Procedure Name: Drug/Device Accountability, Dispensation, and Return	**Number:** SOP 11 v3.0
Subject: Clinical Research	**Effective Date:** July 01, 2004
Linked Policy: Clinical Research Operations & Compliance Policy	**Revised Date:** April 11, 2023

PURPOSE:

This SOP outlines to the receipt, storage, dispensing, reconciliation and return or authorized destruction of investigational product(s) (i.e., drugs, biologics and/or devices) in accordance with federal and district regulations and Sponsor requirements, if applicable.

SCOPE:

The Investigation Drug Services (IDS) Pharmacy must be used for all studies that involve FDA regulated Drugs/Devices. A study may be granted permission not to IDS Pharmacy by the Clinical Research Office of the MFA. Only when this special permission has been granted would this Guidance Document be used. This applies to research team members responsible for the receipt, storage, dispensing, reconciliation and return or authorized destruction of investigational product(s) (i.e., drugs, biologics and/or devices) that are NOT under the responsibility/management of the MFA Investigational Drug Service.

RESPONSIBILITY:

This Guidance Document sets forth responsibilities for research team members involved with the receipt, storage, dispensing, reconciliation and return or authorized destruction of investigational product(s) (i.e., drugs, biologics and/or devices) associated with clinical research studies conducted at GWU MFA if they are not under the responsibility/management of the MFA Investigational Drug Service. The principal investigator retains this responsibility unless the investigator has expressly delegated this duty to a research team member and the delegation is documented on a study specific Delegation of Authority Log.

PROCEDURES:

Receipt and Inventory of Investigational Products:

1. Upon receipt of the investigational product by the research team or Research pharmacist, inventory the shipment, verifying that the information on the packing slips matches exactly with what has been sent to the site, including: lot/serial number/batch number or code mark, amount, quantity/type per carrier/container and date of receipt.

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2. Complete a Master Investigational Drug/Product Accountability Record. See Sample Master Investigational Drug/Product Accountability Record.
3. Immediately bring any discrepancies to the attention of the Sponsor. Maintain documentation of any discrepancies and their resolution in the site regulatory binder.
4. If the Sponsor includes a form in the shipment to acknowledge receipt, obtain the proper signature and forward the form to the Sponsor maintaining a copy in the site regulatory binder.
5. Ensure that any supplies required for the blinding of the investigational product are available.

Storage:

- Store the investigational product in a secure location with access limited to the essential research team members, according to the storage requirements outlined in the protocol or supplied by the Sponsor in some other documentation.
- Maintain a storage area temperature log for all refrigerators/freezers storing investigational products, as applicable. See Sample Temperature Log.
- Monitor refrigerators/freezers containing investigational products on a daily basis, excluding weekends.
- Follow all regulations, including those of District of Columbia in addition to any requirements specified by the Sponsor, for investigational drugs classified as controlled substances.

Dispensing:

- Upon receipt of an investigational product, the dispensing party shall provide pertinent clinical information to whoever is involved with the receipt, storage, dispensing and administration of the investigational product. See Sample Investigational Drug Data Sheet.
- Assure that each time an investigational product is dispensed, the dispensing party documents the dispensing of the product in a Drug Preparation/Dispensing Log. See Sample Study Drug Preparation/Dispensing Log.
- Continually verify that investigational product supplies are adequate to meet research subject enrollment/visit needs and are within an appropriate expiration date.
- If emergency breaking of the study blind is medically necessary, promptly document all circumstances and notify the Sponsor as well as the IRB.

Return/Destruction of Investigational Product:

- During a closeout visit, if any, the monitor will prepare the investigational product to be returned to the Sponsor after all documentation is confirmed. On long-term studies, return investigational products at designated intervals.

