Policy and Procedure	
Title:	**Associating Patient Records with Informed Consents - Research**
Maintained by:	Baylor St. Luke's Medical Center Research Office
Reviewed by:	Health Information Management Call Center
Approved by:	Sr. Vice President and Chief Operating Officer
Effective date:	April 2022
Next review date:	April 2025

REVISION SUMMARY

Date	Referenced Section(s)	Change
March 2017	Whole Document	New
March 2022	Procedure, A, a and b	Added scanning information for HIM

SCOPE

Applicable to:
CHI St. Luke's Health–Baylor St. Luke's Medical Center (BSLMC)
Department(s): 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 policy and procedure - *Protocol Administrative Review - Research*

Informed Consent - A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.

POLICY

Baylor St. Luke's Medical Center requires that signed consent forms are associated with research patients' electronic medical records for all studies utilizing informed consent.

PROCEDURES

A. Association Timeline

a. If the patient has consented before a BSLMC visit, the study team must send a copy of the signed informed consent form to the hospital for association prior to the visit and to the Health Information Management Department to be scanned into the electronic medical record.

b. If the patient has not yet consented when the BSLMC visit occurs, a copy of the signed informed consent form should be sent to the hospital for association as soon as feasibly possible and to the Health Information Management Department to be scanned into the electronic medical record.

B. Association Methods

a. Study teams should reference the Guide to Conducting Clinical Research at BSLMC for information on how to associate informed consent forms with medical records.

b. For radiology procedures, BSLMC Research Office will request a copy of the informed consent form and forward it to Health Information Management for association with the patient's medical record.

C. Compliance Review

a. To ensure compliance with this policy, the BSLMC Research Office conducts monthly reviews of all research encounters from the previous month. Study teams will be notified of missing informed consent forms and will be responsible for sending a copy of the informed consent form to Health Information Management as described above.

D. 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 REFERENCES

Policy and Procedure, *Protocol Administrative Review – Research*

RELATED DOCUMENTS

Guide to Conducting Clinical Research at BSLMC