Category: Study conduct-All studies (Government funded/NGO funded/Regulatory)

Title: Return /Destruction of Investigational product
SOP No.: DCP 23/08
Date first effective: 1 Jan 2026 **Review date:** 31 Dec 2026

Department of Clinical Pharmacology, 1st Floor, New MS Building,
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1. Purpose

This standard operating procedure (SOP) describes the requirements for the return or destruction of Investigational Product [IP].

2. Scope

This SOP applies to all procedures related to the return or destruction of IP.

3. Responsibilities

Principal investigator (PI), Co-investigator (Co-I), Study Coordinator, Pharmacist or any other appropriately qualified staff in the team, as delegated by the Principal Investigator, will be responsible for the return/destruction of IP in connection with all clinical studies.

4. Applicable rules, regulations and guidelines

- National Ethical Guidelines for Biomedical and Health Research involving Human Participants (2017), https://ethics.ncdirindia.org/ICMR_Ethical_Guidelines.aspx, last accessed on 1st January 2026.
- New Drugs and Clinical Trials Rules (2019), https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/New-Drugs/, last accessed on 1st January 2026.
- ICH HARMONISED GUIDELINE GOOD CLINICAL PRACTICE (GCP) E6(R3), https://database.ich.org/sites/default/files/ICH_E6%28R3%29_DraftGuideline_2023_0519.pdf, last accessed on 1st January 2026.
- India GCP guidelines (Draft, September 2024), https://ethics.ncdirindia.org/asset/pdf/Indian_GCP_guideline.pdf, last accessed on 1st January 2026.
- National Ethical Guidelines for Biomedical Research Involving Children.https://ethics.ncdirindia.org//asset/pdf/National_Ethical_Guidelines_for_BioMedical_Research_Involving_Children.pdf last accessed on 1st January 2026.
- Standard-Operating-Procedures of Institutional Ethics Committee, Seth GS Medical College and KEM Hospital, Mumbai

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https://www.kem.edu/wpcontent/uploads/2025/03/SOPs_V7_effective_from_9th_Dec_2024_Seth_GSMC_&_KEMH_Mumbai.pdf V7-effective-from-9th-Dec-2024_.pdf (last accessed 1st January, 2026)

5. **References to other applicable SOPs:**

- SOP No / Version No. 18/09: Archiving documents.
- SOP No / Version No.20/08: Inventory and distribution of IP.

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6. Detailed Instructions

1. The study participant will return all study-related supplies to authorized study personnel (the study coordinator or pharmacist) as per protocol and also all unused medication/s at the subsequent visit or at end of the study.
2. The Study pharmacist will count the returned drug and compare this with the amount of drug expected to have been used since the previous study visit.
3. For IP administered at the site, the study pharmacist will do a real time check on the accountability
4. He/she will update the appropriate sections of the IP dispensing and IP accountability log, including an explanation of discrepancies, if applicable. The appropriate data will also be entered into the CRF. Any sponsor specific log will also be filled.
5. The Study pharmacist will keep the Drug Dispensing log and the IP accountability CRF pages updated, regardless of when the monitor performs final accountability log review.
6. The Study pharmacist will store the returned drug in a secure area until it is verified by the study monitor.
7. Whether the drug is returned to the sponsor or destroyed on-site as per hospital SOPs will be determined by the instructions in the study protocol. It will be the site's policy to preferably return the Investigational Product (IP) to the sponsor for destruction.

A. Return of IP to Sponsor

1. Depending on the protocol, the study drug will be returned to the sponsor at the end of the trial or at intervals specified by the sponsor.
2. The Study Coordinator will follow the protocol or other instructions from the sponsor or CRO to decide whether empty containers must be returned.
3. The Study Coordinator/Pharmacist will coordinate with the Monitor to determine which carrier is preferred for the shipment, mode of transfer, transport conditions and if the monitor needs to complete an independent drug accountability review before it is shipped back to the sponsor.

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4. Unless instructed otherwise by the monitor, the Study Coordinator will:

- Perform an inventory of the drug supplies (Refer to SOP No / Version No.20/02: Inventory and distribution of IP)
- Compare this with the study medication records
- Document discrepancies in the CRF
- Complete the Drug Return/Destruction Form (if provided by the sponsor or CRO)
- Include a copy of the signed and completed Drug Return Form with the drug shipment and place the original in the trial master file

B. <u>On-Site Destruction of Study Drug</u>

1. If the sponsor or CRO requires on-site destruction of the study drug, the Study Coordinator should:

- Obtain written confirmation from the monitor identifying the specific study drug that can be destroyed.
- Obtain appropriate paperwork concerning destruction of the drug that is required in the site's SOPs (e.g., signed incineration records) and place a copy in the study file.
- Biosafety check All precautions are followed.
- Provide the monitor with written proof of study drug destruction from the site.
- Complete the Drug Return/Destruction Form or similar form provided by the sponsor or CRO.
- Provide a signed copy of the form to the monitor and retain the original in the trial master file.

C. <u>Study Drug Record Retention</u>

At study completion, the Study Coordinator will file all drug records with other regulatory documents in accordance with the record retention policy for the study. (Refer to SOP No / Version No. 18/9: Archiving documents).

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Reviewer as appropriate:

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