

<b>Procedure</b>	
Title:	<b>Protocol Administrative Review - Research</b>
Maintained by:	Baylor St. Luke's Medical Center Research Office
Reviewed by:	Baylor St. Luke's Medical Center Research Office
Approved by:	Senior Vice President and Chief Operating Officer
Effective date:	January 2022
Next review date:	January 2025

### **REVISION SUMMARY**

<b>Date</b>	<b>Referenced Section(s)</b>	<b>Change</b>
Mar 2017	Full document	Major language revisions
Jan 2022	Section A and B	Minor language updates

### **SCOPE**

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

Department(s):  
 Baylor St. Luke's Medical Center (BSLMC) Research Office  
 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.

### **POLICY**

Baylor St. Luke's Medical Center (BSLMC) requires administrative approval for all research to be conducted in BSLMC space or with BSLMC protected health information (PHI). Approval requires submission of a completed Administrative Application, which is reviewed or acknowledged by all BSLMC areas directly impacted by the study as well as executive leadership.

### **PROCEDURES**

#### **A. Submission of administrative application**

- a. To initiate the administrative review process, study teams must submit the BSLMC Administrative Application through the BSLMC Application System, with all required documentation to the BSLMC Research Office. The application should be submitted as early as possible in study start-up activities to minimize delays for initiation at BSLMC.
- b. IRB approval is not required at time of submission but is required prior to administrative approval. IRBs accepted by BSLMC are listed on the BSLMC research website and online in the US DHHS Office for Human Research Protections (OHRP) *Database for Registered IORGs & IRBs, Approved FWAs, and Documents Received in Last 60 Days*, under CHI St. Luke's Health Baylor College of Medicine Medical Center.
- c. If the study is a device trial, then the device purchase agreement and related documents must be routed for hospital assessment and approval. This process must be completed before administrative approval can be given. Please see the policy and procedure *Impact Assessment of Investigational/Humanitarian/Post-Market Devices* for process details.
- d. BSLMC requirements for credentialing and badging of research staff:
  - i. PI is responsible for ensuring all study personnel conducting study activities at BSLMC are appropriately badged and/or credentialed for each study.
  - ii. Personnel who are delegated duties that include technical proficiency and/or collecting biological samples, or who require write access in Epic, must complete the full Allied Health Professional credentialing process. Review and approval of credentialing requires at least 120 days.
  - iii. Personnel whose duties include only communicating with patients may submit an abbreviated application for initial badging and Epic view-only access.
  - iv. BSLMC requires PI sponsorship confirmation for each study team member on each study. Contact the BSLMC Research Office regarding specific contacts for badging and credentialing requirements.

## **B. Review of administrative application**

- a. Upon receipt of the application, the BSLMC Research Office will review the application for completeness.
- b. BSLMC Research Office will route the completed application to all affected hospital service areas, departments and research oversight committees for review and approval.
- c. Based on the schedule of events, BSLMC Research Office will create a fee schedule listing hospital pricing for procedures to be performed at the hospital.
  - i. See hospital policy and procedure *Billing Compliance-Research* for more information.

- ii. While not required for administrative approval, per Centers for Medicare and Medicaid Services regulation, a completed qualifying clinical trial coverage analysis is required for all therapeutic studies. Study teams must provide a copy upon BSLMC request.
  
- d. BSLMC Research Office will conduct a CHI compliance review of the application to ensure compliance with HIPAA authorization requirements and conflict of interest disclosure; check for debarment of investigators; and verify regulatory committee approvals and compliance with CHI national policies. Study team will be notified of any concerns.

### **C. Approval of administrative application**

- a. Once the administrative application packet is complete, it will be routed for BSLMC executive review and approval.
  
- b. Renewal of administrative approval is not required. The study team should notify the BSLMC Research Office of any changes to the study conduct which may impact BSLMC or BSLMC patients.

### **D. 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)**

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

Policy and Procedure, *Billing Compliance – Research*

#### **RELATED DOCUMENTS**

Guide to Conducting Clinical Research at BSLMC