Clinical Trials Administration Committee (CTAC)
Meeting Minutes
May 4, 2022
12:00 – 1:00 pm
Zoom Conference Call

In attendance:	Bertram (OCCC)	Kimberly (SOM/CCTS)
	Croker (CCTS)	Lee (DOM)
	Fitz-Gerald (CCTS)	Logan (University Compliance)
	Gilbert (SOD)	Marchant (CTAO)
	Gordon (HSIS/CCTS)	McClintock (IRB)
	Goss (SHP)	Miller (OVPR)
	Horn (OVPR)	Nichols (SOO, OVPR)
	Joiner (DOM)	Rizk (CTAO)
		Specht (OnCore)
Unable to attend:	Bates (Health System Compliance)	Gutierrez (CCTS)
	Boles (SOM)	Schwebel (OVPR)
	Cotten (OVPR/OSP)	Smith (SON)
	Farough (Health System)	Wasko (SOB)
Guests:	Bradford (CCTS)	Frison (OVPR)
	Clements (OSP)	

1. **Review of CTAC minutes from April 6th meeting:** The minutes were reviewed and approved.

2. **Updates**

    a. **OnCore** (Specht): Ms. Specht noted that the latest edition of the Accrual Report, rolled out last month to study teams, utilizes a color-coding scheme (Green/Yellow/Red) to indicate at easy glance how recruitment for a trial is progressing. She outlined that the OnCore team continues to provide 'unmanaged' visit reports to let them know which visits are outstanding, so they can be addressed expeditiously. As a reminder, all visits should be updated within 48 hours of the scheduled visit time with the participant to ensure accurate information flows to the billing office. Ms. Specht also notified the Committee that the System Administrator III role had been filled this week with a start date of June 1st. Lastly, she mentioned that the OnCore team will begin holding weekly Q/A sessions via Zoom similar to the IRB's virtual office hours. A short discussion followed surrounding best channels of communicating this information to Departments.
    Action:
        1. Internal evaluation to continue by OnCore team to identify areas for further improvement based on lessons learned from the Onsemble conference last month.
        2. Begin weekly Q/A sessions to assist study teams with their OnCore questions.

b. **IRB Metrics & Process** (McClintock): Mr. McClintock updated the Committee on the status of review time for Expedited studies which saw an increase from Q1 to Q2 of 16 calendar days. Renewed efforts to improve this shorten this time have been successful for Q3 with a reduction to 13 calendar days compared to Q2. The IRB continues to monitor important metrics to ensure efficiency in processes which speaks to the IRB's involvement in a couple of sub-committees regarding process improvement, as well as participant accrual (referenced later in the minutes in item 7). Virtual IRB office hours are ongoing with Mr. McClintock tracking attendance data to understand trends. In response to a question by Dr. Croker, Mr. McClintock mentioned that the 'real-time reviews' continue to be piloted with more information to come on that topic at a future meeting.
Actions:
    1. Continue efforts to improve IRB throughput rates and enact process changes to enable such improvement.
    2. Speak with various UWIRC community board members as part of the effort to re-examine internal positions relative to utilization of EMR data to aid in participant recruitment efforts.

c. **Data Coordinating Centers** (Kimberly): Dr. Kimberly reminded the Committee that DCC activities which include research and scholarship have been deemed as appropriate by UAB leadership and Office of Counsel. A document (attached) outlining the charge and governance of an advisory committee was circulated prior to the meeting and the highlights were addressed. Dr. Nichols added that besides scholarship, the DCC Assessment Group will help ensure adherence to 21 CFR parts 312 and 812, particularly when UAB will take on sponsor/investigator responsibilities. In response to a question from Mr. Marchant, Dr. Kimberly stated that details regarding the submission process of DCC proposals to the Assessment Group for review need to be finalized.
Actions:
    1. Finalize DCC governance committee charter.
    2. Outline a workflow for submission of proposals to the committee for review.

d. **Device Trials Investigator Agreements** (Kimberly): Dr. Kimberly referenced the process document (attached) that had been drafted with University Compliance and Office of Counsel and distributed to the Committee earlier this week for review. The key points addressed by Dr. Kimberly spoke to the regulatory nature of the agreements and the fact that institutional leadership believe these agreements are suitable for a Principal Investigator to sign. Mr. Miller and Ms. Clements noted that they had suggestions for some further modifications to be considered. Dr. Kimberly responded that for the sake of efficiency, it would be best if all suggestions could be compiled into a single response for Compliance, OOC and OOR. Mr. Miller agreed, and along with Ms. Clements, will forward comments and suggestions to Dr. Kimberly.
Action:
    1. Mr. Miller to work with Ms. Clements to compile comments and edits for consideration by Offices of University Compliance and Counsel prior to finalization.

