Guidelines for Using the Clinical Research Unit

The Clinical Research Unit (CRU) is available for use by Upstate faculty for IRB-approved clinical research studies. The Medical Director and the Nurse Manager will review each request to use the CRU to ensure appropriate staffing and subject safety. Studies may not commence until final IRB approval has been granted and the following procedures have been completed:

**Procedure:**
Complete and submit the CRU Questionnaire/Application on IRBNet.org. The questionnaire, located in IRBNNet, can be uploaded and completed with the initial New Study Package. The study submission is shared (read only) with the CRU Administrator on IRBNet.

If there are questions or concerns regarding the feasibility of conducting the study on the CRU, it will be helpful to contact the CRU Nurse Manager early in the process. The protocol should be shared with the CRU prior to formal submission on IRBNet. The CRU will review the new project and the CRU Questionnaire for expectation of services that are needed to perform study visits. The assigned IRB number will also be the reference number for the CRU. After your project is approved by the IRB and the CRU, contact the CRU Nurse Manager to schedule an in-service with the CRU staff. The CRU staff will have reviewed the approved IRB project documents prior to the in-service. If there are any questions or concerns regarding the questionnaire, contact the CRU Medical Director or Nurse Manager at 315-464-5721.

Please refer to “Welcome Packet for the Clinical Research Associate (CRA)” on CRU website.

The Medical Director, Nurse Manager, and CRU staff will review the CRU questionnaire, application and the study protocol to assess equipment and supply needs, nursing competency, patient acuity and monitoring needs; and will either approve the use of the CRU, disapprove the use of the CRU, or suggest modifications to the procedures proposed to be performed at the CRU. This decision will be communicated to the Principal Investigator (PI) through IRB Net. Depending upon services requested, additional training for CRU staff may be requested.

**Charges/ Budget Information:**
If it is anticipated that the CRU is going to be used for a study, the PI or Clinical Research Assistant (CRA) will contact the Nurse Manager of the CRU when creating the budget. The anticipated CRU fees will be sent to the Clinical Trials Office to ensure the study budget is sufficient to cover the costs. This step should occur before the PI approves the budget.

The Nurse Manager will meet with the PI and/or CRA to review the protocol and establish a visit level for each visit on the protocol utilizing the Charge Leveling Form. The visit level charges may vary during the study according to the protocol and services provided at each visit. The CRU offers additional services of a Nurse Practitioner, and/or CRA assistance. The Nurse Manager can assist you with how these services can be provided and their associated charges.

The fee schedule is as follows:
- Level 1 - $15.00  
  CRA: $50.00/hr.
- Level 2 - $25.00  
  NP: $60.00/hr.
- Level 3 - $50.00
Level 4 - $75.00  
Level 5 - $100.00

After each visit, a CRU staff member will post the appropriate visit level into EPIC as a hospital charge, using the IRB study number and de-identifier subject #. CRU charges are handled differently than normal EPIC charges. The designated CRA will receive a monthly statement for each study from the Finance Department.

The PI or CRA will need to contact the Nurse Manager if there are any changes to the protocol. These charges may result in charges to visit charges. If the study requires the use of Clinical Pathology for laboratory tests, a Research Request Form (F90093) is filled out by the CRA and submitted to pathlab@upstate.edu.

Orders:  
Written orders are required for each study visit on a CRU Physicians Orders template Form F82767. The orders should include the study’s IRB number, visit number, and charge to be entered, along with all tasks to be completed by CRU staff at the visit per protocol requirements. A Physician Order guideline will be provided to serve as a guide for completing order-sets for study visits. Visit orders should be finalized after the in-service and sent to Nurse Manager as “final” orders.

CRU Staff Education:  
The PI or designated study team member will be requested to conduct an educational in-service of the protocol, written orders, and any specialized equipment for the CRU staff before initiation of the study at the CRU. This is also the time to instruct the CRU staff on study specific procedures, devices, and use of other study specific equipment required for the project. Delegation logs will be signed by staff who have been trained and will be performing specific tasks.

The Nurse Manager will assist you to coordinate a day/time for the study team, lab technician, and staff nurses to attend. The in-services will take place at the IHP in a designated conference room reserved by the nurse manager.