Investigational Device Management

VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES

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1. PURPOSE

This Standard Operating Procedure defines the processes and procedures for the receipt, inventory, storage, dispensing, reconciliation, return, or authorized destruction of an investigational device used in a clinical research setting at a VCU/VCU Health facility and/or affiliate.

2. REQUIREMENTS

Research projects using investigational devices are required to comply with Investigational Device Exemption (IDE) regulations as outlined in FDA 21 CFR 812. Good clinical practice requires that investigators ensure any investigational device used in a clinical research study is strictly and accurately accounted for. This includes, but is not limited to, maintaining records of receipt, inventory, storage, dispensing, reconciliation, return, and authorized destruction of the investigational device(s).

Device accountability demonstrates that an investigational device was dispensed and/or administered according to the study protocol and helps provide validity to the study data, verify patient case histories, detect possible lot variations, and assist in identifying patients who have received investigational devices should recovery or replacement of the devices be necessary to minimize health risks.

3. DEFINITIONS

Medical device- An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is recognized in the official National Formulary or the US Pharmacopoeia, or any supplement to them; intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or; intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Investigational Device -A device, including a translational device, that is the object of an investigation.

Device Accountability Log -A device accountability log is a document that tracks and documents when and how an investigational device has been used throughout the life of a research project. A device accountability log should be maintained for any research project that uses study-supplied devices.

4. PROCESS

Upon receipt of the investigational device(s) on-site until it is used during the research study, returned to the sponsor, or destroyed on-site at the sponsor's request, the following procedures should be followed.

A. Upon receipt of investigational devices, inventory the shipment to ensure that information on all packing slips matches exactly the contents of the containers, including, but not limited to:
   - Quantity received
   - Unique identifiers such as lot numbers or serial numbers
   - Package Quantity per dispensing package

   Any identified discrepancy should immediately be brought to the attention of the sponsor and/or supplier and resolved.

B. If the shipment includes an "Acknowledgement of Receipt" form, the required signature(s) should be obtained and the form returned to the sponsor/supplier per instructions. Should an "Acknowledgement of Receipt" form not be included in the shipment, the packaging slip should be signed and dated with the date of receipt. A copy of the "Acknowledgement of Receipt" form or signed packaging slip should be filed in the regulatory binder.

C. Ensure that the devices required for the study are within an appropriate expiration date as applicable.

D. All investigational devices must be stored in a secure environment with access limited to only study personnel assigned the responsibility for said access, as noted on the study delegation log. Investigational devices must be stored separately from regular stock to ensure investigational stock is reserved strictly for research participants.

E. Devices should be stored according to the storage requirements per the protocol or supplementary document. Ensure the devices are stored at the appropriate temperature and maintain a daily storage area temperature log if climate control is required.

F. Each time an investigational device is used or dispensed, the PI or their designee will document the dispensing of the device on the device accountability log contemporaneously. Documentation should include, but is not limited to:
   - Date (and time, if appropriate) of dispensing
   - Participant's study number and/or initials
   - Unique device identifiers such as lot numbers or serial numbers
   - Quantity dispensed
   - Name or initials of individual distributing the investigational device
   - Date (and time, if appropriate) of return (if applicable)
   - Quantity of investigational device returned (if applicable)

G. Investigational device supplies should be periodically reviewed to ensure supplies are adequate and within an appropriate expiration date. If additional inventory is needed, the sponsor and/or supplier should be notified immediately.

H. Device accountability logs must be available for review by monitors and/or auditors.

I. At the conclusion of the study or when investigational devices expire, the investigational device(s) must be returned to the supplier or disposed of on-site according to the study protocol.

J. If investigational devices are to be returned, prior to return of investigational devices, ensure all documentation regarding receipt, storage, distribution, and return of the devices is complete and accurate. The device accountability log must be verified before shipment is processed. Documentation of the return shipment (i.e., mailing slip) should be filed in the regulatory binder.

K. If investigational devices are to be destroyed, written authorization from the sponsor is required and destruction should be undertaken in accordance with applicable VCU and VCU Health policies and Occupational Safety and Health Administration (OSHA) requirements. Documentation of the destruction of the investigational device(s) should be provided to the sponsor upon completion and filed in the regulatory binder.

L. All documentation regarding the device, including but not limited to packing slips, shipment receipts, accountability records, and disposal instructions, should be filed in the study-specific regulatory binder and maintained on file as outlined in CR-CO-555 Record Retention and Archiving.

M. For sponsored studies that do not prescribe a specific device accountability log, as well as for VCU sponsor-investigator studies, a template VCU Device Accountability Log is available for the study team.

5. REFERENCES

A. Code of Federal Regulations

- 21 CFR 812 – Investigational Device Exemptions

B. Good Clinical Practice

- ICH Harmonised Guideline Guideline For Good Clinical Practice E6(R3)
    - Section 3 – Sponsor
        - Section 3.13.2 – Manufacturing, Packaging, Labeling, and Coding Investigational Product(s)
        - Section 3.15.3 – Supplying and Handling Investigational Product(s)

C. VCU

- VCU/VCU Health System Clinical Research Standard Operating Procedures
    - CR-CO-555 Record Retention and Archiving
- Occupational Safety and Health Administration (OSHA)

Review/Revision History CR-IP-410

Version No.	Effective Date	Description
CR-IP-410.3		• Updated definitions • Aligned with ICH E6(R3) • Updated references • Biennial review performed • Minor formatting edits • Reference links updated
CR-IP-410.2a	08-01-2020	• Links updated
CR-IP-410.2	08-01-2020	• Biennial review performed • Minor formatting edits • Reference links updated
CR-IP-410.1	08-10-2018	• Original