Clinical Trials Administration Committee (CTAC)
Meeting Minutes
February 7, 2024
12:00 – 1:00 pm
Zoom Conference Call

In attendance:	Boles (HSOM)	Kimberly (HSOM/CCTS)
	Croker (CCTS)	Logan (University Compliance)
	Fitz-Gerald (CCTS)	Marchant (CTAO)
	Gilbert (SOD)	Matthews (OSP)
	Gordon (HSIS/CCTS)	McClintock (IRB)
	Goss (SHP)	Miller (OVPR)
	Horn (OVPR)	Rizk (CCTS/CTAO)
	Irvin (SOPH)	Schwebel (OVPR)
	Jackson (Health System Compliance)	Smith (SON)
	Joiner (DOM)	Specht (OnCore)
Unable to attend:	Bertram (OCCC)	Nichols (SOO/OVPR)
	Brown (Health System)	Pitts (Health System)
	Lee (DOM)	Wasko (SOB)
Guests:	DeBlasio (OCCC)	
	Moon (CCTS)	

1. **Review of CTAC minutes from January 3rd meeting:** The minutes were reviewed and approved.

2. **Updates:**

   a. **IRB Metrics & Process (McClintock):** Mr. McClintock opened the discussion by noting that industry trial data relative to through-put rates did not slow as much during the holidays as anticipated. He also shared that the OIRB plans to change how Board meetings are staffed for local reviews to aid turn-around times. Additionally, he stated that they plan to make some changes to training and onboarding for new staff in the office. Dr. Gilbert then inquired about having PIs on stand-by during Board meetings to address questions in real time to avoid delays to which Mr. McClintock replied that the option was worth exploring. This approach is slightly different than 'real-time' IRB reviews where PIs are present and the application is amended during the meeting in order to approve it right then. Dr. Kimberly then asked Mr. McClintock to be thinking about items for discussion at the partnership meeting with WCG later in the week.
   Actions:
      1. Continue to develop additional training opportunities for OIRB staff.
      2. Identify ways to improve efficiencies in both internal operations as well as departmental submissions to improve Time to Activation (TTA).
      3. Mr. McClintock to consider items for discussion at upcoming WCG partnership meeting to advance our shared mission of expedient regulatory reviews.
      4. Discussion of NYU proposal deferred.

b. **OSP Operations (Hedberg):** Ms. Hedberg was out of town for a meeting, so the topic was deferred until next month.

Actions:

1. Continue discussions to make meaningful revisions to standard industry contract language to aid in negotiation timelines.

c. **OnCore Operations (Specht):** Ms. Specht stated that the new 2-tiered Research ChargeMaster previously discussed was loaded into OnCore and activated on Monday January 29th. Going forward, all new industry-sponsored clinical trials will be charged at 150% of Medicare for Health System billable activities, while all other trials will continue at the 100% rate. The Financials Project implementation continues with 50/54 Management Groups in the high priority category fully trained. The last 4 will be completed by March. All others will be added as industry trials are initiated by those groups.

Action:

1. Continue implementation of the use of the Financials module across campus.

d. **Accruals to Trials (Rizk):** Dr. Rizk reminded the committee that we have been tracking accruals in OnCore, especially industry trials, since last summer through the Accrual Report which is distributed to PIs and research managers during the life of each trial. An effort is underway to better understand the characteristics of 'Zero Accrual' trials across campus. Presently, these seem to be constituting about 10-13% of total trials. The discussion continued by reviewing the many ways that assistance is made available to aid recruitment efforts. These include Recruitment Plan development, Feasibility Assistance, and the IllumiCare pilot. Dr. Smith mentioned that she has not been receiving Accrual Reports despite having some trials in OnCore. Ms. Specht replied that she would follow-up to ensure those are distributed. Ms. Fitz-Gerald reminded members that it is never too early to ask for assistance with Recruitment Plan development with the optimum time coming during the project and budget development period.

