UNIVERSITY OF SOUTH ALABAMA

CT 306 INVESTIGATIONAL PRODUCT FOR IN-OFFICE

EFFECTIVE DATE: July 2023

Purpose

The purpose of this policy and procedure is to delineate requirements for receipt, storage, dispensing, return, transport and recordkeeping of the inventory of investigational products. This SOP supports Good Clinical Practice and federal regulations.

Scope

This SOP covers control and recordkeeping of investigational products obtained for use in human subjects' research that are housed in or managed by the University of South Alabama Clinical Trials Office.

Definitions

Investigational Product: The test article (drug or device) that is the object of the investigation, placebo(s) and/or comparator(s) used in the clinical study.

Principal Investigator: The individual of record who assumes the authority and responsibility for the conduct of a clinical study.

Study Sponsor: When a clinical trial is conducted under an investigational new drug application (IND) or investigational device exemption (IDE), the IND or IDE holder will be considered the sponsor. When a clinical trial is not conducted under an IND or IDE, the single person or entity who initiates the trial, by preparing and/or planning the trial, and who has authority over the trial, will be considered the sponsor.

Policy

Any investigational products that do not require reconstitution or storage by a licensed pharmacist may be stored within the Clinical Trials Office (CTO) or other research space outside of a pharmacy, at the discretion of the Clinical Trials Office Director. The study sponsor and CTO Director should be made aware of and agree to the intent to manage investigational products within the CTO during study start-up. Any proposed changes to IP storage and management must be first agreed upon by the sponsor and CTO Director except to avoid immediate damage to IP.

Procedure

The below procedures delineate the steps that must be followed when IP is managed by the CTO.

Responsibility

1. The Principal Investigator is responsible and accountable for the storage, distribution, inventory, and documentation of the investigational product (IP).

2. The Principal Investigator may delegate accountability, yet not responsibility, to qualified study personnel to perform functions related to the investigational product.

3. Prior to the start of the study, the Principal Investigator or his/her delegate should ensure all appropriate notification/approval/clearance of the IP from appropriate sources (i.e. IRB, research review committee, pharmacy, etc.)

4. While determining feasibility: perform a final check on the required IP storage conditions to ensure the IP can be stored as per the requirements set forth by the sponsor/or as designated by the protocol.

5. If the investigational product is subject to the Controlled Substances Act, DEA regulations apply. The PI shall ensure adequate precautions to prevent theft or diversion, and ensure compliance with requisite controls for inventory tracking, access, and disposal.

Receipt of Investigational Product

1. Seek confirmation from the sponsor /clinical research organization (CRO) regarding the anticipated date of the IP delivery and the quantity of the IP to be delivered.

2. Once the IP is delivered, the designated study site staff should check for any inconsistencies. The temperature should be within the designated parameters set forth by the protocol, Investigator Brochure, and/or Instructions for Use. Any temperature deviation should be reported to the sponsor per protocol. Compromised IP should be quarantined until a directive is given by the sponsor.

3. The packing slip should be compared to the IP delivered. Items such as the quantity, lot number, kit number, etc. should be verified. Any discrepancies should be reported per protocol.

4. The IVRS, IWRS, or equivalent should be updated, if applicable.

5. File all shipping records and/or signed receipt slips/delivery notices in the study file.

6. Update the quantity on protocol specific drug accountability log.

Storage of the Investigational Product

1. Ensure the IP is stored immediately according to the conditions stated in the protocol and that the location is secure and limited to research personnel.

2. Ensure the storage premises shall be in an area that is designated for IP only and should not be stored with non-clinical trial medications, biologics, or devices. IP should be stored separately by protocol. The premises should be secured with limited access by study personnel only.

3. Storage temperature should be recorded using a continuous monitoring system. The minimum and maximum temperatures should be recorded.

4. Ensure the randomization code has been received, and properly documented, if applicable.

5. Store unused IP for return to the sponsor/CRO. Store in a secure location, separate from active inventory.

7. When discrepancies or violations of the storage condition are detected, report such problems to the sponsor/CRO. Any temperature deviation should be reported to the sponsor per protocol. Compromised IP should be quarantined separate from active inventory until a directive is given by the sponsor.

