



# Introduction to The Clinical Research Unit

*INVESTIGATOR ORIENTATION*

# Overview

- ▶ The Clinical Research Unit (CRU) provides infrastructure to assist investigators with conducting clinical and translational research studies. Both researchers and subjects can expect state-of-the-art services to include excellent participant nursing care, and keen attention to detail.
- ▶ Hours of Operation:
  - ▶ 8:00 AM – 5:30 PM (Monday – Friday, except hospital holidays)
  - ▶ Walk-In Phlebotomy Services – 9:00 AM – 4:30 PM (Monday-Friday, except hospital holidays)
- ▶ [https://youtu.be/V7JaGnK\\_FCM](https://youtu.be/V7JaGnK_FCM)

# Available Resources

- ▶ Outpatient Space
- ▶ Temporary (up to 24 hours) Specimen Storage
- ▶ Nursing Support:
  - ▶ Medical history and physical exams by Nurse Practitioners
  - ▶ Investigational drug administration
  - ▶ Adverse event monitoring to include telemetry and standard monitoring
  - ▶ Specimen processing – hematology slide preparation, plasma, buffy coat, and serum extraction
  - ▶ Pre-procedure COVID testing (for research studies only)

# Access to CRU Resources

- ▶ Investigators interested in using CRU resources must complete an application and receive approval from the CRU Administration Committee. Requests to use the CRU may be assigned through the IRB/RUTH submission process by completing the Ancillary Review Form and assigning CRU via the Manage Ancillary Review tab. The CRU application can be completed by using the RUTH Ancillary Office Survey form in Redcap. The redcap survey form must be uploaded and included with the IRB/RUTH submission.
- ▶ After receiving CRU approval, the next step is to submit MD orders and arrange an in-service meeting with CRU staff.

# MD Orders

- ▶ Ordered procedures must be in alignment with clinical trial protocol, and consent forms
- ▶ Investigators must collaborate with study coordinators to develop MD orders, reflective of the latter while adhering to hospital policies and procedures
- ▶ MD orders are reviewed by CRU nursing prior to scheduling an in-service meeting. See samples below
- ▶ [Template - Sample Medical Clearance.docx](#)
- ▶ [Template - Sample Blood Draw.docx](#)
- ▶ [Template - Sample Infusion MD Orders.docx](#)

# Role of The In-Service Meeting

- ▶ Required before scheduling participants
- ▶ Describes study procedures and reviews required nursing services
- ▶ Identifies and troubleshoots potential logistical challenges

# Scheduling Participants at The CRU

- ▶ Scheduling is done through the CRU Visit Request System, an eRAP based system. For more information regarding obtaining access to this system, and creating New Research Study Addition in EPIC, please contact Kaitlyn Ennis, [Kaitlyn.ennis@mssm.edu](mailto:Kaitlyn.ennis@mssm.edu)
- ▶ To maintain a safe environment, scheduling of Walk-In Phlebotomy Only participants is done by emailing [scheduling-.crc@mountsinai.org](mailto:scheduling-.crc@mountsinai.org) or calling 212-241-6041 ahead of requested appointment time to confirm that space is available.

# CRU Medication Policy

- ▶ All investigational drugs administered at the CRU must be dispensed from The Department of Pharmacy, Investigational Drug Service.
  - ▶ Contact: [ivy.cohen@mountsinai.org](mailto:ivy.cohen@mountsinai.org)



# CRU Contact Information

- ▶ Scheduling [schedule-.crc@mountsinai.org](mailto:schedule-.crc@mountsinai.org)
- ▶ Kaitlyn Ennis, Program Coordinator [Kaitlyn.ennis@mssm.edu](mailto:Kaitlyn.ennis@mssm.edu)
- ▶ Margaret Garrett, FNP, Nurse Manager [Margaret.garrett@mountsinai.org](mailto:Margaret.garrett@mountsinai.org)
- ▶ Rachel Posner, Associate Dean [Rachel.posner@mssm.edu](mailto:Rachel.posner@mssm.edu)
- ▶ Scott Sicherer, MD, Medical Director [scott.sicherer@mssm.edu](mailto:scott.sicherer@mssm.edu)