

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. The questionnaire, on-line located in the IRBNet Library, can be uploaded with the initial New Study Package. Ensure that the study is shared (read only) with the CRU Administrator on IRBNet. If there are any questions or concerns regarding the questionnaire, contact the CRU Medical Director or Nurse Manager at (315.464.5721).

The Medical Director, Nurse Manager, and CRU staff will review the 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 of the study. 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. The visit level charges may vary during the study according to the protocol and services provided at each visit. The CRU also has available experienced research Physician Assistant (PA) and CRA's to assist with IRB submission and protocol implementation.

The fee schedule is as follows:

Level 1 - \$15.00	CRA: \$50.00/hr.
Level 2 - \$25.00	PA: \$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. 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 changes 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 Physician Order 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's order guide can be provided to serve as a template for these 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. 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 in the CRU conference room.