CLINICAL RESEARCH CENTER (CRC) INVESTIGATOR'S MANUAL

Office of Clinical Research
Baylor College of Medicine

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General Information

The Baylor College of Medicine (BCM) Clinical Research Center (CRC), managed by the BCM Office of Clinical Research (OCR), provides both hospital-based and outpatient comprehensive infrastructure and nursing support to investigators who conduct patient-oriented clinical trials (Phase I-IV), metabolic studies, translational studies and pilot trials in all clinical areas. The CRC welcomes protocols funded by a variety of sources – federal, foundation or industry.

About the CRC

*The **Inpatient CRC*** is a hospital based unit located at Baylor St. Luke's Medical Center (BSLMC) (6720 Bertner Avenue) 20th floor inpatient unit. There are two dedicated inpatient research rooms to support early phase, complex, and overnight studies.

*The **Outpatient CRC*** is located at Baylor College of Medicine McNair Campus (7200 Cambridge St. Houston, TX, 77030). There are two dedicated research exam rooms on the 7th floor and an infusion suite on the 9th floor to support outpatient studies.

In addition to inpatient and outpatient facilities, the CRC also provides nursing support to Baylor's affiliated institutes, as applicable.

The CRC is staffed by a team of dedicated research nurses specially trained to perform simple to complex research studies. CRC staff work closely with study teams to ensure clinical study activities are conducted safely and appropriately, according to the workflow and sampling schedules of Institutional Review Board-approved protocols.

Cost Structure

CRC rates are based on resource allocation of services provided, including CRC administrative startup and management, hourly staffing, CRC location, study funding source, meals, and basic medical supplies. All other procedures, tests, and supplies will incur a separate charge. Study teams must coordinate with the BSLMC Research Office during the administrative review process to obtain hospital pricing for research procedures. See CRC Cost Structure here: https://www.bcm.edu/research/research-offices/office-of-clinical-research/clinical-research-center/fee-schedule.

Resources and Services

Nursing staff is trained to perform the following procedures. Annual competency-based training insures proficiency in these test procedures. Training for additional research specific procedures may be added as new studies are initiated.

- Two dedicated inpatient rooms
- Two dedicated outpatient exam rooms
- Outpatient infusion suite
- Lab processing area

- Refrigerated centrifuge and -80°C freezer
- EKG
- Basic medical supplies
- Vital signs, height and weight measurement
- Observation
- Assistance with physical examinations
- IV infusion pumps
- Phlebotomy and blood sampling per protocol
- Central/peripheral line access and site care
- Medication administration
- Adverse event management
- Patient meal services
- Access to BSLMC's pathology lab
- Access to BSLMC's dedicated research pharmacy

Directions and Parking

Inpatient CRC:

Baylor St. Luke Medical Center (BSLMC): https://www.bcm.edu/about-us/map/baylor-st-lukes-medical-center

Outpatient CRC:

Baylor College of Medicine Medical Center (McNair Campus): https://www.bcm.edu/about-us/map/baylor-college-of-medicine-medical-center

Contact Information

BCM CRC Website: https://www.bcm.edu/research/research-offices/office-of-clinical-research/clinical-research-center/resources-and-services

For general CRC questions or scheduling support, email crc-support@bcm.edu

Hospital Services

BSLMC offers many services that study teams may utilize during CRC visits. Study teams should discuss all anticipated service needs with the CRC during the feasibility and logistics meetings.

Pathology – Laboratory & Tissue Collection

The BSLMC pathology laboratory can provide specimen processing and storage for studies conducted in the CRC. The laboratory is located in room P120 on the 1st floor of BSLMC, 6720

Bertner, by the purple elevators. BSLMC pathology laboratory has a -80°C freezer, refrigerated and ambient centrifuges, and table space which may be utilized for research specimen processing. Study teams are responsible for processing, storage, and transport of specimens.

Tests and tissue collection may be ordered through the pathology laboratory, outside of CRC functions. These services will incur additional fees to the CRC hourly charge.

Research Pharmacy

BSLMC requires that all investigative product is labeled and dispensed through BSLMC research pharmacy. Study teams should indicate pharmacy services are required on the BSLMC Administrative Application and in initial feasibility discussions with the CRC, so that the pharmacy may be included in study discussions. The pharmacy will work with the study team and CRC to determine dispensing and transport details for the study.

