

# STANDARD OPERATING PROCEDURE (SOP)

**TITLE: INVESTIGATIONAL PRODUCT MANAGEMENT**



**DO NOT USE THIS SOP WITHOUT FIRST CHECKING IT IS THE LATEST VERSION**

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<b>Applicable Clinique Research Site(s):</b>	All

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<b>Signature:</b>	
<b>Date:</b>	February 2020

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## **1. PURPOSE:**

The purpose of this SOP is to describe the procedure of Investigational Product Management undertaken at Clinique Research and to ensure:

- All relevant parties (sponsors and sites) are consulted and can support the project.
- The proposed trials are a strategic fit and aligns with Clinique Research's core values.
- Research projects have the best possible outcome in terms of recruitment, patient safety, budget, and time frames.

## **2. SCOPE:**

All clinical trials to be monitored and managed at Clinique Research.

## **3. APPLICABILITY:**

This applies to all Clinique Research employees, contract staff and to all relevant external persons or parties proposing to engage in the clinical trial services at Clinique Research.

## **4. GLOSSARY OF TERMS:**

Please refer to Clinique Research SOP Glossary of Terms (see Related Documents).

## **5. PROCEDURE:**

### **5.1 Prior to receipt of Investigational Product (IP)**

- The Principal Investigator (PI) must identify an area with restricted access and appropriate temperature control for IP storage.
- Identify assigned team members who would be responsible for IP receipt, storage, dispensing, accountability and recording the temperature for the storage area and returning or destruction of the IP.
- Such persons must be identified on the study delegation log.

### **5.2 Receipt of Investigational Product (IP)**

- Upon receipt of the IP shipment at the site, the CTC/delegated member will unpack the IP box and check the IP inventory against the shipping form.
- Checking the inventory will include the following:
  - Checking the packaging numbers
  - Unique Kit numbers/IP number
  - Lot/batch numbers

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- Number of IPs in the container (s)
- IP expiry date
- Any discrepancies (e.g. tampering/ breakage of the IP kit, mismatch in the number of kits, temperature excursions etc) identified must be documented and informed to the sponsor/Clinique Research’s point of contact immediately and seek advice for the next steps.
- Such IP must be stored separately and must be dispensed only after confirmation from the sponsor/Clinique Research/designee. This must be done by the person designated for IP accountability.
- If the inventory matches the drug received, the pharmacist/delegated person will sign and date (*note: mention logger temperature present in the IP container on the receipt form*) on the shipping receipt or Investigational Product Receipt Form, return a copy to the sponsor, and file the original in the Trial Master File (TMF).
- Shipment inventory must be completed as per the study specific procedure (e.g. IVRS or IWRS, accountability log etc).
- The IP must be immediately transferred to the designated storage area at conditions as mentioned in the protocol.
- The temperature of the storage area must be recorded with a calibrated thermometer for the temperature range once daily or as mentioned in the protocol. It is strongly recommended that accurate temperature must be recorded.
- If available maintain the hard copy of auto generated temperature logger.

## 5.3 Investigational Product Storage

- Temperature of the IP storage area must be maintained on a 24-hour basis. The temperature will be recorded once daily or as mentioned in the protocol. The capture of minimum and maximum values of temperature will be recorded only if specified by the sponsor/Clinique Research.
- In case a temperature excursion is noted, the CTC/designated study team member must inform Investigator, who will inform Sponsor/Clinique Research telephonically followed by email at the earliest and try to identify the cause of temperature excursion.
- Site to take remedial actions in consultation with sponsor/Clinique Research.
- IP that has undergone a temperature excursion must be kept separately and must not be dispensed till a confirmation from sponsor/Clinique Research is obtained i.e. the IP is “fit for use”.

#### 5.4 Investigational Product Dispensation

- The IP must be dispensed by the CTC/delegated member to subjects randomized on the study after fulfilling the eligibility criteria in accordance with the protocol.
- Upon dispensing the IP the CTC/delegated member must note following in the source note and IP package:
  - Trial/Study ID number (both source notes and IP package)
  - Initial of the subject (both source notes and IP package)
  - Date of IP dispensing (both source notes and IP package)
  - Batch number and quantity of IP dispensed (in the source note)
  - Expiry date (in the source note)
- This information must be captured in Real-time basis on the IP stickers available on IP containers, in the subject source notes as well as in the Drug Accountability Logs.
- The CTC/delegated member will maintain a record of drug dispensed to and retrieved from each subject. To accomplish this, the CTC/delegated member will use the CRF or drug accountability diary, if any and only if provided by the sponsor/Clinique Research.
- The CTC/delegated member will explain to each subject the drug accountability needs for the study (e.g., the need for the subject to return unused, partially used, and empty packages).
- Requests for IP resupply must be done as per the study specific procedures.

