USC Clinical Trials Office (CTO)

Answers to CTO’s who, what, when, and how questions

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Your Clinical Trials Office (CTO)

✓ Started its work on July 01, 2013
✓ Director
✓ Sr. Contract Managers
✓ Clinical Trial Financial Administrator (MCA Analyst)
✓ Budget Specialists
✓ Three main operational components:
  i. Contract Review, Negotiation, and Execution
  ii. Medical Coverage Analysis
  iii. Budget Development and Negotiation
✓ Transition from Pre-award to Post-award – Billing and Accounting Services
✓ Coordinating efforts with other units and departments involved in clinical trial management, including hospital billing and compliance office
Clinical Trial Initiation In True 2.0

- PI/Research Coordinator responds to all questions and provides mandatory documents (i.e. study protocol, proposed Clinical Trial Agreement if provided, and sponsors first proposed budget) for CTO’s review (please refer to True 2.0 training slides).

- CTO will review the submission to confirm that all required documents and information have been provided (different documents depending on the type of submission – i.e. CTA, CDA, or non-industry MCA request).

- Once this is confirmed, submission is accepted and assigned to appropriate person (depending on the type of Submission). For example, in the case of a CTA, assignments are made to the Contract Manager and the Financial Administrator responsible to conduct the Medicare Coverage Analysis.
Contract Review, Negotiation, and Execution

- The Contract Manager reviews the proposed agreement.

- Revised version of the agreement (redlined) is sent back to the sponsor for their review and comments.

- The goals is to move our processes in a way that by the time there is a mutually acceptable version of the agreement terms, the other components of our processes i.e. Medicare Coverage Analysis and budget development and negotiation are either done or close to be completed.

- Contract terms, MCA, budget, IRB consistency checklist + IRB approval = Study activation
Medical Coverage Analysis

- Financial Administrator conducts the Medicare Coverage Analysis (MCA) to identify and distinguish cost categories (i.e. S, I, and O).

- Final MCA document facilitates the generation of Research Order Form that in turn allows proper identification of procedures and the source of their funding for billing purposes.

- Once the MCA is completed, the Financial Administrator assigns the study to CTO Budget Specialists responsible for PI’s department/therapeutic unit for budget development and negotiation in accordance with the MCA.
Budget Development and Negotiation

- The Budget Specialist works with the PI and RC to develop USC’s response to sponsor’s initial proposed budget.

- USC’s first budget is sent to sponsor; budget negotiation begins.

- Arriving at a mutually acceptable budget and payment terms with sponsor completes the third component of CTO’s activities.
Transition from Pre-award to Post-award – Billing and Accounting Services

- Study Activated – KC budget summary is sent to DCG KC administrator.

- Final Agreement and budget information is entered in IRIS.

- Final documents (executed Agreement, final MCA, and budget are sent to True.
Questions?