Clinical Trials Administration Committee (CTAC)
Meeting Minutes
August 4, 2021
12:00 – 1:00 pm
Zoom Conference Call

In attendance:

Bertram (OCCC)
Boles (SOM)
Busby (OCCC)
Cotten (OVPR/OSP)
Croker (CCTS)
Farough (Health System)
Fitz-Gerald (CCTS)
Gilbert (SOD)
Gordon (HSIS/CCTS)
Gutierrez (CCTS)
Horn (OVPR)
Joiner (DOM)
Kimberly (SOM/CCTS)
Logan (University Compliance)
Marchant (CTAO)
McClintock (OVPR/IRB)
Miller (OVPR)
Nichols (SOO, OVPR)
Redden (SOPH)
Sandefur (OnCore)
Schwebel (CAS)
Wasko (SOB)

Unable to attend:

Bates (Health System Compliance)
Dransfield (DOM)
Motl (SHP)
Pickering (SON)
Rizk (CTAO)

1. **Review of CTAC minutes from June 2nd meeting:** The minutes were reviewed and approved.

2. **Updates**

   a. **Project eRA** (Cotten): Ms. Cotten reported that the remaining vendor demostrations had been completed since CTAC's June meeting. Based on the demonstrated functionality and the feedback provided through surveys of those attending the demonstrations, an executive decision was made to move forward with InfoEd Global, the current eRA vendor, to implement their completely new system. The timeline for installation will be available in the coming weeks. The expectation is that 7 modules (many of which are not currently available in the current instance) will be implemented independently of the current system to allow for a smooth transition from one to the other. Manuals and training will be developed internally and appropriate personnel resources will be added to ensure timely progress on the project. Ms. Cotten noted that decisions must be made on which records will be transferred to the new system. She assured everyone that records not transferred will still be available through archives (eg, previous records in ESIS).

   Action:
   1. Monthly updates to CTAC on progress toward full implementation of all modules.
   2. Ms. Cotten noted that she is available for virtual office hours for PIs in the School of Medicine on Thursday's at 2:00pm.

   b. **IRB Update** (McClintock): Mr. McClintock reported that the WIRB Consent Checklist went live on June 1st and that no negative feedback had been received to date. He stated that there will be a meeting next week with WCG to discuss ways to potentially improve the process. In terms of the virtual 'drop-in' clinics that have been held recently, Mr. McClintock stated that after being overwhelmed with demand at the initial one, they adjusted staffing and workflow improved. Based on continued interest, the IRB will hold these clinics every other week starting next week and will be monitoring trends in terms of the issues raised to see what topics are most popular. Lastly, he brought up ongoing work in the area of Time to Activation (TTA) and spoke about staffing changes,

some of which was due to turnover. After looking at a couple of complementary options, the IRB decided to engage Advarra for a short-term consultancy which will include bringing in 3 people to assist in addressing a backlog of submissions over the course of 13 weeks starting in mid August.

Action:

1. Advarra to review internal processes to further enable efficiencies in operations (and reduce TTA) with CTAC members providing ongoing counsel on efforts.

c. **OnCore** (Sandefur): Mr. Sandefur started by noting that OnCore Financials training was completed for all current users. Wave 3 of Phase 2 of OnCore Enterprise implementation is ongoing which will encompass all clinical trials (with and without clinical billables through the Health System) as well as other clinical studies. The inclusion of all clinical trials is a directive of the President's Risk Cabinet. This effort will sizeably increase the number of trials in OnCore. The new 2021 update of the ChargeMaster was recently completed and implemented. This update is an annual occurence to ensure that the prices for clinical activities in OnCore are up to date based on the released Medicare rates and is used for setting costs during the budget negotiation process in study start-up. The OnCore team has begun testing the newest version to the software (2020 R3) and expects it to be ready for production in late September.

Action:

1. Continue with Phase2, Wave 3 implementation.
2. Prepare to release a new version of OnCore in September.

d. **Trial Accrual Strategies** (Kimberly): Dr. Kimberly reported that the Trial Accrual working group has continued to identify aids in developing recruitment plans and that a survey has been distributed through Trending in Trials (TNT) to gauge the best times for Town Halls to discuss resources available across campus, including the Trial Innovation Network (TIN) and the Recruitment Innovation Center (RIC). Mr. Marchant will assist in the development of recruitment plans upon request.

Action:

1. Contact Dr. Kimberly or Mr. Marchant to provide feedback on best times to conduct Town Hall.
2. Contact Mr. Marchant for support in developing participant recruitment plans.

e. **R2Ops-HSR** (Nichols): Mr. Nichols reminded CTAC of the guidance on OVPR website with regard to protocols for R2Ops, both at the bench and in human subjects research. For HSR, screening remains active, testing of research participants is available and masking indoors in any building is required. Guidance with regard to quarantine and isolation procedures will be re-evaluated given the new context of the delta variant of SARS-CoV2. The value of reminding all study teams was discussed and encouraged. Dr. Nichols mentioned that if someone tests positive that is in a common work setting, then one should contact either Employee or Student Health (depending on the person involved). Dr. Joiner shared that if someone screens positive, the protocol is to utlize the web-based form, found within the guidance document, to schedule testing. Dr. Nichols reminded the Committee that the R2Ops guidance mirrors the UAB Medicine guidance so as information changes in it, appropriate modifications will be made in guidance relative to research.

1. **Action:**
    a. Screening of participants and masking of participants and study personnel are required.
    b. Testing of research participants is available as previously done.

3. **LOA Process Improvement for Devices** (Kimberly): Dr. Kimberly reminded the Committee that device trials typically require approval by University Hospital through the Letter of Agreement (LOA). This process has not been predictably efficient or expeditious. With the support of Tony Jones, President of the

HSF, Patterson's hospital team undertook a process improvement initiative, led by Ms Christine Smith, a newly engaged management engineer. By understanding the necessary steps involved and incorporating a new project management platform (Monday.com), the staff are now able to transparently communicate to one another about the status of each LOA in the workflow, which aids in identifying bottlenecks. This has led to a reduction of just over 50% in the median time for approval (154 days to 74 days), with the stated goal of goal of 60 days, to ensure that the LOA is not a hindrance to trial activation for devices going forward.

Action:

1. Continue improvement of the LOA process to achieve the stated goal of a median of 60 days.

4. **CTAC Update: Council of Deans** (Kimberly): Dr. Kimberly shared slides (see attached) from a presentation to the Council of Deans on July 28th to apprise them of ongoing work as it pertains to the Clinical Trials Administration Committee, which began with an overview of the Charter signed by President Watts in February of 2018. He went on to describe the work of the various sub-committees that have been active over the past several months, as well as forward-looking work on uninformative trials which has taken on a national lens of prominence recently. Dr. Kimberly shared Trial Expenditure data since 2013 for UAB that reflected a continual trajectory of growth and emphasized that a constant eye toward excellence enables us all to succeed in these efforts both today and into the future.

   Action:

   1. Dr. Kimberly to present an annual update to the President's Risk Cabinet later in August.

5. **Next meeting:** September 1st (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