8. Measures should be in place to ensure the stability of the IP during unexpected and/or emergency events. Refer to CT106 SOP for Emergency Preparedness.

Dispensing of the Investigational Product

1. Review sponsor or CRO provided procedures regarding protocol requirements for dispensing/administering applicable IP.

2. Follow protocol requirements regarding IP and medication administration. When protocol specifically allows, abide by hospital-specific procedures for medication administration.

3. For randomized studies, follow the study randomization procedures in allocating the assigned IP to the trial subject.

4. Investigator or designated research staff will check the expiration date prior to use or dispensation of the IP.

5. Follow sponsor/protocol-defined procedures to track identifiers for the IP in blinded studies. Ensure each subject received the correct IP and document the expiration date.

6. For open-label studies, dispense the correct IP and/or the correct dosage to each subject and document the expiration date.

7. When administering intravenous IP, arrange for proper facility location/room ahead of time.

8. For self-administered IP, provide instructions to the subject on how to use the IP.

9. Give the subject instructions of how to complete a diary, if applicable.

10. Instruct the subject to return any unused or remaining IP and all packaging at the next study visit or in accordance with protocol.

11. Count the IP when the subject returns unused and/or remaining IP.

12. Document all IP dispense/administration and return activity on the protocol specific drug accountability log, which shall include as applicable, yet is not limited to:
    a. Subject and IP identifier
    b. batch number
    c. date and time of IP preparation
    d. expiration date(s)
    e. quantities dispensed/administered, returned and/or destroyed
    f. administration start times and completion times
    g. initials or signature of the qualified study personnel member who performed the specific activity

13. Report to the sponsor and IRB any IP discrepancies, abnormalities or defects as applicable.

14. No IP may be used if it has been quarantined unless cleared by the sponsor.

<u>Return/Reconciliation of the Investigational Product</u>

1. Ensure that the reconciliation process has been discussed and agreed upon with the sponsor.

2. Ensure the accountability has been checked by the study monitor, if applicable.

3. Follow the protocol for returning the IP to the sponsor or local destruction of IP, if protocol specified.

4. For the return of IP to the sponsor, document the following on the trial specific reconciliation log:

a. Description of what was returned (drug name, dosage, lot number, batch number, etc.)
b. Quantity
c. Initial or signature and date of qualified study personnel coordinating the return
d. Keep and file shipping documentation (as applicable)

5. For disposal/destruction of IP locally, document the following on the trial specific reconciliation log:
    a. Specific IP disposed/destroyed
    b. Quantity
    c. Date/time of destruction
    d. Initial or signature and date of the qualified study personnel coordinating the destruction

6. The study team may liaise with the sponsor for arrangements of retrieval of the used IP(s) by the study monitor or local destruction of the IP(s) when the storage facility is full or as required per protocol.

7. The reconciliation of IP log(s) should be regularly maintained and updated in the investigator site file.

Transport of the Investigational Product

The following procedures apply when IP is transported from its current storage address to another storage location, or when IP is transported to an off-site location.

1. Investigational products will only be transported on an as needed basis. The number of times IP is handled and transported must be kept to a minimum.

2. Investigational products should only be transported by study staff delegated to dispense IP.

3. An Investigational Product Transport Form will be completed each time unused IP is transported.

4. The protocol specified temperature conditions must be maintained during transport. Appropriate packing materials, including but not limited to a transport container, ice packs, gel packs, and/or dry ice can be used to assist with temperature control.

5. If IP is moved outside of its currently housed building, a temperature reading device should be kept in the transport container throughout the transportation process. Temperatures will be monitored and recorded on the Investigational Product Transport Form.

6. If the temperature goes out of range during the transport, report such problems to the sponsor/CRO. Any temperature deviation should be reported to the sponsor per protocol. Compromised IP should be quarantined until a directive is given by the sponsor.

7. IP should be delivered directly from the point of origin to the intended destination without stopping at other locations in route.

Additional Resources

RELATED FORMS:
Investigational Product Transport Form
Drug Accountability Log

RELATED POLICIES:
CT-106 Emergency Preparation and Continuity Plan

History

N/A

Next Review Date

July 2026

Responsible Party

Director, Clinical Trials Office