

Clinical Research Center

Investigator’s Manual

**Table of Contents**

*Ctrl+Click on the page number to jump to a page*

[General Information 4](#_Toc486346272)

[About the Center 4](#_Toc486346273)

[Resources and Services 4](#_Toc486346274)

[Directions and Parking 5](#_Toc486346275)

[Contact Information 5](#_Toc486346276)

[Hospital Services 6](#_Toc486346277)

[Pathology – Laboratory & Tissue Collection 6](#_Toc486346278)

[Research Pharmacy 6](#_Toc486346279)

[Meal Service 7](#_Toc486346280)

[Language & Translation Service 7](#_Toc486346281)

[Vascular Access Service 7](#_Toc486346282)

[Patient Transport Service 7](#_Toc486346283)

[Initiating a study at the CRC 8](#_Toc486346284)

[Requesting CRC Support 8](#_Toc486346285)

[Developing Orders and Flowsheets 8](#_Toc486346286)

[Study In-service 9](#_Toc486346287)

[Visit Scheduling Procedures 11](#_Toc486346288)

[Documents needed for each CRC visit 11](#_Toc486346289)

[CRC Scheduling Process 11](#_Toc486346290)

[Externally-Based Study Equipment and Supplies 12](#_Toc486346291)

[During the Visit 14](#_Toc486346292)

[Patient Arrival 14](#_Toc486346293)

[Adverse Event Management 14](#_Toc486346294)

[After the Visit 14](#_Toc486346295)

[Medical Record Management 14](#_Toc486346296)

[Billing 14](#_Toc486346297)

[Appendix I 15](#_Toc486346298)

[CRC Map 15](#_Toc486346299)

[Appendix II 16](#_Toc486346300)

[Sample Request for CRC Support 16](#_Toc486346301)

[Appendix III 17](#_Toc486346302)

[Clinical Research Center Study Initiation Workflow 17](#_Toc486346303)

[Appendix IV 18](#_Toc486346304)

[Example A – Physician Orders 18](#_Toc486346305)

[Example B – Nursing Orders/Flowsheet 19](#_Toc486346306)

[Appendix V 20](#_Toc486346307)

[Sample CRC Subject Registration Form 20](#_Toc486346308)

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# General Information

The Baylor St. Luke’s Medical Center (BSLMC) Clinical Research Center (CRC) is a hospital-based unit providing comprehensive infrastructure for clinical studies. Launched in June 2016, the Center provides inpatient and outpatient research services and resources for 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 Center

The BSLMC Clinical Research Center is located in the Texas Medical Center at Baylor St. Luke’s Medical Center (6720 Bertner Avenue), 20th floor inpatient unit. The Center provides the following resources and services for a flat hourly rate based on the study’s funding source. As of May 201Study requirements not listed below will be billed separately, with pricing determined by prior negotiation.

The CRC is staffed by dedicated acute care nurses specially trained to perform 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.

The BSLMC CRC charges a flat hourly rate based on the funding source of the study. The rate is $90/hour for industry-sponsored studies and $50/hour for non-industry-sponsored studies. The charge includes nursing time, room, and basic medical supplies and is the same for both inpatient and outpatient. All other procedures, tests, and supplies will incur a separate charge. Study teams should work with the BSLMC Research Office during the administrative review process to obtain hospital pricing for research procedures.

Study teams should contact the CRC as early in the study initiation process as possible. See below: [*Initiating a study at the CRC*](#_Initiating_a_study)*.*

## Resources and Services

* Two dedicated inpatient rooms
* 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
* Refrigerated centrifuge and -80oC freezer
* Access to BSLMC’s pathology lab
* Access to BSLMC’s dedicated research pharmacy

CRC nurses can conduct clinical procedures but may not conduct research procedures requiring specialized training such as administering questionnaires or consenting patients.

