Clinical Trials Administration Committee (CTAC)
Meeting Minutes
May 3, 2023
12:00 – 1:00 pm
Zoom Conference Call

In attendance:	Boles (HSOM)	Kimberly (HSOM/CCTS)
	Croker (CCTS)	Logan (University Compliance)
	Fitz-Gerald (CCTS)	Marchant (CTAO)
	Gilbert (SOD)	Matthews (OVPR)
	Gordon (HSIS/CCTS)	McClintock (IRB)
	Goss (SHP)	Nichols (SOO, OVPR)
	Horn (OVPR)	Rizk (CCTS/CTAO)
	Irvin (SOPH)	Smith (SON)
	Joiner (DOM)	Specht (OnCore)
		Wasko (SOB)
Unable to attend:	Bertram (O'Neal)	Miller (OVPR)
	Brown (Health System)	Pitts (Health System)
	Jackson (Health System Compliance)	Schwebel (OVPR)
	Lee (DOM)	
Guest:	Howard (CCTS)	Ritchey (CCTS)
	Oliver (CCTS)	

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

2. **Updates**

   a. **OnCore** (Specht): Ms. Specht opened by announcing that the version upgrade will be completed the first weekend of June. She then mentioned that attendance to the weekly Q/A sessions remained low, but that she expects it to increase with the Financials module full implementation. This expansion will help study teams with budgeting and invoicing practices.

      Actions:
      1. Continue weekly OnCore Q/A sessions to provide assistance and ongoing training to the clinical research community.
      2. Identify the manageable target percentage of late 'occurred' visit entries and report at the June meeting.
      3. Continue efforts to complete the latest system upgrade in early June.

   b. **IRB Metrics & Process** (McClintock): Mr. McClintock stated that efforts to bolster staffing for the office continue with one new hire and two more offers being extended. The phone script project continues its development in a joint effort with the Clinical Research Support Program (CRSP). Next steps include dissemination of training along with modifications to the IRB application to include references. The completion of its rollout is slated for early summer. Dr. Kimberly posed a question about the measurement of training effectiveness surrounding the phone script, to which Mr. McClintock explained that it will be a tough variable to measure given its interdependencies on other factors. Mr. McClintock continued by mentioning ongoing efforts to put a formal agreement in place with Advarra to align its processes more closely with

those of the Western IRB (WIRB). Lastly, discussions are underway with a sponsor surrounding a Master ICF template.

Actions:

1. Continue efforts to improve IRB throughput rates and enact process changes to enable such improvement.
2. Conduct a deeper analysis into why submissions appear to be trending down over the past few years and determine if there are any primary areas responsible for this pattern.
3. Complete the phone script dissemination.
4. Finalize the agreement with Advarra to standardize expectations with the other primary commercial IRB (WIRB).

c. **CBR Metrics** (Marchant): Mr. Marchant reminded the Committee that the Clinical Billing Review office has a bifurcated process (full v modified) that was enacted several years ago in conjunction with the University and Health System Compliance Offices and that enables reviews submitted by qualifying teams to be streamlined for better efficiency while maintaining compliant billing practices. He shared that while the overall goal across all new submissions is ten business days, the office is currently tracking at a mean of seven (Fulls-8 & Modifieds-6) as of May 2nd. He then shared that the current volume of the office is tracking considerably higher this year compared to last year with total submissions across all types listed at 155 as of April 30th; whereas the office received 346 for the entirety of 2022. Mr. Marchant mentioned that CBR continues to conduct its Q/A reviews on an annual basis with 15 having been completed over the past year with no additional findings. Lastly, he shared that the office conducted its annual departmental educational sessions in October/November 2022 with 21 meetings held. Given that staff are the primary attendees of these meetings, Mr. Marchant suggested that CBR should be included in investigator trainings such as CITP. Dr. Rizk and Ms. Fitz-Gerald suggested further discussion in order to coordinate that with the OnCore overview provided by Ms. Specht.

Actions:

1. Dr. Rizk, Ms. Fitz-Gerald, and Ms. Specht to coordinate with Ms. Guyton on ensuring investigators are knowledgeable about compliant billing practices.
2. Continue monitoring Medicare Coverage Analysis (MCA) operations to ensure they are timely and compliant with regulations.
3. Mr. Marchant to follow-up with Mr. Logan and Ms. Crenshaw on current practices to maintain alignment with institutional expectations.

d. **Radiology Over-reads** (Bolding): Deferred to June's meeting.

e. **ClinicalTrials.gov** (Howard/Ritchey):
Ms. Howard presented several metrics related to UAB conformance to ClinicalTrials.gov expectations. Since she and Ms. Ritchey took over its oversight in 2021, UAB's record of timely completion of data entry has improved substantially while maintaining a high volume that rivals other peer research institutions such as Duke and Yale. Ms. Howard noted that CRSP team is available to work with PIs and to assist with completion of records. She stressed the importance of Departments notifying them whenever study PIs change or PIs leave UAB so that record integrity may be maintained. In response to Dr. Rizk's suggestion, Ms. Howard indicated that a list of non-compliant PIs may be obtained by Departments from her or Ms. Ritchey.