BSLMC research pharmacy dispensing fees are specified in a study-specific pharmacy fee agreement with the study team. Upon dispensation, fees are charged to the study account through Epic.

The BSLMC Research Pharmacy is located in the hospital (6720 Bertner) on the fourth floor, off the yellow elevators. Shipments are accepted Tuesday through Thursday. Shipment information should be sent to the research pharmacist and confirmation of acceptance received before the shipment is scheduled.

Study teams may contact the research pharmacy directly with questions:

Punit M. Hinsu, PharmD, MBA, MPH
Clinical Pharmacist II, Research & Investigational Drug Service Pharmacy
Baylor St. Luke's Medical Center
Pharmacy Department, Room Y404
6720 Bertner Avenue
Houston, TX 77030

Office: 832.355.4893
Fax: 832.355.4794
Pager: 713.605.8989 Pin #25403
Email: phinsu@stlukeshealth.org

Meal Service

Subjects who are at the CRC for more than four hours will be provided with meals ordered from the main BSLMC kitchen, unless otherwise directed by study team. Study teams should notify CRC nurses of special dietary requirements for each patient. Meal services are included in the CRC hourly fee.

Language & Translation Service

CRC nurses are not able to provide translation services. However, BSLMC offers 24/7 translation services via Language Line Solution over three-way phones placed in patient rooms throughout the

hospital. There is no charge for this service. In addition, individuals may interpret for a patient if they have received qualification in the language through a testing agency. Study teams anticipating a need for translation services should discuss with the CRC.

Vascular Access Service

Assistance with vascular access is available when desired. The vascular access team is a roving hospital team of specialized phlebotomists experienced in difficult vascular access situations. The CRC nurses can request vascular access assistance when needed or when directed by the study team. Advance reservations are not required but advance notice is helpful for ensuring quick service.

Patient Transport Service

BSLMC offers in-hospital transport services for its patients, bed or wheelchair as needed. Transport between institutions, such as from Baylor Clinic to BSLMC, may require advance planning. Study teams should discuss anticipated transport needs during logistics discussions with the CRC so appropriate arrangements can be made.

Initiating a study at the CRC

Requesting CRC Support

- Investigators who require nursing support, needs to complete OCR online service request form at https://orit.research.bcm.edu/OCRServiceRequest/Login.aspx

- All studies that require BSLMC resources (inpatient CRC, pharmacy, radiology, etc.) will also need to complete BSLMC online administration application at https://orit.research.bcm.edu/R5T80IF3WH2/BSLMCAdminApplication/Login.aspx?ReturnUrl=%2fR5T80IF3WH2%2fBSLMCAdminApplication%2fBSLMCAdminApplication%2fHome%2fHome.aspx

- Below are the requested documents to assess CRC feasibility:

    1. CRC application
    2. Protocol
    3. Schedule of events
    4. Clinical Trial Agreement (CTA) if industry funded
    5. Study budget
    6. Other as needed such as pharmacy manual, lab manual, etc.

- Upon submission of the CRC application, a feasibility meeting will be scheduled to go over the details of activities to be performed by the CRC. This meeting is very detailed and intended to launch development of the physician and nursing study orders, which precisely describe the actions of the CRC nurses at each visit time point. The following attendees are required for CRC feasibility review.

    1. Principal Investigator
    2. Study coordinator/Study admin contact
    3. CRC Nurse Manager
    4. Pharmacist (if study requires study drug)
    5. Representative from hospital/unit if inpatient CRC is requested.

- Following CRC feasibility meeting, OCR internal feasibility meeting will be conducted. CRC nurse manager will present CRC study to the OCR leadership to assess the feasibility. Study Budget is required for OCR feasibility.

- Study team will be notified of the feasibility determination.

- CRC nurse manger will draft orders and nursing flow sheets and will send to PI for review and approval.

- All studies are required to utilize the BCM Clinical Trial Management System (CTMS) Financial Module for study budget build prior to CRC approval.

