Information for Clinical Research Monitors - MUSC Charleston Campus

South Carolina Clinical & Translational Research (SCTR) Institute & the Office of Clinical Research (OCR)

MUSC
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Research

Version Date: 24-Feb-2025
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Welcome to MUSC

On behalf of the South Carolina Clinical & Translational Research (SCTR) Institute and the Office of Clinical Research's Research Opportunities & Collaborations (ROC) team, welcome to the Medical University of South Carolina!

The ROC team has created this **Information for Clinical Research Monitors** document to provide key information to help you prepare to monitor research data at MUSC. At a minimum, information in this document is updated every 6 months, or more frequently as needed, to reflect changes to policies and processes. Therefore, we recommend referring to the website (https://research.musc.edu/resources/ocr/industry) for the most up-to-date version.

We value the sponsors and contract research organizations that partner with MUSC on the cutting-edge clinical research that offers new treatments and hope to our patients. Thank you for helping to ensure the safety of our participants and the integrity of our research data.

--The Research Opportunities & Collaborations Team

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About the SCTR Institute and Office of Clinical Research

MUSC is home of the South Carolina Clinical & Translational Research Institute (SCTR), a research infrastructure hub funded by the National Center for Advancing Translational Sciences (NCATS), part of the National Institutes of Health (NIH).

The Office of Clinical Research (OCR) provides a centralized office for industry sponsor and contract research organization relations, clinical research billing and financial compliance, and research education at the Medical University of South Carolina.

The purpose of the OCR is to provide an effective and efficient infrastructure to support MUSC investigators in developing, implementing, and reporting on clinical research studies at MUSC.

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Site Monitoring Visits: Scheduling

Site monitoring visits may be conducted on-site or remotely.

Monitors must contact the MUSC study team to schedule monitoring visits. Visits should be conducted within the study team's working hours of operation.

The Site Visit Request Form is required for **Oncology studies**; monitors will be contacted by the Oncology team after the form is submitted.

It is recommended that monitoring visits are scheduled **6-8 weeks* in advance** to allow MUSC study teams adequate time for scheduling ancillary services and site personnel and to ensure access to necessary systems and study materials.

*Please note that during the holiday season, study teams have limited availability and need to prioritize patients' study visits; advanced planning is recommended.

Investigational Drug Services (IDS) does not take on-site appointments on Tuesdays; monitors should take this into consideration when scheduling a site visit.

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Prior to the Site Monitoring Visit

When scheduling, provide the study team with who and what will need to be seen (e.g., PI, IDS, Lab, etc.). If this is not done prior to the visit, the study team cannot guarantee access to the person or place requested during the site visit.

Monitors should advise the MUSC study team if any additional visitors will be accompanying them during the visit to ensure adequate space is available.

Prior to the scheduled visit, please provide a confirmation letter with an agenda for the visit. If possible, please send at least 1-week prior to the visit.

Monitors who arrive prior to the agreed upon site visit time should wait for the primary study coordinator to arrive before starting the review. If a later than scheduled arrival is anticipated, monitors should notify the primary study coordinator.

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Electronic Health Record (EHR) Access & Security Requirements

MUSC adheres to all state and federal laws as well as all other applicable regulatory requirements in recognition that medical records are confidential and shall not be released or disclosed to any unauthorized persons.

For additional information, see MUSC's Statement on Epic Compliance with 21 CFR Part 11: https://medicine.musc.edu/departments/centers/bmic/quick-links/epic-part-11-compliance

- An EHR Access Request must be submitted each time a monitor performs activities that require access to MUSC electronic medical records (Epic). MUSC research staff need **at least 10 business days** to complete the access request process.
- To set up access to patient charts, the monitor will provide MUSC research staff with a list of the study participant ID numbers for review and the duration of the site visit (start date/time, end date/time) **at least one week prior to the scheduled monitoring visit.** Monitors will have access ONLY to patient charts on the list and for the designated time of the monitoring visit.
- Laptops should allow for the installation of plugins and other applications that may be needed to connect to and run the applications needed for monitoring activities at MUSC.
- When on-site, monitors may use the MUSC Guest network for internet access.
  Refer to Internet Access in the Visitor & Campus Information section of this packet.

