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)
  - 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 (_______)
  - Email OCR (clinicaltrials@ucsf.edu) to confirm obtain billing grid/CA
- Clinical Trial Agreement (CTA)/contract review: 2 weeks (_______)
  - Non-Industry Sponsor: https://osr.ucsf.edu/find-my-osr-staff
  - 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/): 1 week (_______)
  - Parnassus: Scott.Fields@ucsf.edu or Mission Bay: Shirley.Chen@ucsf.edu
- Request CTSI/CRS budget estimate: https://accelerate.ucsf.edu/research/crs/guidelines 2 weeks (_______)
  - Email completed budget request form to: crsbudgetrequest@ucsf.edu
- Provide OCR with signed approved CRS budget estimate and pharmacy quotes 2-3 weeks(_______)
- 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
  - Email Protocol Manager, Teresa Luu: CRSProtocolServices@ucsf.edu 1-2 weeks(_______)
  - Need initial CA and CRS budget estimate approved prior to scheduling
- 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 CRSProtocolServices@ucsf.edu)
- Schedule start-up meeting with CRS/PCRC (CRSProtocolServices@ucsf.edu) 1-2 weeks (_______)