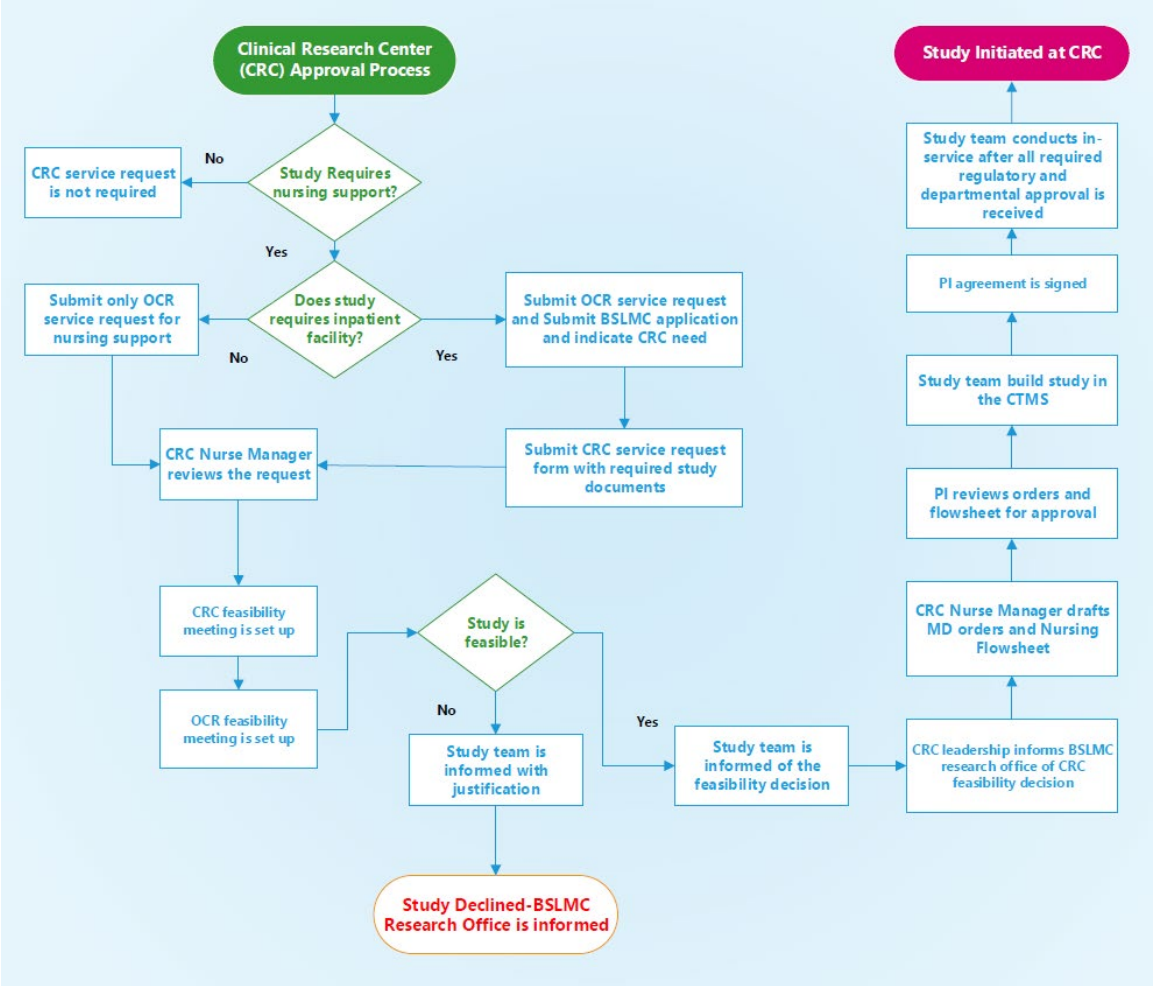
- Pharmacy approval is required prior to CRC approval if the study involves investigational product.

- CRC approval will be granted once all regulatory and departmental approvals are received. See CRC approval flow chart below for additional details.

- Study team are encouraged to invite CRC nurses for the site initiation visits to train on the nursing component of the trial.

- Please note that before a study begins at CRC, study team is required to conduct in-service. Depending on the complexity of the trial, CRC nurse manager may decide to do a mock visit to train CRC nurses.

CRC Study Approval Process flowchart:



Developing Orders and Flowsheets

Physician orders and nursing orders/flowsheets are required for all CRC studies. Physician orders are loaded into Epic and should list all procedures to be completed for the visit, so that a complete record is available in the patient's electronic medical record. Nursing orders/flowsheets are used by nurses to conduct all study activities and should detail all equipment, supplies, and times for all activities to be performed in the CRC.

Orders should describe what is to be performed by the CRC nurse (e.g. blood draws, frequency of vital signs, diet and activity orders, medication administration, physicians to be notified in case of emergency, study coordinator pager and / or phone numbers). If blood specimens are to be drawn, study teams must provide the type of tube in which the specimen should be drawn, and any special handling instructions (e.g. invert 6 times, place on ice, pre-chill tube). Note that pharmacy orders are created by the research pharmacy, not the CRC.