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- Before shipment, inventory returned and unused investigational product supplies; compare products with investigational drug/device records. Document explanations for all discrepancies.
- Package investigational product for return to the Sponsor. Include product inventory and/or shipping records in the shipment. Maintain a copy in the site regulatory binder. Ship returned material via a carrier specified by the Sponsor.
- Update the Master Investigational Drug Accountability Record accordingly.
- Upon written authorization from sponsor, destroy investigational product following OSHA and biohazard materials policies. Contact the Research Pharmacist, if any, prior to investigational product destruction at the site.
- Provide documentation to the Sponsor regarding the destruction of investigational product and maintain a copy of documentation in the site regulatory binder. See Sample Record of Destruction of Investigational Drug.
- Update the Master Investigational Drug Accountability Record accordingly.

Return of Investigational Product by Subject:

- After use of the dispensed investigational product by the research subject, return all of the used container/units, if applicable, to the Research Pharmacist or the locked storage site.
- Document any discrepancies between amounts used by the research subject and expected return amounts.
- Store returned product in a locked secure area until shipped back to the Sponsor.

Review and Revision

This SOP shall be reviewed every 2 years. This SOP may be reviewed more frequently if it does not reflect current operations.

Attachments

Sample Master Investigational Drug Accountability Record
Sample Patient Investigational Drug Accountability/Dispensation Record
Sample Investigational Drug Data Sheet
Sample Record of Destruction of Investigational Drug

REFERENCES:

21 CFR 312.62	Investigator recordkeeping and record retention.

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21 CFR 812.140	Records.
ICH E6 (R2)	Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2)
	Section 8.3.25

MASTER DRUG ACCOUNTABILITY LOG

Study:	**Coordinator:**

Drug Name, Dosage Form & Strength:

Sponsor:	**Protocol:**	**Site #:**
IRB #:	**P.I.:**	

Date	Pt's Initials	Pt's Study No.	Dose	Quantity Dispensed (D) or Received (R)	Balance Forward / Balance	Lot #	Initials	Comments

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The GW Medical Faculty Associates

Office of Clinical Research

PATIENT ACCOUNTABILITY LOG &

STUDY DRUG PREPARATION/DISPENSING

Study		**IRB # :**	
Pt. Initials		**Pt. Study Number**	
Drug Name, Dosage Form & Strength: **Regimen:** **Storage:**			
Sponsor:	**Protocol #:**	**P.I.:**	**Site #:**

Date	Visit	Quantity Dispensed	Bottle #	Lot #	Initials	Quantity Returned to IDS	Date Returned	Initials	Comments (Drug not returned & why, etc)

Investigational Drug Data Sheet

Principal Investigator (PI)/Department:	
PI Phone: Pager: Other:	
Sub/Co-Investigators:	
Protocol Title & Number:	
Sponsor: GWU IRB #:	
IND Number (If not noted, check to see if one is required.):	
1.	Drug name (generic, trade, and name to be used in labeling):
2.	Therapeutic class, brief pharmacology and pharmacokinetics:
3.	Indications for use in the study:
4.	Other indications (non-study related, if any):
5.	Dosage(s)/strength(s) used in study:

6.	Route of administration in this study:
7.	Storage requirements (refrigeration, room temperature, etc.)
8.	Does this medication require any preparation? Explain in detail.
9.	If intravenously administered, are there any compatibility, infusion (rate, volume, etc.), toxicity concerns? Explain in detail.
10.	Expected therapeutic effects:
11.	Anticipated adverse effects:
12.	Based on teratogenicity, carcinogenicity, mutagenicity, reproductive and other toxicity studies, are there any special handling/preparation requirements? Describe in detail.
13.	Other information:

Record of Destruction of Investigational Drug

Date of Destruction:	
Protocol Title:	
Protocol Number:	
Sponsor:	
IRB Number:	
Principal Investigator:	
Method of Destruction:	
Drug Name:	
Quantity Destroyed:	
Strength, Dose Form(s):	

Lot Number(s):	
Name of Dispensing Party:	
Signature of Dispensing Party:	
Name and Title of Witness:	
Witness Signature:	