

**Clinical Trials Administration Committee (CTAC)**  
**Meeting Minutes**  
**June 3, 2020**  
**12:00 – 1:00 pm**  
**Zoom Conference Call**

In attendance:

Bertram (OCCC)	Ladores (SON)
Busby (OCCC)	Marchant (CTAO)
Cotten (OVPR/OSP)	McClintock (IRB)
Crocker (CCTS)	Miller (OVPR)
Dransfield (DOM)	Motl (SHP)
Farough (Health System)	Nichols (SOO, OVPR)
Fitz-Gerald (CCTS)	Redden (SOPH)
Gilbert (SOD)	Rizk (CTAO/CCTS)
Gordon (HSIS)	Roberson (UAB Compliance)
Horn (OVPR)	Sandefur (OnCore)
Joiner (DOM)	Schwebel (CAS)
Kimberly (SOM/CCTS)	Wasko (SOB)

Unable to attend:

- Bates (Health System Compliance)
- Mack (SOM)
- Nabors (DON/CCTS)

1. **Review of CTAC minutes from May 6<sup>th</sup> meeting:** The minutes were reviewed and approved with minor edit.

2. **Updates**

a. **OnCore PI Meetings (Rizk, Sandefur):** A meeting was held on Friday May 22<sup>nd</sup> with PIs who have a larger volume of studies in OnCore. This discussion was led by Drs. Kimberly, Rizk, and Gutierrez in addition to Mr. Sandefur and Gordon. One of the primary areas for discussion was to help PIs understand the data within OnCore and the importance of keeping that data accurate which aids not only the study teams but also the institution relative to reporting needs. By understanding what those data elements are, the PIs are better able to monitor their staff's engagement in the system to keep those data current which is a 'win-win' for everyone. One question raised by Dr. Rizk for consideration is whether we have the ability as an institution to enable bi-directional information flow between OnCore and IMPACT so that OnCore reflects pertinent patient information in the research record such as 'death' status.

**Actions:**

1. Continue building understanding across the investigator community to enable cleaner data within OnCore for reporting purposes at all levels.

b. **Time to Activation: IRB-Industry Trials (McClintock):** The TTA-IRB Pilot conducted within the O'Neal Comprehensive Cancer Center (OCCC) has shown an improved process time prior to WIRB submission as discussed at prior CTAC meetings. Based on this outcome, the practice will be expanded first to all trials managed by the OCCC

Clinical Trials Office (CTO), with the intention of expanding campus-wide. Mr. McClintock, in conjunction with the CTO and the CTAO, will start the process of phasing organizations into the process so that all areas may experience the same shortened pre-submission process time to assist in improving overall time to activation (TTA).

**Actions:**

1. Mr. McClintock, Ms. Busby, and Dr. Bertram will coordinate a phased in approach to implementing the new procedure more broadly across trials managed by CTO resources.
  2. Mr. McClintock and Mr. Marchant to implement a phased plan for incorporating the University into the revised process to achieve greater reductions in TTA.
- c. **Cancer Center Initiative (Busby):** OCCC has engaged Huron to review the processes for oncology studies which influence accrual to trials and TTA. A task force has been convened and charged with reviewing the report provided by Huron (due in late July) and to make recommendations on appropriate actions. Given the competing renewal due by the OCCC in May 2021, which will include data compiled much earlier as noted by Mr. Bertram, timely responses in the process are paramount to success.
- d. **Pilot: Single Identifier (Marchant):** Following the February CTAC update provided by Dr. Nichols and Mr. Matthews, the initiative took a hiatus due to COVID-19. Discussions continued recently between the Office of Research (Oort) and CTAO. Work is currently underway to develop a strategy for communications, training, and support to enable the enterprise expansion of the prior pilot work in the OCCC. The Department of Surgery has agreed to serve as the Phase I participant to enact the previously created process to determine if any modifications are needed before continuing to other units such as the Department of Medicine, which is currently slated to be engaged in Phase II.

**Actions:**

1. Mr. Marchant to work with Mr. Matthews and others in OoR to initiate the expansion of the Single Identifier.
3. **Re-opening for Clinical Research (Nichols/Kimberly):** Dr. Nichols discussed the need to create a separate document specific to Human Subjects Research for 'UAB Re-Entry' efforts. This document was released on May 17<sup>th</sup> and includes the delineation of the duration of participant contact on campus distinguishing 'close contact' and 'non-close contact'. All activities must first be outlined in an Operational Plan created by PIs/research areas and vetted by the appropriate Department (SOM) or School/College (outside SOM) leadership. Mr. Miller noted that these plans do not require review/approval by the Office of the Institutional Review Board (OIRB). Studies with approved operational plans may re-open for close in-person contact with participant on June 9<sup>th</sup>.
- a. 'Morning Coffee': Dr. Kimberly cited a series of 7AM Zoom discussions started this week on Monday/Wednesday/Friday with intentionally small group (20-25) of clinical researchers which provide an opportunity for various issues to be considered. One such issue included the desire to know who will cover the cost of the required COVID testing for participants, when a participant screens positive for COVID. While the payor

(insurance, JCDH, CARES Act) may vary, the main point is that the participant will not pay for this required testing. These discussions have proven fruitful thus far, so they are expected to continue next week. All members of CTAC are invited to attend.

- b. FAQs (updates): Dr. Nichols reminded the group that the documents related to re-entry and resumption of in-person research operations are ‘living’ documents and will continue to be updated as new information is available. The updated information will be presented through a series FAQs to enable one to see what’s been updated to stay apprised.

**Actions:**

1. Iterative updates the R2Ops information.
2. Attend the Morning Coffee sessions as one’s schedule allows.

**4. Research Models and Institutional Practices (Kimberly):**

- a. What is working/what is not: As a continuation of last month’s discussion, Dr. Kimberly again asked the Committee for comments on ways that they have seen the Limited Business Model brought about by COVID-19 lead to innovative methods of working and collaborating across campus.
- b. Dr. Nichols opened the discussion by inquiring about the status of the plans to identify a potential replacement for IRAP. Ms. Cotten replied that given the current fiscal state of the University, those plans had been placed on hold for the foreseeable future. She also reported that discussions were underway with the vendor (Infused) to look at untapped functionalities not previously explored with the system such as an eForm for Office of Sponsored Programs (OSP) which would replace the use of the current Extramural Checklist and the Responsible Personnel List. Other items mentioned included the ability to personalize the look of the system for individual users including dashboards as well as a direct portal for federal system uploads.
- c. Dr. Rizk raised the use of remote consenting and visits as ‘lessons’ that have worked for sites.
- d. Mr. Miller discussed the collaborative efforts between IT and the OIRB to transition from DocuSign to AdobeSign in the coming days with AdobeSign being both CFR Part 11 and HIPAA compliant. Dr. Rizk asked if AdobeSign would be able to assist with electronically capturing signatures on the Delegation of Authority Log, which has proven historically difficult in a remote setting.
- e. Additional ‘lessons’ included remote monitoring visits and supply chain issues related to PPE.

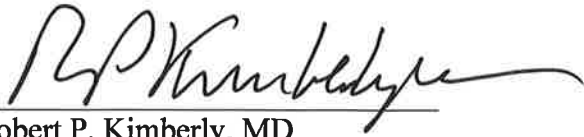
**Actions:**

1. Send additional ‘lessons learned’ to Dr. Kimberly and Mr. Marchant.

**5. New Business/Open Floor (all):** No additional comments.

**6. Next meeting:**

- a. July 1, Noon. Zoom Conference Call (to be provided)



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