Investigational Device Management	CR-214
Clinical Research Standard Practices	**Effective Date:** September 2024

SCOPE AND PURPOSE This document is applicable to the following roles within Penn State College of Medicine and Penn State Health entities engaged in clinical research:

X	Principal Investigator	X	Regulatory Specialists
X	Sub-Investigators	X	Key Study Ancillary Personnel
X	Study Coordinators/Associates	X	Financial Analyst/Contract Management Accountants
X	Data Specialist		Central Research Office Personnel

This standard operating procedure (SOP) describes the processes at this investigative site for the receipt, inventory, storage, dispensing, reconciliation, return, or authorized destruction of an investigational device used in a clinical research setting.

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.

This SOP may be shared with Sponsors and/or CROs upon request.

POLICY AND PROCEDURE STATEMENTS

1. Receipt and inventorying of investigational device
    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:
        i. Date of device receipt
        ii. Quantity received
        iii. Unique identifiers such as lot numbers or serial numbers
        iv. Package Quantity per dispensing package

b. Any identified discrepancy should immediately be brought to the attention of the sponsor and/or supplier and resolved.
c. 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.
d. Ensure that the devices required for the study are within an appropriate expiration date.

2. Storage of Investigational Device
    a. 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.
    b. 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.

3. Dispensing of Investigational Device
    a. 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.
    b. Documentation should include, but is not limited to:
        i. Date (and time, if appropriate) of dispensing
        ii. Participant's study number and/or initials
        iii. Unique device identifiers such as lot numbers or serial numbers
        iv. Quantity dispensed
        v. Name or initials of individual distributing the investigational device
        vi. Date (and time, if appropriate) of return (if applicable)
        vii. Quantity of investigational device returned (if applicable)
    c. 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.
    d. Device accountability logs must be available for review by monitors and/or auditors.

4. Return/destruction of Investigational Device
    a. 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.
    b. 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.

c. If investigational devices are to be destroyed, written authorization from the sponsor is required and destruction should be undertaken in accordance with applicable 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.
d. 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.
e. For sponsored studies which do not prescribe a specific device accountability log, as well as for sponsor-investigator studies, a template Device Accountability Log is available for the study team on the CTO website (https://infonet.pennstatehershey.net/web/clinical-trials-office/resources)

RELATED POLICIES AND REFERENCES

Code of Federal Regulations: Investigational Device Exemptions (21 CFR 812)

Code of Federal Regulations: PreMarket Approval of Medical D (21 CFR 814)

Code of Federal Regulations: Investigational New Drug Application (21 CFR 312.50, 56, 59, 60, 61, 62, 68, 69)

Compliance Program Manual, Bioresearch Monitoring Program, Clinical Investigators and Sponsor-Investigators (Program# 7348.811); U. S. Food and Drug Administration; 22 July 2020

Guidance for Industry Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring; U. S. Food and Drug Administration; August 2013

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APPROVALS

Approved:	Kevin Gardner, Jr., MS, BSN, RN, CCRC Director, College of Medicine Clinical Trials Office Adam McDowell, BA, JD, CRA Director, Office of Research Affairs, Contracts Thomas Brydebell Director, Office of Research Affairs, Grants Elizabeth Galgocy, MEd, RN, CIP Director, Research Quality Assurance, Human Research Trials

Authorized:	Neal Thomas, MD, MSc Associate Dean of Clinical Research Sheila Vrana, PhD Associate Dean of Research

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CONTENT REVIEWERS AND CONTRIBUTORS

Director, College of Medicine Clinical Trials Office

Director, Office of Research Affairs, Contracts

Director, Office of Research Affairs, Grants

Director, Research Quality Assurance, Human Research Trials

HISTORY OF REVIEWS AND REVISIONS

February 2024	
Scope and Purpose	Updated "Financial Analyst/**Contract Management Accountants**". Added "Regulatory Specialists" and "Central Research Office Personnel." Notation made that this SOP may be shared with Sponsors and/or CROs upon request.
Approvals	"Authorized" and "Approved" switched to align with CR-101.
History of Reviews and Revisions	Section added.