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EHR Access Request Process

1

- The MUSC study team will Request New Account within Epic CareLink. (Monitors should notify the MUSC study team **if they have ever logged into the MUSC CareLink portal**, as the same login information may be able to be used if the last log-in was within the last 90 days.)

2

- Basic external research monitor information (name, work email, work phone) will be entered by the MUSC study team to complete the request.

3

- The MUSC Epic research team will email the monitor their log-in information (username and password) and notify the MUSC study team that the monitor has been contacted and their account created.
- The first time the monitor logs in, they will be asked to (a) agree to the research user/monitor terms and conditions; and (b) change their password to one that only they know—and not use the one created for them by the MUSC Epic research team.

4

- Once the monitor is logged in, participants' charts that have been released to them can be reviewed by clicking on either the Patient Lists tab or the clinical review tab.
- The MUSC study team will provide the monitor with the Epic Tip Sheet entitled "External Research Monitors: Accessing Research Participant Records".
- Contact the MUSC Help Desk at 843-792-9700 with log-in problems or questions.

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Regulatory & Source Documents

- Regulatory and source documents may be stored electronically and/or on paper. Monitors should contact the MUSC study team to determine what methods are used for the study.
- MUSC research staff have the option to utilize Advarra's Electronic Regulatory (eReg) system to house essential regulatory documents. Monitors should contact the MUSC study team to determine if the eReg system is used for the study.
  - For studies utilizing eReg, monitors can be granted a ***Reviewer*** role to view selected regulatory files. It is recommended that monitors request access to the eReg system **at least one week prior to the scheduled monitoring visit.**
    - First time eReg users are required to complete training as a part of the 21 Code of Federal Regulations (CFR) Part 11 Compliance measures. In addition, training helps ensure users are equipped with basic knowledge and understanding of the system.
    - eReg should not include study participants' private health or identifiable information; thus, items like signed consent forms, source documents or safety events are stored outside of the eReg system.

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E-Reg Access Request Process

1. The MUSC study team will submit a ‘Contact Record’ Request form for a new account and first-time training access. (Monitors should notify the MUSC study team **if they have previously completed training and logged into the eReg system.**)
2. Basic external research monitor information (name, work email, work phone) will be entered by the MUSC study team to complete the request.
3. First-time users: eReg administrators will enroll the monitor into the required online training and email the steps to complete training requirements through activation.
4. Once the final, completed training is verified by eReg administrators, the eReg account will be activated, and the eReg administrators will email the monitor the eReg log-in information (username and password).

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Investigational Drug Services (IDS)

169 Ashley Avenue
Main Hospital Room 161
Charleston, SC 29425

843-792-9643 (p)
843-792-2834 (f)
idspharm@musc.edu

Hours of Operation*: Monday through Friday, 6:30 am to 5:00 pm (Closed on major holidays)

**An IDS staff member is on-call after hours, weekends and holidays.*

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Investigational Drug Services (IDS) Cont.

Scheduling Site Visits

- The monitor should contact the MUSC study team to coordinate appointments with IDS.
- Appointments with IDS must take place during IDS operating hours on Mondays, Wednesdays, Thursdays, and Fridays. **Please note: IDS does not offer on-site appointments on Tuesdays.**
- Initial site visits (following enrollment of the first patient of a study) can be scheduled as soon as the patient is enrolled.
- Routine site visits must be scheduled **at least a month in advance**.
- If the monitor is not able to keep their appointment, they must give at least 24-hour notice of cancellation. Regardless of notification lead time, if a monitoring appointment is cancelled, the monitor may be subject to an additional 2 to 4 week wait time to reschedule their appointment dependent on IDS schedule availability.

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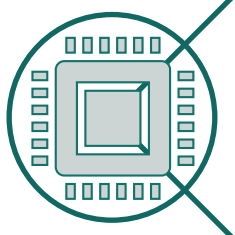
Investigational Drug Services (IDS) Information



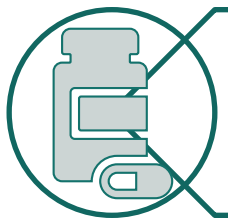
Monitors will be granted access, as requested, to Temperature Logs, Calibration Certificates, and investigational product (IP) dispensing and inventory management records via the web-based accountability system ***Vestigo***.

Account details and instructions for access will be sent by the Vestigo system via email to the monitor. Monitors are expected to review the provided documents prior to their arrival.

