

Clinical Trials Administration Committee (CTAC)
Meeting Minutes
May 1, 2024
12:00 – 1:00 pm
Zoom Conference Call

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

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

2. **Updates:**

- a. **IRB Metrics & Process (McClintock):** Mr. McClintock stated that turnaround times for industry clinical trial reviews remain on target. UAB IRB review times have climbed in recent months given a recent staffing shortage but are expected to decrease once the new hires are fully trained and operational. The RAPID website, which posted turn-around times, is no longer in use, but the goals continue as follows: Industry (55 days), Full-Local (90 days), Expedited (60 days), and Exempt (30 days).
Mr. McClintock noted that at a prior meeting, Dr. Kimberly had requested scenarios where delays in review times were encountered might assist in a ‘root cause’ analysis to assist in review time improvement. Dr. Kimberly expressed interest in industry sponsored research clinical trials initially and eventually addressing all clinical trials. Dr. Kimberly also inquired about the effectiveness of ‘Real Time Review’. Mr. McClintock replied that the pilot concluded and one of the identified barriers to full implementation was the IRB staff time required. All agreed though that alternative efforts, including pre-submission review, would be worthwhile to explore to improve throughput rates, starting with industry trials but then including other types as well.

Actions:

1. Mr. McClintock to provide a list of specific examples to Dr. Kimberly, Mr. Marchant, and Dr. Rizk to assist in a ‘root cause’ analysis for prolonged review times.
2. Follow-up with CRSP on impact of regulatory pilot project with Pediatrics.
3. Emphasize ways to improve efficiencies in both internal operations as well as departmental submissions.

- b. OSP Operations/eRA (Hedberg/Matthews):** Ms. Hedberg began by mentioning that OSP is putting together a workgroup of industry trial agreement submitters to be led by Renee Clements in order to conduct an institutional review of the current process to identify ‘speed bumps’ in the UAB touchpoints with the goal of shortening the throughput rates for the execution of agreements.

Mr. Matthews updated the committee on the eRA system review. Mr. Matthews reminded the committee of the process in which the University has been involved over the past four years to identify an alternative solution for the InfoEd IRAP eRA platform. On April 18th an executive committee accepted the recommendation to move forward with the solution offered by Huron. That recommendation will be submitted to the UA Board of Trustees in early June for approval. This will initiate a 2-3 year process of implementation that is anticipated to be conducted in 3 Phases: Contracts/Agreements & Conflicts of Interest, Human Subjects Protection, and Laboratory Animals. A large part of the implementation will be incorporating change management throughout the process. It is expected that Pre-Implementation will begin later this summer. CTAC members were asked to assist as needed throughout the hefty effort.

Actions:

1. Continue discussions to make meaningful revisions to standard industry contract language to aid in negotiation timelines.
2. Committee members interested in engaging in the process review for industry agreements are encouraged to contact Ms. Hedberg for inclusion.
3. Committee members advised to be ready to assist in upcoming eRA implementation as needs arise.

- c. OnCore Operations (Specht):** Ms. Specht mentioned that the system upgrade to Version 2023 R3 is scheduled for the weekend of May 10th. The financials project continues with training along with ensuring all appropriate studies are entered in a timely fashion, which is an effort being led by the QA Analyst. This activity has greatly improved system utilization according to Ms. Specht. Ms. Specht stressed the importance of managing visits in OnCore in a timely manner due to downstream financial implications.

Actions:

1. Complete system upgrade the weekend of May 10th.
2. Continue implementation of the use of the Financials module across campus as new industry sponsored clinical trials come online.
3. Continue cross-referencing new pending accounts with new industry-sponsored clinical trials in OnCore to ensure they are being entered into OnCore as required.

- d. Managing Visits (Marchant):** Mr. Marchant reviewed what ‘managing visits’ actually entails and why it is important in the conduction of a clinical research study. In summary, the visits in a study are outlined in the OnCore calendar, which includes the schedule of billable activities to take place at each visit. Billable activities often include a mix of standard-of-care and research charges. When a visit occurs, if the study team member does not indicate that occurrence in OnCore, the research-related clinical billable activities are not flagged as such for the billing offices. This absence of information leads the billing offices to assume that all of those activities are appropriate standard of care activities to bill to the participant’s health insurance. The Health System has a series of time-consuming cross-checks and billing revisions which can be avoided by the timely “occurring” of visits in OnCore. Dr. Rizk, Mr. Marchant, and Ms. Specht will continue to use the Managed Visits report from OnCore to work with study teams, divisions and departments to facilitate timely occurring of visits. Mr. Marchant asked CTAC members including Dr. Smith (Nursing), Dr. Bertram (OCCC), and Dr. Goss (Health Professions) to assist in the process for all Schools.

Actions:

1. Mr. Marchant to contact representatives across CTAC and other areas of campus.
2. Ms. Specht to speak further with Mr. Gordon about providing a billing report from the Health System to OCCC in follow-up to several technical questions posed by Dr. Bertram.

e. Budget Tool Development (Fitz-Gerald): Ms. Fitz-Gerald informed the committee that the budget development tool previously discussed in recent meetings has completed its developmental phase and is available across campus. It has been presented to the HSOM Clinical Chairs, is in use by several large clinical trial groups, and will be discussed in the CRSP-led CRP Research Seminar on Thursday June 6th. Additional information relative to the Seminar will be forthcoming through usual channels such as *Trending in Trials* in the coming weeks. CTAC members were encouraged to contact Ms. Fitz-Gerald and schedule a 1-on-1 tutorial for themselves or their colleagues. Ms. Fitz-Gerald noted that tutorials will be announced at the conclusion of the Seminar. The training session is expected to be taped and housed on the CCTS [Clinical Trials Kiosk](#) upon completion. Dr. Kimberly mentioned that the recent presentation to clinical department chairs across HSOM on its use was well received. Those slides are being distributed to the committee along with the final Meeting Minutes.

Actions:

1. Ms. Fitz-Gerald, along with other members of the tool development workgroup, will conduct a Research Seminar on the use of the budget tool on June 6th.
2. Committee members urged to inform their colleagues about the upcoming seminar and to schedule time with Ms. Fitz-Gerald for an individual tutorial on its use.

3. Clinical Trials Day/Week (Oliver): Ms. Oliver reminded the committee that this year's International [Clinical Trials Day](#) will be celebrated on Monday May 20th. Additionally, this year will include not only an event on the actual day at Wallace Tumor Institute lobby from 7:30-9:30am with food, fun, and swag, but also events through the remainder of the week (Tuesday-Friday). Some of these include a research participant panel, a CRP staff summit, and an online networking event. Ms. Oliver encouraged the Committee to continue spreading the word and ask people to register in advance to ensure appropriate quantities of food at the event at WTI on Monday. If any questions arise, you may direct those to Ms. Oliver at eroliver@uab.edu.

4. New Business: None proposed at this time.

5. Next meeting: June 5th



Robert P. Kimberly, MD
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Chair, Clinical Trials Administration Committee

CC: **Anupam Agarwal, MD**
SVP for Medicine and Dean-Heersink SOM

Christopher Brown, PhD
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