PURPOSE:

This standard operating procedure (SOP) applies to the activities involved in the collection and handling of laboratory specimens from patients enrolled in clinical studies subject to investigational new drug (IND) regulations for drugs and biologics during all phases of development.

DEFINITIONS/ABBREVIATIONS:

- **Case Report Form (CRF):** A Case Report Form can be either paper (CRF) or electronic (eCRF). These forms are used to collect data that is then submitted to the sponsor of the clinical trial. The CRF is constructed to collect pertinent information to the clinical trial from the patient's records.
- **Central Laboratory:** A laboratory designated by the clinical trial sponsor, which will process and store human specimens, to include pathology, urine and blood specimens, for clinical research purposes.
- **Clinical Research Associate (CRA):** Clinical Trials staff responsible for oversight and coordination of lab related procedures and data management.
- **Clinical Research Nurse/Coordinator (CRC):** Clinical Trials staff responsible for oversight and coordination of assigned protocols
- **Clinical Trials Office (CTO):** Centralized clinical trials staff, responsible for the conduct and support of the SLUHN clinical trial functions
- **Electronic Medical Record (EMR):** A digital / electronic version of a paper chart and documents that contain all of the patient's medical history.
- **Institutional Review Board (IRB):** Independent ethics committee formally designated to approve, monitor, and review biomedical and behavioral research involving human subjects.
- **International Air Transport Association (IATA):** The governing body that creates regulation for international air transport, including regulations controlling the transport of Dangerous Goods By Air
- **Local Laboratory:** A laboratory within the St Luke's University Health Network (SLUHN), or one designated by the patient's health insurance, which will process human specimens, to include pathology, urine and blood specimens.
- **Occupational and Safety Health Administration (OSHA):** The main federal agency charged with the enforcement of safety and health legislation.
- **Principal Investigator (PI):** Lead investigator, responsible for the sound conduct of the project in accordance with the protocol and regulations.
- **St. Luke's University Health Network (SLUHN)**
- **Standard Operating Procedures (SOPs):** Detailed, written instructions to achieve uniformity of the performance of a specific function.

SCOPE:

Effective Date(s):	Revision Date(s):
9/4/14	4/17/15; 4/8/16

This SOP applies to all clinical research site personnel involved in the conduct of clinical research.

This policy describes the process:

- Starting from the time a research nurse/coordinator consents a patient onto a clinical trial
- Ending when SLUHN has completed the close out visit of the clinical trial

This policy is applicable to:

- All clinical trials at SLUHN conducted by the CTO, which may include Industry or Government Sponsored Trials, Cooperative Group Trials, and Investigator-Initiated Trials.

PERSONNEL RESPONSIBLE:

This SOP applies to members of the clinical trials research team involved in the collection and handling of laboratory specimens of patients enrolled on a clinical trial. This includes the following:

- Principal Investigator (PI)
- Research Nurse/Coordinator (CRC)
- Clinical Research Associate (CRA)

ROLES:

The following information describes which areas and associated roles that shall adhere to this policy:

- **Principal Investigator:** The PI or designee shall be responsible for clinical trials conduct and overall oversight at SLUHN.
- **Clinical Research Nurse/Coordinator:** The CRC or designee shall be responsible for ensuring laboratory specimens are collected at the required time points per the clinical trial protocol and/or lab manual and maintaining CRFs pertinent to the collection, documentation, and shipment of these specimens.
- **Clinical Research Associate:** The CRA shall be responsible for collection, processing and shipment of laboratory specimens as required by the clinical trial protocol.

PROCEDURES:

- All staff members involved in the shipping of laboratory specimens will have completed IATA training for shipping of dangerous goods.
- The CRA or designee shall maintain inventory of, and perform quality control of, central laboratory specimen kits, shipping logs, and protocol specific manuals.
- Pathology slides shall be requested from the pathology department and processed per protocol and/or laboratory procedure manual requirements.
- Every effort shall be made to inform the pathology department of protocol specific requirements prior to the day of procedure for fresh tissue procurement. CRA or designee

shall provide a copy of pathology requirements to the pathology department at the time of request for archival tissue specimens.