IDS records are sorted by the study's IRB internal reference number (e.g., "HR/PRO number" or the "CTO number" assigned by the Oncology Clinical Trials Office.)

Binders for current studies are stored in the IDS office; records for closed studies are stored in our storage warehouse in North Charleston.

Monitors may take originals from the IDS binders at the close of study, but copies must be made and stored with the rest of the IDS records in the study binder. **Per HIPAA, any copies made that contain patient-identifying information MUST be de-identified before leaving the IDS office. This includes name, date of birth, prescription number, and MRN.**



Per policy, IDS will not store any used hazardous drugs or their used containers. Returned drug containers from patients will be destroyed immediately after drug accountability is performed by IDS staff. Drug containers used during sterile or non-sterile compounding will be destroyed immediately after drug preparation.

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IDS Policies & Procedures

- The IDS complies with all federal, state, and institutional standards that govern medication use processes during the conduction of a clinical trial. These processes include the oversight of the acquisition, accountability, storage, security, packaging, labeling and distribution of drugs used in clinical research.

- **STORAGE:**
  IDS offers storage at room temperature, refrigerated temperatures in one of six refrigerators (2-8°C), frozen temperatures in a -20°C (a 2nd unit is available for back-up) and one of two ultra-low freezers (-70 to -80°C), and a vapor phase liquid nitrogen freezer (≤ 130°C). All refrigerators and freezers are connected to emergency back-up power.

- **TEMPERATURES:**
  Temperatures are monitored remotely 24 hours a day, 7 days a week by a centralized electronic monitoring system, ViewPoint. The system records temperatures every 5 minutes. The system is set to alert IDS of an issue prior to going out of sponsor approved temperature ranges (Ex: pre-alarm limit for the refrigerators are 3°C and 7°C). In the event of a temperature alarm during hours, an alert is emailed to IDS staff. In the event of an alarm after hours, the on-call IDS pharmacist is paged, and staff can log in to assess the alarm. If the storage location temperature deviates from sponsor permitted temperature ranges, IDS will notify the sponsor as soon as possible, quarantine IP until further direction is received and provide as much information as possible regarding the temperature excursion.

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IDS Policies & Procedures Cont.

- **ACCESS:**
  IVRS or IXRS access (i.e. ClinPhone, e-CTS, etc.) must be provided for all permanent staff members. IDS staff are cross-trained on all studies.

- **EXPIRATION/RE-TEST DATING:**
  All IP is required to have an expiration/re-test date on the vial/box/etc. If expiration/re-test dates are not posted on the vial/box/etc. an IDS staff member will obtain the appropriate dating from the sponsor or designee and manually transcribe the information to the vial/box/etc. If the sponsor or designee has a re- labeling method identified for IP with respect to expiration/re-test dating, it is expected the appropriate information will be forwarded to the IDS by the sponsor in a timely manner.

- **INVESTIGATIONAL AGENTS:**
  - IDS does not provide services for studies that involve medical devices that have no drug involvement.
  - IDS is able to manage controlled substances within Schedules II-V but is not licensed to manage Schedule I substances.

- IDS related Standard Operating Procedure(s) may be requested through the Research Opportunities & Collaborations team at ResearchOppCollab@MUSC.edu.

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Research Nexus Laboratory

96 Jonathan Lucas Street, Suite 217
Charleston, SC 29425
https://research.musc.edu/resources/sctr/programs/participant-and-clinical-interactions/research-center/lab

South Carolina Clinical & Translational Research (SCTR) Institute

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Research Nexus Laboratory Information

- The Research Nexus Lab is a newly renovated, secure, limited-access site that includes:
  - Eight work benches
  - Six -80°C freezers
  - Six refrigerated centrifuges
  - Two biological safety cabinets
  - One liquid nitrogen freezer and one fume hood
- As a matter of quality control, monitors may not tour the Research Nexus Lab. The lab remains locked at all times with badge access for authorized Nexus personnel only. Monitors may view the lab from a window in the hallway and request to speak to laboratory personnel. An appointment is not required.
- The Research Nexus Lab houses hundreds to thousands of specimens for clinical trial studies at any given point in time. The proper storage of these samples is imperative to maintaining sample integrity.
- Note: It is a requirement for all Nexus Laboratory members to complete IATA shipping training (Shipping and Transport of Regulated Biological Materials). These training modules can be accessed through the CITI Program or by following the link: https://research.musc.edu/resources/ori/irb/education. Once these trainings are completed, electronic certificates must be saved and uploaded to the personnel certifications folder: \NexusShares\CTRC\Lab\Lab IATA, CITI Certificates, CVs\IATA

