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**Value(s):** *Safety, Excellence, Efficiency*

**Policy Number:** **CRU U-01**

**Approved by:** Director of Nursing, Ambulatory  
Services & CRU Medical Director

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## **Guidelines for Using the Clinical Research Unit**

### **Policy:**

The Clinical Research Unit (CRU) may be used by Upstate faculty for 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 the IRBNet. The questionnaire, 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 (315.464.9000 or 315.464.5721).

The Medical Director, Nurse Manager, and CRU staff will review the questionnaire 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 PI through IRBNet.

### **Charges/ Budget Information:**

If it is anticipated that the CRU is going to be used for a study, the Principal Investigator (PI) or study coordinator will contact the Nurse Manager of the CRU (315.464.5721) when creating the budget. This step should occur before the PI signs the approval of the budget.

The Nurse Manager will meet with the PI and/or study coordinator to review the protocol and establish a visit level for each visit on the protocol. The visit levels may vary according to the protocol and services provided at each visit. A charge will be calculated for use of the room when research personnel use the space, but don't utilize the CRU staff. The CRU fees will be sent to the Clinical Trials Office to ensure the budget is sufficient to cover the costs of the study.

Based on the protocol procedures and Leveling Criteria Form, CRU visit fees will be determined. The Leveling Form is a tool used to establish charges for the services provided by hospital personnel and/or room use at the CRU.

The fee schedule is as follows:

- Level 1 - \$15.00
- Level 2 - \$25.00
- Level 3 - \$50.00
- Level 4 - \$75.00
- Level 5 - \$100.00.

The Fiscal Service Department (FSD) will apply any discounted rates assigned to the CRU. The study will be invoiced at the discounted rates. These discounts will be provided to all federally funded, foundation, industry, or government sponsored trials.

A CRU staff member will post this level into CAIS as a hospital charge. This charge will be displayed on every study coordinator's Research Billing report. Research subjects must be flagged to the appropriate study in CAIS using the IRB number in order for the charges to appear on the study coordinator's Research Billing report. Note that for discounted studies, the charges will look like full hospital charges. The discount is completed in the FSD, not on the CAIS system. The invoice should have the appropriate discounted charge applied.

The PI or coordinator will need to contact the Nurse Manager if there are any changes to the protocol to update any visit charge changes.

**Orders:**

Written orders are required for each visit of a study. The orders should include the study number (IRB number), visit number, and charge to be entered, along with all tasks to be completed by CRU staff at visit per protocol requirements.

**CRU Staff Education:**

The PI or designated study team member will 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.

**Originating Department: Clinical Research Unit**

**Contributing Department(s): Clinical Trials Office**

**References: CM I-04 Investigational Drugs, Administrative Policy R-08 Research Support from University Hospital**