- All local laboratory orders shall be entered into the appropriate EMR (Epic for inpatients and Allscripts for outpatients) by the CRC or designee prior to or at time of patient's study visit and authorized by the PI or designee.
- Central laboratory specimens will be drawn and processed by the CRA or CRC or designee according to the requirements of the study protocol.
- Appropriate precautions based upon OSHA guidelines and the SLUHN institutional policy for laboratory specimen collection shall be observed for each specimen collected.
- CRA shall order dry ice as needed for specimen shipment.

GENERAL INSTRUCTIONS

Role	Step	Activity
CRA or designee	1.0	Ensure all necessary laboratory specimen kits and current version of manuals are available
CRC, CRA or designee	1.1	Alert the pathology department of fresh tissue procurement at the time the procedure is scheduled, and send protocol specific requirements to the pathology department for review.
CRC or designee	1.2	Obtain and/or enter local laboratory orders into the appropriate EMR (Epic for inpatients and Allscripts for outpatients).
Not Applicable	---	**NOTE:** Specific steps with regard to registration and billing compliance for Specimen Collection will not be addressed in this SOP. ***Please refer to SOP 107.***

COLLECTION OF SPECIMENS

Role	Step	Activity
CRC, CRA or designee	2.0	Observe appropriate precautions based upon OSHA guidelines and the SLUHN institutional policy for laboratory specimen collection.
CRC, CRA or designee	2.1	Note the date and time of the collection, patient identifiers, and any other required information on the specimen containers for all local and central laboratory specimens.
CRC, CRA or designee	2.2	Document the procedure in the patient's Research Shadow Chart and/or on the case

		report form.

PROCESSING OF SPECIMENS

Role	Step	Activity
CRC, CRA or designee	3.0	Process all local laboratory specimens according to the policies of the SLUHN laboratory.
CRC, CRA or designee	3.1	Process all central laboratory specimens according to the specified protocol and/or laboratory procedure manual (e.g. centrifuge speed, duration, temperature requirements).
CRC, CRA or designee	3.2	Label all specimens with corresponding patient identifiers, and the date and time of collection as specified in protocol and/or laboratory manual.
CRC, CRA or designee	3.3	Complete the laboratory requisition forms for any central laboratory specimens
CRC, CRA or designee	3.4	Retain a copy of the laboratory requisition forms, and file a copy in the patient's study chart. Enclose the original with the specimen when shipped.

SPECIMEN STORAGE

Role	Step	Activity
CRA or designee	4.0	Monitor the performance of the equipment used for specimen storage (refrigerator, freezer) and maintain a monitoring record (e.g. a daily temperature chart).
CRA or designee	4.1	Ensure alternative storage capabilities are available in case of emergency (e.g. power failure).

SHIPMENT OF SPECIMENS

Role	Step	Activity
CRA or designee	5.0	Prepare and package the specimens according to the shipping instructions specified in the protocol and/or central laboratory procedure manual.
CRA or designee	5.1	Ensure shipping materials and documents are in compliance with IATA biological specimens or dangerous goods transportation regulations.

CRA or designee	5.2	Retain a copy of the shipping documents and file it in the patient's record.
CRA	5.3	Order dry ice for delivery to site when required based on protocol specific specimen shipping instructions

RESOURCES:

- St. Luke's University Health Network Laboratory Specimen Collection Manual
- International Air Transport Association www.iata.org
- Occupational Safety and Health Administration www.osha.gov

Endorsed by: SOP Committee (6/24/14; 4/17/15; 4/8/16)
Approved by: Tracy Butryn, Director of Clinical Trials and Research (8/4/14; 4/17/15; 8/4/16)