

# INVESTIGATOR-INITIATED PIPELINE

For assistance, please contact your appropriate school for assistance:

Massey Cancer Center: [masseyactpm@vcu.edu](mailto:masseyactpm@vcu.edu)

School of Medicine: [SOMCT@vcuhealth.org](mailto:SOMCT@vcuhealth.org)



## 1. Assessment

Draft protocol and study related documents (located under HRPP/IRB tab).

## 2. Start-up

### Study Activation

- Budget/cost coverage analysis
- Subject injury language
- Contract negotiation
- PROC/VCUHS intake form or PRMC
- Ancillary review
- IRB review

### Study Set-up

- Regulatory files (SiteVault)
- Staff training/delegation
- OnCore
- Site initiation
- Regulatory filing (IND/IDE)



## 3. Conduct

### Recruitment

- Advertising
- Recruitment
- Screening
- Consenting

### Management

- OnCore
- Ordering and scheduling
- Biospecimen management
- Participant follow-up
- Reimbursement/compensation
- Research billing
- Participant records
- Data collection
- Safety monitoring
- Re-consenting

### Oversight/maintenance

- SiteRegulatory file maintenance
- IRB continued review
- Amendments
- Reportable events
- Regulatory reporting
- Data management
- Data query resolution
- Study monitoring/audits



## 4. Closure

- Close out visit
- IRB closure
- Archiving records
- Clinicaltrials.gov results reporting

