# INDUSTRY OR GOVERNMENT **PIPELINE**

For assistance, please contact your appropriate school for assistance:

Massey Cancer Center: masseyactpm@vcu.edu School of Medicine: SOMCT@vcuhealth.org

1.

**Assessment** 

Confidentiality

protocol/syno

qualification

agreement

Review

psis

Site





3.

Conduct

Closure

- Close out visit
- IRB closure
- Archiving records
- Post-award closure
- Regulatory closeout



Start-up

### **Study Activation**

- Budget/cost coverage analysisBudget/cost coverage
- Subject injury <u>language</u>
- Contract negotiation
- PROC/VCUHS intake form or PRMC
- Ancillary review
- IRB review

#### Study Set-up

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

#### 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

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