

Clinical Research Unit (CRU) Inpatient Services, NMH

CRU Inpatient Services leverage the expertise of research nurses in a highly controlled setting to carry out complex protocols. The CRU Nurse serves as the primary nurse, carrying out research and clinical activities; the treating investigator serves as the Attending Physician. Most participants are admitted to Feinberg 10 East. Studies whose participants are healthy, medically stable, and not in need of highly specialized clinical care benefit most from these services. GOALS

- Support clinical research requiring an inpatient research setting for >24 hours.
- Provide a highly controlled research environment for healthy or medically stable research participants.
- Ensure protocol and regulatory compliance:
 - o Clinical research nurses are trained and experienced in rigorously following research protocols
 - o Clinical research nurses complete Good Clinical Practice (GCP), research ethics, and protocol training

AVAILABILITY

- Hours
 - Advance scheduling with at least 72 hours' notice is key to ensuring bed and staff availability.
 - Services are available in 24-hour increments.
 - o Inpatient services may be available on a limited basis as follows; contact us to discuss.
 - Weekends
 - NM observed holidays, e.g., for patients in immediate need of treatment with an investigational drug, such as for a patient with acute leukemia. See NMI or call the CRU for a list of holidays.
 - We cannot guarantee coverage of all requested visits on weekends or holidays.
 - o CRU CoreLab is available to process specimens received 7:30am-5pm, Monday Friday.
 - Complex processing (meaning that requiring a laboratory technologist) may be available outside of these hours; contact us to discuss.
 - Investigational Drug Services (IDS) business hours are Monday-Friday, 8AM 4:30PM. Contact IDS at NMInvestigationalDrugServices@nm.org for information about the availability of investigational products outside of these hours. For urgent issues and/or off-hours enrollments, page the on-call IDS pharmacist at 1-6557 (or search NMI Web Paging for 'Pharmacist Investigational, Pharmacy').
- Scheduling
 - o 72 hours' notice is required for ALL visits, more notice is strongly encouraged whenever possible.
 - Email <u>CRUSCHEDULE@nm.org</u> or call 312-926-4452 to confirm the desired dates are available before submitting a registration form.
 - We will accommodate schedule changes to the best of our ability, but may not always be able to.

BEST PRACTICES FOR STUDY TEAMS

- When submitting your study to CRU:
 - o Indicate how much advance notice of the need for CRU Inpatient services will be provided
 - Consider the need for an investigator to serve as the attending physician for research participants; with availability 24/7 while the participant is admitted
 - Consider "the right care, in the right bed, with the right caregivers," especially for medically complex
 participants. For example, an oncology patient might benefit most by admission to an oncology service and
 the engagement of CRU Mobile Inpatient Services.
- Study activities to highlight at or prior to submission include, but are not limited to:
 - Medication administration
 - o Safety monitoring, labs, VS, EKGs, etc.
 - o Post medication administration observation for adverse effects
 - Specimen collection and processing
 - Any complex, novel, and/or serial protocol driven activities
- To discuss preparations for a new study or revisions to an established one: <u>CRUCRNC@nm.org</u>.
- If your study is particularly complex or novel, please request a pre-submission feasibility consult.



