START-UP, REVIEWS & PRE-AWARD CTMS WORKFLOW

1. SPONSOR REACHES OUT WITH INTEREST OR INVESTIGATOR INITIATES STUDY
- Sponsor shares protocol synopsis
- Sites might be asked to complete feasibility questionnaire
- PI/Institution states interest in and decide to move forward

2. SPONSOR REVIEW AND SITE QUALIFICATION – (if relevant)
- ·Study Team determines if the study is qualified, feasible, and being pursued? IF YES
- Request Regulatory Packet
- Pharma sponsors usually send regulatory package and guidelines

3. REQUESTS CDA FROM SPONSOR
- The CDA /NDA will be submitted by the study team/department/CTO to OSP to Execute the CDA/NDA
- If the sponsor has a Master CDA/NDA with Pitt proceed to step 3.

4. INITIAL SUBMISSION IRB
- Study Team will begin application to the IRB and get the Study ID to use on the Clinical Study Registry submission.

5. SUBMIT TO CLINICAL STUDY REGISTRY (CSR)
- Study Teams/Department will submit study information to the "Clinical Study Registry" once study has been deemed a clinical trial per the NIH Clinical Trial Definition.
- Study Team/Department team members can begin OnCore Prerequisite Training

6/7. FINALIZE REGULATORY SUBMISSION
- Study Team to compile regulatory documents
- Study Team submits protocol to IRB and IRB Record is created in PittPRO, or another IRB record might be created (if an external IRB is used).
- PittPRO IRB will be interfaced with OnCore CTMS
- BRANY IRB will be interfaced with OnCore CTMS
- A link for both PittPRO and BRANY will be available in Oncore to facilitate access.

SYSTEM INTERFACE PUSHES PROTOCOL INFORMATION
- ·OnCore CTMS receives protocol information from the Clinical Study Registry (CSR).
- Once data is submitted it will sync and pull data from other key administrative systems at Pitt such as PittPRO, MyRA,and MyFunding

8. IRB REVIEW PROCESS AND STATUS UPDATE
- ·PittPRO /BRANY IRBs are integrated with OnCore CTMS for direct access to files and statuses.
- If using external IRBs the Study Team/Department will need to record the IRB decision in OnCore manually.

9. CTO PREPARES STANDARD OF WORK
- This document will outline the responsibilities of services and delineate support needs.
- The CTO has flexibility when working with teams and services might vary and be determined based on needs.

10. STUDY INITIATION MEETING PREPARATION
- Study Teams/Department will send required documents to the CTO SIM Team.

11. CTO HOSTS SIM
- The CTO meets with the Study Team/Department to learn more about the study and review the documentation.
- CTO provides SLA to team.
- CTO reviews Minimum Footprint in OnCore CTMS
- PI, Primary Coordinator and Research Manager have completed training.

12. MEDICARE COVERAGE ANALYSIS (MCA)
- The CTO performs MCA
- Complete QCT checklist in OnCore
- Enters CA and links to Charge Master

13. CALENDAR BUILD
- CTO builds calendar based on protocol.
- Department/Study Team Reviews Calendar
- CTO makes requested updates.
- **Department/Study Team approves calendar with sign off**
- CTO to release calendar to OnCore

14. MCA REVIEW & APPROVAL
- Department/Study Team to Review final determination
- The CTO processes MCA reconciliation if needed
- MCA Fiscal Review by UPMC/Revenue Cycle
- **PI to review, and approve Coverage Analysis in OnCore - Sign Off**

15. BUDGET BUILD
- CTO to set up budget template in OnCore CTMS
- CTO to export budget for Department/Study Team to begin budget negotiations.
- Budget is finalized and CTO begins reconciliation
- CTO to release budget in OnCore

16. OSP CTA
- CTO supports study team with submitting to MyFunding for OSP to begin CTA review.
- OSP negotiates the CTA
- Execution of the agreement and activation of the award.
- Contract review is complete.

17. SPA Account Creation
- SPA sets up account in financial system

18. IRB APPROVAL
- Department/Study Team submits IRB Approval in OnCore if using an external IRB.
- If using PittPRO or BRANY the record will be created via system interface.

19. PREACTIVATION
- Department/Study Team to complete SIV
- **Protocol Sign Offs - Primary Coordinator, Department Manager or PI**
- CTO confirms account is created by Sponsored Projects Accounting (SPA)
- CTO confirms Contract is fully executed
- Letter from Sponsor
- IRB Approval
- CTO to confirm study ready to be opened to accrual.

20. Open Study to Accrual
- Department/Study Team to open study to accrual
- Study is ready to start enrolling patients