Clinical Research and Trials Management Process Flowchart

Submit CDA for Review to OCTA. Once CDA is finalized, request Master Protocol from Sponsor.

Review Protocol for Feasibility (science/business perspective) & Identify Study Staff (PI, Sub-I, CRC, RATERS, other clinicians).

Identify Ancillary Services (ACTRI, Imaging, PET, HERC, IBC, COI, Pharmacy, etc.)

Determine the IRB of record Central [Advarra, WCGIRB, other] or Local [UCSD].

Submit protocol to Kuali via Kuali Login/protocols and obtain a six-digit IRB#.

With IRB#, Submit study proposal for Contract/Budget services via Kuali Login/Research and obtain a KP# for tracking purposes.

With IRB#, Request Coverage Analysis CA request to ensure proper billing.

Submit ACTRI services request (clinic, pharmacy, imaging, regulatory, project management as needed).

Submit Protocol/IRB# for HERC review, when radiation is involved. Contact: Jeff Wagner j7wagner@ucsd.edu.

Request ACTRI In-Service Request and request clinical conductor account.

Schedule SIV for Study Personnel.

Ensure CTA (contract) is finalized and the Project’s COA (chart string) is set up by OCTA.

Sponsor, SOP and CITI training certificates filed.

Log & Track all Study Supplies/Equipment Received for sponsor & vendors.

Complete Research Account form in Velos once COA (chart of accounts/string) is available. If applicable, complete lab & imaging forms.

Create Study Binders:
- Regulatory
- Financial
- Subject

Create Study Documents (Source docs, EEG orders, request OPDX prescription from pharmacy).

Notify Ancillary Departments of study activation and provide COA for rechargers.

Request ACTRI In-Service Request and request clinical conductor account.

Schedule SIV for Study Personnel.

Begin Patient Recruitment.

Close study with Sponsor/CIRB, Submit Close out to Kuali IRB, Velos, ACTRI, notified all Ancillary Services.

Perform Study Visits (scheduled visits in Clinical Conductor).

Invoice and Reconcile Account throughout Study Duration. Issue Final Invoice.

Manage Subject Visits in Velos and Complete/Enter Study CRFs in EDC.

Manage AEs & Protocol Dev.

Site Initiation Visit (SIV) – Pharmacy schedules their own SIV (Must have IRB approval, Contract (CTA), Velos Account, & ancillary departments approval prior to SIV).

Monitor Visits:
- Respond to queries
- Track, document & and file all queries until resolved.