[SITE NAME]

STANDARD OPERATING PROCEDURE

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<tr><td>Prepared by:</td><td>Reviewed by:</td><td colspan="2">Approved by:</td></tr>
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Purpose:
This standard operating procedure (SOP) describes the operations followed by the [SITE LOCATION] [SITE NAME] and affiliated health systems for the management of investigational product (IP) to ensure that the protocol and regulatory requirements are performed.

Scope:
This SOP describes procedural pathways for managing investigational products used in clinical trials at [SITE] to ensure accurate accountability according to protocol, institutional policies and regulatory requirements.

Materials:
N/A

Definitions:

Investigational Product: An investigational product refers to a preventative (vaccine), a therapeutic (drug or biologic), device or diagnostic (including placebo) used in a clinical investigation.

Investigational Drug: a drug or biological drug that is used in a clinical investigation.

Investigational Device: Investigational device is a device that is the object of a clinical investigation.

Responsibility:

This SOP applies to the clinical departments and [SITE] Institutions that are involved with the accountability of the investigational products for clinical research involving human subjects.

Background:

An investigational product (IP) is experimental by definition and includes drugs and devices. For this reason, any investigational drug or device being utilized in clinical research at this site must be accurately accounted for throughout the receipt, storage, dispensing and disposition (return/destruction). The principal investigator is ultimately responsible for IP management and administration; however, this responsibility may be delegated to another staff member such as a pharmacist or clinical research coordinator (CRC). The investigator should ensure that the IP is used only in accordance with the IRB approved protocol.

Depending on the protocol, an IP may include study-specific concurrent medication/treatment such as the comparator drug/placebo and rescue medication.

Procedure:

Note: Investigational drugs used at [SITE] may be received, distributed, and controlled either by [SITE] Department of Pharmaceutical Services or the authorized principal investigator only after approval by the Investigational Drug Pharmacist, to ensure appropriate level of oversight according to federal and state regulations for drug storage. Refer to the [SITE] Pharmaceutical Services Policy and Procedure Manual for Investigational Drug Management.

Investigational devices used at [SITE] shall be managed by the authorized Principal Investigator (PI) or personnel as delegated by the PI, including the receipt, storage, dispensing and disposition (return/destruction).

1. Receipt of investigational product (IP)

Prior to shipment, the PI or delegated research team member should work with the sponsor/clinical research organization (CRO)/supplier to confirm the recipient, anticipated date of the IP delivery and the quantity of the IPs to be delivered.

Upon receipt of the investigational product, inventory the shipment and ensure that the information on the packing slips match exactly with the content. Verify the following:

a. Name of IP Received, Quantity, Lot Numbers, Expiration Dates, Serial Numbers, Sizes, Device Codes
b. Condition – ensure that the IP is not damaged
c. Check the environmental monitoring device/data for IP shipment, as applicable
d. Maintain shipping records and/or signed IP receipt slips within the regulatory/pharmacy file.
e. Notify the sponsor as directed per the protocol upon receipt
f. Quarantine IP if the condition of the product is altered or if the IP has experienced a temperature excursion and notify the sponsor immediately. IP is not viable for use until it is released by the Sponsor/CRO

Ensure that any supplies required for the blinding/randomization of the IP are available.

Other members of the clinical research team can assist in promptly bringing any discrepancies to the attention of the sponsor and Principal Investigator/Study Coordinator if warranted.

2. Storage of IP

For investigational drug, it may be stored in the pharmacy or at the clinical site. For investigational drug stored at the clinical site, the investigational pharmacist shall approve proper storage prior to study initiation.

All IP shall be stored according to the requirements stated in the protocol/additional documentation provided by the sponsor/CRO/supplier.

a. Store the IP in a dedicated and secure place with access limited to research personnel.
b. Temperature controlled/monitored/recorded.

Follow Federal and State regulations for the proper storage of controlled substances required at this investigative site.

3. Dispensing/Accountability

a. Study staff may only perform duties as delegated by PI (e.g. dispensing, administration).
b. An order by the PI/Sub Investigator must be entered into EPIC or other electronic health record or a written authorization available prior to dispensing the IP. In addition, any documentation that would be completed for standard of care must also be placed in EPIC.
c. Document the IP accountability (dispensed/used and return history) for each subject on a trial-specific IP accountability form. The accountability form may be in an approved software system for example Vestigo. Ensure that each time study medication or device is dispensed or utilized, the accountability form is completed and updated upon return. Documentation will include, but not limited to:
    - The subject's identifier (e.g. subject
    - number) The IP identifier (e.g. name/code of IP)
    - The batch number/expiry date
    - If device, device packing information (serial number, size,
    - etc.) The date and quantity dispensed
    - If drug, the date and quantity the IP/package was returned by subject
    - The initials/signature and date of the designated staff responsible for dispensing and collecting returned IP
d. Note any compliance issues (e.g. missed doses, devices opened but not used) and discrepancies (e.g. missing containers, packaging disposed prior to documentation) on the accountability log, upon discovery document reason for discrepancy, initial/sign, date and time and report to the sponsor, if applicable.
e. Accountability should be routinely reviewed, and the Sponsor/CRO/supplier should be contacted as needed to maintain adequate supply of IP.
f. Provide guidance to the subject as applicable to IP (e.g. diary completion, return of unused/remaining IP and containers).

4. Return to Sponsor/destruction of IP

a. At the conclusion of the study or directed by the sponsor, ensure that all documentation regarding receipt, storage, dispensing, and return of IP is complete, accurate, and ready for review at the monitor's visit, as applicable. For investigational drug, collaborate with the *[SITE] Department of Pharmaceutical Services* Investigational Drug Team for scheduled monitoring visit.
b. Destruction of IP at this site, must be authorized in writing by the sponsor and in accordance with OSHA and biohazardous waste policies. Maintain a copy of sponsor approval and destruction records in the regulatory files.
c. The research staff member responsible for IP disposition shall initial/sign and date the documents at the time of the return to the sponsor/CRO. File the shipping records and confirmation of receipt within the regulatory file.

d. Provide the sponsor with written documentation of the destruction of the IP.

History of Revisions to SOP

Effective Date	Nature of Revision