Clinical Trials Administration Committee (CTAC)
Meeting Minutes
July 1, 2020
12:00 – 1:00 pm
Zoom Conference Call

In attendance:

Bertram (OCCC)
Busby (OCCC)
Cotten (OVPR/OSP)
Croker (CCTS)
Dransfield (DOM)
Farough (Health System)
Fitz-Gerald (CCTS)
Gilbert (SOD)
Gordon (HSIS)
Horn (OVPR)
Joiner (DOM)

Kimberly (SOM/CCTS)
Marchant (CTAO)
McClintock (IRB)
Miller (OVPR)
Motl (SHP)
Nichols (SOO, OVPR)
Rizk (CTAO/CCTS)
Roberson (UAB Compliance)
Sandefur (OnCore)
Schwebel (CAS)

Unable to attend:

Bates (Health System Compliance)
Ladores (SON)
Mack (SOM)
Nabors (DON/CCTS)
Redden (SOPH)
Wasko (SOB)

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

2. **Updates**
   a. **OnCore** (Sandefur): Financials training continues with virtual overview courses provided to Surgery, Orthopedics, Cardiology, and OB/GYN in June. A software upgrade will be conducted on July 10th and will be the last patch prior to the next major upgrade this fall to v16. The Divisions of Infectious Diseases and Nephrology are working through issues that might be encountered in clinical trials without clinical billables, including the prevention of data being sent to the billing offices and determining how to register participants who do not have a UAB Medicine Medical Record Number (MRN).
   Actions:
      1. Continue the OnCore Expansion Pilot and apply lessons learned to the overall implementation of OnCore across all trials on campus.
      2. Continue the Financials implementation to enable the use of OnCore for budgeting/invoicing within trials.

   b. **Time to Activation: IRB-Industry Trials** (McClintock): The TTA-IRB Pilot conducted within the O'Neal Comprehensive Cancer Center (OCCC) since mid-2017 has shown an improved process time prior to WIRB submission when compared to the 'normal' process. Mr. McClintock displayed data (attached) which reflected a mean difference in total review time of 25 calendar days between the 2 processes which reflects a 38%

reduction. Based on this outcome, the practice will be expanded campus-wide. Mr. McClintock met with Mr. Marchant in late June to begin the discussions on rolling out the process change across all Orgs on campus so that everyone may experience the same shortened pre-submission process time to assist in improving overall time to activation (TTA).

Actions:

1. Mr. McClintock and Mr. Marchant to implement a phased plan for incorporating the University into the revised process to achieve greater reductions in TTA.
2. Continue providing regular updates to CTAC on IRB approval data to understand trends over time so adjustments may be made as needed to processes.

c. **Single Identifier** (Marchant): As a follow-up action item from June's meeting, Mr. Marchant and Mr. Mike Matthews conducted a training session with the Department of Surgery in mid-June on how to register one's project (trial) in IRAP in order to obtain an IRB number prior submitting the full application for review. The training took ~25 minutes to complete via Zoom, including questions, which walks the trainees through the process outlined in pictorial form in a step-by-step guide. Given the simplicity of the process, which typically takes less than a minute once trained, it was determined that a campus-wide roll-out would be appropriate. Mr. Marchant began meeting by phone with organizational leaders across campus in late June to introduce the initiative, answer questions, and outline next steps which includes gathering a list of people who will need the training. Those meetings are ongoing but are expected to be completed by mid-July with training scheduling to follow. Zoom-based training should be completed by early August.

Actions:

1. Mr. Marchant to work with Mr. Matthews and others in OoR to complete the expansion of the Single Identifier initiative.

d. **IRAP Improvements** (Cotten): Ms. Cotten reported that eForm expansion plans for the Office of Sponsored Programs are still underway which would enable a replacement for the Extramural Checklist and Responsible Personnel List. Also mentioned was the ability to have a direct portal for federal submission uploads. Ms. Cotten also addressed a recent glitch in the system due to an upgrade which disabled the release of IRB letters to investigators. This has since been corrected and IRB letters are being distributed.

Actions:

1. Continue exploring ways to improve/expand the functionality of the IRAP system to improve research administration operations.

e. **COVID-19 Impact on IRB Activities** (McClintock): Mr. McClintock presented data (attached) which showed the difference in pre- and post-COVID submissions to the IRB for industry-sponsored trials between 2019 and 2020 (6-month periods). This reflects a 23% decrease in submissions (75 v 58).

f. **Re-opening for Clinical Research** (Nichols/Kimberly): Dr. Kimberly reminded the Committee about the plan to conduct 'Morning Coffee' and "Afternoon Tea" sessions with PIs and Study teams across campus to discuss issues encountered with re-opening.
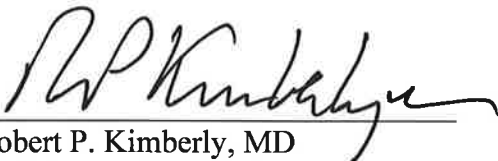
These 1-hour sessions, which were well attended, enabled PIs and their team members to discuss questions regarding COVID-related operational plans for research activities.

    i. **Screening/Testing**: Dr. Joiner reported that an online form to register for COVID-19 testing is being developed for research participants who screen positive for COVID-19 symptoms. For those who do require testing, participants instructed to be tested by their local healthcare provider or for those who wish, they may choose to be tested at the downtown test site run by UAB personnel on University Blvd near 22nd Street South. 5 appointment slots have been allocated for these participants during the 9:00 am hour each day. All results will be reported back to the research team and to the participants. Dr. Joiner expected the process to be ready for initiation on Monday July 6th. Several strategies for communication of the new process to PIs and their staff with additional written communication to come through mechanisms such as the *Trending in Trials* newsletter were discussed.

    ii. **Visits & Enrollment**: Mr. Gordon reported on OnCore data (attached) that reflected the difference in both enrollment and visit trends in clinical studies during the past quarter since COVID across both Oncology and non-Oncology related studies. These data demonstrated that while Oncology visits had taken a modest dip in activity with non-Oncology visits showing a greater change. CTAC will continue to monitor these types of data to understand the ongoing financial impact and recovery process from COVID-19 on the University.

    iii. **FAQs**: Dr. Nichols reported that the FAQs are posted on the Office of Research's COVID-19 related webpage and that they continue to be updated as needed. He reported that updates may be sent to Dr. Kent Keyser, Dr. Chris Brown, or himself.

    iv. **Communication Strategies**: There is continued effort to communicate updates to the research community through a variety of means as it relates to COVID's impact as well as other initiatives.

3. **New Business/Open Floor** (all): Mr. McClintock mentioned that AdobeSign adoption was moving forward which helps enable further use of eConsent in addition to electronic routing of forms for signature. Dr. Kimberly mentioned this being possibly beneficial to the upcoming External Advisory Board (EAB) discussion as a part of the OCCC's renewal.

4. **Next meeting:**
   a. August 5, Noon. Zoom Conference Call (to be provided)

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