

<b>Policy and Procedure</b>	
Title:	<b>Clinical Research Center – Mission and Operations</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:	To Be Determined: Month and Year document is loaded to PolicyManager™
Next review date:	To Be Determined: Month and Year [indicate 1, 2, or 3 years – may not be more than 3 years after the effective date]

### **REVISION SUMMARY**

<b>Date</b>	<b>Referenced Section(s)</b>	<b>Change</b>
June 2017	Full Document	New Document

**SCOPE** This policy applies to all studies conducted in the Baylor St. Luke's Medical Center (BSLMC) Clinical Research Center (CRC).

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

Department(s):  
BSLMC Research Office  
BSLMC Clinical Research Center  
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.

**Clinical Research Center** – A hospital-based unit providing comprehensive infrastructure for clinical studies, both inpatient and outpatient, for phase I-IV clinical trials, metabolic studies, translational studies and pilot trials in all clinical areas.

### **POLICY**

It is the policy of Baylor St. Luke's Medical Center to support clinical research through operation of a clinical research center at the hospital.

### **PROCEDURES**

- A. The mission of the Clinical Research Center (CRC) is to support and advance clinical research activities at BSLMC.

- B. The hospital achieves this goal through providing clinical space and clinical nursing staff to support the CRC.
- C. The BSLMC Research Director and BSLMC Research Office work closely with CRC staff to provide study oversight and administration.
- D. The CRC is available for inpatient and outpatient trials in all clinical areas where staff have the technical and professional capability to carry out required study activities.
  - a. In coordination with the study team, the CRC will review study activities prior to accepting a study, to ensure staff can conduct all requested activities.
  - b. CRC staff may conduct clinical activities only. CRC staff may not perform study-specific activities, such as questionnaires.
- E. The CRC will assess an hourly charge for its services to cover costs, as determined by BSLMC Finance. This charge is two-tiered, with different rates for industry and non-industry studies, and will be discussed with study teams prior to CRC approval of the study.
- F. All studies conducted in the BSLMC CRC must receive BSLMC administrative approval, including CRC approval, and IRB approval, prior to study initiation in the hospital.
- G. Study teams must provide in-service training for CRC staff before study initiation at the CRC.
- H. Study teams should consult the CRC Investigators' Manual for more information on the CRC.

**CROSS-REFERENCE(S)**

Baylor St. Luke's Medical Center – Clinical Research Center (CRC) Investigator's Manual  
Policy & Procedure – Protocol Administrative Review – Research  
Baylor St. Luke's Medical Center – Clinical Research Center Investigator's Manual  
Guide to Conducting Clinical Research at Baylor St. Luke's Medical Center