## Directions and Parking

Preprinted maps from the Bates lobby to main registration and the emergency room registration are available for distribution to patients. See [Appendix I](#_Appendix_I).

All investigators should budget for parking. The most convenient parking for patients is TMC Garages 1 and 2 and valet in front of 6720 Bertner Avenue. Please visit CHI St. Luke’s website <http://www.chistlukeshealth.org/parking> for parking information. Reimbursing patients for parking is the responsibility of the study team.

## Contact Information

**Baylor St. Luke’s Medical Center**

**Clinical Research Center**

713-798-6024

[BSLMC-CRC@bcm.edu](mailto:BSLMC-CRC@bcm.edu)

Physical Location:  
6720 Bertner Avenue

20th floor

Houston, Texas

Mailing Address:

Baylor St. Luke’s Medical Center

Clinical Research Center

Attn: Research Director

One Baylor Plaza, MS BCM122

Houston, TX 77030

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# 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](mailto: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

The 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

Study initiation at the CRC requires BSLMC administrative approval, which includes review and approval by the CRC. However, study teams are encouraged to involve the CRC as early as possible in study planning to ensure the CRC can meet study needs. Please see the study initiation work flow in [Appendix III](#_Appendix_III).

Study teams may contact the CRC at any time to initiate feasibility discussions. At a minimum, the study team should be able to provide the following information:

* Principal Investigator
* Primary coordinator or study contact
* Draft or finalized protocol
* Estimated number of subjects to visit the CRC
* Visit(s) and procedure(s) to be done at the CRC
* Anticipated/Target start date at CRC

The study team may contact the CRC via email ([BSLMC-CRC@bcm.edu](mailto:BSLMC-CRC@bcm.edu)) to request an initial feasibility assessment. The CRC will complete the assessment via email or in-person meeting, typically the latter.

The CRC will inform the study team if the initial assessment indicates the CRC can accommodate the study. If affirmative, the study team should proceed with submitting a BSLMC Administrative Application, including the CRC Service Request form (see sample form in [Appendix II](#_Appendix_II)).

Upon submission of the administrative application, a logistics 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.

Following the logistics meeting, the CRC administration will begin development of the study orders. See [*Developing Orders and Flowsheets*](#_Developing_Orders_and)*,* below. The CRC will develop the orders cooperatively with the study team. The final orders must be approved by the Principal Investigator. Once the orders have been finalized, the CRC will administratively approve the study on behalf of the CRC. Full administrative approval by BSLMC is required for the study to be approved for initiation at the hospital and the CRC.

## 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 done by the 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.

See [Appendix IV](#_Appendix_IV) for examples of physician and nursing orders.

## 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 [BSLMC-CRC@bcm.edu](mailto:BSLMC-CRC@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?

# 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 registration form (see [Appendix V](#_Appendix_V) for example)
    - Subject’s signed research informed consent form
    - Signed physician’s orders
    - Signed pharmacy orders, if applicable

## CRC Scheduling Process

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 [BSLMC-CRC@bcm.edu](mailto:BSLMC-CRC@bcm.edu), along with signed physician’s and pharmacy orders, as applicable. The CRC subject registration form is available on the [BSLMC Research webpage](http://www.chistlukeshealth.org/research) under “Conducting Research at Baylor St. Luke’s”. Signed physician’s orders and pharmacy orders may be sent later if needed - they are required prior to visit but not necessary for scheduling.
2. **CRC will verify documents are complete and current:** If yes, CRC will verify requested visit date and time are available. Currently, appointments are accepted for Tuesday-Thursday and two Sundays/month, 24 hours a day, subject to first-come, first-serve room availability. Please contact [BSLMC-CRC@bcm.edu](mailto:BSLMC-CRC@bcm.edu) if you would like to verify availability.
3. **CRC will schedule Epic visit through BSLMC Patient Access Services.**
4. **CRC will fax registration form, orders, and consent to BSLMC Patient Access Services (PAS).**
   1. 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
   2. BSLMC Patient Access Services conducts insurance verification from information provided on registration form.
5. **CRC notifies BSLMC Research Office of the visit and confirms with study team**
   1. BSLMC Research Office will associate the encounter with the EPIC study account so visit charges fall to the study.
   2. CRC sends visit notification email to study team, CRC nurses and [BSLMC-CRC@bcm.edu](mailto:BSLMC-CRC@bcm.edu)
      1. Visit notification includes all study documents needed by CRC team for the visit.
6. **Study team verifies all information in visit notification is correct**
   1. In case of visit change/cancellation, study team notifies [BSLMC-CRC@bcm.edu](mailto:BSLMC-CRC@bcm.edu) immediately.