3. **Clinical Billing Review (CBR) Operations** (Marchant): Mr. Marchant reminded the Committee of the efforts to improve operations, including throughput rate, of CBR several years ago. As a part of those efforts, three initiatives were agreed upon through partnering with both University and Health System Compliance offices. The first was the goal to review all submissions within an average of 10 business days. The CBR Tracker enables monitoring in real-time. Based on data reviewed just prior to the meeting, the current average time is 9 business days. Mr. Marchant emphasized that this number varies with volume, staffing levels, etc. The second initiative to engage Departments in annual educational training is held each fall. This past year CBR partnered with the OnCore team as a part of the submission process reengineering to use those trainings to roll-out the newly consolidated submission process that went live on November 15th 2021. There were 18 trainings conducted over 2 months, which included 30 therapeutic areas. Lastly, CBR regularly conducts Quality Assurance (QA) analyses in order to ensure that a sample of trials that are eligible for 'modified' review rather than 'full' are re-reviewed to verify that if a full review had originally been conducted, nothing additional would have been found. Approximately 10% of the annual modified review count go through this process. In 2021 that included 109 studies, so an assortment of 11 studies were selected with no additional findings determined. Mr. Marchant credited the ongoing educational sessions as the reason why the modified process continues to be a success. Dr. Kimberly asked if the proportion of studies qualifying for "fast track" review had increased over the last year and if new study teams had qualified for such review after participating in the training programs. Mr. Marchant indicated that he would review available data to address these questions. He closed by mentioning that regular discussions are held with Health System Compliance, which was not represented in the meeting, to ensure all activities are in alignment with expectations surrounding appropriate billing practices.
   Action:
   1. Continue efforts to conduct coverage analyses within the expected timeline while maintaining quality of reviews and submissions through educational efforts.
   2. Review of data on the proportion of studies qualifying for expedited review and on the impact of training on bringing new study teams up to the performance levels expedited for expedited review.

4. **Huron Tool Utilization in OSP** (Cotten): Tabled until June due to Ms. Cotton's absence.

5. **Informatics Gateway** (Croker): Primary discussion tabled until June in the interest of time, but Dr. Croker reiterated that it is an important concept to articulate to PIs that the EMR is available for use in several different facets of investigation, underscoring the critical need for multidisciplinary expertise to maximize the value and utility of the data for research purposes. She shared this link for distribution to investigators.
   Action:
   1. Discuss *Informatics Gateway* in greater detail at June meeting.

6. **CTAC-CTI Finance Sub-Committee** (Kimberly): Dr. Kimberly shared that the Finance, comprised of several CTAC members as well as financial officers from the HSOM and VPR office, continues to meet regularly to ensure budgetary alignment for initiatives.
   Action:
   1. Continued engagement by the Sub-Committee to review expenses and budget accordingly to fund efforts surrounding the Clinical Trials Initiative.

7. **CTAC Accrual Sub-Committee** (Kimberly): Dr. Kimberly reiterated the charge of the group relative to improving recruitment and retention across the clinical trials with current initiatives focused on charging PIs to create thorough Recruitment Plans prior to initiating their trials. Assistance is currently available through the Clinical Research Support Program (CRSP) at no cost to study teams. Since the effort began on January 3rd, PIs have been reaching out, mostly in an effort to improve upon ongoing trial recruitment. Going forward, efforts will be made to contact study teams at the onset of the trial prior to study initiation in a pro-active effort to enhance recruitment strategies and their funding.
   Action:
   1. CRSP to contact PIs at the onset of the study start-up period to offer assistance in their Recruitment Plan development.

8. **Reminder**
   a. Clinical Trials Day (Bradford): Event to be held in WTI Lobby on May 20th from 7:30-9:30am with food, speakers, information, and giveaways. Go to this link to register and distribute to others in respective areas. Twitter feed: #AdvancingDiscovery

9. **New Business/Open Floor:** No additional items raised at this time.

10. **Next meeting:** June 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-Heersink SOM