The CRC will work with the study team to create the orders and flowsheets. Finalized orders and flowsheets must be reviewed and approved by the Principal Investigator.

Example Physician Order:

CHI St. Luke's Health
Imagine better health.℠

Baylor St. Luke's Medical Center Clinical Research Center Physician Order Set

For each visit to the CRC, please forward the signed orders along with the signed pharmacy orders, signed consent, call center form, and completed eligibility checklist to BSLMC-CRC@LISTSERV.BCM.EDU at least (3) business days before the visit. You will receive receipt and scheduling verification by email.

Protocol Number:			
Study title:			
Study Visit:			
Participant Name:		☐ Male ☐ Female	
BSLMC MRN or DOB:		Age (years):	
Allergies:			
Diagnosis:			
Attending MD:			
Coordinator Name:		Phone:	

☐	Admit to BSLMC CRC 20 Tower on (DATE)_____ as outpatient with a bed
☐	Obtain initial vital signs: HR, RR, BP, Temperature, and pulse oximetry
☐	Obtain Height and weight
☐	Physical Examination
☐	Obtain single 12-lead EKG per protocol study day
☐	Insert peripheral IV for serial sample collections
☐	β-hCG pregnancy test per protocol
☐	Obtain blood samples per protocol
☐	Obtain Urine Sample per protocol
☐	Diet: High Calorie/High Fat
☐	Remove PIV at the completion of the study serial sampling and discharge patient from CRC

_____
MD Printed Name

_____ _____
MD Signature Date & Time

Example Nursing Flowsheet:

CHI St. Luke's Health

Protocol Title
(H-)
Baylor St. Luke's Medical Center Clinical Research Center
Nursing Instructions/Flowsheet
Visit Number

Subject ID: _____ Date of visit: ____/_____/_____
Principal Investigator:

Coordinator:

Equipment/Supplies needed:

On day of Admission: Study coordinator escorts patient to BSLMC Main Admitting, completes hospital registration and escorts patient to Clinical Research Center (20T).

On admission (performed by nursing):			
Name:		Date of Birth/Age:	
Heart Rate (#/min):		Blood Pressure (mmHg):	
Respiratory rate (#/min)		Temperature (°F):	
Oxygen Saturation (%):		Height/Weight:	
Experiment Time (HH:MM)	**Clock Time (00:00)**	**Procedure(s)**	
Prior to 00:00	N/A	☐ Record vital sign and weight *Vital signs and pulse oximetry measurements should be completed prior to collection of blood samples and should be completed within 10 minutes prior to dosing. Subjects should be seated for at least 5 minutes prior to vital sign and pulse oximetry measurements.* ☐ PI will perform physical exam ☐ Start one PIV for serial sample collection ☐ Obtain Pre-dose blood sample per protocol	
00:00		☐ Administered first dose of study drug with a high fat and high-calorie meal and with water. Dose must be taken within 30 minutes of starting breakfast	
1:00 (±2 minutes)		☐ Post-dose blood Sample	
2:00 (±15 minutes)		☐ Post-dose blood Sample	
4: 00 (±15 minutes)		☐ Post-dose blood Sample	
6:00 (±30 minutes)		☐ Post-dose blood Sample	
8:00 (±30 minutes)		☐ Post-dose blood Sample	
12:00 (±2 hours)		☐ Post-dose blood Sample	
Prior to Discharge (performed by nursing):			
Heart Rate (#/min):		Blood Pressure (mmHg):	
Respiratory Rate (#/min):		Temperature (°F):	

_____ / _____ / _____
Print Name Signature Date
09/09/19_ZH

Study In-service

The study team must provide an in-service training before the first study visit at the CRC. The purpose of the study in-service is for the study team to provide hands-on training of study visit conduct to the CRC nurses. The study team must know their protocol and procedures, and be capable of explaining the important details of the study to the CRC staff. All details important to the conduct of the study at the CRC should be worked out prior to the in-service. The study in-service must be completed 1-3 weeks prior to study initiation at the CRC. If conducted too far in advance, a mini-refresher may be needed.

