1. INTRODUCTION AND PURPOSE

When applicable, this standard operating procedure (SOP) describes the processes at this investigative site for the receipt, storage, dispensing, reconciliation and return or authorized destruction of the investigational drug/device.

2. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.50 General responsibilities of sponsors
21 CFR 312.56 Review of ongoing investigations
21 CFR 312.59 Disposition of unused supply of investigational drug
21 CFR 312.60 General responsibilities of investigators
21 CFR 312.61 Control of the investigational drug
21 CFR 312.62 Investigator recordkeeping and record retention
21 CFR 312.68 Inspection of investigator’s records and reports
21 CFR 312.69 Handling of controlled substances

January, 1988 Guidelines for the Monitoring of Clinical Investigations
May 9, 1997 International Conference on Harmonisation: Good Clinical Practice: Consolidated Guideline
21 CFR 800 General Medical Devices
21 CFR 803 Medical Device Reporting
21 CFR 812 Investigational Device Exemptions
FDA website: U S Food and Drug Administration Home Page
OHRP website: HHS - Office for Human Research Protections
ICH website: ICH

3. PROCEDURES

A. Pre-study start up

Prior to IRB review, contact:

- The Research Pharmacist if utilizing a drug, to obtain review and sign-off for investigational drugs. Obtain Pharmacy sign-off on the Internal Services Checklist.
- Materials Management if utilizing a device to obtain review and sign-off on the Internal Services Checklist for investigational devices. Complete the Research Use of an Investigational Device form and include with the initial IRB application.
- Clinical Engineering in the event that the investigational device utilizes a battery or contains and electronic component.
B. Receipt and inventorying of test article

When the test article is received, ensure that the information on the packing slip matches exactly with the shipment that has been sent to the site, including:

- Amount
- Lot numbers
- Quantity per carrier/container (if easily verified)
- Integrity of the packaging seal
- Protocol number

Promptly bring any discrepancies to the attention of the sponsor.*

If the sponsor requires acknowledgement of receipt, respond as directed by the sponsor. This may be via IVRS or mailed receipt provided by the sponsor. Retain copy of the communication or receipt for regulatory files.*

B. Storage

Store study drug/device in a specific, well identified; secure location with access limited to authorized personnel. Store according to the storage requirements detailed in the protocol, or supplied by the sponsor* in a supplementary document.

Refer to MMC pharmacy policies for investigational drugs:
- Investigational Drug Trials and Clinical Research Policy
- Emergency use of Test Articles (FDA-Regulated Investigational Drug or Biologic or Device) Inpatient and Ambulatory Surgery
- Maine Medical Center as the Secondary Institution for Research Policy-Inpatients and Ambulatory Surgery

Refer to MMC procedures for handling of investigational devices:
- Research Use of an Investigational Device
- Maine Medical Center Operating Room Investigational Device Procedure

Controlled substances require specialized registration, record keeping, dispensing and storage. Consult with MMC pharmacy for controlled substances used in research.

Ensure that study drug/device is stored at the appropriate temperature, maintaining a storage area temperature log, if appropriate.

If applicable, ensure that the randomization code has been received.

Ensure that study drug/device supply is adequate and has not exceeded the expiration date.

* May not apply to non-industry sponsored trials
Document all circumstances related to damaged devices, packages opened inadvertently, etc.

C. Dispensing of test article

Ensure that each time study drug/device is dispensed or employed; the drug/device accountability form is completed.

1. Documentation for drugs will include (additional information may be required by the sponsor*) see Drug Accountability Log:
   - Amount (and lot number, if appropriate) dispensed
   - Initials of individual dispensing study drug
   - Subject’s study ID number
   - Subject’s initials
   - Date (and time, if appropriate) of dispensing
   - Date (and time, if appropriate) study drug returned
   - Amount of study drug returned
   - Document administration of drug in MMC information system, if applicable.

After use by the study subject, return all used medication containers/units, if applicable, to the research pharmacist. If any containers/units are missing, document the reason.

Note any discrepancies between amounts of study medication used by subjects and amounts expected to be returned and document the reason, if required.

2. Documentation for devices will include (additional information may be required by sponsor*) see Device Accountability Form:
   - Name of individual dispensing study device
   - Subject’s study ID number (other identifiers may be utilized per protocol)
   - Date (and time if appropriate) of dispensing study device
   - Date study device returned, if appropriate

After a device is utilized, return all other unused devices to a secure location, or to the sponsor* if required.

Alert the designated sponsor representative when additional supplies of study drug/device will be required.*

Ensure proper documentation and communication when study medication is transferred.

Assure that unblinding procedures are clearly communicated in writing.

If emergency breaking of the test article blind is medically necessary follow the study specific
unblinding procedures per protocol.

Document all circumstances appropriately.

**D. Return/destruction/dispensation of test article**

Ensure that the test articles are available for the monitor to inventory and prepare for return shipment to the sponsor or for destruction.*

At the conclusion of the study, ensure that all documentation regarding receipt, storage, dispensing, and return of test article is complete, accurate, and ready for review at the monitor’s termination visit.*

Provide the sponsor with written documentation of the MMC destruction policy and/or destruction of the study drug.*

Maintain a record of the return or destruction of test articles in the regulatory files.

**3. LINKS AND RESOURCES**

Maine Medical Center Institutional Policy (link)
Investigational Drug Trials and Clinical Research Policy (link)
Emergency Use of Test Articles (link)
Maine Medical Center as the Secondary Institution for Research Policy- Inpatients and Ambulatory Surgery (link)
Sample Device Accountability Log Attachment A
Sample Drug Accountability Form Attachment B
Internal Services Checklist (link)
Research Use of an Investigational Device –Sign off Attachment C
Maine Medical Center Operating Room Investigational Device Procedure Attachment D