

Policy and Procedure	
Title:	Tissue Collection Process - Research
Maintained by:	Baylor St. Luke's Medical Center (BSLMC) Research Office
Reviewed by:	BSLMC Pathology BSLMC Research Office
Approved by:	BSLMC Director of Laboratory Services, Pathology Department
Effective date:	May 2022
Next review date:	May 2025

REVISION SUMMARY

Date	Referenced Section(s)	Change
March 2017	Full document	New document

SCOPE

Applicable to:
 CHI St. Luke's Health–Baylor St. Luke's Medical Center (BSLMC)

Department(s):
 BSLMC Research Office
 BSLMC Pathology (Pathology)
 All groups involved in research activities at BSLMC

DEFINITION(S)

Administrative Approval– All research to be conducted at or in conjunction with a BSMLC facility must be approved by the designated chief officer, or an individual with delegated authority, prior to data collection or study initiation. The administrative approval process includes a review of each protocol to ensure protection of patients and staff, conduct feasibility, hospital compliance and compensation for resource utilization. See administrative approval policy and procedure *Protocol Administrative Review – Research* for approval process.

POLICY

Tissue collection procedures at BSLMC must be reviewed and approved by BSLMC Pathology before collection can occur.

PROCEDURES

A. Research Tissue Collection Process Setup

- a. Study teams shall submit the requested tissue collection information on the BSLMC administrative application.

- i. Tissue samples for research are only to be collected under IRB-approved protocols and only after receiving BSLMC administrative approval.
 - ii. Research tissue requests will be considered in addition to clinical pathology requirements.
- b. BSLMC Pathology will review the study information and work with the study team on specific processing based on study needs.
 - c. The principal investigator (PI) is responsible for coordinating collection between clinical team, study team, and Pathology.

B. Tissue Requisition

- a. When a research participant is scheduled for a procedure that involves research tissue procurement, the study team shall inform Pathology in advance via email and submit an Epic requisition for the collection.
- b. Pathology shall review the requisition and contact the study team with any questions.
- c. Tissue shall be collected, processed, and dispensed in the manner approved by Pathology.
- d. Tissue will not be collected without a signed informed consent on file. The informed consent should be attached to the Epic requisition and/or sent to Pathology before collection occurs.
- e. Tissue may not be collected outside of the approved collection process without prior notification and approval of Pathology.

C. Guide to Conducting Clinical Research at BSLMC

- a. Study teams should refer to the Guide for specific details on the procedures described in this policy.

CROSS-REFERENCE(S)

BSLMC Policy and Procedure, *Protocol Administrative Review – Research*

RELATED DOCUMENTS

Guide to Conducting Clinical Research at BSLMC