

Clinical Trials Administration Committee (CTAC)
Meeting Minutes
February 2, 2022
12:00 – 1:00 pm
Zoom Conference Call

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

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

2. **Updates**

- a. **IRB Process Improvements** (McClintock): Mr. McClintock updated the Committee on ongoing efforts to maintain progress made through collaboration with Advarra to reduce throughput times for Exempt and Expedited studies. Based on metrics followed by Mr. McClintock, these continue to hold fast as expected. The IRB is now shifting its focus to Convened and Commercially-reviewed studies with an expectation of reducing those review times as part of the ongoing effort to improve Time to Activation (TTA).

Actions:

1. Maintain workflow process improvements and accelerated throughput rates relative to TTA to ensure efficient operations.
2. Identify process improvements to be enacted for Convened and Commercially-reviewed studies.

- b. **Data Coordinating Centers** (Kimberly/Nichols): Dr. Kimberly reminded the Committee of the opportunities that have historically occurred and continue to arise for Investigators to serve point on organizing and running DCCs for studies. These activities are highly encouraged when scholarship and research are an integral part of the effort. Recent discussions with the Council of Deans affirmed support of such opportunities; an advisory group for Chairs and Research Deans will be chartered with inclusive membership to assist in evaluating team capacities and potential regulatory issues. Potential membership will include expertise in data security, date management, contracts and disciplinary expertise. To avoid unnecessary delays with the advisory process, the goal of having all reviews completed within 10 business days was proposed.

Actions:

1. Develop a Charter for the advisory group including membership and operating procedures and constitute the group.
 2. Dr. Kimberly and Ms. Cotten to further discuss how to incorporate the decisions of the advisory group into the contract submission process so there is awareness among OSP reviewers.
- c. **Device Trials Investigator Agreements** (Kimberly): Dr. Kimberly discussed the 1572-like agreements in the device clinical trial space and why it is important to not confuse their regulatory nature with contractual language. He shared that Dr. Joiner from Medicine had collected roughly 18 agreements for review to ensure the standard language found in them would not raise them to a level of review suggested by Office of Counsel. He indicated that Office of Counsel would like to identify a process to streamline the review and processing of these Agreements.
- Action:**
1. Dr. Kimberly to finalize and document a plan with Counsel for reviewing device trial agreements going forward to improve efficiency in the process.
- d. **OnCore** (Gordon): Mr. Gordon introduced Ms. Ashley Specht who began February 1st as Manager of the OnCore Enterprise team. He also mentioned that the OnCore upgrade, originally planned for late last year, will be completed this Friday (February 4th). It is expected to take place after normal business hours but that reminders will be distributed given the sometimes atypical nature of clinical trial activities.
- Action:**
1. Complete the annual upgrade of the software the first weekend of February.
- e. **Accrual Workgroup/Recruitment Plan Assistance** (Fitz-Gerald): Since last month's report on the topic, Ms. Fitz-Gerald indicated that 3 requests have been received for CRSP assistance. To aid in these requests, a new email has been created to direct queries (CRSPrecruitment@uabmc.edu). As a part of this process, Ms. Horn is providing assistance to the team in identifying vendors of digital media services, and these resources will be added to the online *Clinical Trials Kiosk* for reference. Dr. Kimberly then asked Dr. Rizk and Mr. Marchant to discuss recent efforts that are underway for the *SOM Road Show*. Dr. Rizk began by outlining the content being delivered across all Departments and Divisions at routine faculty meetings, which includes items related to recruitment. Mr. Marchant added that 3 sessions have been held so far since starting in January and will continue through early April with about two dozen presentations scheduled at the moment during that span.
- Action:**
1. Continue the *SOM Road Show* presentations to update faculty on current initiatives in clinical trials including recruitment.
 2. Continue efforts to raise awareness of Recruitment Plan Assistance by CRSP for study teams.
- f. **Greenphire eCards** (Marchant): Mr. Marchant opened by reminding the Committee of the expression of interest by faculty, including Dr. Gilbert, in an eCard option on campus to pay participants dating back to 2019. Mr. Marchant then updated the Committee on recent discussions with Greenphire, which serves as our ClinCard vendor. Recent conversations made UAB aware that Greenphire has an eCard solution ready for piloting with a 'proof of concept' initiated in early January. While Greenphire does not expect to have a flexible option available (both eCards and ClinCards) until 2023, they acknowledged UAB's repeated desire for a virtual solution and is willing to make it available to us sooner than planned for others. UAB is now expected to begin implementing eCards in the May/June timeframe, which will enable Departments to have the option available to pay participants on a study in a virtual manner simply by adding an email address to a participant's profile. There will be a transition period as the new platform uses the Visa financial platform rather than MasterCard, which is currently utilized by our ClinCards. Mr. Marchant and

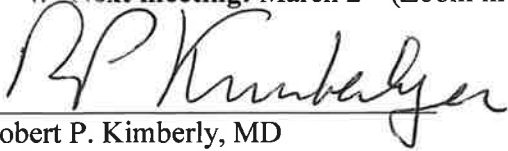
Financial Affairs will continue discussions in earnest with Greenphire as May draws closer and more information will be made available to the Committee about the launch shortly thereafter.

Action:

1. Initiate implementation plans with Greenphire for an eCard solution to be added to the current participant payment system.

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

4. **Next meeting:** March 2nd (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