##  Clinical Research Center

## 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

**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 10-30-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?