
Clinical Research Enterprise (CRE)

Standard Operating Procedures

Study Drug Transport

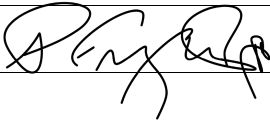
SOP #: 3.09

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Approval: **Approved By**

Date



1.18.2023

Revision History:	Version	Effective Date	Description
	2.0	30-Sep-2022	Updated to include information on temperature maintenance and security of IP transport.
	3.0	18-Jan-2023	Updated to address situations in which IP is required to be transported between buildings not connected by internal hallways.

Purpose

The purpose of this SOP is to describe the process for transportation of Study Drug.

References

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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. Storage of Study Drug

Study Drug may be stored in one of the following locations depending on the trial. Please note that for any individual trial, study drug will be stored in only one location. For specific study drug storage location, please refer to study specific 1572.

II. Study Drug Storage Locations

- UAB Investigational Drug Services Pharmacy
UAB Hospital
North Pavilion, room 3470
1802 6th Avenue South
Birmingham, AL 35249
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- UAB Community Health Building on 20th
930 20th Street South
Birmingham, AL 35205
- UAB Community Health Building on 19th
933 19th Street South
Birmingham, AL 35205

III. Investigational Product Transport

- Investigational products (IP) will be dispensed from one of the three locations above in accordance with site procedures and the protocol for dispensing, labeling, and accountability of investigational product. Once properly prepared and labeled the Study Coordinator will be responsible for the transport of IP to the clinic in which the patient will be seen. IP will be transported in a secure, lockable receptacle that can maintain the appropriate temperature of the drug. Ambient, frozen, or refrigerated gel packs will be used to maintain the temperate of the IP. Patient care areas are typically connected to storage areas through interior crosswalks however in some circumstances IP will need to be transported by car or outside on foot. Details of transport will be discussed with sponsor prior to study start and throughout the course of the study.