Clinical Research Enterprise (CRE)

Standard Operating Procedures

Investigational Drug Accountability

SOP #: 3.03

Version: 2.0

Author(s): Patrick Frazier, Haley Sanford, Alesha Isbell

Approval:

Approved By	**Date**
	**7.1.2024**

Revision History:

Version	**Effective Date**	**Description**
2	7/1/2024	Updated drug destruction guidelines

Purpose

The purpose of this SOP is to describe the process for Accountability and Destruction of Investigational Product.

References

- U.S. Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA), and Guideline for Good Clinical Practice (GCP) requirements.

Scope

This SOP applies to all members of the CRE staff.

Allowable Exceptions

This SOP is meant to be followed without deviation. However, it is an allowable exception to follow procedures specified in a protocol or by the sponsor. If a deviation from this SOP occurs, a description of this event will be written and filed with this list of SOPs and the protocol.

I. RESPONSIBLE PERSONNEL

This SOP applies to those members of the clinical research team involved in inventorying, storing, dispensing, or arranging for the return/destruction of study drug. This includes the following:

- Principal investigator
- Sub-investigator
- Research Nurse
- Study Coordinator

II. DETAILS

Step 1: Preparing for a New Investigational Drug Study

The pharmacist will determine the following, as appropriate:

- Physical location(s) where the ID will be stored throughout the study, including the adequacy of the size of the storage area;
- Whether the ID should be received and managed by the UAB research pharmacy;
- Specific procedures for the security and management of the ID;
- Need for refrigeration;
- Need for special equipment for storing and securing the drug; and
- Communications plan in the event the blind needs to be broken
- Whether additional nursing support will be needed and arrange as appropriate

Step 2: Receipt and inventorying of study drug

Upon receipt of the study drug, the research pharmacist will inventory the shipment, ensuring that the information on the packing slips matches exactly with what has been sent to the site, including:

- Amount
- Lot numbers
- Quantity per carrier/container (if easily verified)

Promptly bring any discrepancies to the attention of the sponsor.

Verify receipt of investigational product per sponsor specific procedures.

Retain a copy for the study file, especially at the end of the study.

Ensure that any supplies required for the blinding of the study drug are available.

Step 3: Storage

Investigational drugs will be securely stored in a locked location, restricting access to appropriate persons and according to conditions specified in the protocol.

Ensure that study drug is stored at the appropriate temperature, maintaining a storage area temperature log, if appropriate.

Please note that once study drug has expired, temperature logs and excursions will not be tracked unless otherwise noted.

Follow any special requirements for controlled substances required at this investigative site in addition to those specified by the regulations.

Ensure that the randomization code, if appropriate, has been received.

Step 4: Dispensing of study drug

Ensure that each time study medication is dispensed, the drug accountability form is completed

Documentation will include:

- Amount (and lot number, if appropriate) dispensed,
- Name of individual dispensing study drug,
- Subject's study ID number,
- Subject's initials,
- Date (and time, if appropriate) of dispensing,
- Date and time of study drug returned,
- Amount of study drug returned.

After use by the study subject, return all used containers/units. If any containers/units are missing, document the reasons.

Note any discrepancies between amounts used by subjects and amounts expected to be returned and document the reasons.

Ensure that study drug supplies are adequate and within an appropriate expiration date.

Alert the monitor when additional supplies will be required.

If emergency breaking of the study drug blind is medically necessary, document all circumstances appropriately. Refer to the sponsor and / or protocol for guidance on breaking the blind.

Step 5: Return/Destruction of study drug

At the conclusion of the study, ensure that all documentation regarding receipt, storage, dispensing, and return of used containers is complete, accurate, and ready for review at the monitor's termination visit.

Ensure that the study drug is available for the monitor to inventory and prepare for return shipment to the sponsor/CRO, if appropriate.

Destruction of study drug at this site, upon written authorization from the sponsor to do so, may be undertaken so long as such procedures are permitted by this site's OSHA and biohazard materials policies.

All investigational products must be placed in a UAB yellow barrel (SharpSafety Chemotherapy Container Hinged Lid, or similar container) with a biohazard label and placed in a fiberboard box for incineration by UAB Support Facility.

Contact CRE Facilities Project Manager to order yellow bin.

Contact UAB Environmental Health and Safety to request biohazard label and fiberboard box and to schedule pickup.

At the conclusion of the study, all documentation regarding receipt, storage, dispensing, and return will be verified for completeness and accuracy. Provide the sponsor with written documentation of the destruction of the study drug.

A copy of all accountability will be maintained in the study regulatory files.