PI receives protocol from sponsor and reviews for feasibility (adequate staffing, subject population, academic importance, etc.). Decides to proceed with study.

PI disseminates study information to Office of Sponsored Programs (OSP), department budget manager, and IRB.

**Roles**
- PI
- OSP

### Internal Approvals
- Submit ePA-005
- Submit COI disclosure to ORC annually and submit updates as necessary
- Sign ePA-005 electronically

### Approvals Required for OSP Signature
- IRB-approved protocol and ICF
- ePA-005 fully signed
- Medicare Assurance Document, as required
- COI disclosure completed
- Contract fully negotiated
- Effort reports up-to-date

### Budgeting
- Negotiate budget with input from OSP, as necessary
- Submit finalized budget to OSP
- Submit Medicare Assurance Document to Research Billing Office, as required

### OSP
- Send sponsor contact information, contract, protocol, fee agreement to OSP
- Review contract and protocol, negotiate acceptable agreement and payment terms with sponsor
- Keep PI informed of progress (obtain PI and department approval for unusual terms as necessary)
- Send negotiated contract to PI for review and signature
- OSP signs contract and returns to sponsor
- OSP assigns project number after executed contract is returned by sponsor. OSP sends copy of contract to PI.

### IRB
- Submit protocol package to IRB
- IRB approval obtained (PI notifies OSP)
- Send approved Informed Consent Form (ICF) to OSP

### Budgeting
- PI submits OSP project number to hospital to receive research billing number from Research Billing Office