Clinical Trials Administration Committee (CTAC)
Meeting Minutes
June 1, 2022
12:00 – 1:00 pm
Zoom Conference Call

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

1. **Review of CTAC minutes from May 4th meeting:** The minutes were reviewed and approved.

2. **Updates**

   a. **OnCore** (Specht): Ms. Specht announced that the OnCore Q/A sessions had commenced and are currently being held on Thursdays from 2:00-3:00pm. After an initial phase of study team participation, she noted that attendance has dropped off. In discussion of optimal times for such sessions, Mr. McClintock noted that OIRB provides a 2-hour window for attendees during midday with 3 reminders (1 week prior, the day prior, and the day of) which has seemed to help the IRB sessions. Given the large number of events already held during midday on Thursdays, Ms. Specht indicated that the OnCore team would likely look at another day and time and thanked everyone for their input. Ms. Specht also reminded the committee of Mackenzie Roberts starting her new role as a System Analyst on the team, which is a replacement for Lisa Williams who retired recently. Ms. Roberts comes to OnCore from the billing office. Additionally, Ms. Specht stated that the team is making modifications to the Unmanaged Visits Report based on suggestions from Dr. Rizk. Lastly, the committee was apprised of an update to the OnCore environment to Version 2021 R3 which is underway with testing.
   Actions:
      1. Complete system upgrade to Version 2021 R3.
      2. Determine an optimal time for weekly Q/A sessions to assist study teams.

   b. **IRB Metrics & Process** (McClintock): Mr. McClintock reported that the IRB is maintaining throughput times on reviews. The Real-Time Review pilot continues, as well as the effort of the CTAC-IRB subcommittee's work on using the EMR-derived information to determine patients for telephone outreach; the vetting of appropriate phone script(s) with the CSAB is underway. Dr. Kimberly asked whether IRB metrics are available for different types of studies (eg, 'clinical trial v non-clinical trial' status). Mr. McClintock replied that he is eager to learn what types of metrics are desired so he can determine if this information is or could be made available.
   Actions:
      1. Continue efforts to improve IRB throughput rates and enact process changes to enable such improvement.

2. Work with the CTAC-IRB subcommittee to identify desired metrics enabling differentiation in review times for studies identified as 'clinical trials' compared to those that are not.

c. **Data Coordinating Centers** (Kimberly): Dr. Kimberly reminded the Committee that DCC activities, which include research and scholarship, have been deemed as appropriate by UAB leadership and Office of Counsel. After last month's discussion, Dr. Kimberly stated that additional edits were suggested to the Charter and that a final document may be circulated relatively soon. Since the May CTAC meeting, 2 studies have been submitted with the most recent one reviewed within 2 business days after receipt. The workflow discussed at the May CTAC meeting is expected to be completed this month and circulated at the next CTAC meeting. Along with the workflow, a form for completion by the PI and/or Department Chair will be created to assist the reviewers.
Actions:
    1. Finalize DCC governance committee charter.
    2. Outline a workflow and submission document for final circulation to CTAC.

d. **Device Trials Investigator Agreements** (Kimberly): Dr. Kimberly noted that additional edits of the Agreement have been proposed including clarification that the document would be applicable to all device trials, regardless of sponsor type. The final version may be circulated for use very soon following final approval by Office of Counsel as well as University Compliance.
Action:
    1. Final version of the Agreement to be approved by Office of Counself and University Compliance prior to circulation for use among device trial investigators at UAB.

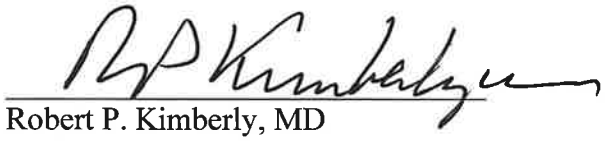
3. **Informatics Gateway** (Croker): Dr. Croker presented slides to the committee (attached) that outlined the 'what' and the 'how' that constitutes the Informatics Gateway, which enables researchers across UAB to utilize clinical data, -- including health records, claims data, social determinants, census and other information, -- to explore scientific questions and advance discovery. Given the data within the EMR is not created for research purposes, it often proves challenging to the scientists, which is why Dr. Croker noted it is best if they do not endeavor this effort alone, but rather take a team approach. The Informatics Gateway is a portal to engage informaticists, biostatisticians and clinician investigators (faculty, trainees & staff) to refine scientific questions, align study design with hypotheses to be tested, talk through what data can be leveraged to inform discrete and complex variables and to establish analytic plans. This teamwork then segues to an 'ETA' approach for data Extraction &Transformation in the creation of Analysis-ready data sets. Biostatisticians, including those represented by the CCTS BERD, are then well equipped to collaborate in the analyses. For more information on engaging in the Informatics Gateway process, one may go here.

Following the presentation, questions arose regarding the need for Data Use Agreements, especially for collaborative studies with the potential for transferring EMR data to external entities. This topic spurred considerable conversation, including the need for further education of investigators interested in retrospective chart reviews. Dr. Rizk volunteered to add information to the Clinical Investigator Training Program (CITP) that she co-leads along with Ms. Fitz-Gerald. Dr. Kimberly closed the discussion by noting the existence of CIGSAP that governs health system data and is co-chaired by Joan Hicks with whom he would follow-up.
Actions:
1. Dr. Kimberly to discuss the DUA process with Joan Hicks as it pertains to EMR data sharing with external researchers.
2. Ms. Cotten, Mr. McClintock, and others to coordinate efforts to ensure that the appropriate documentation is in place when EMR data may be shared with external entities and that UAB investigators are aware of the guidelines for such sharing.

4. **IllumiCare** (Marchant/Gordon): Mr. Marchant outlined the discusions that he, Mr. Gordon, and Dr. Rizk have been having in recent months with an external vendor, IllumiCare, which may develop a tool to enable clinicians at the point-of-care to have potential trial options available for therapeutic consideration based on both structured and unstructured EMR data. This effort would be a collaborative partnership with the vendor through a pilot to be initiated later this month among 3 therapeutic areas (Nephrology, Cardiology, and Rheumatology) with the expectation that the vendor might modify the product based on the feedback from the users as the pilot progresses. Mr. Marchant noted that other vendors have been considered, but that this one is a collaboration by virtue of the assistance UAB will be providing in its development. The pilot does not currently have an end date but may take up to a couple of years with the prospect of adding other pilot sites later in the process.
   Action:
   1. Initiate pilot with IllumiCare to begin testing their product to see if it improves recruitment efforts for clinical trials where the primary contact point for participants may be at the point of clinical care.

5. **New Business/Open Floor:** Dr. Kimberly announced that given July's CTAC meeting falling so closely to the Independence Day holiday on July 4th, we would look at alternative dates for a combined July/August meeting.

6. **Next meeting:** TBD



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-Heersink SOM