Clinical Research Unit

Institute for Human Performance
505 Irving Ave
First floor -Room1223
464-9000 or 9003
History

- Early 1950’s
  - Upstate and Duke University were the first NIH funded clinical research units.

- Lost NIH funding in 1991, due to the lack of investigators and clinical research studies to continue the program.

- With the loss of the NIH grant, SUNY Upstate continued the CRU on a smaller scale with state funding.
History:

• Clinical research has been part of the Upstate Medical University mission before the first cornerstone was laid. Prior to opening the new hospital in 1965, research was conducted at The Good Shepard Hospital on Marshall Street.

• Research began on the 8th floor at Upstate in 1965 and remained there until the move to IHP in 2003.
Function

The CRU is a multi disciplinary unit serving a variety of departments and specialties to conduct both industry and investigator sponsored research protocols. The CRU provides support for conducting approved outpatient clinical research. Principal Investigators provide research coordinators for patient recruitment, data management and Case Report Form (CRF) completion. CRU staff will schedule patients, provide support, labs, EKGs, and a number of detailed study related tasks.

There are currently 75 active protocols being conducted on the CRU. Active protocols are ongoing, those open to enrollment, or ongoing subject visits. On a weekly to monthly timeframe, there are about 20 protocols with frequent patient visits. In addition, one to four new protocols are being reviewed and approved for CRU use each month.

Non-research patients are admitted for specialized studies that utilize the expertise of the CRU staff. This would be at times that do not interfere with research.
Who’s who

• Dr. Jeremy Shefner, M.D., PhD.
  • Professor and Chair of Neurology
  • Director of Translational Research

• Director: Arnold M. Moses, M.D., FACE
  • Distinguished Service Professor of Medicine

• Cheryl Dunseath RN BSN
  • Clinical Manager

• Irene Knowles
  • Administrative assistant
Contacts

- Administrative Office, Irene Knowles
  - 4-9000  Fax 4-9011

- Cheryl Dunseath RN BSN Clinical Manager
  - 4-5721 fax:4-5722

- Nurses Station
  - 4-9003 or 4-9004

- CRU Fax
  - 4-9002
Staffing

- The staff of the CRU is highly experienced, and most are certified in clinical research. The nursing staff often assists new coordinators in their role.

- There are also many grant supported coordinators who are a good resource for investigators and staff.

- A laboratory technician processes packaging and shipping of specimens.

Pamela Suddaby RNBSCCRP
Gail Tyndall RNBSCCRP, Beverly Lusky RN
Teresa Koulouris RN, Steve Ecker RN
Research lab technician: Erin Dwyer
Facilities

- The Clinical Research Unit (CRU), is an Upstate Medical University supported specialized unit dedicated to conducting clinical research funded by government, industry or foundations.

- The CRU contains a nurses station, 9 rooms, a room for meeting with sponsors, and 2 labs for processing specimens.

- DXA and MRI services as well as other meeting areas are adjacent on the first floor.

- Located on the first floor of the Institute for Human Performance (IHP), which offers barrier free access.

- Parking and handicap parking are directly behind the building.

- The unit contains a pantry, stretcher beds, O₂, defibrillator, oximetry, glucometer, refrigerated centrifuge, -80 and -20 degree freezer, two laboratories, and EKG machine, office space for monitors, and analog/modem for transmitting data.

- The CRU has a secure, locked area for storing study medications and supplies.
Description

- The unit has 9 private patient rooms and is staffed by 5 RNs.

- The CRU is a discrete unit, separate from inpatient care facility.

- In addition to the patient rooms, the unit is equipped with handicapped accessible restrooms, a kitchen, medication room, testing areas, two labs and conference space.

- The CRU is open from 0700-1630 Monday through Friday. Under special circumstances, arrangements can be made for extended time.
Eligibility for use

Any member of the SUNY faculty may utilize the resources of the CRU for implementation of projects approved by the Institutional Review Board for the Protection of Human Subjects (IRB) and the CRU Director.

The Principle Investigator must be a physician or Ph.D. If an investigator is a Ph.D or other scientist, a MD with staff privileges at Upstate may collaborate to write patient orders and monitoring clinical issues.
Types of investigator initiated research

There are about 22 investigators using the CRU at this time. The highest volume comes from:

- **Endocrinology** - diabetes, pituitary, and metabolic bone disorders.
- **Neurology** - ALS, multiple sclerosis, seizures, and parkinson’s disease.
- **Gastroenterology** - hepatitis C and crohn’s Disease.
- **Psychiatry** - schizophrenia, and attention deficit disorder.
- **Oncology** - ovarian and peritoneal cancer.
- **Radiology studies** - MRI, mammography and PET scans in breast cancer.
Some areas of expertise

- Amyotropic Lateral Sclerosis
- Diabetes Mellitus
- Glucose Modulation studies
- Growth Hormone Deficiency
- Hepatitis C
- Multiple Sclerosis
- Osteoporosis
- Paget's disease
**Basic information on use of the CRU**

- Once a protocol is approved by the IRB, a CRU application must be completed.

- After review by the CRU director and nurses, the PI is notified and the protocol is assigned a CRU number and the PI educates the nursing staff on the project details prior to patient enrollment.

- The nurses and administrator can be very helpful in getting this process started.
MD orders

- Using the protocol as the guide, preprinted orders are written.

- Every detail remains constant. Every visit can have a specific set of orders.

- Each visit is given an intensity rating called leveling criteria that standardizes the CRU charge for each visit.
Lab processing

• The protocol dictates what data (specimens) are collected.

• Sponsor supplies kits for each visit.

• The kits are organized and stored and in the CRU
Communication

• Good Research involves a great deal of communication between all of the team members.

• The CRU provides a cooperative, collegiate environment for successful clinical research.

• As always, the research office will answer specific research (IRB) and budget questions.

• For CRU specific questions, call extension 4-9003, or 5721 to speak with a nurse.
Monitor site visit

- Quiet, private areas are available for monitors. After the visit, the coordinator can communicate to the nurses, the queries that involve them. In addition, they can communicate improvements or changes that need to occur.
Site visit

• Sponsor of a protocol will make periodic site visits.

• The sponsor will be interested in the staff's experience and ability to successfully conduct the study. The sponsor will scrutinize the facility to ensure that it meet the needs of the study.
Goals

- Increase technology in all aspects of research: recruitment, randomization of treatment groups, data collection and documentation.

- Reach outside the confines of the CRU to assist with clinical research throughout Upstate Medical University.
**Conclusion**

- Our goals in clinical research are to conduct quality clinical research with reliability of results, compliance with standards of good practice, and protection of study participants.

- Expand and adapt to the changing environment in clinical research.