct deposit for routine visits only.
 - iii. Travel payments still made by University check.
 - iv. Allows for easy reporting by Study or Participant as well as those who require 1099s for tax purposes.
 - v. Decentralizes the payment process as approvals are issued within Departments.
 - vi. A single card is assigned to a single participant so the card can be used across all studies in which that participant takes part.
- b. An update was provided for the implementation.
 - i. 10 Departments in SOM were originally identified for Wave 1. Eight pay participants making them eligible for entry:
 - 1. Emergency Department
 - 2. Anesthesiology
 - 3. Ophthalmology
 - 4. Dermatology
 - 5. Pediatrics
 - 6. Cell, Developmental & Integrative Biology
 - 7. OB/GYN
 - 8. Pathology
 - ii. Data (studies/users) has been collected for all 8 Departments.
 - iii. Data entry is complete for 5 of the Departments.
 - iv. One Department has been trained with others currently being scheduled.
 - 1. Departments go-live once training is complete.

(2) CTAC Charter

a. The draft CTAC charter, discussed in the February CTAO Advisory Committee meeting, was revised based on suggested feedback. The updated version

(attached) was presented to the President's Risk Cabinet on Tuesday, February 20th, discussed and approved unanimously by the Cabinet.

- b. CTAC replaces CTAO Advisory Committee
- c. The floor was opened for discussion of the new Charter and several points were considered:
 - 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 subcommittees which then report to the full group.
 - iii. To fulfill its mission as outlined in the Charter, CTAC will make recommendations regarding policy and procedure to the President and the President's Risk Cabinet for approval and adoption.

(3) CBR review process streamlining

- a. 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 discussed with Compliance (Teresa Bragg, Brian Bates) and agreed upon. Current full review often takes up to 40 hours while streamlined review is anticipated to take several hours.
- b. Streamlining will be available to very 'low probability of change' protocols submitted by research groups with demonstrated experience in devising appropriate budgets.
- c. Back-end quality control procedures will be implemented as well as routine individualized educational briefings with all Departments.

(4) New Business

a. OnCore implementation is proceeding well. UAB has been selected by Forte to receive the Award for Excellence in Clinical Research Operations.

(5) Next meeting:

a. April 4th at Noon in FOT

Robert P. Kimberly, MD

Senior Associate Dean for Clinical and Translational Research

Cc: Chris Brown, PhD, VP Research

Selwyn Vickers, MD, Senior VP Medicine and Dean SOM