ASSESS FEASIBILITY

- Sponsor selects site
- PI assesses feasibility:
  - Protocol viability
  - Study costs
  - Patient population
  - Personnel needs
  - PI availability

SIGN CONTRACT

- Sign contract questionnaire as requested by Dept. Staff
- Verify COI disclosures
- Sign contract as requested by SPA

OVERSEE BUDGET

- Oversee budget negotiations
- Sign internal forms and route to SPA

SUBMIT MATRIX & IRB

- Submit MATRIX and IRB application to IRB for review
- Revise/provide additional information to IRB as needed

REQUEST RESEARCH STUDY BUILD

- Request Research Study Build
- Manage financial activity
- Submit data to sponsor
- Submit IRB continuation
- Order drug/supplies
- Generate invoices

HOST SITE INITIATION VISIT BY SPONSOR

- Host site initiation visit by sponsor
- Recruit/enroll subjects
- Meet with site monitor
- Attend investigators meetings

RECONCILE WBS

- Reconcile WBS activity
- Ensure receipt of final payment
- Prepare SPA closure documents
- Retain records in compliance with sponsor requirements

CLOSE STUDY

- Close WBS
- Retain records in compliance with institutional policy

CONFLICTS OF INTEREST DISCLOSED

- Conflicts of interest disclosed
- Conflicts managed
- CITI training complete for all personnel on budget

INTERNAL FORMS APPROVED BY INSTITUTION

- Internal forms approved by institution
- Coverage Analysis Completed

CONTRACT FULLY EXECUTED

- Contract fully executed
- IRB approved
- WBS account set up
- Training requirements met

IRB ACTIVE

- IRB active
- WBS active
- Subjects recruited/enrolled

WBS CLOSED

- WBS closed
- IRB closed
- Study documents in storage

For questions contact Sponsored Programs Administration (SPAdmin) 402.559.7456