Clinical Trials Administration Committee (CTAC)
Meeting Minutes
June 2, 2021
12:00 – 1:00 pm
Zoom Conference Call

In attendance:	Boles (SOM)	Marchant (CTAO)
	Cotten (OVPR/OSP)	McClintock (OVPR/IRB)
	Croker (CCTS)	Motl (SHP)
	Farough (Health System)	Nichols (SOO, OVPR)
	Fitz-Gerald (CCTS)	Pickering (SON)
	Gordon (HSIS/CCTS)	Redden (SOPH)
	Horn (OVPR)	Rizk (CTAO/CCTS)
	Kimberly (SOM/CCTS)	Schwebel (CAS)

Unable to attend: Bates (Health System Compliance)
Bertram (OCCC)
Busby (OCCC)
Dransfield (DOM)
Gilbert (SOD)
Joiner (DOM)
Logan (University Compliance)
Miller (OVPR)
Sandefur (OnCore)
Wasko (SOB)

1. **Review of CTAC minutes from May 5th meeting:** The minutes were reviewed and approved.

2. **Updates**

   a. **Project eRA** (Cotten): Ms. Cotten reported that 2 vendor demos (Cayuse & Kuali) had taken place in May with 5 more scheduled in the first half of June. Each one lasts 2 hours with about 75 invites extended for UAB leaders and employees to attend. Each attendee is asked to complete a survey to provide feedback on the vendors. Based on that feedback, a second round of demonstrations in July will take place with 2-3 finalists to go more into greater depth on their respective systems' functionality. Each of the demonstrations is recorded and will be posted on the Project eRA website. Additionally, budget estimates are required from each vendor for consideration as well. The final recommendation by the University will be submitted to the Board of Trustees in August for discussion and potential approval at the September Board meeting.

   Actions:
   1. Identify a vendor with whom to partner in implementing the new eRA system.
   2. Continue providing monthly updates to CTAC on progress toward full implementation of all modules.

   b. **IRB Update** (McClintock): The new Consent Form Checklist for WCG IRB (WIRB) submissions was rolled out to trialists this past week for use. This is expected to decrease administrative burden on study teams and ultimately help shorten time to activation (TTA). The IRB process improvement workgroup, constructed following last month's CTAC meeting, convened in late May for the first time. A few of the recommendations from that group include the following: generate feedback from both high and low volume submitters to the IRB to determine recurring issues, increase communications to study teams through various channels (including theVPR and CCTS websites), and develop opportunities for researchers to have 'walk-in' hours via Zoom with senior IRB staff for Q&A (which is expected to kick-off on June 17th from 11-1).

Actions:

1. Consent language discussions to continue with Advarra until resolution.
2. Continue reviewing internal processes to further enable efficiencies in operations with CTAC members providing ongoing counsel on efforts.

c. **OnCore** (Gordon for Sandefur): OnCore Financials training continues across campus with July 1st still the target for completion. Wave 2 of Phase 2 of OnCore Enterprise implementation for industry-sponsored trials without clinical billables through the UAB Health System went 'live' on May 1st in 13 Management Groups. Mr. Gordon mentioned that the ongoing collaborative efforts among PowerTrials, Clinical Billing Review, and the Billing Office to re-engineer processes for billable procedures through the Health System to create a more streamlined approach for information flow during trial initiation and management continues with a Pilot in 2 Departments (Dermatology & Urology) and is expected to be expanded to a third very soon. The updated Oncore ChargeMaster is now tentatively scheduled for completion in late July. Lastly, a new version of OnCore (2020 r3) is anticipated to be released in the near future.

Actions:

1. Continue Financials implementation to enable the full use of OnCore for budgeting/invoicing within trials.
2. Finalize process re-engineering for information flow relative to billable services through the Health System.
3. Complete the annual ChargeMaster update.
4. Prepare to release a new version of OnCore.

3. **Procedural eConsent/Remnant Tissue** (Kimberly): Dr. Kimberly reminded the Committee of presentations from the past 2 months about eConsent for the surgical procedure and for HIPAA authorization, especially in relation to use of remnant tissue, coupled with clinicl data, for research. Implementation is proceeding with the hospital and the efficiency gained through connectivity to the EMR is most helpful. Dr. Kimberly also reminded the Committee that if the tissue is collected solely for the purpose of research, then a study specific Human Subjects Protocol and consent with IRB approval is needed.

Action:

1. Communicate to Investigators across campus the capabilities of TBR to increase awareness.

4. **Trial Accrual Strategies** (Kimberly et al): Dr. Kimberly announced that the initial meeting was held by the workgroup following a couple of months of preliminary work, with a number of items recognized as nascent steps toward improving efforts across campus. These included the following:
   a. Increase communications across various channels to bring awareness to PIs of assets available on campus to assist efforts;
   b. Bolster training opportunities to both PIs and staff in recruitment and retention 'tools';
   c. Explore potential ways to increase the creation and implementation of recruitment plans during the early stages of trial development and initiation;
   d. Offer voucher-supported budget and negotiation support through the Clinical Research Support Program (CRSP) to ensure line items are identified to cover recruitment costs

   Report capability will be developed in OnCore to provide appropriate tracking of recruitment across trials and how those efforts align with goals for the respective trials. Dr. Kimberly reminded the Committee that these initial steps are just the beginning of the work by the group.

Action:

1. The trial accrual workgroup will continue to meet and devise ways to improve both recruitment and retention across campus while keeping CTAC apprised of those efforts.
2. Review by the Committee of ongoing work at other institutions or services provided by vendors which are being reviewed in addition to materials from the NCATS Trial Innovation Network:
   a. UMN Feasibility Review
   b. OSU Recruitment & Retention

c. UF Recruitment
d. Acclinate
e. Deep 6AI

5. **Training Strategies & Expectations** (Fitz-Gerald): Ms. Fitz-Gerald followed up the accrual workgroup discussion by sharing various ways that training in recruitment is already being provided to both faculty and staff at UAB. Some of these include the Clinical Investigator Training Program (CITP) and 'CITP on the Go' podcasts, Research Seminar Series, Lunch & Learn sessuibs, and specifically focused workshops. The most recent training was held on May 20th which covered topics such as i2b2, coordinator testimonial on a large genetically focused population-based study (All of Us), and overviews of Uber Health and ThreeWire. Trainings will continue into the future with all of the material archived on the Clinical Trials Kiosk on the CCTS website which includes videos, podcasts, and other helpful media.
   Action:
   1. Review topics of all training modules and podcasts to ensure that they are addressing current/new issues as well as fundamental principles.
   2. Ongoing trainings to be conducted in best practices for recruitment and retention with ideas requested from CTAC members for new content, all of which will be available for ad hoc asynchronous review through the Clinical Trials Kiosk on the CCTS website.

6. **Clinical Trials Activity Update-FY20 v FY21** (Nichols): Dr. Nichols opened by discussing the various ways that we track clinical trial activity year over year, which includes numbers of trials, dollars contracted across trials, and expenditures applied against trials. Given the amount of uncertainty UAB faced this time last year in the early weeks of the COVID pandemic, it has been especially telling to compare this year to last year since activities have rebounded.

Fiscal Year	Number of Trials	Contracted Dollars	Expenditures
2020	95 (year to date)	$22.6M	$77.0M (total)
2021	131 (year to date)	$75.0M	$47.8M (ytd)

   Based on current projections, it is anticipated that we have ~$82M by the close of the fiscal year which would put us in the top 10 nationally among public institutions.

7. **New Business/Open Floor** (all): No new business offered at this time.

8. **Next meeting:** July 7th (Zoom meeting)

RP Kimberly MD

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