Transfer of Participants Between Institutions		
VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
SOP No.: CR-CO-580.3	Status: Final	Version Date: 07/22/2025 Effective Date: 08/04/2025

1. PURPOSE

This Standard Operating Procedure establishes the standards and processes for transferring research participants between institutions and to ensure that proper guidelines are in place for the safety, compliance, and continuity of care of research participants in clinical research studies at VCU/VCU Health institutions, affiliates, and participating sites.

2. REQUIREMENTS

A research participant may choose to transfer their care to another institution for any reason. A research participant may be transferred to another institution at the request of the enrolling Principal Investigator (PI). This policy does not apply to temporary relocations, such as travel, unless the temporary relocation is extended beyond acceptable visit windows.

3. DEFINITIONS

N/A

4. PROCESS

A. If a VCU PI is accepting a research participant from a non-VCU facility/program, the following procedures are to be be followed:

- The research study must be approved by the Institutional Review Board (IRB) of record for the accepting institution prior to accepting the research participant.
- The participant's request/need for transfer must be confirmed by both the PI at the transferring institution and the VCU PI. Approval of the transfer by both PIs will be documented in the research record.
- If externally sponsored, documentation of approval by the study sponsor must be received prior to transfer of the participant's care and filed in the research record.
- The transferring participant must sign the VCU site's approved study-specific informed consent form prior to engaging in any research activity or treatment at a VCU facility.

- The transferring institution is responsible for submitting all data (raw data and query responses) required by the protocol and sponsor up to the date of transfer. Documentation that all data required to the date of transfer has been completed and submitted to the sponsor must be received from the sponsor prior to transfer of the participant's care and research records. Follow-up responsibility and data submission after the date of transfer are the responsibility of the VCU PI.

- All documentation sent between sites must be sent using secure means with the security measures taken documented in the regulatory binder or investigator site file.

- The enrolling institution and/or sponsor will provide all medical and administrative information necessary to determine the appropriateness of the placement and to enable continuing care of the research participant. This information may include, but is not limited to, current medical findings, diagnoses, a brief summary of the course of treatment followed in the transferring institution, nursing and dietary information, ambulation status, and pertinent administrative and social information, as appropriate.

- The transferring institution will be responsible for effecting the transfer of the participant, including arranging for appropriate and safe transportation and care of the patient during the transfer (if applicable), along with key participant records, in accordance with applicable federal and state laws and regulations.

B. If a VCU PI is transferring the care of a research participant to a non-VCU facility, the following procedures are to be followed:

- The research project must be approved by the IRB of record at the accepting institution prior to transfer of the research participant.

- The participant's request/need for transfer must be substantiated by both the VCU PI and the PI at the accepting institution. Approval of the transfer by both PIs will be documented in the research record.

- If externally sponsored, documentation of approval by the study sponsor must be received prior to transfer of the participant's care and research records.

- The VCU PI is responsible for submitting all data (raw data and query responses) required by the protocol and sponsor up to the date of transfer. Documentation that all data required to the date of transfer has been completed and submitted to the sponsor must be received from the sponsor prior to transfer of the participant's care

and research records. Follow-up responsibility and data submission after the date of transfer are the responsibility of the accepting PI.

- The VCU PI will provide to the accepting institution all medical and administrative information necessary to facilitate the continuing care of the research participant. The VCU PI is responsible for obtaining authorization from the research participant to facilitate the transfer of research data.

- If applicable, the VCU PI will be responsible for facilitating the transfer of the participant, including arranging for appropriate and safe transportation (if applicable) and care of the patient during the transfer in accordance with applicable federal and state laws and regulations.

5. REFERENCES

N/A

Review/Revision History CR-CO-580		
Version No.	**Effective Date**	**Description**
CR-CO-580.3	08/04/2025	● Clarified purpose to emphasize safety, compliance, and continuity of care during participant transfers ● Updated terminology for consistency (e.g., “VCU site’s approved study-specific informed consent form”) ● Revised to specify that procedures apply to both incoming and outgoing transfers involving VCU PIs ● Aligned language for IRB requirements and study sponsor documentation ● Added expectations for secure transfer of documentation with notation in regulatory binder ● Specified participant data submission responsibilities before and after transfer ● Emphasized the need for participant authorization for data transfer ● Minor grammar and formatting edits for clarity ● Biennial review performed

CR-CO-580.2	06-01-2021	● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-CO-580.1	06-01-2018	● Original