START-UP, REVIEWS & PRE-AWARD CTMS WORKFLOW

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

INITIAL CONSULTATION WITH CTO Study Teams/Department will meet with CTO to discuss study needs and details. **SUBMIT TO CLINICAL STUDY REGISTRY (CSR)** Study Teams/Department will submit study

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.

INITIAL **SUBMISSION IRB**

• Study Team will begin application to the IRB and get the Study ID to use on the Clinical Study Registry submission.

SYSTEM INTEGRATION **PUSHES PROTOCOL INFORMATION**

- OnCore CTMS receives protocol information from the Clinical Study Registry (CSR).
- Once confirmed during the initial consultation that the study team wants to utilize OnCore. The PittPRO ID will be obtained and the CSR status will be changed to approved.

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

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.

MEDICARE COVERAGE ANALYSIS (MCA)

- The CTO drafts MCA & Completes QA
- Updates Billing Grid in OnCore and completes QCT checklist

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

SUBMIT TO

MYFUNDING

Study Team submits to MyFunding PERIS[™] for the School Review process by Research Administration

Office

BUDGET BUILD

- CTO to set up budget template in OnCore CTMS
- CTO provides export of the budget to Department/Study Team to review.
- Budget is reconciled and finalized in OnCore.
- CTO to release budget in OnCore

MCA REVIEW & APPROVAL

- Department/Study Team reviews and approves
- PI to review, and approve Coverage Analysis in OnCore -Sign Off
- The CTO finalizes MCA and submits to OSPARS for Fiscal Review

CTO HOSTS SIM

- The CTO meets with the Study Team/Department to receive final approval on all deliverables
- CTO documents deliverable approval on SOW
- CTO confirms CTA and all relevant documents are ready for submission to OSPARS

- 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.
- Documents Final Approval on SOW

IRB APPROVAL

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

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.

OPEN STUDY TO ACCRUAL

- Department/Study Team to open study to accrual
- Study is ready to start enrolling patients

SPA ACCOUNT CREATION

 SPA sets up account in financial system

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information to the

"Clinical Study Registry"