**Regulatory Checklist for Study Closeout**

This guidance is intended to guide the principal investigator (PI) and the study team on what must occur when a study is ready to be closed. This guidance document doesn’t include any financial or contractual documentation that may need to be closed out. Please contact your research administrator for information on the financial or contractual documentation needed. The regulatory closeout should occur prior to the financial/contractual closeout.

Documentation/actions for all studies:

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

[ ]  For documents that have been maintained on paper: Identify and document the location where the study documents will be archived so they can be easily retrieved in case of an FDA audit

* + Identify the date that documentation can be destroyed. (Based on the state records management program, [Public Records Act in the Code](https://law.lis.virginia.gov/vacodefull/title42.1/chapter7/) of Virginia, by VCU's [Records Management policy,](https://policy.vcu.edu/doctract/documentportal/08DA32A740D31ACEF3DE09FFC487DA40) sponsor, and regulatory requirements.)

[ ]  Add end dates to delegation of authority (DOA) log

* + Ensure the PI has signed and dated all pages as required by the DOA template being used

[ ]  Receive sponsor approval to close

* + Do not close if they are asking for any outstanding items

[ ]  Obtain a copy of the completed case report forms (CRFs)

* + Prior to obtaining a copy of the completed CRFs, ensure all the data has been entered into the EDC and that the CRFs have been signed off by the PI as applicable

[ ]  Confirm all adverse events, deviations, and violations have been submitted to the IRB and sponsor as applicable

[ ]  Confirm leftover samples have either been destroyed or stored (and location) for future use based on the protocol

[ ]  IRB closeout

* + This should be the last item done

Documentation/actions specific to drug studies:

[ ]  Confirm all drugs have been destroyed or returned

* + Obtain a copy of the completed drug accountability log and destruction certificate (if drug accountability and destruction was done by a pharmacy or cell lab)

Documentation specific to device studies:

[ ]  Confirm all devices have been destroyed or returned

Documentation specific to VCU-held IND/IDE studies:

[ ]  Submit to FDA

* + If the IND/IDE has multiple studies under it, submit to the FDA alerting them that that specific study has been completed
	+ If the IND/IDE only has the study that is being closed, submit an IND/IDE final report to the FDA

Action specific to investigator-initiated studies:

* Investigator-initiated studies requiring result reporting on clinicaltrials.gov:

[ ]  Submit results on clinicaltrials.gov as applicable

**Contact**

Please contact for questions regarding this document:

OVPRI Regulatory Affairs

indide@vcu.edu

**Document History**

|  |  |  |
| --- | --- | --- |
| **Version** | **Version Date** | **Brief Description of Change** |
| 1.0 | 04/25/2024 | Initial |
| 2.0 | 07/09/2024 | Added checkboxes |