

Introduction to the Clinical Research Unit

Clinical Research Unit Overview

- Services
 - nursing, specimen processing
- Hours
 - 8 AM- 5:30 PM weekdays
 - 9 AM – 4:30 PM walk-in phlebotomy hours (Closed hospital holidays)

Updating CRU Paperwork

- Revised paperwork must be submitted whenever a change is made to the protocol that necessitates full IRB board review.
- Any changes to patient care, even in one-time situations, must be approved prior to being carried out on the CRU.

Nursing Services Available

- Outpatient nursing care
- History & Physical Exams by NPs
- Administration of Infusions
- Telemetry & Standard Monitoring
- Phlebotomy/Intravenous Access
- Investigational Drug Administration
- Sample Processing

Role of the In-service

- May be required after final Administrative Committee review
- Carried out before any admission but after the orders have been reviewed
- Describes the study procedures and reviews the nursing needs of the study
- Identifies potential logistical problems

Scheduling

Scheduling at the CRU is through the CRU Visit Request system, an eRap based program. For information about accessing this system contact Joanne Zephir, joanne.zephir@mssm.edu

Orders

- Must be aligned with the protocol, consent forms, and procedures.
- Investigators must work with coordinators to develop orders that clearly reflect the above, and match hospital policies and procedures, as well as any flow sheets/case report forms.
- Orders are pre-reviewed by CRU nursing prior to initiation.
- Resources are available online.

Example of Outpatient Orders

**THE MOUNT SINAI HOSPITAL
NEW YORK, NEW YORK 10029
ORDER SHEET**

INSTRUCTIONS:

1. ENTER ALL ORDERS FOR PROCEDURES AND DRUGS FOR THE PATIENT.
2. TO CALL ATTENTION TO THE ORDER, NAME AND DRUGS MUST BE WRITTEN ON "ORDER INDICATOR" SHEET ON FRONT COVER OF ORDER BOOK.
3. URGENT ORDERS MUST BE CALLED TO THE ATTENTION OF THE NURSE IN CHARGE.
4. DOCTOR'S SIGNATURE MUST FOLLOW EACH SET OF ORDERS.
5. TO DISCONTINUE AN ORDER: A COMPLETE NEW ENTRY MUST BE MADE. MEDICATIONS NOT PRESCRIBED AS TO A SPECIFIC DURATION WILL BE STOPPED AFTER FOUR (4) DAYS. CONTROLLED DRUGS (E.G. NARCOTICS, BARBITUATES, ETC.) WILL BE AUTOMATICALLY STOPPED AFTER THREE (3) DAYS.

DATE
NAME
UNIT NO.
SEX / AGE
SERIAL NO.
LOCATION
PHYSICIAN SERVICE

ORDERED		IN ACCORDANCE WITH THE HOSPITAL FORMULARY SYSTEM CURRENTLY STOCKED DRUGS WILL BE DISPENSED	DISPOSITION		
DATE	TIME	ORDER	SIGNATURE	TIME	DATE DISC.
		Study: _____ GCO #: _____ PI: _____ (office: _____, cell: _____) Co-I: (if applicable) _____ (office: _____, cell: _____) Study Coordinator: _____ (office: _____, cell: _____)			
		Visit 1 Screening /Medical Clearance			
		<ul style="list-style-type: none"> • Verify signed consent and HIPAA forms • Vital signs • Height (cm) • Wt (kg) • Physical Exam • Blood draw to MSH Lab: (4ml LTT, 5ml gold TT) <ul style="list-style-type: none"> ○ Hematology: (4ml LTT) <ul style="list-style-type: none"> ▪ CBC w/ diff & plts ○ Chemistry: (5ml gold TT) <ul style="list-style-type: none"> ▪ Comprehensive Metabolic Panel ▪ Bilirubin, Direct ○ Endocrinology: (5ml gold TT) <ul style="list-style-type: none"> ▪ TSH ○ Virology: (5ml gold TT) <ul style="list-style-type: none"> ▪ Hep B Surface Ag ▪ Hep C Anti HCV antibody • Urine Collection to MSH Lab: (10ml YTT x 2) <ul style="list-style-type: none"> ▪ Drug Abuse Screen, Urine ▪ Urinalysis ▪ Pregnancy (♀ of child-bearing potential only) • 12-lead EKG • Discharge patient 			

Medication Policy

All investigational drugs administered at the CRU must be dispensed from the Mount Sinai Medical Center Investigational Drug Service.

For more information please contact Ivy Cohen,

Ivy.cohen@mountsinai.org

Specimen Processing

- Samples may be stored temporarily
- Limited specimen processing such as:
 - Centrifugation
 - Slide preparation
 - Aliquot
 - Buffy Coat
- Up to 24 hours of specimen storage

CONTACT INFORMATION

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