UC San Diego
SCHOOL OF MEDICINE
Department of Neurosciences

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#

Submit proposal for contract/budget services via Clinical Trial Intake. The study will be created in & a Research Administrator will be assigned to PI

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

Submit Regulatory Package to Sponsor

Request a* Velos Account Required for all studies, regardless of CA

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 OPRX prescription from pharmacy)

Request ACTRI In-Service Request and request clinical conductor account
Schedule Clinic Training for Study Personnel.

Notify Ancillary Departments of study activation and provide COA for rechargers

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

Sponsor, SOPs and CITI training certificates filed

Site Initiation Visit (SIV) – with team & IDS Pharmacy. IDS manages their own communications with sponsors.
(Must have IRB approval, Contract (CTA), Velos Account, & ancillary departments approval prior to SIV)

Begin Patient Recruitment

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

Perform Study Visits
(scheduled visits in Clinical Conductor)

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

Manage AEs & Protocol Dev.

Invoice and Reconcile Account throughout Study Duration. Issue Final Invoice

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

*Requires a COA (project#) to initiate request.