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Clinical Trials Administration Committee (CTAC)
Meeting Minutes
April 3, 2024
12:00 – 1:00 pm
Zoom Conference Call

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

1. **Review of CTAC minutes from March 6th meeting:** The minutes were reviewed and approved.

2. **Updates:**

    IRB Metrics & Process (McClintock):
    a. Mr. McClintock reported that overall the metrics for IRB approval turnaround times are holding steady although Industry study turnaround lengthened slightly last quarter. A further assessment is needed to better understand what potential causes both within and outside the IRB's control have contributed to these changes. Dr. Kimberly asked Mr. McClintock if he could provide specific examples of situations with prolonged IRB approval times to facilitate a "root cause" assessment.
    b. As a follow-up to last month's report on the NYU engagement, Mr. McClintock reminded the Committee that the project's purpose was to develop a tool to facilitate communication between institutions involved in Single IRB activities. NYU is currently reassessing its plan by discussing with various eRA vendors alternative options for syncing across these various digital systems.
    c. Relative to staffing, Mr. McClintock noted that following 6 months of stability across the office, there have been announced departures of Protocol Analysts along with the retirement of Leslie Cooper (Associate Director) this summer. The IRB is currently working with HR on the creation of a Career Ladder for its staff. Prompted by a question from Dr. Rizk, discussion ensued about the IRB's inability to retain an Analyst who is moving overseas due to a denial by HR for this person to work remotely. While there are some domestic laws that prevent remote workers to reside in certain states such as CA while working in AL, the UAB guidelines for international

remote work were not immediately clear. A suggestion was made that a list of "not-feasible" locations (US states or other countries) would be good to have for reference

d. Actions:
1. Mr. McClintock to provide a list of specific examples of extended IRB approval times to Dr. Kimberly, Mr. Marchant, and Dr. Rizk.
2. Identify ways to improve efficiencies in both internal operations as well as departmental submissions.
3. Coordination of regulatory activities with CRSP personnel.

OSP Operations (Hedberg):
a. Ms. Hedberg opened comments by noting that staffing on the Industry team in OSP has lost 2 officers. One of these persons was moving abroad, but attempts to retain this person through a remote work option were denied by HR in a similar circumstance to the IRB.
b. Ms. Hedberg briefly mentioned that they are currently evaluating 2 eRA systems (Huron and Cayuse) with sandbox instances available for testing across campus.
c. Lastly, Ms. Hedberg implored the Committee to let PIs in their respective areas know that OSP is available to help guide them in all situations relative to a grant/contract submission. She stated that if any questions arise and it is not clear where to go, investigative teams can simply contact her directly and she will assist. Dr. Rizk suggested making more detailed information available on the Clinical Trials Kiosk and including more suggestions in Trending in Trials to better direct PIs. Ms. Fitz-Gerald suggested that utilizing upcoming avenues like the monthly Research Seminar or quarterly Lunch & Learn is also an option.

Actions:
1. Continue discussions to make meaningful revisions to standard industry contract language to aid in reducing negotiation timelines.
2. Continue review of processes to understand where meaningful changes may be made to save time in working with Departments.
3. Provide more detailed guidance for PIs to better understand OSP operations as it relates to submissions.
4. Committee members to communicate to PIs within their areas to direct queries to Ms. Hedberg as needed.

Project eRA Status (Matthews):
Mr. Matthews noted that today (April 3rd) is the last vendor demo, which have been taking place over the past month. There have been 18 demos in all, which have each lasted approximately 2 hours. Currently feedback is being received and reviewed from across campus. These responses will be compiled and discussed by the Executive Steering Committee led by Dr. Brown on April 18th in order to make a final decision on a vendor. Following this, the pre-implementation phase will commence. Mr. Matthews referenced the new webpage where the University community may follow the project's progress. Dr. Kimberly inquired about expectations for the future system compared to the current IRAP system to which Mr. Matthews replied that either system (Cayuse or Huron) would be a marked improvement over current state.

Actions:
1. Finalize a decision on the new system and initiate pre-implementation.
2. Keep CTAC members apprised of project's progress and what they may do to assist.

e. OnCore Operations (Specht): Ms. Specht opened by stating that testing continues for the system upgrade to Version 2023 R3 and is expected to be completed next month. The financials project continues with training to ensure that all appropriate budgets are entered in a timely fashion. Ms. Specht mentioned that some of the team attended the annual Onsemble conference

last month where they continue to learn from other users across the country. At the conclusion, Dr. Kimberly inquired if the new eRA system would be compatible with OnCore to which Mr. Matthews responded that either option would allow integrations with existing systems on campus such as OnCore and Oracle.

Actions:
1. Continue training and implementation of the Financials module across campus.
2. Continue monitoring new industry-sponsored clinical trials to ensure they are being entered into OnCore as required.

3. Clinical Trials Day/Week (Oliver): Ms. Oliver announced that this year's International Clinical Trials Day will be celebrated on Monday May 20th. As an expansion of recent years' activities, this year will include not only an event on the actual day (May 20th) at Wallace Tumor Institute lobby from 7:30-9:30am with food and fun, but also events through the remainder of the week (Tuesday-Friday). You can find details here. Some of these include a research participant panel, a CRP staff summit, and an online networking event. Ms. Oliver encouraged the Committee to spread 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 croliver@uab.edu. In closing, Ms. Oliver shared an upcoming active learning event on consenting participants that will be held at Bevill Biomedical Sciences Room 170 on April 29th at 1:00pm.

4. New Business: None proposed at this time.

5. Next meeting: May 1st

Robert P. Kimberly, MD
Senior Associate Dean for Strategic Initiatives
Chair, Clinical Trials Administration Committee

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

   Christopher Brown, PhD
   VP-Research