SAMPLE POLICY/PROCEDURE TEMPLATE
INVESTIGATIONAL DEVICE ACCOUNTABILITY

SOP NUMBER	**INVESTIGATOR/DEPT**
EFFECTIVE DATE **REVISED**	**PROTOCOL ID (I.E., TITLE, OR SPONSOR, OR IRB #)**

APPROVAL	
_____	_____
SIGNATURE (*DEPARTMENT DIRECTOR OR PRINCIPAL INVESTIGATOR*)	**DATE**

1. INTRODUCTION

This document describes (*PI name or department*)'s policies/procedures for the receipt, storage, dispensing, reconciliation, accountability, and return or authorized destruction of investigational devices used in human research.

2. SCOPE

This policy/procedure includes steps from the time the study device is received on-site until it is either returned to the sponsor or destroyed on-site at the sponsor's request.

3. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 812.100	General responsibilities of investigators.
21 CFR 812.110	Specific responsibilities of investigators
21 CFR 812.140	Records
April 1996, 4.6	International Conference on Harmonization (ICH); E6 Good Clinical Practice (GCP): Consolidated Guidance
Element I.7.B	Association for the Accreditation of Human Research Protections (AAHRPP) Evaluation Instrument

4. APPENDICES *(IF APPLICABLE)*

Appendix I Sample Device Accountability Form

5. RESPONSIBILITY

The Principal Investigator is responsible and accountable for the distribution, storage, and inventory of the investigational device involved in the IRB approved clinical study. The PI may delegate responsibility for the investigational device to other qualified study personnel involved in the study, but may not delegate accountability.

The following members of the study team(s) may be involved in inventorying, storing, dispensing, or arranging for the return/repair/destruction of study device:

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- Principal investigator
- Co-Investigator
- Clinical Research Manager
- Research Nurse/Coordinator
- Support Staff

Refer to the study personnel delegation log in the applicable study records for names of the individuals fulfilling the above roles, and additional responsibilities as they may apply.

6. PROCESS OVERVIEW

a. Receipt and Inventorying of Study Device
b. Storage of Study Device
c. Use/Dispensing of Study Device
d. Monitoring of Study Device
e. Return/Destruction of Study Device

7. PROCEDURES

a. Receipt and Inventorying of Study Device

List responsible study personnel as appropriate: [example] Research Nurse/Coordinator Support Staff	Upon receipt of the study device, inventory the shipment, ensuring that the information on the packing slips matches exactly with what has been sent to the site. Document verification of the following information where applicable and as directed in the protocol (i.e. *on device receipt log; by checking, dating, signing shipping record):* • Receipt date • Lot, serial, or model numbers as applicable, • Device type/batch number or code mark as applicable, • Quantity per carrier/container (if easily verified) Ensure the device(s) labeling clearly states investigational use and includes any applicable warnings or precautions. Do not re-label, deface, or change the labeling without prior written permission of the sponsor. Promptly bring any discrepancies to the attention of the

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	sponsor/supplier. If the sponsor includes a form in the shipment to acknowledge receipt, obtain the appropriate signature and forward the form to the sponsor. Retain a copy of shipping documents and packing slips for the regulatory files. If applicable, ensure that any supplies required for the blinding of the study device are available.

b. Storage of Study device

List responsible study personnel as appropriate:	Ensure inappropriate or inadvertent use of the device does not occur by storing the study device in a secure environment with access limited to essential research personnel. If applicable, ensure the study device is stored in the appropriate environmental conditions and temperature in accord with details in the protocol or supplied by the sponsor in a supplementary document; maintain a storage area temperature log, if appropriate. For devices to be returned to the sponsor, store in a secure location, separate from active inventory. Ensure that the randomization code, if appropriate, has been received.

c. Use/Dispensing of Study Device

List responsible study personnel as appropriate:	Ensure that each time the study device is used/dispensed, the applicable device "disposition" or "accountability" form is completed. Documentation includes but is not limited to: • Quantity (and lot number, if appropriate) used/dispensed, • Name of individual dispensing study device,

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	• Protocol identifier (name and/or number), • Subject's number, • Subject's initials, • Date (and time, if appropriate) of use/dispensing, • Other information as described in the study protocol. The form will be signed or initialed by the staff person dispensing/using the device. Note any discrepancies between quantities used/dispensed and quantities expected to be returned, and document the reasons.
List responsible study personnel as appropriate:	Ensure that study device supplies are adequate and within an appropriate expiration date. Alert the monitor when additional supplies will be required.
List responsible study personnel as appropriate:	If emergency breaking of the study device blind is medically necessary, document all circumstances appropriately.

d. Monitoring of the Device

List responsible study personnel as appropriate:	In accord with local, sponsor, and/or manufacturer guidelines, ensure appropriate measures are taken at assigned intervals for maintenance of the device (i.e., calibration, electrical safety, etc…). Ensure evaluation of the relationship of the device to all unanticipated problems, and/or adverse events is documented and reporting requirements are met in accord with institutional, sponsor, and/or federal regulations.

e. Return/Repair/Destruction of Study Device

List responsible study personnel as appropriate:	At the end of the study, ensure all documentation regarding receipt, storage, dispensing, and return of used containers is complete, accurate, and ready for review and verification at the monitor's termination visit.

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	Ensure that unused study device is available for the monitor to inventory and prepare for return shipment to the sponsor.
List responsible study personnel as appropriate:	After explants, unsuccessful use of the device, or at the end of the study, follow the sponsor's instructions for containing/packaging the device for a return shipment as appropriate. If any containers/units are missing, document the reasons. Each time return of the study device to the sponsor is necessary, the applicable device "disposition" or "accountability" form is completed. Documentation includes but is not limited to: • Date (and time if appropriate) of study device return, • Quantity of study device returned, • Return identification number (as may be assigned by sponsor), • Name of individual who prepared return shipment, • Reason for the return (i.e., sterilization expiration date; repair; sponsor safety recall, etc…)
List responsible study personnel as appropriate:	Destruction of study device at this site, upon written authorization from the sponsor to do so, may be undertaken so long as such procedures are following OSHA and biohazard materials policies. Provide the sponsor with written documentation of the destruction of the study device including if applicable, the identification of the person responsible for the destruction. Maintain a copy of all accountability documents in the regulatory files.