

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

Welcome Packet for Coordinators

Who's Who?

Medical Director:	Ruth Weinstock, MD, PhD
Nurse Manager:	Teresa Koulouris, MS, CNS, RN, CCRP
Registered Nurses:	Sandra Compton, RN, CCRP Julianne Francey, BA, RN, CCRP Kimberly Hope, BS, RN, CCRP Sandra Hayles, MS, NP, RN Amy King, BS, RN, CCRP Katherine McPhee, MS, NP, RN Melissa Rogers, BS, RN, CCRP Rebekah Wheeler, RN
Research Support Specialist:	Susan Hubbell, BS
Physician Assistant:	Michelle Taylor, RPA-C, MS, MT (ASCP)

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 with the CRU. When you submit your project for IRB approval, please share your package with CRU Administrator on IRBnet. The assigned IRB number will also be the reference number for the CRU.

Follow the link below for helpful information for new coordinators and/or investigators conducting clinical research. Robin Cerro from Research Administration, is available to meet with you for an "initiation" visit and to review reporting requirements as well as procedures that need to be followed when performing research on human subjects.

http://www.upstate.edu/researchadmin/document/initiation_visit_flyer.pdf

Initial Meeting/ In-Service

After your project is approved by the IRB, contact the CRU Nurse Manager to schedule an in-service with the CRU staff. Your study protocol is available on IRBNET.org, and the nurses will review it prior to the in-service. The initial meeting with the CRU staff offers an opportunity to get to meet our staff, to review the protocol, source documents, and laboratory manual to discuss and clarify the physician's orders. This is also the time to instruct the CRU staff on study specific procedures, devices, and other study specific equipment required for the project.

Written Orders

Study-specific orders can 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 protocol usually necessitate a change in the physician's orders. Changes or clarifications to the order-set can be made easily, however, please notify the CRU Nurse Manager when this is done to ensure protocol compliance. Orders can be e-mailed to the Nurse Manager saved 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 prior to the in-service for clarity and prior to implementing the study visits.

Laboratory Services

Outside Laboratories:

The sponsor generally specifies which outside laboratory will be receiving the specimen and will supply kits for each visit. The kits are stored in the CRU Laboratory. The CRU staff will help in organizing lab kits and supplies, along with monitoring expiration dates for laboratory materials. The nursing staff will draw the specimen or collect the urine. The CRU staff processes the specimens for shipping and will arrange pick-up by the courier (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 from the CRU in advance with the CRU staff and/or Nurse Manager. 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 as a STAT pick-up by the Upstate Courier Service, dispatch number 315-464-5227. The supervisor contact is David Latour. If Clinical Pathology is preferred for labs, 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. i.e. faxed to name of physician. Results obtained for research can be scanned into EPIC if approved. All research laboratory specimens 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, 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 demonstrate how to insert the visits into the GroupWise calendar.

If week-end or evening visits are required, (or canceled) please notify Nurse Manager for adequate staff scheduling and operational needs. Nurse Manager will notify 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. 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 to 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 blood draw supplies are needed. In this case, excess supplies should be covered by the state budget. If you have questions concerning which supplies are associated with an additional charge, please contact the CRU Nurse Manager.

The CRU offers additional services of a Physician Assistant, 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:

<http://www.upstate.edu/parking/visitor.php>

Drug & Equipment Accountability

For many studies, the study medication is shipped from the sponsor, and dispensed through 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 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 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, and/or in person) is essential for the 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!