## Externally-Based Study Equipment and Supplies

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.

1. The CRC should be notified in advance of any external equipment required for the study.
2. Equipment should be labeled with the study IRB number, Principal Investigator’s name, and contact information.
3. 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.
4. Prior to transporting the equipment to BSLMC, externally-based study equipment must be cleaned by study staff according to manufacturer’s instructions.
5. 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.
6. 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
7. Between subjects, and when equipment becomes soiled, externally-based equipment must be cleaned on site according to manufacturer’s instructions.
8. External cleaning supplies must remain with study staff. Cleaning supplies cannot be stored at BSLMC.
9. 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.
10. 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:

1. 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.
2. 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.
3. 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.

# During the Visit

## 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). See the map in [Appendix I.](#_Appendix_I)

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).

## 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

## 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.

# Appendix I

## CRC Map



# Appendix II

## Sample Request for CRC Support



#### **Request for Clinical Research Center Support**

**Instructions:** To request study support from the Baylor St. Luke’s Medical Center (BSLMC) Clinical Research Center (CRC), please complete this form and submit it to [BSLMC-CRC@bcm.edu](mailto:BSLMC-CRC@bcm.edu)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | | | |
| IRB of record #: |  | Principal Investigator: |  | |
| Study funding source: | ☐ Industry ☐ Non-industry | | | |
|  | | | | |
| Expected/requested CRC start date: |  | Estimated study duration (years/months/days): | |  |
| Anticipated total number of subjects to be seen at CRC: |  | Anticipated total # of CRC visits per subject: | |  |
| List each expected CRC visit with the anticipated day of the week, start time, and number of hours. | | | | |
|  | | | | |
|  | | | | |
| Completed | In the schedule of events attached to your administrative application, clearly indicate which procedures will be performed by CRC nurses and which will be performed by study staff. | | | |
| **Study supplies and equipment** | | | | |

|  |  |  |
| --- | --- | --- |
| Please list **all** supplies and equipment needed by the study during CRC visits. Add rows as needed. When relevant, provide detailed information, such as manufacturer and model number or tube color and volume.  Certain supplies and equipment are available from BSLMC, including: access to ice, a 4°C refrigerator, vital sign machine, weighing scale, refrigerated centrifuge, ultra-low freezer and basic medical supplies. The BSLMC Research Office will work with you to determine which items will be provided by the CRC and by the study team. | | |
|  | |  |
|  | |  |
|  | | |
| **REVIEWED/APPROVED BY PRINCIPAL INVESTIGATOR:** |  | |
|  | Signature/Date | |

