SCOPE:	**DOMAIN OF APPLICATION:**
Define how investigational products used in clinical trials are handled and stored within the institution. Ensure that the use of investigational products is conducted ethically and in compliance with applicable laws and regulations.	Pharmacy department **ANNEXES:** EM-F-42: Temperature and Humidity Log
REFERENCE DOCUMENTS: - Food and Drug Administration (FDA) – E6(R2) Good Clinical Practice: Integrated Addendum to International Conference on Harmonization (ICH) E6(R1) Guidance for Industry, 2018. - West Suffolk National Health Service (NHS) Foundation Trust – Clinical Trials Involving Investigational Medicinal Products and Medical Devices Policy, 2017. - Ministry of Public Health (MOPH), Lebanese Republic – Clinical Trial Regulations. Minister Decree No. 1159/1, 2014.	**DEFINITIONS AND ABBREVIATIONS:** - GCP: Good clinical practice*: international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well – being of trial subjects are protected. - IMP: Investigational Product or investigational medical product*: A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use. - CRA: Clinical Research Associate

POLICY:

PH-PO-39:

The pharmacy department is responsible for the oversight, storage, control and record keeping of any investigational product used for human research.

Investigational drugs are accessible only to authorized Pharmacy personnel.

The responsibility for investigational product accountability at the trial site rests with the investigator/institution.

The investigator/institution may/should assign some or all of the investigator's/institution's duties for investigational product accountability at the trial site to an appropriate pharmacist who is under the supervision of the investigator/institution.

The IMP is used only in accordance with the protocol approved by the institution's Ethics Committee.

The IMP is handled in the pharmacy department by a qualified clinical pharmacist in coordination with the Site Study Coordinator for Clinical Trials.

I. IMP shipment

- The IMP shipment form to present to the ministry of health is signed by the chief pharmacist.
- The pharmacy maintains records regarding shipment of the IMP.

II. Receipt of the IMP

- Investigational drugs should be sent from the sponsor directly to the pharmacy and to the responsible pharmacist.
- Investigational drug pharmacist examines the received IMPs in order to ensure that all the IMPs are present, intact, correctly labeled and shipped in appropriate conditions.
  The following is checked and recorded in the drug accountability form or electronic capture system as required by the sponsor:
  - Name/identification number of the IMP

- Clinical trial protocol identification
- Dosage form, size, concentration/strength
- Date of receipt
- Quantity received
- Expiry date
- Batch/serial number
- Number and quantity of any randomization codes received
- Any discrepancies; The latter are directly communicated to the sponsor via the monitor/CRA

- Every individual vial or bottles in multi pack cartons are counted rather than the outer carton label.
- The pharmacy maintains records regarding receipt of the IMP.

III. Storage of the IMP:

- IMP is stored according to the conditions specified on IMP's label by the manufacturer/sponsor.
- IMP is stored in a securely locked closets separated from the pharmacy stock, to which only the clinical pharmacist has access. In the absence of the clinical pharmacist, only the pharmacy director may access the IMP storage area.
- IMP for multiple protocols is stored separately from each other. Distinct storage shelves are allocated for each protocol.
- Appropriate monitoring and documentation of storage conditions is performed.
- Manual or electronic temperature checks are done daily or as required by the sponsor and recorded on the Medication Storage Temperature and Humidity Log (EM-F-42)
- Temperature devices may also be provided by the sponsor.
- During the study, any expired drug is removed and kept away from the other non-expired drugs.

IV. Dispensing of the IMP

- Dispensing is done according to the specific information provided in the protocol.
- The IMP is dispensed upon the investigational drug pharmacist receipt of the protocol's investigator or sub-investigator prescription that includes all the following information:
  - Trial site number
  - Protocol name and/or number
  - Patient number
  - IMP name, dose, route of administration, and schedule of administration
  - Name of the prescribing investigator or sub-investigator, and signature.
  - A copy of the electronic randomization when applicable.
- IMP dispensing records are completed at the time of dispensing and include:
  - Trial site number
  - Protocol name and/or number
  - Patient number
  - Date of dispensing
  - Treatment number/batch number
  - Quantity dispensed
  - Dispensing pharmacist initials
- Dispensing is only done after the return of unused and empty containers.
- The pharmacy maintains records regarding the use of IMP by each subject.

V. Return of IMP by the protocol participating subjects:

- Participants return any unused or empty IMP containers to the pharmacy.
- Date and quantity of returns are documented on the drug accountability records with the clinical pharmacist initials.

- Return drugs are stored in a manner that is distinguishable from unused stock.
  Temperature checks for the returned stock will be performed if requested by the sponsor.
- Any dangerous or contaminated products (needles, syringes, broken ampoules) should be stored in appropriate containers until disposal.

VI. Transfer and distribution to other institutions

- IMP can only be transferred to another site after the approval of the sponsor, investigator and clinical pharmacist, and provided the sponsor has fulfilled all applicable regulatory requirements.
- Transfer records should be kept in both sites

VII. Return of IMP to the sponsor

- Used and unused IMP is returned to the sponsor at the sponsor's request. This may occur when:
  - Protocol is completed or closed, and/or
  - Protocol participating subjects have returned all used and unused IMP to the pharmacy, and/or
  - IMP has expired, and/or
  - A quality concern arises, leading to prompt recall of the IMP

  Return to the sponsor will only be made when reconciliation between received and returned IMP is performed and accurate
- Disposal/destruction of the used/unused IMP is the responsibility of the sponsor. No destruction is allowed at the institution.
- The clinical pharmacist maintains records regarding disposition of the IMP

VIII. Retention and archiving of records

All records related to the protocol are kept for 15 years in a secured place or for longer period if required by the sponsor.

IX. Protocol participating subjects counseling and education

Is performed by the Site Study Coordinator for Clinical Trials in collaboration with the clinical pharmacist when required

X. Monitoring compliance

1. Manually:

Accurate IMP accountability is performed using the following formulas:
- Actual number taken = number dispensed - number returned
- Predicted number taken = amount per day x number of days
- Percentage of compliance = Actual/predicted x 100
- Number of missed doses = predicted – actual

2. Using scan barcode:

Upon receiving the returned medications from the subjects, every box is scanned, the previously taken date and the accountability date are placed and the number of returned medications is checked.