To arrange an in-service, contact the CRC at crc-support@bcm.edu

Prepare 10 copies of the following documents for the in-service:

- A one-page study summary
  - Physicians Orders
  - Nursing Orders/Flow sheets
  - Study team contact list, stating title and role, phone #, pager #, fax # and order of call for issues
  - Special instructions regarding patient care
  - Copies of information on any drugs that will be given (packet insert, info from the PDR, patient instruction materials)

Plan to conduct a 30-minute presentation covering:

- Study overview:
  Purpose
  Number of subjects to be seen in the CRC
  Patient population
  Study design
- A brief overview of the diagnosis
- Visit schedule
  When does enrollment start and when will it end?
  The length of visits
  Times the subjects will be seen (a.m. appointments for fasting labs?)
  Days required (do they tie in with MD availability?)
- Visit details
  Who attends visits?
  What other testing in the med center is coordinated around the CRC visit?
  Special equipment needed
  Procedures to be done at which visit (impacts on staffing and scheduling)
- Consent process
  Will study team consent patients in the CRC?
- Medications
  Indication (Experimental? Conventional?)
  Pharmacy preparation
  Route of delivery
  Placebo controlled?
  Premeds required?
  Side effects

Post administration management of side effects

- Phlebotomy
  Central line access required?
  Number and types of tubes to be drawn
- Special needs of the subjects
  Will they be traveling long distances? (Drive from suburbs, out of state travel)
  Special comfort measures (provide meal upon arrival, Emla cream on IV or port site prior to arrival, transport services)
  What other hospital areas will they be visiting before or after the CRC visit?
  Description of other procedures they may be having in case they ask nurses questions.
  Will the patients have physical limitations?
- Special services
  Will the study team reimburse patient parking?
  Will meals be provided?

Example In-service Information Sheet:

Clinical Research Center
CLINICAL TRIAL NURSING INFORMATION SHEET

H-#

NAME OF PROTOCOL:	
RESPONSIBLE INVESTIGATOR:	
RESEARCH NURSE/COORDINATOR:	
PHASE OF STUDY: I II III IV	
AIM OF STUDY:	
PATIENT POPULATION:	
DRUG INFORMATION:	
POTENTIAL SIDE EFFECTS:	
NURSING INTERVENTIONS REQUIRED:	
POINTS OF SPECIAL ATTENTION:	
PHARMACOKINETIC STUDIES:	
LAB REQUIREMENTS:	

Visit Scheduling Procedures

The below procedure is used for scheduling both inpatient and outpatient visits. Before scheduling a visit at the CRC, the study must have received IRB and BSLMC Administrative approval and the study team must have completed in-service training for the CRC nurses. For visit scheduling, study

teams provide the required documentation and the CRC schedules the encounter with the hospital. Reservations are made on a first come, first serve basis based on availability of space and nursing personnel. Study teams are encouraged to notify the CRC as early as possible of visits, preferably one week, but no later than two business days prior to the visit. **CRC nurses must have access to investigators and primary coordinator through phone numbers and/or pagers at all times.**

Documents needed for each CRC visit

In advance of each visit to the CRC, the study team must provide:

- CRC Call Center Registration Form for Clinical Research Visits
- Subject's signed research informed consent form
- Eligibility checklist, if applicable
- Signed physician's orders
- Signed pharmacy orders, if applicable

CRC Scheduling Process for studies at BSLMC, inpatient unit.

1. **Study team requests visit:** Please schedule visits as far in advance as possible, preferably at least one week. When ready to schedule a visit, the study team submits the completed CRC subject registration form and signed consent to crc-support@bcm.edu, along with signed physician's and pharmacy orders, as applicable. The CRC subject registration form is available on the BSLMC Research webpage under "Conducting Research at Baylor St. Luke's".
2. **CRC will verify documents are complete and current:** If yes, CRC will verify requested visit date and time are available. **CRC will schedule Epic visit through BSLMC Patient Access Services.**
3. **CRC will fax registration form, orders, and consent to BSLMC Patient Access Services (PAS).**
    a. The consent will be associated with the patient's Epic record, as required by the hospital for research participants. Consents may be uploaded later if consent obtained the day of the visit
    b. BSLMC Patient Access Services conducts insurance verification from information provided on registration form.
4. **CRC notifies BSLMC Research Office of the visit and confirms with study team**
    a. BSLMC Research Office will associate the encounter with the EPIC study account so visit charges fall to the study.
    b. CRC sends visit notification email to study team, CRC nurses and crc-support@bcm.edu
        i. Visit notification includes all study documents needed by CRC team for the visit.
5. **Study team verifies all information in visit notification is correct**
    a. In case of visit change/cancellation, study team notifies crc-support@bcm.edu immediately.

