

Title: <b>Investigational Device Accountability, Storage, Distribution and Return</b>	*Applicable to: <b>Beaumont Health</b>	Effective Date: <b>01/12/2018</b>
Policy Owner: <b>Administrative Director</b>	Document Type: <b>Policy</b>	Last Periodic Review Date: <b>01/12/2018</b>  Functional Area: <b>Clinical Research SOP's, Research Institute</b>

**\*For This Document, Beaumont Health Includes:**

- Beaumont Corporate Shared Services
- Beaumont Hospital, Dearborn
- Beaumont Hospital, Farmington Hills
- Beaumont Hospital, Grosse Pointe
- Beaumont Hospital, Royal Oak
- Beaumont Hospital, Taylor
- Beaumont Hospital, Trenton
- Beaumont Hospital, Troy
- Beaumont Hospital, Wayne
- Beaumont Medical Group
- Beaumont Pharmacy Solutions
- Post Acute Care

**I. PURPOSE:**

This standard operating procedure (SOP) describes the processes for the receipt, storage, distribution, reconciliation, return, or authorized destruction of an investigational device used in a clinical research study at Beaumont Health (BH).

**II. SCOPE:**

This SOP applies to all clinical studies at BH. It describes the steps followed from the time the investigational device is received on-site until it is used during the clinical research study, returned to the sponsor, or destroyed on-site upon sponsor request.

**III. RESPONSIBILITY:**

This SOP applies to key research personnel involved in inventorying, storing, distributing, or arranging for the return/destruction of investigational device in connection with clinical studies carried out at BH.

**IV. PROCEDURES:**

**A. Receipt and inventorying of investigational device**

1. Upon receipt of the investigational device, inventory the shipment to ensure the information on the packing slips matches exactly what has been received by the site, including:
  - a. Quantity received
  - b. Special identifying numbers, such as lot numbers, serial numbers and/or sizes

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- c. Package quantity (per carrier/container)
- d. Condition of investigational device.
- 2. Promptly bring any discrepancies to the attention of the sponsor.
- 3. If the sponsor includes a separate “acknowledgement of receipt” form in the shipment, obtain the appropriate signature and date and forward the form to the sponsor/contract research organization (CRO). Retain a copy of the acknowledgment of receipt form and packaging slip for the regulatory files.
- 4. If the sponsor does not provide an acknowledgement of receipt form, the packaging slip should be signed and dated with the date the investigational device was received at the site. Packaging slips should be filed in the regulatory binder and upon request, faxed to the sponsor.
- 5. Ensure any supplies required for the blinding of the investigational device are available.
- 6. Ensure information about randomization procedures have been received, if appropriate.

**B. Storage of investigational device**

- 1. Store investigational device inventory in a secure environment with access limited to essential research personnel.
- 2. Store investigational device according to the storage requirements detailed in the protocol or supplied by the sponsor in a supplementary document. If climate control is required, ensure the investigational device is stored at the appropriate temperature and maintain a storage area temperature log.
- 3. If an investigational device must be stored in patient care areas, such as the catheterization lab or procedure areas ensure device is stored separately from regular stock in a locked cabinet with limited access.
- 4. Investigational device must be specially labeled and precautions are taken to ensure test stock is reserved strictly for research participants.
- 5. Do not store investigational devices in patient care areas prior to Institutional Review Board (IRB) approval for the study.

**C. Distribution of investigational device**

- 1. Ensure all key research personnel involved in investigational device accountability are:
  - a. Appropriately listed on the “Delegation of Authority Log” in the regulatory binder
  - b. Listed on the Institutional Review Board (IRB) key personnel roster
  - c. Performing activities appropriate to their job categories and licensures. For example, a Research Nurse Clinician may distribute an investigational device while a Research Assistant cannot. [Refer to research personnel Weighted Job Questionnaires (WJQ’s)].
- 2. Ensure each time the investigational device is distributed or used, the device accountability form is completed contemporaneously. Documentation will include:
  - a. Quantity distributed/used

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- b. Special identification numbers, such as lot number, if appropriate
  - c. Name and signature of individual distributing investigational device
  - d. Participant number
  - e. Participant initials
  - f. Date (and time, if appropriate) of distribution/use
  - g. Date (and time, if appropriate) of investigational device returned
  - h. Quantity of investigational device returned.
3. Ensure investigational device supplies are adequate and within an appropriate expiration date.
  4. Alert the monitor/sponsor when additional inventory is needed.
  5. If emergency breaking of the investigational device blind is medically necessary, follow procedures outlined in the protocol, informing the Principal Investigator (PI) and sponsor prospectively (if possible), and documenting all circumstances appropriately.

**D. Return/destruction of investigational device**

1. At the conclusion of the study, ensure all of the documentation regarding receipt, storage, distribution, and return of used containers is complete, accurate, and ready for review at the monitor’s close out visit.
2. Ensure the investigational device supply is available for the monitor to inventory and prepare for return shipment to the sponsor/CRO.
3. If directed by sponsor to return an investigational device without a monitor present, final inventory should be verified by two qualified key personnel.
4. Upon written authorization from the sponsor, destruction of investigational device may be undertaken in accordance with applicable Beaumont policies and Occupational Safety and Health Administration (OSHA) requirements.
5. If asked to destroy an investigational device without sponsor representative present, two qualified BH personnel, such as doctors, nurses or key personnel, should verify a final inventory.
6. Provide the sponsor with written documentation of the destruction of the investigational device.
7. Maintain a copy of returned shipment or destruction of investigational device documentation in the regulatory files.

**V. 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

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21 CFR 312.62 Investigator recordkeeping and record retention  
 21 CFR 312.68 Inspection of investigator's records and reports  
 21 CFR 812 Subpart C: Responsibilities of Sponsors  
 21CFR 812 Subpart E: Responsibilities of Investigators  
 Guidelines for the Monitoring of Clinical Investigations, January 1988  
 FDA Internal Compliance Program Guidance Manual 7348.811: Clinical Investigators, September 1993  
 International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline, May 1997

## **VI. REFERENCES TO OTHER APPLICABLE SOPs:**

Research Administration Policy [\*Responsibilities of the Principal Investigator\*](#)  
 Clinical Research Policy [\*Responsibilities of the Research Team\*](#)  
 Clinical Research Policy [\*Study Close Out Visit\*](#)  
 Clinical Research Policy [\*Regulatory Files and Study Subject Records\*](#)  
 Clinical Research Policy [\*Data Management\*](#)

## **CORPORATE AUTHORITY:**

Beaumont Health (“BH”) as the corporate parent to William Beaumont Hospital, Botsford General Hospital, and Oakwood Healthcare Inc., (“Subsidiary Hospitals”) establishes the standards for all policies related to the clinical, administrative and financial operations of the Subsidiary Hospitals. The Subsidiary Hospitals, which hold all health facility and agency licenses according to Michigan law, are the covered entities and the providers of health care services under the corporate direction of BH. The Subsidiary Hospitals’ workforces are collectively designated as BH workforce throughout BH policies.