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1. Purpose

This Standard Operating Procedure (SOP) describes the procedures for Investigators to maintain and ensure accountability and proper storage of the investigational devices at UTHealth Houston.

2. Scope and Responsibility

It is the responsibility of the Principal Investigator (PI) to ensure accurate and complete accountability and proper storage of the investigational device 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.

3. Definitions

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

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

4. Policy

4.1 The PI must maintain ensure that investigational devices are used only in approved protocols and under the direction of appropriate members of the research team.

5. Procedures

5.1 General Responsibilities:

5.1.1 The PI may delegate responsibilities to an appropriate member of the study team.

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

5.1.3 The PI should not represent the investigational device as safe or effective for the purposes for which it is under clinical study or otherwise promote the product.

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

- a. Study name and number
- b. Study Medical device name
- c. Lot number
- d. Sponsor name and place of business
- e. FDA required statement: "CAUTION: Investigational Device - Limited by US law to investigational use."
- f. Subject numbers and/or visit numbers
- g. Special instructions regarding use/storage
- h. For investigational devices, an Instructions for Use (IFU), user manual or other labeling that includes contraindications, hazards, warnings, precautions, adverse effects, interfering substances and devices
- i. Expiration date
- j. Quantity in container
- k. Any other information required in the applicable investigational product labeling regulations

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5.2 Accountability:

- 5.2.1 The PI or designee should ensure that information on packaging slip matches exactly with what the site has received.
- 5.2.2 The PI or designee should also check the number of devices, device type, lot numbers, batch numbers etc and update the device accountability log with relevant information immediately.
- 5.2.3 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 device label without prior approval from the study sponsor.
- 5.2.4 Copies of shipping inventory and packing slips should be maintained in the regulatory binder, along with an updated Device Accountability log.
- 5.2.5 The PI or designee should provide access to study monitors to assess investigational device accountability during monitoring visits.

5.3 Storage:

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

5.4 Dispensing:

- 5.4.1 Study device should be used only for study subjects under PI's personal supervision or under the supervision of a properly trained sub-Investigator.
- 5.4.2 Accountability Log should be updated every time a device is dispensed, used or returned.
- 5.4.3 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.

5.5 Disposal:

- 5.5.1 Upon completion or termination of the study or at the sponsor's request, PI or designee should return to the sponsor any remaining supply of the devices obtained for the specific purpose for a research study.
- 5.5.2 Only with the written authorization of the sponsor (and in compliance with the Federal Regulations and institutional policies) the investigator can discard the device or retain the device.

6. References

- 6.1 FDA Regulations - 21 CFR 812.100

7. Appendices

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7.1 Device Accountability Log

If you find errors in this document, contact clinicaltrials@uth.tmc.edu

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