

Title: **Investigational Medications**

Scope: **Network**

Manual: **Pharmacy Services Policies & Procedures**

Origination Date: **04/01/1998**

Revision Dates: **04/2013, 08/2013, 08/2016**

Review Dates: **10/2003, 04/2004, 05/2005, 05/2006, 06/2007, 06/2008, 06/2009, 06/2010, 06/2011, 06/2012, 06/2013, 06/2014, 06/2015, 06/2016**

I. Purpose:

To provide guidance regarding the proper procedures for handling, storing, dispensing, and recording necessary information related to investigational medications

II. Definitions:

Investigational medication – An investigational medication is a substance that has been tested in the laboratory and has been approved by the U.S. Food and Drug Administration (FDA) for testing in people. Clinical trials test how well investigational drugs work and whether they are safe to use. An investigational drug may be approved by the FDA for use in one disease or condition but still be considered investigational in other diseases or conditions.

III. Procedure:

- Investigational drugs or protocols may be administered to patients under the following circumstances:
 - The protocol has been reviewed and approved by the St. Luke’s University Health Network Institutional Review Board or designee, or,
 - When currently available therapeutic modalities have been of no benefit and treatment with the investigational drug would be expected to be of benefit or when an investigational drug would offer a clearly superior treatment alternative to currently available therapy, or,

- When a patient on a protocol from another institution is admitted and the attending physician chooses to continue treatment.
- When a patient on a protocol from another institution is admitted, the attending physician must obtain a copy of the protocol and signed consent form.
- Investigational medications will be administered with an approved protocol. The investigational protocol will be made available to the Pharmacy staff.
- An appropriate informed consent form must be completed prior to the first administered dosage.
- The principal investigator, co-investigator(s), designee or pharmacist will make arrangements to obtain the investigational drug.
- The clinical trial staff/pharmacy staff will ensure that the prescription written for a patient participating in an NCI clinical trial is written by a physician who has an active CTEP registration. If the study prescription is written by a person who is not registered with CTEP as an investigator, the prescription must be co-signed by an active registered investigator. The physician's CTEP status will be checked at <http://ctep.cancer.gov/branches/pmb/>
- Study prescription is written for a registered study participant.
- Study prescription is written appropriately and patient meets protocol-defined criteria for treatment.
- Investigational drugs will be profiled by the pharmacy and listed on the patient's MAR for the time that the therapy is active.
- Patients on a protocol from another institution will have their investigational drugs verified (labeling), profiled on the MAR and dispensed as a "Home Med".
- All investigational drugs dispensed through the Pharmacy will be labeled and include any required information from the study protocol.
- Upon approval of the principle investigator, registered nurses may administer the investigational drug. Prior to this approval, the nurse must be given and demonstrate an understanding of the medication actions, side effects and adverse reactions.
- All investigational drugs will be secured in the Pharmacy separately from other pharmaceuticals. For some protocols it may be necessary to store study medications outside of the Pharmacy. In those instances, the study medications will be stored in accordance with all state and federal regulations and institutional policies. These areas will be periodically monitored to ensure compliance.
- Disposal of empty and partial containers of investigational medications will be in accordance with pharmacy and hospital waste management policies. The pharmacy will not save used

chemotherapy or biologic vials for review by monitors.

Investigational product destruction will be documented per protocol.

- If there has been an excursion outside of the sponsor’s acceptable temperature range, medication will be quarantined until the sponsor determines the medication is acceptable for continued use.
- Expiration date(s) for clinical trial medications will be checked every 3 months. Expired or adulterated investigational medications will be quarantine until return to the sponsor or destruction on site.
- Unused and expired study medication will be returned to the sponsor at the end of the study or destroyed on site.
- Documentation will be maintained by the Pharmacy and forwarded to the principal investigator when requested at the conclusion of the study or during an audit.

IV. Attachments

N/A

V. References

Joint Commission: MM 06.01.05, MM 04.01.01
Handbook for Clinical Investigators Conducting Therapeutic Clinical Trials Supported by CTEP, DCTD, NCI: Section 14.2

VI. Policy Responsibility

Allentown	Pharmacy and Therapeutics	Development/Review/Revision
Anderson	Pharmacy and Therapeutics	Development/Review/Revision
Bethlehem	Pharmacy and Therapeutics	Development/Review/Revision
Miners	Pharmacy and Therapeutics	Development/Review/Revision
Monroe	Pharmacy and Therapeutics	Development/Review/Revision
Quakertown	Pharmacy and Therapeutics	Development/Review/Revision
SLWEEC	Pharmacy and Therapeutics	Development/Review/Revision
Warren	Pharmacy and Therapeutics	Development/Review/Revision

VII. Disclaimer Statement

This policy and procedure is intended to provide a description of a course of action to comply with legal requirements and/or operational standards. There may be specific circumstances not contemplated by

this policy and procedure that may make compliance either unclear or inappropriate. For advice in these circumstances, consult with your Chain of Command, Administrator on Call, Clinical Risk Management, Legal Services, Accreditation and Standards, or Compliance Officer, as appropriate.

VIII. Approval

Pharmacy and Therapeutics Committee annually.