

STANDARD OPERATING PROCEDURE

Receipt of Clinical Trial Shipments – NON GMO needing Ultra cold storage

1 Scope

This procedure documents the requirements for the activities associated with receipt and acceptance of shipments of clinical trial materials (CTM) in the Royal Children's Hospital (RCH) pharmacy department. The procedure also describes the recording of applicable information during receipt activities to ensure the site operates in accordance with Good Clinical Practice (GCP) principles and protocol/pharmacy manual specific requirements when managing CTM.

2 Responsibilities

2.1 Pharmacist/Pharmacy Technician

- (i) Ensure that staff involved in processes associated with the receipt of CTM have completed Good Clinical Practice training meeting Minimum Criteria v.2.0 for ICH E6 (R2) GCP Investigator Site Personnel Training identified by TransCelerate BioPharma, Inc., as necessary to enable mutual recognition of GCP training among trial sponsors.
- (ii) Ensure that all equipment and consumables required are assembled prior to the receipt of CTM.
- (iii) Complete all necessary records associated with receipt process for CTM according to Institutional, Study Protocol and Regulatory requirements.

3 Procedure

- 3.1 The pharmacy is locked and inaccessible to all non-pharmacy staff. Any non-pharmacy staff within the pharmacy will be supervised by a pharmacist or a pharmacy technician under the supervision of a pharmacist.
- 3.2 Couriers report to the rear door of the pharmacy to gain access to the pharmacy bulk storage area. A door bell (or similar) must be pressed and access can only occur by manual opening of the rear door by a member of the pharmacy staff.
- 3.3 Couriers are accompanied to the Clinical Trials Pharmacy receipt area within the MCRI freezer farm.
 - The shipments will remain in their shipping containers and are placed on the floor as close to the ultra-cold freezer as possible for timely shipment accessibility and staff safety.
- 3.4 Upon accessing the CTM shipment, clinical trials pharmacy staff will stop any temperature monitoring data loggers present within the shipment and if required record the time the temperature loggers were stopped and take any photographs of the shipment as per the sponsors requirements. Data loggers requiring download will have:
 - Downloaded files saved into the online clinical trial folder
 - The printed summary signed, dated and filed in the pharmacy site file
 - The logger is destroyed, stored or returned to the courier as required.ALARMED loggers will be handled as per the shipment and protocol requirements.
- 3.5 The shipment will be immediately opened and the following will be completed as soon as possible:
 - The CTM inspected for damage
 - The CTM will be placed into the appropriate monitored storage conditions.
- 3.6 Couriers will be accompanied out of the MCRI freezer farm by pharmacy staff.

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- 3.7** The following actions will be completed preferably at the time of transfer to the freezer or as soon as possible and no later than 24 hours after receipt:
- The CTM compared to the shipping documentation provided.
 - Protocol specific accountability logs will be completed as required.
 - Protocol specific interactive response technology requirements will be completed as required.
 - Protocol specific documentation receipt requirements will be completed as required.
 - Protocol specific temperature monitoring data logger documentation receipt requirements will be completed as required as described in section 3.4
 - Paperwork related to the shipment will be filed in the protocol specific pharmacy site file which is stored in the clinical trials pharmacy.
- 3.8** Any queries related to receipt of a shipment will be handled as per the shipment and protocol requirements as soon possible after the query is identified.
- 3.9** Shippers will be prepped for pick-up or discarded per sponsor-provided instructions.

Any protocol specific requirement for quarantining shipments upon receipt will be followed in the event that the conditions requiring quarantine of a shipment have been met.

Prepared By:	Kee Lin Lim	Final Approval Date: Jan 2024
Approved by:	Donna Legge	
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