#### 5.5 Investigational Product Return

- The study subject will return all drug and study-related supplies to CTC/delegated member on the specified visit mentioned in the protocol.
- The CTC/delegated member will count the returned drug and compare this with the amount of drug expected to have been used since the previous study visit.
- CTC/delegated member must document IP returned by the subject in the subject's source file as well as in the drug accountability log as per the study requirement.
- In case of missing IP or extra IP, the CTC/delegated member must obtain the information from the Subject and document the clarification provided in the source notes, drug dispensing log and CRF. This documentation should be done in real time basis.
- The CTC/delegated member will keep the Drug Dispensing Log and the drug accountability CRF pages updated, regardless of when Clinical Research Monitor will perform final accountability.
- The CTC/delegated member will store the returned drug separately in a secure area until it is verified by Clinique Research Monitor.



- Whether the drug is to be returned to the sponsor or destroyed on-site will be determined by the instructions in the protocol.
- The documentation of the destruction/ return must be maintained in the TMF.

### 5.6 Return of IP to Sponsor

- As specified in the protocol, the IP will be returned to the sponsor at intervals or at the end of the study. The CTC/delegated member will follow the protocol or other instructions from the Sponsor or Clinique Research Monitor to decide whether empty containers must be returned.
- Clinique Research Monitor will perform the independent drug accountability review and will seal the drug that need to be shipped back to the Sponsor/Clinique Research.
- Clinique Research Monitor will arrange the preferred courier for the shipment of used and/or unused IP back to the sponsor/Clinique Research.
- The CTC will arrange for a gate pass for the shipment that needs to send back to sponsor/Clinique Research.
- Unless instructed otherwise by the Clinique Research Monitor, the CTC/delegated member will:
  - Perform an inventory of the drug supplies.
  - Compare inventory with the study medication records.
  - Document discrepancies in the CRF or in a memo to file.
  - Complete the Drug Return/Destruction Form (in presence of monitor) or similar form 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 study file.

### 5.7 Onsite Destruction of IP

- If the sponsor/Clinique Research request for on-site destruction of the IP, the CTC/delegated member should:
  - Obtain a copy of the site's SOP of Waste Management from department of Microbiology for IP destruction/disposition, provide a copy to the monitor, and file a copy in the TMF.
  - Obtain written confirmation from the Clinique Research Monitor identifying the specific IP that can be destroyed.
  - Obtain appropriate paperwork concerning destruction of the drug that is required in the site's Waste Management SOPs and place a copy in the TMF.
  - Provide the Clinique Research Monitor with written proof of IP destruction at site.

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- Complete the Drug Return/Destruction Form or similar form provided by the sponsor/Clinique Research.
- Provide a signed copy of the form to the Clinique Research Monitor and retain the original in the TMF.

## 5.8 IP Record Retention

- At study completion, the CTC will file all drug records with other regulatory documents in accordance with the record retention policy mentioned in the protocol.

## 5.9 Applicable Staff

- This SOP applies to those members of the study team involved in the process receipt, storage, dispensing, and return or destruction of Investigational Product (IP). These include the following:
  - Principal Investigator (PI)
  - Clinical Trial Coordinator (CTC)
  - Pharmacist
  - Research Nurse
  - Support Staff

## 5.10 Staff responsible for implementation

- The research dept, PI and delegated Site staff will ensure that at the time of implementation of the SOP, that the research team at the clinical research unit in the trial site are trained and in the event that an SOP is modified, provide training regarding the change(s) and ensure their compliance with the changes.
- The PI will ensure that the research team involved in the conduct of the study will comply with this SOP.
- Inform IRB that this SOP will be implemented within the institution.

## 6. VERSION CONTROL:

Document History	
Version	Summary of Changes
1.0	N/A – First Issue

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## 7. APPENDIX:

Temperature Log

IP Accountability Log

IP Subject Dispensation Log