Investigational Device Management

VCU/VCUHS 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/VCUHS 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 and 21 CFR 814. Good clinical research practice requires that investigators ensure any investigational device used in a clinical research project be 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 research 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

Investigational Device

A medical device is defined, in part, as any health care product that does not achieve its primary intended purposes by chemical action or by being metabolized. Medical devices include, among other things, surgical lasers, wheelchairs, sutures, pacemakers, vascular grafts, intraocular lenses, and orthopedic pins. Medical devices also include diagnostic aids such as reagents and test kits for *in vitro* diagnosis (IVD) of disease and other medical conditions such as pregnancy. An investigational device may be an unapproved device or an approved product that is being tested for a currently unapproved use.

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 clinical 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.

D. All investigational devices must be stored in a secure environment with access limited to only research 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 VCUHS 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 the VCU/VCUH Clinical Research SOP, CR-CO-555 Record Retention and Archiving.

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

5. REFERENCES

A. Code of Federal Regulations
- 21 CFR 812 – Investigational Device Exemptions
- 21 CFR 814 – Premarket Approval of Medical Devices

B. Good Clinical Practice
- ICH E6: Harmonized Tripartite Guideline for Good Clinical Practice
  - Section 5 – Sponsor
    - Section 5.13 – Manufacturing, Packaging, Labeling, and Coding Investigational Product(s)
    - Section 5.14 – Supplying and Handling Investigational Product(s)

C. VCU/VCU Health System Clinical Research Standard Operating Procedures
- CR-CO-555 Record Retention and Archiving

D. IRBs
- VCU IRB Written Policies and Procedures
  - Section #XVI-1 – Review of Medical Devices
  - Section #XVI-2 –Humanitarian Use Devices
  - Section #XVI-3 – Emergency Use of an Investigational Drug, Device, or Biologic
  - Section #XVI-5 – Expanded Access to Unapproved Drugs, Devices, and Biologics
  - Section #XVI-7 – Control of Investigational Drugs, Devices, and Biologics
  - VCU Study Conduct Toolkit: Drug/Device Accountability
- Policies of the IRB of Record, if not the VCU IRB

Review/Revision History CR-IP-410

Version No.	Effective Date	Description
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