Action:

1. Ms. Specht to follow-up with Dr. Smith about Accrual Reports distribution.
    1. Follow-up note: Dr. Smith's protocols are handled by the O'Neal CCC CTO and accrual data are currently distributed to investigators within the O'Neal according to their protocols. Discussions regarding coordination are planned.

e. **IllumiCare (Marchant/Gordon/Rizk):** Mr. Marchant started by noting the recent distribution of lapel buttons to pilot participants including providers and research staff that read 'Ask Me about Clinical Trials'. These will be more broadly disseminated in the coming months as a part of ongoing efforts to aid patient engagement/recruitment at the point of care. He then reviewed the ongoing pilot efforts from the past several months for the Clinical Trials recruitment at the point of care application developed by IllumiCare. Pilot sites include Nephrology, Rheumatology, GI/Hepatology, Cardiology, and Family Medicine. The Health System's contract, which has covered the cost to date, is being extended 3 months and will take it through March 2024. Follow-up meetings are being help with pilot site leaders to provide updated utilization data and inquire about how to better support them in getting non-PI providers engaged. Mr. Marchant commented that recent discussions have turned to strategizing about ways to enhance the recruitment process given that the challenges seem to be more centered on the people involved than the tech, which appears to accomplish what it was designed to do. Dr. Joiner provided feedback from some sites within DOM that included the lack of APP involvement and challenges by providers to recall how to interact with the application during visits. Dr. Rizk discussed the past efforts to educate providers at faculty meetings and the struggle to follow-up due to faculty meeting agenda demands. Mr. Marchant agreed that APPs

could be better involved and that areas are open to include any providers that they desire to have access to the application by simply submitting their names and Cerner IDs to him. Additionally, areas have been invited to add new studies to the application.

Action:

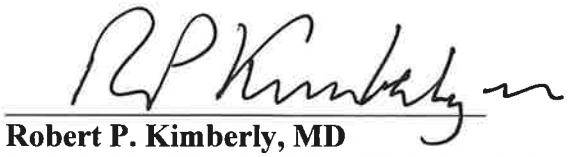
1. Continue adding new studies to the application and remind pilot sites to respond to the nudges and refer appropriate patients where possible for research team follow-up.

f. Participant ePayments (Marchant): Mr. Marchant provided an update to December's meeting surrounding the need to expand the participant payment platform to include an option to pay via a fully digital eCard; this goal dates back to a request made by Dr. Gilbert in September 2019. Since that time, UAB has launched the Tango application, but this is only used for international payments. Domestic payments continue primarily via Greenphire ClinCards and University Checks. Mr. Marchant noted that the contract with Greenphire is up for expiration/renewal in April 2025 so efforts must occur now to determine what other options may be available on the market, especially given the growing call for an ePayment method given the change in research demands in a post-COVID world. Discussions are ongoing with a vendor named Mural Health that proposes to provide several modalities for paying participants electronically including Venmo, PayPal, Zelle, ACH, and Push to Debit in addition to physical means like Checks and Reloadable Cards. Additional reviews are needed to better understand regulatory compliance such as 1099 reporting and technical capacity. Lastly, Mr. Marchant and Dr. Gilbert noted the recent Bill proposed in Congress to make clinical trial participation payments tax exempt and how it would aid in recruitment efforts in especially vulnerable or underserved populations. You can track the Bill's (H.R. 7090) progress here.

3. **New Business:**

   a. Dr. Croker inquired if anyone had experienced difficulties in getting UAB Hospital Pharmacy costs covered in NIH-funded budgets. Dr. Rizk replied that she had not encountered issues with her NIH trials. Dr. Croker is to follow-up with Dr. Rizk for further details on her experiences.

4. **Next meeting:** March 6th



Robert P. Kimberly, MD
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Chair, Clinical Trials Administration Committee

CC: **Anupam Agarwal, MD**
SVP for Medicine and Dean-Heersink SOM

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