

<b>Policy and Procedure</b>	
Title:	<b>Billing Compliance – Research</b>
Maintained by:	Baylor St. Luke's Medical Center (BSLMC) Research Office
Reviewed by:	Patient Financial Services Health Information Management
Approved by:	Senior Vice President and Chief Operating Office
Effective date:	April 2022
Next review date:	April 2025

### **REVISION SUMMARY**

<b>Date</b>	<b>Referenced Section(s)</b>	<b>Change</b>
March 2017	Full document	Entire document was restructured and revised. Details added for better understanding.

### **SCOPE**

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

Department(s):  
 BSLMC Research Office  
 Finance  
 Health Information Management

### **DEFINITION(S)**

**Administrative Approval**– All research to be conducted at or in conjunction with a BSMLC facility must be approved by the CEO, or a member of the BSLMC executive team with delegated authority and hospital CFO, 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.

**Standard of care** – Items or services that are typically covered benefits when provided outside a clinical trial, and would be routinely provided to the research subject even if not on a clinical research study.

**Research-related charges** - Items or services that are not routinely covered benefits and are typically paid for by the sponsor.

**Investigational Device Exemption (IDE):** Exemption issued by the FDA which allows an investigational device to be used in a clinical study in order to collect safety and effectiveness

data. An IDE may be held by a commercial sponsor or an investigator.

## **POLICY**

It is the policy of Baylor St. Luke's Medical Center (BSLMC) to bill for services rendered through a research protocol. Items deemed standard of care will be billed in the routine manner to the patient or their insurer. Research-related charges will be billed based on the guidelines outlined by the specific research protocol and budget.

## **PROCEDURES**

### **A. Research Pricing and Accounts Setup**

- a. Research Pricing.
  - i. Study teams may contact the BSLMC Research Office at any time for assistance with BSLMC pricing for study feasibility or budget preparation purposes.
  - ii. BSLMC Research Office will work with BSLMC Finance to provide hospital pricing for items deemed research.
  - iii. BSLMC Research Office will provide the principal investigator with a fee schedule for hospital charges. Professional billing is separate and is not billed by the hospital.
- b. Research Study Accounts Setup.
  - i. BSLMC Research Office will set up research study accounts for each approved study in the appropriate clinical information systems.
  - ii. Special set up for Device studies:
    - a. Prior to a study, Investigational, humanitarian, and post-market device studies must undergo a BSLMC financial analysis to determine impact to the hospital. See policy and procedure: *Impact Assessment of Investigational/Humanitarian Devices*.

### **B. Research Patient Association and Encounter Linking**

- a. Association of patient records and linkage of research encounters to Epic study accounts is required to ensure appropriate billing.
- b. Failure to associate patients and encounters with research study accounts will result in charges automatically routing to patients and/or their insurance.

### **C. Epic Research Work Queue Processing and Charge Resolution**

- a. Charge assignment.

- i. Study teams must classify visit charges as research or standard of care. This ensures correct billing to the research study account or the patient account.
- b. Research study account billing.
  - i. The study team must review monthly study bills to ensure pricing matches that provided in the financial agreement. Payment should be made according to bill instructions.
- c. BSLMC review of research charges
  - i. The BSLMC Research Office conducts monthly account reviews to ensure research billing compliance. If any variances are found, the study team will be contacted for resolution.
  - ii. The BSLMC Research Office also conducts monthly reviews of IDE studies to ensure investigational devices are charged correctly and accounts coded for research. If any devices are found to be charged incorrectly, the study team will be contacted for resolution.
  - iii. Results of these account reviews are reported quarterly to Catholic Health Initiatives.

#### **D. Maintenance of research patient study enrollment status**

- a. Study teams are responsible for maintaining current patient status in Epic.

#### **E. Guide to Conducting Clinical Research at BSLMC**

- a. Study teams should refer to the Guide, available on the BSLMC Research website, for specific details on the procedures described in this policy.

#### **CROSS-REFERENCE(S)**

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

BSLMC Policy and Procedure, *Impact Assessment of Investigational/Humanitarian/Post-Market Devices*

#### **RELATED DOCUMENTS**

Guide to Conducting Clinical Research at BSLMC

[National Coverage Determination \(NCD\) for Routine Costs in Clinical Trials \(310.1\)](#)

[Investigational Devices Exemptions: FDA Regulations 21 CFR 812](#)

[FDA E6 Good Clinical Practice Guidance for Industry](#)

[Charging for Investigational Products – FDA Information Sheet](#)