Clinical Research Unit (CRU)
At the Institute for Human Performance (IHP)

Welcome Packet for the Clinical Research Associates (CRA)

Who’s Who?

**Medical Director:** Ruth S. Weinstock, MD, PhD

**Nurse Manager:** Teresa Koulouris, MSN, RN, CCRP

**Registered Nurses:**
- Sandra Compton, RN, CCRP
- Julianne Francey, BA, RN, CCRP
- Kimberly Hope, BSN, RN, CCRP
- Sandra Hayles, MSN, RN, NP
- Amy King, BSN, RN, CCRP
- Katherine McPhee, MSN, RN, NP-C
- Rebekah Wheeler, RN

**Research Support Specialist:** Susan Hubbell, BS

**CRU Nurse Practitioner:** Sheri Stone, MSN, RN, NP-C

Contact Information
Medical Director: 315-464-5740
Nurse Manager: 315-464-5721
Research Laboratory Staff: 315-464-9004
Nursing Station: 315-464-9003 or -9004
Fax: 315-464-9002
Address: 505 Irving Avenue, Room 1223, Syracuse, NY 13210

Getting Started
Thank you for choosing to conduct your clinical research on the CRU. When you submit your project for IRB approval, please share your package with CRU Administrator on [IRBNET.org](https://www.upstate.edu/cru/). Be sure you have completed the CRU questionnaire on IRBNet, CRU services are found on [https://www.upstate.edu/cru/](https://www.upstate.edu/cru/). If there are questions of 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.

In-Service / Delegation Logs
The in-service with the CRU staff offers an opportunity to get to meet our staff. CRU staff will review the protocol, source documents, laboratory manual and pharmacy guidelines. We will
The Nurse Manager can further discuss and clarify the physician’s visit orders at the in-service. 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. Visit orders should be finalized after the in-service and sent to Nurse Manager as “final” orders.

Written Orders
Study-specific orders should be typed and stored on the CRU shared-drive using the required Physician’s Orders template F82767, the Clinical Research Physician’s Orders form. Orders for each visit are created and saved separately in a folder labeled with the IRB number in the CRU shared-drive. Changes in procedures or protocols necessitate a change in the physician’s orders when changes or clarifications to the order-set are needed, please notify the CRU Nurse Manager. Only changes that have been IRB approved can be implemented. Orders should be e-mailed to the Nurse Manager in a PDF format. *Please see the CRU Physician’s Orders Guide; it is a helpful tool for writing your order-sets and associated source documents.

Laboratory Services
Outside Laboratories:
The project sponsor or P.I. specifies which outside laboratory will be receiving the specimen(s) and will supply laboratory kits for each visit. These kits are stored in the CRU Laboratory. The CRU staff will monitor expiration dates for laboratory materials. The nursing staff will draw the specimen or collect the urine. The CRU staff process the specimens, prepare for shipping and will arrange pick-up by the courier when needed (i.e. UPS, Quest, and FedEx). According to the protocol the specimen may be ambient, refrigerated, or frozen. It may be shipped that day or stored in the -80 or -20 freezer or refrigerated to be shipped in batches. Shipping arrangements should be arranged in advance with the Nurse Manager and laboratory technician. Some laboratories do not accept specimens on holidays or Saturdays, so scheduling patient visits accordingly is important.

Internal Laboratories:
Specimens that will be analyzed by University Hospital (UH) Clinical Pathology are couriered to UH (STAT pick-up by the Upstate Courier Service, dispatch number 315-464-5227). The supervisor contact is David Latour. If Clinical Pathology is used, a “control account” is set up for billing purposes, and a down-time requisition is used with a research acronym for billing purposes. We ask that you specify where lab results should be sent when you set-up an account with Clinical Pathology. If it is appropriate (approved) for results to be placed in EPIC, they will need to be scanned into media. Results obtained for research are not automatically placed into EPIC. All research laboratory specimens can receive the discounted research rate (contact: Mike Franz 315-464-4462).

