# Clinical Trials Administration Committee (CTAC) Meeting Minutes July 20, 2022

12:00 – 1:00 pm Zoom Conference Call

In attendance:

Bertram (OCCC)

Jackson (Health System Compliance)

Boles (SOM)

Kimberly (SOM/CCTS)

Cotten (OVPR/OSP) Croker (CCTS)

Marchant (CTAO)

Fitz-Gerald (CCTS)
Gilbert (SOD)

Miller (OVPR)

Lee (DOM)

Gordon (HSIS/CCTS)

Schwebel (OVPR)

Goss (SHP) Horn (OVPR) Smith (SON)
Specht (OnCore)

Hurst (Health System)

Wasko (SOB)

Unable to attend:

Joiner (DOM)

Nichols (SOO, OVPR)

Logan (University Compliance)

Rizk (CTAO)

McClintock (IRB)

1. Review of CTAC minutes from June 1st meeting: The minutes were reviewed and approved.

## 2. Updates

a. **OnCore** (Specht): Ms. Specht announced that the OnCore Q/A sessions have been moved to Tuesdays from 11:00-1:00 each week. Ms. Specht continued by saying that the current Financial Analyst has submitted her resignation to take another role internal to UAB, and the team is actively seeking a new candidate with the position recently posted. Dr. Wasko mentioned the use of Handshake as a means of recruitment, due to its popularity with college students. Several in the gallery took note of this tool for further exploration, especially when experience is less of a need. An update to the OnCore environment to Version 2021 R3 is to be installed starting at 3:00pm this Friday (22<sup>nd</sup>).

# Action:

- 1. Complete system upgrade to Version 2021 R3.
- b. **IRB Metrics & Process** (Miller): Mr. Miller reported on behalf of Mr. McClintock who had a planned absence. He stated that the IRB continues to monitor the <u>RAPID metrics</u> and post them quarterly. These data reflect either an improvement or maintenance of current performance by the IRB. In circumstances where metrics may denote occasional 'backsliding', appropriate measures are taken to immediately address. The Real-Time Review pilot continues and is showing success when enacted; Mr. Miller did mention that finding appropriate studies for this pathway is a challenge because submissions don't often meet the criteria of excellence needed to qualify. Dr. Kimberly inquired if there are any examples of study teams doing a consistently excellent job in this area to which Mr. Miller replied that one recently surfaced which may be spotlighted as an example for 'best practice'. Dr. Kimberly offered to organize an offline discussion to operationalize that 'spotlight' opportunity, perhaps even in-person with snacks.

## **Actions:**

1. Continue efforts to improve IRB throughput rates and enact process changes to enable such improvement.

- 2. Dr. Kimberly to organize a discussion with IRB leadership to highlight best practices in IRB submissions.
- 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. Two reviews have been conducted so far. The DCC Assessment Group is co-chaired by Drs. Kimberly and Nichols. The workflow discussed at the May CTAC meeting will be finalized with Mr. Marchant.

## Action:

- 1. Finalize the workflow and submission document for distribution.
- d. **Device Trials Investigator Agreements** (Kimberly): Dr. Kimberly noted that these 1572-like agreements have been approved by institutional leadership to be treated in the same fashion for devices as they are for pharmaceutical trials and signed personally by the Principal Investigators. **Action:** 
  - 1. Final version of the Agreement to be circulated among device trial investigators at UAB.
- e. Greenphire eCards (Marchant): Mr. Marchant reminded the Committee that we've been exploring the use of an eCard solution since prior to COVID at the request of Dr. Gilbert. After several discussions with our current payment vendor (Greenphire) over the past 2 years, they are finally at a place where their solution is mature enough for implementation at the institution, which will be the second instance of its use across the country. The contract has been received and negotiations relative to both language and cost are well underway. Once it is finalized, a phased implementation will take place which will begin in the School of Dentistry. Follow-up questions were raised by Dr. Smith and Mr. Miller relative to IRB review of the additional piece of information that will require collection to enable the payment through email along with what information will be disseminated in this fashion to ensure privacy is maintained. Mr. Marchant responded that international study payments are already being managed through an eCard solution (Tango) so we can look at our practices with them for guidance. Additional discussions will take place to this regard to ensure alignment of institutional position and practice.

## **Actions:**

- 1. Finalize the contract with Greenphire to enable implementation to begin of the eCard solution.
- 2. Arrange a meeting among Financial Affairs, IRB, and CTAO to ensure alignment of expectations around collection and use of email addresses for payment purposes.
- f. In-State Travel (Marchant): As a follow-up to prior discussions in March, Mr. Marchant reported that Financial Affairs asked for a Memo from CTAC outlining specific examples relative to issues originally submitted for consideration. As a reminder, researchers find it challenging to conduct operations where in-state travel is necessary because of the low rate of reimbursement (daily per diem) which is different from the position for out-of-state (actual cost supported by receipts). The current per diem rate has been in place for several years and no longer aligns with actual costs. The solution is to simply mirror in-state reimbursement practice with out-of-state. Once the examples are received by Mr. Marchant, he will compile and send on behalf of CTAC for Dr. Burnett to submit to the UAB Government Relations team since this is a state-wide position that will be routed to the University of Alabama System office and ultimately to Montgomery for State of AL consideration. The discussion ended with Dr. Schwebel suggesting that the Deans of other non-health related Schools be asked for examples as well with the School of Education being highlighted.

#### **Actions:**

- 1. Committee members asked to provide specific examples to Mr. Marchant by Monday July 25<sup>th</sup> of instances where they had faculty or staff lose money by virtue of conducting their study operations because of the current practice or who take their business outside the state such as staying at a hotel in a nearby neighboring state to be reimbursed at the higher rate to avoid the anticipated loss.
- 2. Mr. Marchant to contact other Schools to ask for examples for non-health related research.

# 3. New Business/Open Floor:

- a. Ms. Cotten announced that it was recently decided that UAB outgoing subawards can be executed upon OSP receipt of IRB approval from the subsite, as long as the Subsite PI and the title matches. This will serve as the IRB approval documentation to complete the subaward execution process. This aligns with UAB policy.
- b. Dr. Kimberly closed by introducing Cayla Hurst to the Committee who recently completed a twoyear administrative fellowship with the UAB Health System and began her new role as Director of Clinical Research Implementation in the ambulatory care space there.

4. Next meeting: September 7, 2022

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