

Clinical Trials Administration Committee (CTAC)  
Meeting Minutes  
June 6, 2018  
12:00-1:00 pm  
FOT 12 Large Conference Room

In attendance: Kimberly (SOM/CCTS), Schwebel (CAS), Redden (SOPH), Nichols (SOO/OVPR), Gilbert (SOD), Joiner (SOM), Marchant (CTAO), Farough (Health System), Gordon (CCTS/HSIS), Sandefur (OnCore), Fitz-Gerald (CCTS), Gerrity (OVPR), Dransfield (SOM), Saleh (SOM/CTAO)

Unable to attend: Ladores (SON), Mack (SOM), Mugavero (SOM), Bragg (UAB Compliance), Bates (Health System Compliance), Nabors (SOM), Motl (SHP)

- 1) Review of CTAC Minutes from May 5<sup>th</sup> (Kimberly)
  - a. Laretta Gerrity asked for clarification on the research study summary discussion in regard to how we are handling blinded studies. Consensus was that treatment of any urgent medical presentation pre-empts study blinding.
  - b. Mark Dransfield suggested we review the Research Study Summary requirement document since it's currently based on the need for the trial to have clinical billables to go into OnCore and then to Cerner.
  - c. The primary intent of the research study summary is participant safety. Bob Kimberly indicated that having an option to allow patients to opt-out of the summary appearing on their medical record was an implementation detail that could be discussed further.

**Recommended actions:**

1. Review the template and wording for the research study summary;
2. Define the workflow for creation and submission of the summary.

- 2) Career Ladders for Clinical Research Professionals (Joiner)
  - a. Cindy Joiner reported that she, Penny Jester and Lakisha Mack have been meeting with Alesia Jones, Chief Human Resources Officer, Brenda Adams, Compensation Manager, and Kent Keyser to discuss the development of a clinical research support career ladder. Materials from other medical centers have been included in the discussions.
  - b. UAB HR supports the project, which has a primary goal of recruitment and retention of qualified personnel, but has indicated that they do not have the personnel power to move this initiative forward. UAB HR has asked SOM to lead the effort on behalf of the University.
  - c. Cindy Joiner reported that Mark Dransfield has agreed to help facilitate the development of the career ladder as a faculty champion of this initiative.
  - d. Currently over 80 job titles have been identified as potentially within the project scope.

**Recommended actions:**

1. Define the scope of clinical research and assess the potential impact of a career ladder across Schools;
2. Establish a project implementation subgroup, now that UAB HR is aligned with the goals and supportive of the initiative, and draw on the Researcher and Scientist career ladder experience.

- 3) Time to Activation initiative (TTA)(Nichols)(Slides attached)

- a. Jason Nichols showed detailed work-flow schematics of two industry-sponsored trial case studies as prototype “process maps” illustrating the inter-dependence of the study team with OSP, IRB, CBR and OnCore calendar development.
- b. CTAC members were asked to consider these maps as the basis for developing process performance metrics that could be provided on a monthly basis to CTAC.
- c. Laretta Gerrity underscored that a root cause analysis of total TTA requires we know the pieces of the process and these schematics indicated these pieces. David Schwebel commented that the iterative exchanges between units might raise issues of accountability and suggested that a process to identify where a study sits at any point in time, (eg on whose desk) be developed.

**Recommended action:**

1. CTAC members to submit feedback to Jason on the schematics to move beyond individual cases and develop a generalizable metric(s) in support of process improvement.
2. Additional process maps will be developed for individual studies to capture the breadth of variability across studies.

4) Standard Budget Fees (Marchant)

- a. Mark Marchant re-introduced the topic by reviewing on-going discussion about 1) what true clinical trial start-up costs are and 2) what start-up fees are at other academic medical centers across the country.
- b. Bob Kimberly asked if UAB is at the national market average in start-up fees, and Mark Marchant replied that his research shows UAB is below market. The purpose of the standard budget initiative is to make sure we develop a full understanding of what our fixed costs start-up and ongoing study costs are.
- c. Bob Kimberly referred to an article published by SoCRA (Society of Clinical Research Associates) about the process of study start up (attachment).

**Recommended action:**

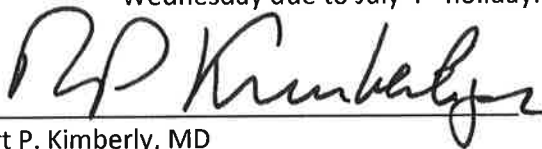
1. An implementation subgroup has developed a prototype for the expected UAB study start-up fees and costs throughout the study life cycle to close out. Additional local and national data are being gathered as part of market analysis.
2. The implementation subgroup will reach out to various study teams and Schools to review the prototype study start-up fees.

5) New Business

- a. None added to agenda

6) Next Meeting:

- a. July 11<sup>th</sup> at Noon in FOT Large Conference Room. \*Please note this is second Wednesday due to July 4<sup>th</sup> holiday.



Robert P. Kimberly, MD  
Senior Associate Dean for Clinical and Translational Research  
Chair, Clinical Trials Administration Committee

Attachments: SOCRA Article  
TTA Update PowerPoint  
Job Classification for Clinical Research PowerPoint  
Job Description Word Document

CC: Chris Brown, PhD, VP Research  
Selwyn Vickers, MD, Senior VP Medicine and Dean SOM