Outlook Calendar: all visits are placed in the shared calendar along with required documents for the assigned nurse to access.

CRC scheduling process for outpatient non-BSLMC studies:

- An email request is required with patient name, MRN (if available), DOB, Address, Phone, Race, and ethnicity.
- The following documents are needed at the time of scheduling:
  - Signed Consent
  - Signed order
  - Eligibility checklist as applicable
- CRC Nurse Manager will schedule visit as applicable in Epic and outlook calendar and will notify study team.

Externally-Based Study Equipment and Supplies (BSLMC inpatient visits)

Many studies provide equipment or supplies which may be utilized during CRC visits. Externally-based study equipment and/or supplies to be used in the CRC must follow the below procedures. All hospital equipment utilized for research must be cleaned and stored according to hospital policy.

a. The CRC should be notified in advance of any external equipment required for the study.

b. Equipment should be labeled with the study IRB number, Principal Investigator's name, and contact information.

c. All equipment which utilizes a power outlet must be cleared for use by BSLMC Clinical Engineering Department, as per hospital policy. The study team should contact BSLMC Clinical Engineering Department at 832-355-8585 to initiate this process.

d. Prior to transporting the equipment to BSLMC, externally-based study equipment must be cleaned by study staff according to manufacturer's instructions.

e. Immediately after cleaning, a clear or white clean plastic bag must be placed over the equipment, such that all parts of the equipment which may be expected to contact a patient or staff member during study procedures are covered.

f. Externally-based study equipment must be transported by study staff in a clean, bagged state to BSLMC. Clean, bagged equipment should be stored in a secure location at BSLMC if not used immediately to maintain cleanliness

g. Between subjects, and when equipment becomes soiled, externally-based equipment must be cleaned on site according to manufacturer's instructions.

h. External cleaning supplies must remain with study staff. Cleaning supplies cannot be stored at BSLMC.

i. Externally-based equipment awaiting transport out of BSLMC for cleaning and storage should be covered with a red bag in the same manner as above.

j. Soiled equipment should be removed from BSLMC or cleaned for storage by the end of the day.

Study supplies brought into BSLMC must follow the below procedures:

a. Single-use study supplies (such as butterfly needles, tubing, vacutainers) must be transported and stored in the original, unopened individual packaging. Sterile supplies should be handled according to hospital policy, except storage will occur off-site.

b. Single-use study supplies stored in bulk and which will not directly contact subjects (such as pipettes) must be transported and stored in a secure container which minimized potential exposure to dust, liquids and other contaminants.

c. Multi-use, non-patient contact study supplies (such as clipboards) should be cleaned with approved BSLMC cleanser if subject contact occurs and/or in case of contamination (such as blood spills) while on-site. Cleaning should occur according to institutional or manufacturer policy if off-site at time of subject contact or contamination.

Study Visit flow (BSLMC, inpatient study)

