Clinical Trials Administration Committee (CTAC)
Meeting Minutes
March 3, 2021
12:00 – 1:00 pm
Zoom Conference Call

In attendance:

Boles (SOM)
Busby (OCCC)
Cotten (OVPR/OSP)
Croker (CCTS)
Farough (Health System)
Fitz-Gerald (CCTS)
Gilbert (SOD)
Gordon (HSIS/CCTS)
Horn (OVPR)
Kimberly (SOM/CCTS)
Marchant (CTAO)
McClintock (OVPR/IRB)
Miller (OVPR)
Motl (SHP)
Nichols (SOO, OVPR)
Redden (SOPH)
Rizk (CTAO/CCTS)
Sandefur (OnCore)
Schwebel (CAS)

Unable to attend:

Bates (Health System Compliance)
Bertram (OCCC)
Dransfield (DOM)
Joiner (DOM)
Logan (University Compliance)
Wasko (SOB)

1. **Review of CTAC minutes from January 20th meeting:** The minutes were reviewed and approved.

2. **Updates**

   a. **OnCore** (Sandefur): Mr. Sandefur reported that Wave 2 of Phase 2 of OnCore Enterprise implementation for industry-sponsored trials without clinical billables through the UAB Health System is slated for a May 1st go-live with 5 research units. This will be followed by Wave 3 on August 1st with 11 units. Just prior to that, the Financials implementation will wrap up on July 31st with the final 14 units completing training. In partnership with the PowerTrials/OnCore Oversight Committee, the team continues to develop custom reporting capabilities specific to Recruitment/Accruals. Mr. Sandefur discussed the ongoing collaboration with representatives from PowerTrials, Clinical Billing Review, and the Billing Office to re-engineer processes to create a more streamlined approach for information flow during trial initiation and management surrounding billable procedures through the Health System.

   Actions:
   1. Continue Phase 2 of implementation for industry-sponsored clinical trials without billables.
   2. Continue Financials implementation to enable the full use of OnCore for budgeting/invoicing within trials.
   3. Complete draft reports to reflect accrual goals and performance measures across campus to aid in recruitment efforts, and circulate for feedback.
   4. Finalize process re-engineering for information flow relative to billable services through the UAB Health System.

   b. **IRB Operations** (McClintock): Mr. McClintock provided a brief update on discussions with WCG/WIRB. Because of recent changes in WIRB's Connexus system, the UAB IRB is no longer able to submit the trial to WIRB on behalf of the PI as planned, and in turn this change has interrupted plans to implement the process, piloted with the Cancer Center, in order to gain

efficiency in submission time for new trials to WIRB. It's unknown at this time whether future changes to Connexus will enable the process to be reinstated. The UAB IRB is working with both WIRB and Advarra, as the 2 primary commercial IRBs used for industry-sponsored trials, to provided updated consent language and instructions to the commercial IRB staff about what is deemed 'acceptable' given the lengthy delays that can arise when Sponsors request to alter that language during the commercial IRB's review of new trials.

Actions:

1. Continue discussions with WIRB and Advarra to set clearer boundaries around standard consent language to reduce review times during trial activation when Sponsors request edits.
2. Continue reviewing internal processes to further enable efficiencies in operations.

3. **Trial Accrual: Strategies for Improvement** (Kimberly): Dr. Kimberly opened the discussion by noting the importance of adequate accrual to support the scientific integrity of the study design enabling meaningful and statistically reliable conclusions to be drawn and by noting the potential financial impact of unrecovered study expenditures in under-performing trials. Dr. Kimberly then opened it up for suggestions from the Committee on ways to improve recruitment.
   - Dr. Schwebel suggested greater penetration in the Social Media with platforms like Facebook, Instagram, and Google ads. Dr. Motl supported such an initiative.
   - Ms. Fitz-Gerald suggested that feedback from current participants on their experiences and communicating these through short videos might help patients understand the benefits of participating.
   - Dr. Rizk noted the importance of clinical research at an AMC such as UAB and making such expectations understood by providers. She noted that providers are typically the entry point for patients in the clinic into the clinical research world. Additionally, she mentioned the need for improving staff stability and having a more patient-centric mindset in our operations to make participation more attractive.
   - Mr. Marchant commented that Sponsor surveys among participants have found that the 3 primary reasons people engage in trials are encouragement by the treating clinician, convenience of access to the study site (eg, relatively close to the patient), and the study makes sense.
   - Ms. Horn noted that recruitment plans are often overlooked by PIs during the assessment of study feasibility either while writing the protocol (IIT) or reviewing one provided by a Sponsor. She suggested more attention to intentional, funded recruitment plans in feasibility assessments.
   - Ms. Busby noted that offsetting travel expenses to the study site is important to patients given the large catchment area of UAB in the southeast.

   Dr. Kimberly noted that these suggestions will contribute to discussions by a subcommittee on how to best to prioritize and move these forward to action. Mr. Marchant will be in contact with volunteers for further engagement.

   Actions:

   1. Dr. Kimberly and Mr. Marchant to coordinate a subcommittee for review of efforts to assist PIs in improving trial accrual and formulating a plan of action assisted by the new accrual reports being created in OnCore.

4. **New Business/Open Floor** (all):
   - Dr. Kimberly apprised the Committee of a collaborative effort between the Health System and the CTAO to provide a process by which research teams can arrange rides through Uber for their participants. Mr. Marchant is serving as the point of contact for the researchers. Additional information is forthcoming. Dr. Schwebel questioned whether Yellow Cab was still available for use; it was assumed that this mode of transport is still available if desired.
   - Ms. Cotten announced that a search is underway to secure a replacement for Dr. Sam Cartner who retired last fall after serving as the Associate Vice President for Research Facilities and Infrastructure. Ms. Cotten shared a link for more information

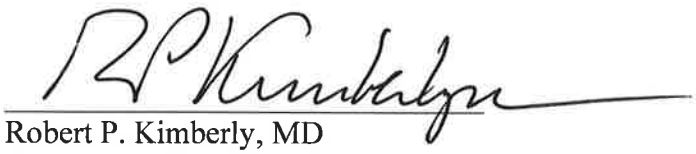
(https://www.parkersearch.com/current-opportunities/university-alabama-birmingham/assistantassociate-vice-president-research). She also mentioned that the Office of Vice President for Research is looking for a faculty member to assist with the Federal Demonstration Partnership of which UAB has been a part for several years. Information on it is attached as an addendum.

- Dr. Gilbert inquired about the status of his query at the last meeting on aligning travel expenses for employees between in-state and out-of-state. Dr. Kimberly reported that the query was elevated to the Vice Presidents for Research and Finance/Administration but that nothing further had been learned to date. Many on the Committee voiced their concurrence that doing so would benefit not only the University but the state at large given the current process makes it more attractive to host meetings out of state rather than within the borders due to 'out of pocket' costs. Ms. Cotten mentioned that she would raise the issue again within the VPR's office to heighten awareness of the need.

Actions:

1. Follow-up of the opportunity to arrange transportation through Uber for research participants (Marchant)
2. Follow-up of the discrepancy between in-state and out-of-state per diems with Dr. Brown and Mr. Bolton, for a waiver policy and/or for discussion with state legislators (Cotton).
3. Distribute information shared by Ms. Cotten to highlight the available opportunities for new positions currently being recruited.

5. **Next meeting:** April 7th (Zoom meeting)



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