Clinical Trials Administration Committee (CTAC) Meeting Minutes January 3, 2024 12:00 – 1:00 pm Zoom Conference Call

In attendance:

Unable to attend:

Guests:

Bertram (OCCC)

Boles (HSOM)
Fitz-Gerald (CCTS)
Gilbert (SOD)
Gordon (HSIS/CCTS)

Horn (OVPR) Irvin (SOPH)

Jackson (Health System Compliance) Kimberly (HSOM/CCTS)

Brown (Health System)

Kimberry (11801VII CC

Croker (CCTS)
Goss (SHP)
Joiner (DOM)

Joiner (DOM)

DeBlasio (OCCC)

Moon (CCTS)

Logan (University Compliance)

Marchant (CTAO)
Matthews (OSP)
McClintock (IRB)
Miller (OVPR)
Rizk (CCTS/CTAO)
Schwebel (OVPR)
Smith (SON)
Specht (OnCore)

Lee (DOM)

Nichols (SOO/OVPR) Pitts (Health System)

Wasko (SOB)

1. Review of CTAC minutes from December 6th meeting: The minutes were reviewed and approved.

2. Updates:

a. IRB Metrics & Process (McClintock): Mr. McClintock noted that the timeline data for commercial IRB reviews remain consistent and on target. He continued by stating that the OIRB continues its efforts to build strong relationships with its higher volume areas across campus. OIRB staff training/development has also been a key focus of late. Toward this end, Mr. McClintock discussed the recent work by Ashley Dancy, the IRB Trainer who has a background in instructional design, through a program called ADDIE (Analysis, Design, Deployment, Implementation, and Evaluation). Dr. Kimberly mentioned a recent outreach by the NYU CTSA relative to an updated Single IRB information exchange platform being developed by a consortium of CTSA institutions. He and Mr. McClintock will discuss the feasibility of UAB participation in the CTAC/IRB subcommittee.

Actions:

- 1. Continue to develop additional training opportunities for OIRB staff.
- 2. CTAC/IRB subcommittee to consider the NYU proposal.
- 3. Identify ways to improve efficiencies in both internal operations as well as departmental submissions to improve Time to Activation (TTA).

b. OSP Operations (Matthews): Mr. Matthews stated that our new Associate Vice President for Research. Virginia Hedberg, will begin on Tuesday January 16th given the institutional holiday that Monday. She will attend her first CTAC meeting in February. Mr. Matthews mentioned tomorrow's (January 4th) virtual office hours that will take place at 2:00pm. He then mentioned the new IRAP tool that enables one to see the status of all industry contracts, which now includes the ability for PI Delegates in addition to PIs. Mr. Matthews closed by mentioning that an RFA was released on December 21st for a new eRA system. The deadline for proposals is February 5th. The RFA is 30+ pages and includes over 300 questions for vendor response. Mr. Matthews anticipates many of the prior vendors to submit responses again from the last RFA.

Action:

- 1. Continue discussions to make meaningful revisions to standard industry contract language to aid in negotiation timelines.
- **2.** Update the committee on the vendor responses to the RFA.
- c. OnCore Operations (Specht): Ms. Specht stated that a new calendar builder, Sara Robinson, has been hired. Training continues for OnCore Financials with areas such as Dermatology, DOM CRE, and Pulmonary already active. The team recently uploaded the latest administrative fees into the ChargeMaster with the subject-related costs expected to be added at the end of the month for the launch of the new 2-tiered ChargeMaster (referenced below).

 Action:
 - 1. Continue implementation of the use of the Financials module across campus.
- d. Research ChargeMaster (Marchant): Mr. Marchant expanded on Ms.Specht's comments by reminding the committee of the plans to introduce a 2-tier ChargeMaster in OnCore for clinical trials with the 2nd tier specific to industry-funded trials at a rate of 150% of Medicare with all other trials continuing at the 100% rate. The go-live date continues to be set for January 29th. Given the holidays, no recent discussions have been had but the workgroup will recommence its weekly rhythm this Friday (January 5th).

Action:

- **1.** Continue efforts to ensure a smooth transition to the new 2-tiered Research ChargeMaster on January 29th.
- e. IllumiCare (Marchant/Gordon/Rizk): Mr. Marchant reminded the committee of the ongoing pilot from the past several months for the Clinical Trials recruitment application developed by IllumiCare. The Health System's contract, which has covered the cost to date, is being extended 3 months, which will take it through March 2024. Dr. Kimberly inquired about success metrics to which Mr. Marchant and Dr. Rizk replied that while it's easy to see app metrics like nudges, opens, and referrals, it is less clear how that translates to accruals. Additional discussions must be had with the vendor to ascertain ability to expand study access with pilot areas as well as the potential need for a University contract given the current agreement is with the Health System. Action:
 - 1. Conduct discussions with IllumiCare for use of its Trials application into 2024.

3. New Business:

a. Dr. Kimberly asked Ms. Fitz-Gerald about any updates relative to the budget harmonization effort. She mentioned that the next workgroup meeting will take place later in the day with a wider audience invited to participate. She expects more to be available to share at the February meeting.

4. Next meeting: February 7th

Robert P. Kimberly, MD

Senior Associate Dean for Clinical and Translational Research Chair, Clinical Trials Administration Committee

CC: Anupam Agarwal, MD

SVP for Medicine and Dean-Heersink SOM

Christopher Brown, PhD

VP-Research