Action:

1. Committee members to speak to their respective School Departments about the importance of departing PIs notifying the ClinicalTrials.gov team (CCTSClinicalTrials.govhelp@uabmc.edu), so that records may be updated accordingly.

2. Reinforce with Executive Administrators and directly with Department Chairs the importance of departing PIs notifying the ClinicalTrials.gov team so that records may be updated accordingly.

f. **XpertTrials** (Kimberly): Dr. Kimberly shared that the contract with the XpertTrials team had been extended another year by the Health System. He explained that the platform is a site that extracts ClinicalTrials.gov data about trials available for recruitment and constructs it in an easily searchable database that's available both internally and externally for use. Mr. Gordon shared his screen to enable everyone the ability to see the site and how it is navigated with ease.

3. **Regulatory Support Pilot** (Croker): Dr. Croker presented data reflecting the impact of the pilot initiative in regulatory support involving the CCTS's CRSP regulatory team and three Divisions in Pediatrics led by Dr. Dan Feig. The high-level takeaways showed a marked improvement in review times for submissions originating from the pilot Divisions as compared to those from the non-pilot Divisions. The pilot groups reduced its 'time to approval' from 71 days to 27 while the non-participating group maintained steady state (65-67 days) which more closely resembled the IRB RAPID metrics found online. Additionally, there was a reduction in IRB-requested revisions by the study team. Lastly, interviews, conducted among the pilot staff, found an overall sense of improved operations, satisfaction with re-direction of regulatory responsibilities and appreciation for the outcomes. Mr. McClintock added that the IRB staff also appreciated the effort as it reduces burden upon them as well.

   Action:

   1. Discussions to continue on ways to expand the pilot for greater efficiencies in operations.

4. **Clinical Investigator Working Group Meeting** (Joiner, Kimberly): Dr. Joiner noted that she and Dr. Kimberly met earlier in the day to discuss how the scope for the group of clinical research PIs (based primarily in Department of Medicine) might evolve going forward. Dr. Joiner said that they would look at additional PIs from other Departments to broaden the representation as well as recognizing that some of the current members had departed due to other responsibilities. The group is scheduled to meet again next week and further discussions will be held at that time to circulate ideas for how the group may be most effective.

   Action:

   1. Committee members to send suggestions for PI representatives from various Departments to Drs. Kimberly and Joiner.

5. **Accruals Initiative**

   a. **Recruitment Plans** (Marchant): Mr. Marchant reported on behalf of Ms. Fitz-Gerald that no requests have been received for assistance for the past couple of months. Proactive efforts continue by reaching out to PIs during the study start-up period to remind them that aid is available to develop plans at no cost if desired. The committee was asked to send suggestions on additional ways to enhance study team and PI engagement.

      Action:

      1. Send ideas to Ms. Fitz-Gerald on ways to get PIs to better engage in the Recruitment Plan development process.

   b. **Accrual Reporting** (Rizk): Dr. Rizk reminded the committee that the reports are generated monthly once the study is initiated in OnCore and sent to the PIs and administrators to keep them apprised of how the study is performing over time relative to its original recruitment goal. Dr. Rizk noted some challenges in the nomenclature used within OnCore compared to how researchers at UAB routinely label the same milestones, which has led to some issues in reporting the data. Discussions are underway to devise a plan to address, which may include

changing terms withinthe system as well as ensuring all affected personnel are trained on the standard language to maintain consistency in use. Additionally, discussions are being conducted with Dr. Edberg's team, which uses the biospecimen management (BSM) functionality of OnCore, to determine how to best meet its needs while also keeping the participant data synchronized with other teams' workflows.

6. **Quick Notes**:

    a. **OSP National Search** (Matthews): In Dr. Schwebel's absence, Mr. Matthews reported that onsite visits have been conducted over the past couple of weeks with two finalists and that the search committee is awaiting feedback on those candidates. The goal is get a final candidate in place by this summer.

7. **Clinical Trials Day** (Oliver): Ms. Oliver reminded the Committee that Thursday May 18th will be celebrated at UAB as Clinical Trials Day with a formalized event taking place from 7:30-9:30am in Wallace Tumor Institute lobby. There will be breakfast served along with brief remarks by several leaders in addition to informational booths for attendees. Ms. Oliver announced that two members of the committee had been awarded medals following last month's triathlon challenge with a Bronze going to Mr. Gordon and a Silver to Dr. Gilbert. Ms. Oliver encouraged the members to continue their efforts as medals are still up for grabs with the finish line another two weeks away.

8. **New Business/Open Floor** (All)**:** No additional comments.

9. **Next meeting:** June 7, 2023

Robert P. Kimberly, MD
Senior Associate Dean for Clinical and Translational Research
Chair, Clinical Trials Administration Committee

CC: Anupam Agarwal, MD, SVP for Medicine and Dean-Heersink SOM
Chris Brown, PhD, VP-Research