Feasibility: 1 month

- ☐ If non-industry funding, contact your RSC first: https://osr.ucsf.edu/find-my-osr-staff 1 week (_____)
- ☐ Confidentiality Disclosure Agreement (CDA) to ITA contact: https://ita.ucsf.edu/ita-professionals
- ☐ Inform your Administrator and perform feasibility assessment (Review of resources)
  - o http://hub.ucsf.edu/feasibility-analysis-scientific-review 1 week (_____)
- ☐ Site Selection Visit (SSV): Arrange tours, pharmacy, CTSI/CRS (PCRC/GCRC), storage, etc. 1 week (_____)

Budget and Contract: 1-3 months

- ☐ Obtain protocol, template ICF, lab manual, NCT #, IND letter, budget template, CTA and enrollment goals & dates
- ☐ To initiate Coverage Analysis (CA) & Budget with OCR: http://tiny.ucsf.edu/OCRrequest 2 weeks (_____)
  - o Email OCR (clinicaltrials@ucsf.edu) to confirm obtain billing grid/CA
- ☐ Clinical Trial Agreement (CTA)/contract review: 2 weeks (_____)
  - o Non-Industry Sponsor: https://osr.ucsf.edu/find-my-osr-staff
  - o ITA contact for Industry Sponsors: https://ita.ucsf.edu/ita-professionals
- ☐ PI/CRC to approve calendar build and initial coverage analysis 1 week (_____)
- ☐ Send protocol to Investigational Pharmacy to request pharmacy quote (https://ids.ucsf.edu/):
  - o Parnassus: Scott.Fields@ucsf.edu or Mission Bay: Shirley.Chen@ucsf.edu 1 week (_____)
- ☐ Request CTSI/CRS budget estimate: https://accelerate.ucsf.edu/research/crs/guidelines 2 weeks (_____)
  - o Email completed budget request form to: crsbudgetrequest@ucsf.edu
- ☐ Provide OCR with signed approved CRS budget estimate and pharmacy quotes
- ☐ OCR creates budget, reviews with study team, and begins sponsor negotiations 2-3 weeks(_____)

IRB and CRS submission: 3-4 months (can be concurrent)

- ☐ Draft IRB application using IRIS (instructions: http://irb.ucsf.edu/new-study) 1-2 weeks(_____)
- ☐ Draft informed consent forms using IRB templates and then have approved by sponsor 2-3 weeks(_____)
- ☐ Schedule CRS/CTSI scientific advisory committee review – note deadlines 2 weeks prior to meeting dates
  - o Email Protocol Manager, Teresa Luu: CRSProtocolServices@ucsf.edu 1-2 weeks(_____)
  - o Need initial CA and CRS budget estimate approved prior to scheduling
  - o Approval required for studies using CRS services (nursing) https://accelerate.ucsf.edu/research/crs
- ☐ Submit IRB/CRS application and request radiation safety approval (if needed) 1 week (_____)
- ☐ Obtain CRS/CTSI scientific approval (2 locations, each location meets monthly) 2-3 weeks (_____)
- ☐ IRB screening changes, resubmit (re-review by sponsor if necessary) 2-3 weeks (_____)
- ☐ IRB committee changes, resubmit (re-review by sponsor if necessary) 2-3 weeks (_____)
- ☐ Complete regulatory documents (1572, COI/financial disclosures, training/delegation logs, etc)

After IRB approval: 1-2 months

- ☐ Provide final consents and approval letter to both OCR, ITA/RMS and sponsor (CRA and Regulatory contact)
- ☐ Obtain final coverage analysis and final signatures on CTA 1-2 weeks (_____)
- ☐ Award set-up and assign chart string (COA) (Contact your Division Administrator) 1-2 weeks (_____)
- ☐ Request APEX study build/ZZ Account (Email OCR at clinicaltrials@ucsf.edu) 1 week (_____)
- ☐ Confirm CRS/CTSI study number (4 digits) and send draft nursing orders 1 week (_____)
- ☐ Schedule start-up meeting with CRS/PCRC (CRSProtocolServices@ucsf.edu) 1-2 weeks (_____)