Clinical Trials Administration Committee (CTAC)
Meeting Minutes
January 20, 2021
12:00 – 1:00 pm
Zoom Conference Call

In attendance:
Bates (Health System Compliance)
Bertram (OCCC)
Busby (OCCC)
Croker (CCTS)
Farough (Health System)
Fitz-Gerald (CCTS)
Gilbert (SOD)
Horn (OVPR)
Joiner (DOM)
Kimberly (SOM/CCTS)
Ladores (SON)
Logan (University Compliance)
Marchant (CTAO)
McClintock (OVPR/IRB)
Miller (OVPR)
Motl (SHP)
Nichols (SOO, OVPR)
Redden (SOPH)
Rizk (CTAO/CCTS)
Schwebel (CAS)
Wasko (SOB)

Unable to attend:
Cotten (OVPR/OSP)
Dransfield (DOM)
Gordon (HSIS/CCTS)
Mack (SOM)
Sandefur (OnCore)

Guests:
Bradford (CCTS)

1. **Review of CTAC minutes from December 9th meeting:** The minutes were reviewed and approved.

2. **Updates**

   a. **OnCore** (Kimberly): Dr. Kimberly reported that Wave 2 of Phase 2 of OnCore Enterprise implementation for industry-sponsored trials without clinical billables through the UAB Health System is being initiated this month. The Financials roll-out also continues, which highlights the continued need for Departments to improve budget development strategies as discussed previously. Dr. Nichols noted that the tracking of accruals in OnCore will enable the institution to meet its requirements through the CTSA and NCI funding structures. OnCore currently includes accrual goals for nearly 90% of all trials. Dr. Schwebel reminded the Committee that while not all trials are in OnCore, he is happy to provide data and serve as a champion for those trialists whose accrual data is not in OnCore to ensure that they are included in analyses going forward as well.

   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. Develop a formal report to reflect accrual goals and performance measures across campus for the next CTAC meeting.

   b. **Time to Activation** (Nichols): Dr. Nichols provided the annual update to the TTA analysis with thanks to Dr. Redden, Ms. Horn and others who provided the data that were used. His initial slide (deck attached) outlined the guidelines for the analysis including the time period, the study type, the data source systems and end points measured. The primary takeaways showed the comparative data since 2014 and the units which included OSP, IRB, CBR, along with 2 new ones for this year (OnCore and PowerTrials). The overall TTA showed no measureable difference from 2019 to 2020

(153 v 154 calendar days), and Dr. Nichols reminded the Committee that the several new processes implemented across offices in the latter part of 2020 would not be captured in these data given the study time period. He also reminded the Committee that the data reflected the entirety of the time the submission was in a respective office which often includes times back with Departments and study teams to address queries. Dr. Rizk suggested that it would be helpful to provide Departments with more granular data which reflected the time spent with study teams. Dr. Redden indicated that those data could be made available for distribution. Dr. Bertram noted that the Cancer Center consistently uses the task check list in OnCore, making such data available within the system.

Actions:

1. Provide TTA data to investigator-champions in order to facilitate their understanding of their role in reducing TTA.
2. Provide a 2021 TTA data report with the same methodology to access process changes currently underway across the University's administrative offices.

c. **Consenting Process-Remnant Tissue** (Bates): Mr. Bates presented slides (attached) which discussed recent efforts by the Health System to incorporate the IRB-approved HIPAA Authorization into the general surgery consent process in order to streamline the use of remnant tissue (obtained during standard of care procedures) for research purposes. Dr. Kimberly thanked Mr. McClintock and his staff for their cooperative and collaborative support of the initiative. This will be implemented initially as a paper process at both the main facility and Callahan but is expected to transition to an eConsent platform in the very near future. Dr. Nichols mentioned a recent discussion with the CCTS Partner Network about how incorporating research consents (including e-consents) into the EMR of partcipants is becoming more widespread and is desired given the EMRs serving as the source files for research purposes.

Actions:

1. Complete implementation of HIPAA Authorization and Procedure Consent enabling remnant tissue availability as biospecimens for research.

d. **Pending Accounts** (Marchant): Mr. Marchant reminded the Committee of continued efforts to monitor Pending Accounts which are provided to Departments at the time an industry-funded trial is submitted to OSP. If an Account does not reflect appropriate effort for both faculty and staff, then a 'hold' is placed on the trial's contract at OSP until the effort is added. A monthly report is provided by Financial Affairs to Mr. Marchant for monitoring usage. The latest report reflected 111 Pending Accounts in total of which 2 new ones and 11 prior did not show effort as expected. This reflects 12% of all Accounts which have been placed on 'hold'with OSP until the effort is added and confirmed in Oracle.

Actions:

1. Continue to monitor monthly activities relative to Pending Account utilization to ensure alignment with University requirements.

e. **Research Study Summaries** (Marchant): Mr. Marchant also updated the Committee on ongoing effort to ensure the timely collection of Study Summaries within PowerTrials for patient safety purposes. A monthly report is provided to Mr. Marchant for ongoing monitoring by the PowerTrials team. The most recent report (January) showed that there were 30 outstanding Summaries needed out of 1,012 studies total (97%). This reflects the recent historical trend seen over the last several months which has ranged from 96% to 99%.

Actions:

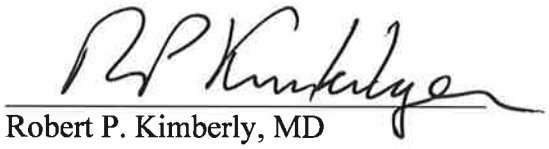
1. Continue to monitor the monthly collection of Study Summaries and report missing Summaries to Departments for creation.

3. **AAHRPP Re-Accreditation** (McClintock): Mr. McClintock reported that the re-accreditation process, which is conducted every 5 years by AAHRPP for our human subjects protection program, was held in the

fall prior to the holidays. He thanked those on the Committee who were a part of the review process, which included more than just members of the IRB, and reported that the institution is officially re-accredited until 2025. He noted that any deficiencies found by the reviewers will be taken into account and addressed in order to improve operations going forward. The Committee thanked Mr. McClintock and Mr. Miller for all of their efforts that made this review a success.

4. **New Business/Open Floor** (all): Dr. Gilbert raised an issue that he encounters in his research relative to the difference in how in-state travel expenses are reimbursed compared to out-of-state expenses. He mentioned that his research staff routinely travel across the state for his extramurally funded research and that travel to Mobile, as an example, often requires overnight stays. Rather than being reimbursed for costs, which is the customary practice for out of state travel, the staff are provided an $85/day per diem which includes food, lodging, fuel, etc. Given current costs, this can require staff to incur substantial out of pocket expenses. He requested that this topic be raised to appropriate institutional leadership for vetting with statewide leaders in Montgomery.
   Actions:
   1. Bring the discrepancy in in-state per diem amount to the attention of appropriate leadership, including Dr. Brown and Mr. Bolton, for a waiver policy and/or for discussion with state legislators. One solution would be that in-state travel reimbursement policy be made the same as the current out-of-state travel reimbursement policy.

5. **Next meeting:** March 3rd (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