Clinical Trials Administration Committee (CTAC)
Meeting Minutes
July 11, 2018
12:00 – 1:00 pm
FOT 12 Large Conference Room

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

1. Introduction of new members:
    a. Mike Bertram (Comprehensive Cancer Center)
    b. Robert Motl (School of Health Professions)
    c. Molly Wasko (School of Business)

2. Review of CTAC minutes from June 6th meeting:
    a. Approved as read without further modification

3. Updates / Reports
    a. **OnCore** (Sandefur) for both Wave 3 implementation and the Financial subproject (notes attached)

        Action: understand the nuances between Enterprise and CCC OnCore processes and how they can be harmonized.
    b. **Clinical Billing Review** (CBR, -- Marchant). The initial goal set in April was a 60% reduction in the backlog of studies awaiting review by July 1st. This goal has been exceeded with a 66% reduction. In terms of throughput for the new submissions awaiting review, there is currently a mean wait time of 11 days with a median of 10 days and a range of 1-41 days.

        Action: The next incremental goal is 80% reduction of backlog by August 1st.
    c. **Time to Activation** (TTA, -- Nichols).
        a. The report from the Society of Research Administrators who were on campus in May to review processes for both the Institutional Review Board (IRB) and

Office of Sponsored Programs (OSP) is expected to arrive on campus in July with their recommendations.

Action: The workflow for the creation and submission of the Research Study Summary will be harmonized with the expected updates in IRB workflow.

b. **Device Trials** (Kimberly). The pathway for approval of device trials involves a series of steps and approvals unique to these studies, and several studies have experienced significant delays in activation.

Action: A CTAC subcommittee is being comprised of Subject Matter Experts (SMEs) for device trials to determine ways to make the process more efficient.

c. **Greenphire** (Marchant). Review of the Greenphire process has shown that personnel in non-covered entities may have access to sensitive information within the participant search page as reflected in the Short Title provided by the sponsoring Department. Discussion with both Financial Affairs and Legal recommended removal of any sensitive information relevant to diseases and listing only the Organization Code, Department, and IRB #. This approach raises a larger question pertaining to patient safety for participants in multiple studies.

Action: A CTAC subcommittee will be created to devise a way that the institution can alleviate any safety risk as much as possible through process changes with the new systems currently being implemented (OnCore, Greenphire, PowerTrials).

d. Analysis of 2 trials recently completing the TTA process to further illustrate the timing of the various players (IRB, OSP, CBR, OnCore) and how they impact TTA.

4. **TriNetX** (Croker). Jennifer provided an overview along with data to illustrate how the paradigm is changing in terms of how pharmaceutical trials are coming to UAB investigators.

Action: Identification of champions for specific clinical disciplines who can assess and distribute specific study opportunities is being pursued.

5. **XpertTrials** (Croker). Jennifer provided a demonstration of UAB's new clinical trial search portal (Xpert Trials) which pulls data directly from ClinicalTrials.gov. The search tool is currently posted on the websites for UABMedicine, CCTS, and CTAO so that potential participants have a multiple ways to search for trials about which they may be interested.

Action: Continue work with XpertDox to refine the NLP search engine and enhance the internally facing dashboard of inquiries to facilitate triage to appropriate study teams.

6. **Clinical Research Staff Career Ladder** (Marchant). Since the June CTAC meeting, an implementation subcommittee has been created that Mark will chair and consists of representatives from 4 Schools/Colleges and Human Resources. Those team members are

LaKisha Mack, Cindy Joiner, Meredith Fitz-Gerald, Mike Bertram, Sigrid Ladores, Paula Garman, Lisa Smoot, and Brenda Adams. Background information has already been received from Duke University, University of Cincinnati, and the Association of Clinical Research Professionals (ACRP). The team is also consulting with the Office of the Vice President for Research who led a similar effort previously for creating a career ladder for research Scientists.

Actions: Immediate steps include determining the # of staff affected by the change, finalizing new job titles/descriptions, mapping current titles to the new titles, developing a communication plan for the institution, and outlining the timeline by which it will be completed. Monthly updates to CTAC will be provided by the subcommittee to keep CTAC abreast of the progress going forward.

(1) New Business

None

(2) Next meeting:

a. August 1st 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