



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 IRBNet, can be uploaded and completed with the initial New Study Package. The study submission is shared (read only) with the CRU Nurse Manager and Medical Director on IRBNet. If there are questions or concerns regarding the feasibility of conducting the study in the CRU, it will be helpful to contact the CRU Nurse Manager early in the process. 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 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, 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.

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) can contact the Nurse Manager with any budget questions. The anticipated CRU fees should 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 can meet with the PI and/or CRA to review the protocol and establish a charge level for each study visit, 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 Leveling & Fee Criteria can be viewed here: [CRU Leveling & Fee Criteria](#)

At each visit, a CRU staff member will post the appropriate visit charge level into EPIC attached to the CRU visit encounter. The designated CRA will be able to work within EPIC to view and monitor these charges.

The PI or CRA will need to contact the Nurse Manager if there are any changes to the protocol.

These charges may result in changes 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.

Refer to policy R-13 Guidelines for Hospital Research Billing, Documentation and Registration.

Orders:

Written orders are required for each study visit on a CRU Physicians Orders template ([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 uploaded into the Clinical Research Unit Team, in the appropriate locked channel.

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 can take place at IHP in a designated conference room reserved by the nurse manager or online via Zoom, Webex or Teams.

Thank you.