**Human Research**

INVESTIGATOR-INITIATED PIPELINE

1. Assessment
   1. Draft protocol and study related documents
2. Start-up
   1. Study activation
      1. [Budget/cost coverage](https://research.vcu.edu/human-research/regulatory-affairs/vcu-clinical-research-coverage-analysis/)
      2. [Subject injury language](https://research.vcu.edu/media/office-of-research-and-innovation/secure/proposalsandawards/rams-spot/osp_subject_injury_language_review_process_for_industry.pdf)
      3. [PROC/VCUHS intake form](https://onetrac.vcu.edu) or [PRMC](https://www.masseycancercenter.org/research/~/link.aspx?_id=ee49e95faa8b44d09b6e89d8e3b48b57&_z=z)
      4. [Ancillary review](https://research.vcu.edu/integrity-and-compliance/compliance/regulatory-committees/)
      5. [IRB review](https://research.vcu.edu/human-research/hrppirb/activities-requiring-irb-review/)
      6. [Clinical trial registration](https://cctr.vcu.edu/support/consultation/clinical-trials-gov/)
   2. Study set-up
      1. Regulatory files
      2. [Staff training/delegation](https://research.vcu.edu/training/citi-training/)
      3. [OnCore](https://cctr.vcu.edu/support/informatics/oncore/)
      4. Site initiation
      5. [Regulatory filing (IND/IDE)](https://research.vcu.edu/human-research/regulatory-affairs/)
3. Conduct
   1. [Recruitment](https://cctr.vcu.edu/support/study-participation-and-recruitment/)
      1. Advertising
      2. Recruitment
      3. Screening
      4. Consenting
   2. Management
      1. [OnCore](https://cctr.vcu.edu/support/informatics/oncore/)
      2. [Ordering and scheduling](https://research.vcu.edu/human-research/ids/)
      3. [Biospecimen management](https://pathology.vcu.edu/research/clinical-pathology-cprs/)
      4. Participant follow-up
      5. [Reimbursement/compensation](https://procurement.vcu.edu/i-want-to/pay-an-individual/compensate-a-research-participant/)
      6. [Research billing](https://intranet.vcuhealth.org/sites/clinical-research/SitePageModern/80467/study-billing) (VCUHS credentials required)
      7. Participant records
      8. [Data collection](https://cctr.vcu.edu/support/research-navigation/starting-data-collection/)
      9. Safety monitoring
      10. Re-consenting
   3. Oversight/maintenance
      1. Regulatory file maintenance
      2. [IRB continued review](https://research.vcu.edu/human-research/hrppirb/other-submissions-and-monitoring/)
      3. [Amendments](https://research.vcu.edu/human-research/hrppirb/other-submissions-and-monitoring/)
      4. [Reportable events](https://research.vcu.edu/human-research/hrppirb/other-submissions-and-monitoring/)
      5. [Regulatory reporting](https://research.vcu.edu/human-research/regulatory-affairs/)
      6. [Data management](https://ts.vcu.edu/about-us/information-security/data-management-system/)
      7. Data query resolution
      8. Study monitoring/audits
4. Closure
   1. Close out visit
   2. [IRB closure](https://research.vcu.edu/human-research/hrppirb/other-submissions-and-monitoring/)
   3. Archiving records
   4. [Clinicaltrials.gov closure](https://cctr.vcu.edu/support/consultation/clinical-trials-gov/)

For assistance, please contact your appropriate school:

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