

Study medication storage and shipment

2R2 SOP14_06Jul2020

Title	Procedures for storage and shipment of study medications
SOP Code	2R2 SOP14_06Jul2020
Effective Date	06 July 2020

1.0 Purpose

The objective of this standard operating procedure (SOP) is to describe the procedures to follow for storage and shipment of study medication during the trial.

Information on study medication dispensing and recording are given in SOP04 (Blinding and dispensing of study medication) and are specific for each site.

The SOP will ensure:

- that actions are in compliance with the standards of Good Clinical Practice
- the safety and protection of study participants
- the quality of the data produced by the study

2.0 Persons/Areas affected

This SOP concerns the site principal investigators and the person in their respective research teams, involved in conducting research with human participants for the study entitled *2R²- Higher dose*

consultation. Until a decision regarding utilization of the drugs is communicated by coordinating center, the drugs exposed to temperature excursions should be quarantined.

For International sites (Indonesia and Vietnam):

5.1.6. Shipment to study site will be arranged by site research team with the producing pharmaceutical company that will ship the study medications directly from production to study site. Monitoring of study drugs conditions during shipment has to be arranged by study coordinator at site or by coordinating center with the pharmaceutical company. The record of temperatures during shipment has to be kept by study site together with the other pharmacy essential documents in the study pharmacy master binder.

5.1.7. In case of occurrence of excursion from recommended temperatures during shipping, coordinating center must be informed. As for point 5.1.5 above, the coordinating center will recommend action regarding the stock of study drugs exposed to temperatures outside the recommended range, after having collected all the information and having had the necessary consultation. Awaiting the decision, the drugs exposed to temperature excursions should be quarantined.

5.2. Study medication storage

5.2.1. At sites, study medication must be stored in a secure (e.g. locked room), dry and clean place, with restricted access to qualified personnel.

5.2.2. The study drug for all arms of 2R2 is rifampin in solid form. Storage conditions for the study drug are specified on the label of the product.

5.2.3. The storage room must be equipped with a thermometer that can record the range of temperatures reached between

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Appendix 2. LOG of Storage conditions for study medication

Sponsor: RI-MUHC, 2155 Guy street, suite 500, Montreal, H2H 2R9, Canada

Protocol Number: < protocol n at site >

Site Number:

Site Investigator:

Room Temperature (15 to 30 C)

Location:

Back-up Location:

Serial Number of thermometer:

Brand