

Storage and Dispensing of Investigational Drugs

I. Purpose

The purpose of this procedure is to describe the requirements for the handling of investigational drugs in human research protocols conducted at Albert Einstein College of Medicine (“Einstein”) or Montefiore Medical Center (“MMC”) under the auspices of the Einstein IRB.

II. Scope

This procedure applies to all human research involving investigational drugs conducted at Einstein or MMC under the auspices of the Einstein IRB.

III. Definitions

None.

IV. Procedure

A. General:

1. All drugs utilized for research protocols (both in-patient and out-patient) are required to be stored and dispensed by the appropriate Hospital Pharmacy.
2. It is the responsibility of the Principal Investigator to contact and make all arrangements with the Director of the Pharmacy.
3. A waiver to this policy may be granted by the Einstein IRB. To apply for a storage and dispensing waiver, a "DRUG STORAGE WAIVER" request must be submitted to the appropriate Director of Pharmacy at the time of the Einstein IRB application review.
4. If the study is to be conducted at more than one site, the application and waiver as appropriate, must be signed by the Director or responsible manager at each site.
5. It is the responsibility of the Principal Investigator, in conjunction with the Director(s) of the Pharmacy or designee, to identify all costs associated with the storage and dispensing of drugs and to include such costs in all grant applications.

B. ICH-GCP Requirements:

1. Manufacturing, handling, and storage of investigational test articles must be performed in accordance with applicable good manufacturing practice.

2. Where allowed or required, the researcher may assign some or all duties for investigational articles accountability at the trial sites to an appropriate pharmacist or another appropriate individual who is under the supervision of the researcher.
3. The Principle Investigator, pharmacist, or other designated individual will maintain records of the product's delivery to the trial site, the inventory at the site, the use by each participant, and the return to the sponsor or alternative disposition of unused products. These records will include dates, quantities, batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the investigational products and trial participants.
4. Investigators should maintain records that document adequately that the participants are provided the doses specified by the protocol and reconcile all investigational products received from the sponsor.

C. Approvals for storage waivers are based on the Joint Commission Standards for Medication Management and the USP 797 Standards for Sterile Compounded Products. The following procedures provide the basis for granting storage waiver approvals:

1. Intravenous medications which meet the conditions for emergency administration.
2. Intravenous medications which will be prepared and used within one hour of compounding and will not exceed 12 hours of administration time may be granted a waiver to prevent treatment delay.
3. Patient-specific prescription vials or kits containing oral medications or syringes, and which are appropriately labeled for outpatient dispensing, may be granted a waiver if it is impractical for the pharmacy to store or dispense the medication.

D. Storage waivers will not be approved for:

1. Antineoplastic agents.
2. Routine intravenous medications requiring IV admixture or compounding.
3. Oral Study medication requiring mixing, pouring or re-packaging from bulk containers prior to dispensing.

V. Effective Date

Effective as of: August 14, 2020

VI. Procedure Management and Responsibilities

Einstein's Office of Human Research Affairs is the Responsible Office under this Procedure. The Executive Dean is the Responsible Executive for this Procedure. The OHRA Director is the Responsible Officer for the management of this Procedure.