**GUIDANCE: <Title>**

**Policy:**  Investigators must maintain ensure that investigational devices are used only in approved protocols and under the direction of appropriate members of the research team.

**Key Terms**

**Investigational device**: A device, including a transitional device, that is the object of an investigation.

**Investigation:** A clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device.

**General Responsibilities:** It is the responsibility of the Principal Investigator (PI) to ensure accurate and complete accountability and proper storage of the investigational products used in a clinical trial. The PI is responsible for maintaining device accountability records from the time of receipt to the time of final disposition (e.g., return to the Investigator) on a per subject basis.

Neither the PI nor any other participating Investigator should represent the investigational product as safe or effective for the purposes for which it is under clinical study or otherwise promote the product.

The information required on the product label or in accompanying labeling may include but is not limited to the following:

* 1. Study name and number
  2. Study Medical device name
  3. Lot number
  4. Sponsor name and place of business
  5. FDA required statement: "CAUTION: Investigational Device - Limited by US law to investigational use."
  6. Subject numbers and/or visit numbers
  7. Special instructions regarding use/storage
  8. For investigational devices, a draft package insert, user manual or other labeling that includes contraindications, hazards, warnings, precautions, adverse effects, interfering substances and devices
  9. Expiration date
  10. Quantity in container
  11. Any other information required in the applicable investigational product labeling regulations

The PI and/or designee must make sure that the sponsor has the correct shipping address of the site to ship investigational products.

**Accountability:** Upon receiving investigational products from the study sponsor, the Investigator or designee will ensure that information on packaging slip matches exactly with what the site has received. The investigator or designee should also check the number of devices, device type, lot numbers, batch numbers etc. It is good practice to update the device accountability log with relevant information immediately.

If there is a discrepancy, the sponsor or supplier of the device should be contacted as soon as possible. The research team should not attempt to re-label or tamper with the deice label without prior approval from the study sponsor.

Copies of shipping inventory and packing slips should be maintained in the regulatory binder, along with an updated Device Accountability log, The PI and/or designee should provide access to study monitors to assess investigational product accountability during monitoring visits.

**Storage:** Study device should be stored in a secure environment with access provided only to key study personnel who have the appropriate authorization. If appropriate, ensure that study device is stored at required temperature and maintain area temp log, if applicable. If the investigational product is blinded, every effort should be made not to break the blind except in the case of an emergency or a protocol-defined situation.

**Dispensing:** It is investigator’s responsibility to ensure that the study device is used only for study subjects under PI’s personal supervision or under the supervision of a properly trained sub-Investigator. A Study Subject Investigational Product Dispensing Form should be used for each subject including visit number, date, lot number, and the amount dispensed, returned, and lost by each study subject.

Study device Accountability Log should be updated every time a device is dispensed or returned.

During routine study monitoring visits and the study closeout visit, the Monitor will verify that investigational product documentation has been accurate and complete throughout the study.

**Disposal:** Upon completion or termination of the study or investigators part of the study or at the sponsor’s request, an investigator must return to the sponsor any remaining supply of the devices obtained for the specific purpose for a research study.

Only with the written authorization of the sponsor (and in compliance with the Federal Regulations and institutional policies) the investigator can discard the device at site or retain the device.

**Applicable Regulations and Guidelines**

* 21 CFR 812.100

**Applicable Institutional Policies and Procedures**

* None

**Attachments**

* Device Accountability Log

**If you find errors in this document, contact** [**clinicaltrials@uth.tmc.edu**](mailto:clinicaltrials@uth.tmc.edu)

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| **Document Number:** | 402-022 |
| **Author:** | Clinical Trials Resource Center |
| **Effective:** | June 1, 2011 |
| **Revision History:** | None |
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