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)
Updated 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.
### Visit 1
**Screening /Medical Clearance**

- Verify signed consent and HIPAA forms
- Vital signs
- Height (cm)
- Wt (kg)
- Physical Exam

- **Blood draw to MSH Lab:** (4ml LTT, 5ml gold TT)
  - **Hematology:** (4ml LTT)
    - CBC w/ diff & plt
  - **Chemistry:** (5ml gold TT)
    - Comprehensive Metabolic Panel
    - Bilirubin, Direct
  - **Endocrinology:** (5ml gold TT)
    - TSH
  - **Virology:** (5ml gold TT)
    - Hep B Surface Ag
    - Hep C Anti HCV antibody

- **Urine Collection to MSH Lab:** (10ml YTT x 2)
  - 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
- Up to 24 hours of specimen storage
<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Extension</th>
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<tbody>
<tr>
<td>Shawana Townsend</td>
<td>Nursing Station</td>
<td>x46041</td>
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<tr>
<td>Joanne Zephir, MHSA</td>
<td>Program Coordinator</td>
<td>x40982</td>
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<tr>
<td>Margaret Garrett, MSN, FNP</td>
<td>Nurse Manager</td>
<td>x41515</td>
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<tr>
<td>Rachel Posner, MPA</td>
<td>Administrative Director</td>
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<tr>
<td>Scott Sicherer, MD</td>
<td>Medical Director</td>
<td>x45548</td>
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