Category: Pre study procedures and Study conduct

Title: Receipt, Inventory and storage of Investigational Product (IP)

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Purpose

This SOP describes the procedures study personnel will use to fulfill the regulatory and ethical responsibilities for receipt, inventory and storage of Investigational Product (IP) used in clinical studies.

1. Scope

The SOP is limited to receipt, inventory and storage of Investigational Product (IP) used in clinical studies.

2. Responsibilities

Principal Investigator, Co-investigator, study pharmacist or any other appropriately qualified member of staff in the team, as delegated by the Principal Investigator, will be responsible for receipt, inventory and storage of IPs.

3. Applicable rules, regulations and guidelines

- New Drugs and Clinical Trials Rules 2019
- ICMR Guidelines for Biomedical and Health Research involving Human Participants 2017
- ICH E6(R3) EWG Draft Guidelines dated 19th April, 2021.

4. References to other applicable SOPs:

SOP No.11/05 Dispensing Investigational Product (IP)
SOP No.22/05 Storage of IP and Maintaining its Temperature Log
SOP No.23/05 Destruction/return of Investigational product

5. Detailed Instructions

1. Upon receipt of the investigational product (IP), the shipment should be inventoried, verifying that the receipt date, lot number, drug type, batch number and quantity on the packing slips are the same as what was actually received.
2. Check the temperature on receiving the shipment from the sponsor.
3. Promptly bring any discrepancies to the attention of the Sponsor/supplier of the drug.
4. Retain a copy of the shipping inventory, packing slips and document inventory in the trial master file.
5. Receipt of IP should be acknowledged and the copy of the same should be kept in the trial master file [if appropriate]
6. The IP should be stored in a secure environment according to requirements listed in the protocol or the investigator's brochure (Refer to SOP No 22/02 Storage of IP and Maintaining temperature log).
7. The expiry date of the drug should be noted, and the drug should be returned, disposed of, in accordance with the approved protocol when the drug is outdated. (Refer to SOP No. 23/04 Destruction/return of Investigational product).
8. IP should be distributed uniformly across the racks in the refrigerator where it is stored.
9. The IP should be dispensed by the designee according to the SOP No.11/05: Dispensing Investigational Product (IP).
10. Drug accountability documentation should be completed on arrival of supplies, each time IP is dispensed, and when IP is returned to the sponsor. (Refer to SOP No. 23/05 Destruction/return of Investigational product)
11. Compliance by the participant with the procedures described in the protocol should be verified. Discrepancies between amount of the drug used by the participants and amount returned and the reasons underlying any discrepancies should be documented. If the participant has not taken the drug as required by the protocol, the PI should determine whether the participant may remain in the study or be withdrawn.

12. When all participants have completed the study medication, the records should be checked for accuracy and should be signed and dated by the PI.
13. During the course of the study, partially used doses, used containers and tubing should be disposed of in the manner described in the protocol, and, if they are biohazards, in accordance with the institution's biohazard policies.
14. At the conclusion of the study, the study drug should be inventoried and prepared to be returned to the sponsor in accordance with the requirements of the sponsor or the manufacturer (SOP No. 23/05 Destruction/return of Investigational product).
15. All documentation regarding receipt, storage, dispensing, and return of used containers must be complete and accurate.
16. A copy of all accountability documents should be maintained in the Trial Master File.

6. Appendix: IP Accountability Log

Study Title:	
Site Name :	**Site Number :**
Sponsor :	
Principal Investigator :	
Investigational Product:	**Lot No :**

Sr. No :	Date	Randomisation No:	Dose	Time of administration	No: of IP used	No: of IP damaged	No: of IP remaining	Signature

Investigator's signature _____ **Date** ____/____/____

7. Glossary

Investigational Product:

- A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use. [I ICH E6(R3) EWG Draft Guidelines dated 19th April, 2021, www.ich.org

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