# Appendix III

## Clinical Research Center Study Initiation Workflow



# Appendix IV

## Example A – Physician Orders

** 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@bcm.edu](mailto:BSLMC-CRC@bcm.edu) at least (3) business days before the visit. You will receive receipt and scheduling verification by email. For questions, please call the BSLMC Research Office at: 713-798-6024.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Protocol Number: | | H-123456 | | |
| Study title: | | MULTICENTER STUDY TO EVALUATE SAFETY OF NEW DRUG IN PATIENTS WITH TYPE 2 DIABETES | | |
| Study Visit: | | Stage 1, baseline visit 1 | | |
| Participant Name: | |  | | |
| Age (years): | |  | ☐ Male ☐ Female | |
| BSLMC MRN or DOB: | |  | Subject # |  |
| Allergies: | |  | | |
| Diagnosis: | | Research Volunteer and Type 2 Diabetes | | |
| Principal Investigator: | | John Lewis | Phone: |  |
| Attending MD: | | Sue Brown | Phone: |  |
| Coordinator Name: | | Sally Smith | Phone: | 713-555-0611 (m) |
| ☒ | Admit to BSLMC CRC 20 Tower on (DATE)\_\_\_\_\_\_\_\_\_\_\_\_\_ as outpatient with a bed | | | | |
| ☒ | Obtain vital signs: HR, RR, BP, & Temperature | | | | |
| ☒ | Check Urine Pregnancy Test for women of child-bearing potential before start of study | | | | |
| ☒ | Insert (2) IV catheters – one for infusion and one for blood draws | | | | |
| ☒ | Draw blood samples per protocol | | | | |
| ☒ | Administer drug infusion per protocol | | | | |
| ☒ | Discontinue IV at conclusion of study | | | | |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

MD Printed Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

MD Signature Date & Time

## Example B – Nursing Orders/Flowsheet

Instructions: This is a template for nursing flowsheet to be created for use by the nurses of the Clinical Research Center (CRC). Please modify as necessary to suit your study.

**Subject #\_\_\_\_\_\_\_\_, Study Visit\_\_\_\_\_\_\_\_\_\_, Study Arm\_\_\_\_\_\_\_\_\_\_\_\_, Date of Visit\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Principal Investigator | | |  | | | | | | | |
| Study Coordinator | | |  | | | | | | | |
| Equipment needed: | | |  | | | | | | | |
| Supplies needed: | | |  | | | | | | | |
| **On admission (performed by nursing):** | | | | | | | | | | |
| Name: | | | |  | | Date of Birth/Age: | | |  | |
| Height (ft’ in ‘’): | | | |  | | Weight (lbs): | | |  | |
| Heart Rate (#/min): | | | |  | | Blood Pressure (mmHg): | | |  | |
| Urine Pregnancy Test: | | | | ☐ N/A (Male) ☐ Negative ☐ Positive (inform investigators) | | | | | | |
| **Experiment Time** | | **Clock Time** | | | **Procedure(s)** | | | | |
| **EXAMPLE** | Prior to 0:00 | N/A | | | * Record vitals, height, weight, blood glucose, blood ketones, and UPT results. * Apply blood pressure cuff - volunteer must be relaxed, no noise, or chatter * Place 20 gauge IV in antecubital fossa of preferred arm. Saline lock IV. * Obtain 10 mL of blood and transfer **equally to** **2 tubes**. Place on ice and saline lock IV.   ☐Get **IV Infusion #1** syringe ready. | | | | |
| **EXAMPLE** | 2:30 | ENTER BY NURSE | | | |  | | --- | | Inject **Priming IV INJ** (**13C5-**Orn, NaH13CO3, 13C6-Arg, 2H2-Cit, 15N2-Orn, and 2H5-Phe**)** with filter into catheter, then flush with saline. |  * Start **IV Infusion #1** (13C6-Arg, 2H2-Cit, 15N2-Orn, and 2H5-Phe) at **8 mL/h** immediately | | | | |
| ADD COLUMNS AND ROWS AS NEEDED | |  | | | ☐ Describe | | | | |
| **Prior to Discharge (performed by nursing):** | | | | | | | | | | |
| Temperature (°F) | | |  | | | | Blood Pressure (mmHg): |  | | |
| Heart Rate (#/min): | | |  | | | | Respiratory Rate: |  | | |
| Heart Rate (#/min): | | |  | | | | Blood Pressure (mmHg) |  | | |

# Appendix V

## Sample CRC Subject Registration Form