**Regulatory Requirements for Transferring Clinical Studies between Principal Investigators**

This guidance is intended to guide the new principal investigator (PI) on what needs to occur when a clinical study transitions to a different PI. This guidance document doesn’t include any financial or contractual documentation that may need to change. Please contact your research administrator for information on your financial or contractual documentation needed.

Documentation/actions for all studies:

[ ]  Sponsor approval prior to initiating the change (for industry or federal-funded studies)

[ ]  Amendment to IRB- This must be submitted and approved

* + This should include updating the informed consent if the study is still open to accrual or if there is a possibility of needing to re-consent participants. If the study is closed to accrual and all participants are off study, the informed consent doesn’t need to be updated but this should be documented that the consent isn’t being revised due to this.

[ ]  Confirm the location of where all study documents are being maintained and gain access to the EDC system being used.

[ ]  Complete study required training (obtain training documentation) for new PI

[ ]  Update the delegation of authority (DOA) log to show that the investigator is now PI and add the end date of old PI

* + If the new PI was previously a sub-investigator (sub-I), the investigator's end date for being a sub-I should be the same date as their start date as PI
	+ If the new PI wasn’t previously on the study, they should complete study training prior to being added to the DOA

[ ]  Collect new PI’s CV, ML, GCP and HSP certificates if not previously collected on study

[ ]  New protocol signature page for current protocol version

[ ]  Updated financial disclosure form (if financial disclosure form specifies investigator’s role)

[ ]  Submissions to all applicable ancillary committees (ex: IBC, PROC, PRMC) notifying them of PI change as applicable

[ ]  Update OnCore when PI change has been IRB approved

Documentation/actions specific to drug studies:

[ ]  New 1572

[ ]  New investigator brochure (IB) signature page for current IB version

[ ]  Notify investigational pharmacy of PI change

* + Email IRB approval memo of change to *investigational.drug@vcuhealth.org*

Documentation specific to device studies:

[ ]  New investigator agreement

Documentation specific to VCU-held IND/IDE studies:

[ ]  FDA submission to alert them of PI change

* + New 1572 (for IND studies)
	+ If the IND/IDE holder is changing, additional documentation needs to be submitted to the FDA. This would include letters from the old and new IND holder transferring and accepting responsibilities of the IND/IDE

Action specific to investigator-initiated studies:

[ ]  Update clinicaltrials.gov record

It is ultimately the new PI’s responsibility to review the documentation previously collected under the previous PI to ensure the accuracy of the collected documentation and that any reportable events were reported.

**Contact**

Please contact for questions regarding this document:

OVPRI Regulatory Affairs

indide@vcu.edu

**Document History**

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