



Procedure Name: Investigational Produce Storage Procedures
Effective Date: March 25, 2010
Revision: 01
Initiating Department: Office of Clinical Trials
Procedure Number: OCT-004
Application: Investigational Product Storage
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OBJECTIVE:

The objective of this procedure is to describe the method of investigational product storage when an investigational product is stored and prepared at a location different from that of the Principal Investigator (PI).

REFERENCES:

OCT SOP# CR-002	Investigational Product Control and Accountability
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SCOPE:

This procedure applies to the protocols where the investigational drug is stored and prepared at a location different from that of the PI.

PROCEDURE:

When the Clinical Research Coordinator (CRC) is located at an address different from that of the PI, the investigational drug may be stored at the CRC’s location in order to have easy access to the drug. The CRC will assure that the investigational product is stored in a double locked space with access limited only to authorized personnel, and in compliance with any special requirements provided by the sponsor.

If the study medication is to be prepared and dispensed by the UNTHSC pharmacist (as in infusion studies), a Drug Transport Log needs to be completed, signed, and filed in the Pharmacy Binder. The original will be filed with the subject’s blinded source documentation.

A sample Drug Transport Log may be found on the following page.

REVISION HISTORY

Rev	DCO	Description of Change	Approved by
1	10-104	Replacement of “policy” with “procedure”; addition of references and change history	MVWB

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 VERIFY THAT THIS IS THE CORRECT VERSION BEFORE USE

UNT-HSC OFFICE OF CLINICAL TRIALS
Investigational Produce Storage Procedures

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DRUG TRANSPORT LOG

Site Number: _____ Investigator Name: _____

Subject Number _____ Pharmacist Name: _____

STUDY MEDICATION PREPARATION

Date Prepared: _____ Time Prepared: _____

Pharmacist Name _____ Pharmacist Signature _____
(Please Print)

TRANSPORT

Date and Time Medication Left Pharmacy Temperature of Transportation Vehicle

How was the medication transported? (By car, van, courier service) _____

Was the infusion bag kept at room temperature during transport? _____

How was the temperature regulated? _____

How was the medication carried? In a cooler (can not be placed on ice) _____

Distance of Transportation _____

Additional comments: _____

Transporter's Name _____ Transporter's Signature _____
(Please Print)

ARRIVAL OF MEDICATION AT STUDY SITE

Date and Time of Arrival at Study Site _____
Acceptable - Unacceptable (Temperature/Condition of Medication at Arrival-circle one)

PI or Coordinator's Name _____ Signature _____
(Please Print)

Additional Comments:

