

|  |
| --- |
| **Policy and Procedure** |
| Title: | **Clinical Research Center – Mission and Operations** |
| 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**

|  |  |  |
| --- | --- | --- |
| **Date** | **Referenced Section(s)** | **Change** |
| 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**

1. The mission of the Clinical Research Center (CRC) is to support and advance clinical research activities at BSLMC.
2. The hospital achieves this goal through providing clinical space and clinical nursing staff to support the CRC.
3. The BSLMC Research Director and BSLMC Research Office work closely with CRC staff to provide study oversight and administration.
4. 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.
	1. 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.
	2. CRC staff may conduct clinical activities only. CRC staff may not perform study-specific activities, such as questionnaires.
5. 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.
6. 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.
7. Study teams must provide in-service training for CRC staff before study initiation at the CRC.
8. 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