Scheduling Subjects
Study participants can be scheduled in the CRUVISIT GroupWise calendar (through proxy access for you by the CRU Nurse Manager) to schedule study visits, and to add notes and reminders associated with the study visit. Once you accept proxy rights for scheduling subject visits on the GroupWise CRUVISIT calendar, the following information is required in the following order for each scheduled visit: IRB#, Visit #, Subject’s name, DOB, Subject # The Nurse Manager can help you with this scheduling procedure.
If week-end or evening visits are required, (or canceled) please notify the Nurse Manager to assure adequate staffing schedule and operational needs. The Nurse Manager will notify the Parking Office and Security with the request for extended or week-end hours.

**CRU Level of Service Charges (LOS)**
Each visit is assigned a charge based on the length and type of service using the CRU Charge Leveling Form, found on the website [https://www.upstate.edu/cru/](https://www.upstate.edu/cru/). This tool standardizes the CRU charge for each visit. The charge with (IRB number, subject number) is entered into EPIC where accounts are billed to the CRA monthly. This ensures that the subject’s insurance is not billed inappropriately. These charges should be reviewed prior to finalizing the project budget, in order to make sure there is adequate funding.

Other charges that need to be paid by the study may include specific required medications or equipment such as anesthetic agents (e.g. lidocaine) or supplies such as biopsy needles. If the nursing staff is required to order these items, they will be charged to the project grant (project and award number required). General care items such as venipuncture supplies are included in your CRU fee unless higher than average phlebotomy supplies are needed. In this case, excess supplies should be covered by the study budget. If you have questions concerning additional charges, please contact the CRU Nurse Manager.

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.

**Parking**
There are 2 options for participant parking: the Madison-Irving garage and/or the IHP Garage. Fees for Madison-Irving are lower, but it is less convenient in inclement weather and for participants who have difficulty walking. To arrange parking at Madison-Irving Garage, contact Republic Parking (315-476-1811). They will set up an account and bill you monthly. You will need to create stickers or vouchers for participants to give to the attendant for tracking fees. For parking in the IHP Garage, stickers may be purchased through the Parking Office at UH (4-4801). Stickers come in different dollar amounts and are placed on the parking ticket to cover the cost, depending on how long the participant’s vehicle was parked. Alternatively, an online validation system can be used. Contact the Parking Office (4-4801) for details. Rates are listed on the Upstate website: [https://www.upstate.edu/parking/](https://www.upstate.edu/parking/)

**Drug & Equipment Accountability**
For many studies, the study medication is shipped from the sponsor, and dispensed through Research Pharmacy. Drugs can only be stored and dispensed at the CRU if an exemption is requested and approved by Pharmacy (contact: Melissa Reale, 315-464-4205). The study coordinator is responsible for ordering medication and for drug accountability. The CRU has a secure, double locked area for storing study medications and/or supplies. Most study-specific equipment can also be securely stored at the CRU (please discuss these needs with the Nurse Manager in advance).

**Payment to Subjects**
If applicable per study, this is the responsibility of the study staff.
Sponsor Site Visit
Please notify the Nurse Manager in advance when you have an upcoming site visit. The CRU staff can be available to conduct a tour and provide any other assistance.

Monitor Visits
A quiet and private room can be available for study monitor visits. If you expect a study monitor visit, please reserve a room in advance. You can call the CRU Nurse Manager, or CRU nursing station to assist you with reserving a designated room. After the visit, the study coordinator can communicate to the Nurse Manager any queries that involve CRU staff. In addition, you can communicate any suggestions for improvements or changes that need to occur.

Communication
Good communication (telephone, email, in person) is essential for the successful implementation of research protocols. The CRU Nurse Manager is available to help you if you have any questions or concerns. Please share pertinent study-specific details with the nursing staff prior to study visits, and during a subject visit, as necessary, to help the visit run smoothly and for the protocols to be followed accurately. For CRU specific questions, please feel free to call the CRU Nurse Manager or Medical Director of the CRU.

Thank you.