**Regulatory Checklist for Study Start-Up**

This guidance is intended to provide the principal investigator (PI) and the study team on what must occur when a study is ready to be opened and before enrollment. This guidance document does not include any financial or contractual documentation that may need to be completed prior to the opening of the study. Please contact your research administrator for information on the financial or contractual documentation needed.

Documentation/Actions specific to all studies:

Obtain IRB approval

Confirm access to EDC (if using electronic CRFs)

Confirm all required [essential records](https://research.vcu.edu/media/office-of-research-and-innovation/clinical/essential_documents.pdf) are filed in the paper or electronic binders

Confirm SIV or initial training has been completed and documented prior to enrolling

Provide start dates and PI sign off for all study members on DOA after initial training

Confirm any required lab kits necessary for the study are on site and available

For studies externally sponsored: Receive sponsor approval to enroll

Documentation/Actions specific to VCU-held IND/IDE studies:

Submit initial application to FDA (if multi-site, include all sites that will be participating – may be done at initial application if known or amendments later) and receive the ‘safe to proceed’ letter prior to initiating study

Submit IRB approval to FDA (once received)

For investigator-initiated studies requiring study registration on clinicaltrials.gov:

Confirm clinicaltrials.gov study record was created

If multi-site study and VCU is sponsor:

Confirm if VCU or other IRB will be IRB of record and obtain approval

Confirm all sites have current protocol, IB, ICF and any other required materials

Confirm required [essential records](https://research.vcu.edu/media/office-of-research-and-innovation/clinical/essential_documents.pdf) are added to the external site’s investigator site

file (ISF) and VCU has required copies that can be added to their trial master file (TMF), prior to enrollment beginning

Documentation/Actions specific to drug studies:

Confirm product has been received by all sites (if applicable) and logged

Documentation/Actions specific to device studies:

Confirm device(s) have been received by all sites (if applicable) and logged

**Contact**

Please contact for questions regarding this document:

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**Document History**

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| **Version** | **Version Date** | **Brief Description of Change** |
| 1.0 | 4/9/2025 | Initial |