

**UNIVERSITY OF COLORADO
DEPARTMENT OF OTOLARYNGOLOGY
STANDARD OPERATING POLICY AND PROCEDURE**

Title	Investigational Drug/Device Inventory Management
SOP #:	OTO 200
Version #:	3
Effective Date:	July 17, 2019
Supersedes:	OTO 200 Investigational Drug/Device Inventory Management

1. POLICY

All investigational drug/device (hereinafter referred to as “investigational product(s)”) inventories will be monitored and accounted for throughout the course of the study. The investigational products must be accounted for at all times and handled according to applicable regulations, Sponsor/funding agency requirements and institutional policies. The participating investigator will not represent the investigational product as safe or effective for the purposes for which it is under clinical study or for any other use.

Investigational products must be stored in a secure environment. Access is limited to key study personnel, according to the storage requirements detailed in the protocol or other instructions supplied by its provider. Only individuals authorized by institutional guidelines and state law are permitted to dispense investigational products to study subjects. Procedures for destruction of any investigational products must comply with institutional requirements and applicable Occupational Safety and Health Administration (OSHA) and biohazard materials policies if appropriate and with the express written authorization of the research Sponsor, or other supplier.

2. SCOPE

These policies and procedures apply to all personnel who conduct or are involved in clinical research of human subjects involving investigational product(s) approved for dispensing by means of an Investigational New Drug (IND) or Investigational Device Exemption (IDE) clinical trial.

3. RESPONSIBILITY

The Principal Investigator is responsible for securing any and all investigational product while in the possession of the investigational site. The Principal Investigator is also responsible for tracking the disposition of all investigational products during the course of the study, from the time of receipt to the time of final disposition (return to Sponsor, on-site destruction, etc.).

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.57	Recordkeeping and Record Retention
21 CFR 312.59	Disposition of Unused Supply of Investigational Drug
21 CFR 312.61	Control of Investigational Drug
21 CFR 312.62	Investigator Recordkeeping and Record Retention
21 CFR 812.110	Specific Responsibilities of Investigators
21 CFR 812.140	Records
ICH E6, 2.12	The Principles of ICH GCP
ICH E6, 4.6	Investigational Product
ICH E6, 5.14	Handling Investigational Product(s)

**UNIVERSITY OF COLORADO
DEPARTMENT OF OTOLARYNGOLOGY
STANDARD OPERATING POLICY AND PROCEDURE**

UCH Guidelines for Perioperative Procedures: Documentation for tracking devices in the operating room

5. REFERENCES TO OTHER APPLICABLE SOPS

OTO 104 – Records Management and Retention

6. ATTACHMENTS

Attachment A: Device Disposition Log

Attachment B: Drug Disposition Log

7. PROCESS OVERVIEW

A. Investigational Product Receipt, Storage and Issue

B. Return or destruction of Investigational Product

8. SPECIFIC PROCEDURES

A. Investigational Product Receipt, Storage and Issue

#	Who	Task		
1.	Principal Investigator or Designee	Perform an inventory upon receiving products ¹ . Record receipt of products on Device or Drug Disposition Log as appropriate		
2.		Retain shipping records (including packaging list and FedEx/UPS shipping receipt) to be maintained with the disposition log(s)		
3.		If there is an urgent need to replace any missing or otherwise discrepant shipment contents, contact Sponsor immediately		
4.		Keep disposition log(s) up to date and readily accessible for monitor, IRB, or FDA audits		
5.		Verify that investigational products are stored in a secure location at the site, with access restricted to authorized personnel and with appropriate monitoring equipment where required		
6.		Verify that investigational product is dispensed or otherwise provided only to subjects enrolled in the clinical study. Use a Device or Drug Disposition Log or a form provided by the Sponsor	Device or Drug Disposition Log	
7.		Verify the use of the investigational product occurs under the direct supervision of the investigator or other approved designee(s). Use an Investigational Device Disposition Form or a form provided by the Sponsor. This information will also be kept in the subject's file and/or medical record	Investigational Device Disposition Form (Implants)	
8.		If applicable, verify that the product blind is not broken except in the case of an emergency or a		

**UNIVERSITY OF COLORADO
DEPARTMENT OF OTOLARYNGOLOGY
STANDARD OPERATING POLICY AND PROCEDURE**

		protocol-defined situation		
9.		If the blind is broken, verify that Sponsor is notified and the exact manner in which the code was broken and that the rationale are noted in the site's file		
Note: ¹ This inventory should include verifying serial numbers, subject numbers and the contents of each kit, against the information provided on the Investigational Product Release Form, labels and labeling.				

B. Return or destruction of Investigational Product

#	Who	Task	Attachment	
1.	Investigator	At study conclusion or termination, account for all supplies of investigational product and return to Sponsor or destroy on-site if authorized by Sponsor in writing.		
2.		Record return or destruction of product on the Device or Drug Disposition Log or a form provided by the Sponsor	Device or Drug Disposition Log	
3.		Device or Drug Disposition Logs must be maintained in accordance with OTO 104 – Records Management and Retention		
Note:				