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 Weinstock, MD, PhD

Administrator: Beth Wells, MSN, RN

***Nurse Manager**:* Kimberly Hope, BSN, RN, CCRP

***Registered Nurses**:* Sandra Compton, BSN, RN, CCRP
Julianne Francey, BA, RN, CCRP
Rebekah Wheeler, BSN, RN-BC, CCRP
Dawn Roder, BSN, RN
Victoria Rigley, BSN, RN-BC
Danika Tarr, RN-BC

***Senior Research Support Specialist**:* Erica Burgeson, BS

***CRU Nurse Practitioner**:* Katherine McPhee, MSN, RN, NP-C

Contact Information

Medical Director: (315) 464-5740
Nurse Manager: (315) 464-5721
Research Support Specialist: (315) 464-9037
CRU Nurse Practitioner (315) 464-9005
Nurses 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 (read-only) with the CRU nurse manager (Kim Hope) and medical director (Dr. Ruth Weinstock) on IRBNET.org, We 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 you will be added to the Microsoft Team "Clinical Research Unit Department Team", if you have not been already. At this point you will be asked to upload your study protocol, blank consent form, Manuals of Procedures (MOP-when available) or other training documents you feel are pertinent in your locked "channel". The CRU staff will review the approved IRB project documents prior to the in-service. When ready, please contact the CRU Nurse Manager to schedule an in-service.

In-Service / Delegations logs

The in-service with the CRU staff offers an opportunity to get to meet our staff, to review the protocol, source documents, laboratory manual and pharmacy guidelines. We will further discuss and clarify the physician's orders at the in-service. This is also the time to instruct the CRU staff on study specific procedures, devices, and other study specific equipment required for the project. Delegation logs will be signed by staff after the in-service allowing clear expectations by staff who will be performing duties assigned on the delegation log. In-services can be scheduled in person or via Zoom, Webex, or Teams.

Written Orders

Study-specific orders can be typed on the required Physician's Orders template F82767, the Clinical Research Physician's Orders form. Orders for each visit should be created and saved separately in a folder labeled with the IRB number in the CRU Microsoft Teams in your departments channel. 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 and updated in Teams, however, please notify the CRU Nurse Manager when this is done to ensure protocol compliance. *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 can be 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 or 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 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 Clinical Pathology are couriered as "ROUTINE", unless specifically ordered as STAT pick-up, by the Upstate Courier Service, dispatch number 315-464-5227. The supervisor contact is Ginnie Hudson. If Clinical Pathology is preferred for labs, they may be ordered in Epic (Lab collect). The patient will be registered for their visit and the lab orders will be released from the research encounter. Those with access to WQ 3783 can either designate labs to be paid by patients' insurance or via study funds. All research laboratory specimens receive the discounted research rate (contact: Mike Franz 315-464-4462).

Scheduling Subjects

Study participants can be scheduled in Epic by the CRA. When scheduling the following information is required to be placed in the appointment notes: department acronym (ie Neuro, Endo, Ortho, Peds Pulm, etc..), IRB#, Visit #, Subject #, and any other important information for the visit (i.e. Consent needed).
See Tip Sheet CRU Scheduling Workflow

*If weekend 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 weekend hours.

CRU Level of Service Charges (LOS)

Using the CRU Charge Leveling Form, each visit is assigned a charge level based on its length and type of services needed. This tool standardizes the CRU charges for each visit. The charge level is entered into their

EPIC visit encounter by CRU staff. 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, equipment or supplies (i.e. lumbar puncture kits, pre-medications). If necessary, the CRA we be required to order these items and they will be charged to the study or 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 study 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 Nurse Practitioner. 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 Laz Parking (315-476-1811). They will set up an account and bill you monthly. Or for parking in the IHP Garage call the Parking Office at UH (4-4801). More information is 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 help conduct a tour or for 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 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, Teams, 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.

Updated 4/25/24.