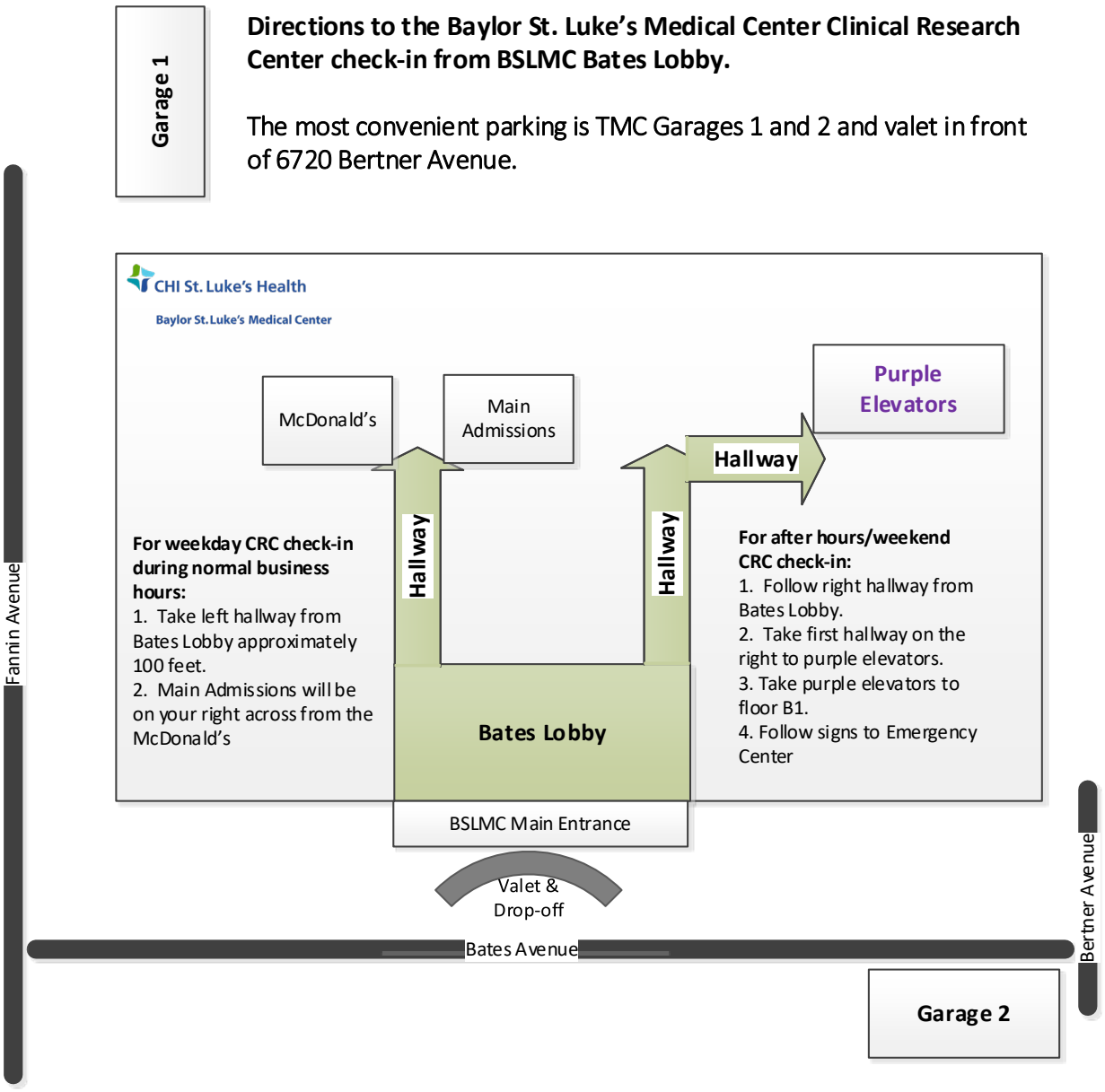
Patient Arrival

During normal business hours, patients should register in BSLMC Main Admissions (6720 Bertner, across from the McDonald's). Main Admissions is open 6AM-6PM, M-F. If Main Admissions is not open, patients may register in the emergency room (purple elevators to B1, follow signs).

Unless prior arrangements with CRC staff have been made, a study team member should meet patients arriving at BSLMC, accompany them through registration and escort them to the CRC (yellow elevators, 20th floor, room 2001).

Directions to the Baylor St. Luke's Medical Center Clinical Research Center check-in from BSLMC Bates Lobby.

The most convenient parking is TMC Garages 1 and 2 and valet in front of 6720 Bertner Avenue.



Adverse Event Management

Adverse events occurring on the CRC are documented in the patient's chart or on the research flowsheet. Investigators are notified of serious adverse events (SAE) immediately. Reporting of Serious Adverse Events (SAE) to sponsors and the IRB is the responsibility of the Principal Investigator.

After the Visit (BSLMC, inpatient study)

Medical Record Management

The CRC creates a patient chart for each visit that includes the research informed consent form, physician, pharmacy and nursing orders, eligibility checklist, registration form, and labs as applicable. The chart is stored in a secure location in CRC administration. In addition, the CRC sends records for research procedures to BSLMC medical records for association with the patient's medical record.

The study team is provided with copies of the completed orders/flowsheets upon completion of the study visit. This will be given to the study coordinator in attendance at the study visit.

Billing

The CRC utilizes BSLMC patient registration, accounting, and billing mechanisms, and maintains records of all research activity on the center. Study teams will receive a monthly invoice for CRC hourly charges, delimited by patient visit. The hourly charge will match that defined in the study financial agreement, created during the BSLMC Administrative Approval process. Study teams should follow invoice instructions to remit payment.