Reference:

SOP Title: Nexus Laboratory Generic Frozen Packaging and Shipping	Version: 6
SOP Number: Nexus-7 (previously CTRC-7)	Effective Date: 02/19/24

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SCTR Research Nexus Laboratory Procedures

Sample Storage

- **Ambient Samples**
  - Samples that are to be stored at ambient temperature will be placed in an enclosed laboratory cabinet that is designated for that purpose. Sample containers will be labeled with a protocol number.
- **Refrigerated and Frozen Samples**
  - All samples that are to be stored refrigerated or frozen are to be placed only in equipment that is under continuous temperature monitoring and connected to an electrical outlet (with an orange socket) that is on an emergency backup power supply.
  - When placing or removing refrigerated or frozen samples, the equipment door is to be left open for the shortest practical time in order to maintain the equipment at the proper temperature. Boxes or containers placed in the freezers should only contain samples that are all associated with one study protocol.
- **Liquid Nitrogen Stored Samples**
  - Liquid nitrogen freezers are to be checked visually twice a week to ensure that they are sufficiently filled with liquid nitrogen.

Reference:

SOP Title: Nexus Sample Storage	Version: 2
SOP Number: Nexus-18	Effective Date: 08/05/22

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SCTR Research Nexus Laboratory Procedures

Sample Storage Continued

- Samples that are to be stored in liquid nitrogen are to be slow-frozen first, usually with a Mr. Frosty device, at -80 degrees for 24 hours. Samples are to be moved as quickly as possible from the Mr. Frosty to the corresponding cryobox in the liquid nitrogen freezer. Freezerworks assigned positions are to be used to keep track of sample location.
- Study samples received or processed by the lab can either be stored short term (hours to days) to long term (months or years).
- All refrigerators and freezers will be checked by an authorized repair service on an annual basis to ensure proper functioning of the equipment. Certificates of annual maintenance will be displayed on the equipment doors.
- In case of equipment failure of a refrigerator or freezer, samples must be moved as quickly as possible to a backup location. Samples will only be returned to the freezer after it has been repaired, and chilled back down to its appropriate temperature. If such an event were to occur, the details should be recorded in the he details should be recorded in the Freezer Incident Tracking Log located on the Nexus Shares drive for future reference:\NexusShares\CTRC\Lab\Equipment Maintenance Records\.

Reference:

SOP Title: Nexus Sample Storage	Version: 2
SOP Number: Nexus-18	Effective Date: 08/05/22

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SCTR Research Nexus Laboratory Procedures (Batch)

Batch Shipment

- Before a batch shipment, there should be some acknowledgement in writing/e-mail that the study team would like the samples to ship out.
- Study teams should allow at least 2 business days to prepare samples for shipment. Time will vary depending on number of samples and shipment requirements.
- Study teams will provide all shippers, airbills, and preferably packing materials (kPA bags, aliquot boxes, absorbent materials).
- Ideally the study team will provide a manifest of samples that can be matched to the stored samples for shipment. In some cases, original requisitions may need to be included and pulled from the Nexus Lab file cabinet.
- A batch shipment form should be filled out for each shipment. This form allows for all batch information to be stored together and easily filed or retrieved.
  - Form must include shipment date, total amount of source tubes charged, and total number of dry ice charges filled out.
  - E-mail or written documents to ship should be attached along with a manifest if provided.

Reference:

SOP Title: Batch Shipment	Version: 3
SOP Number: Nexus-27	Effective Date: 03/01/24

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SCTR Research Nexus Laboratory Procedures

Batch Shipment Continued

- If no manifest is provided, lines on the form should be used to note which aliquots were shipped and other identifiable sample information.
- Form should be filled out for backup samples. This allows a record that can easily be identified.

- Shipment charges only occur if source tubes have not been previously charged for shipment.
- Batch shipment shipper boxes may be larger or require more dry ice than regular shipments. As with regular frozen shipments, the quantity of dry ice will be charged instead of the number of boxes.
- When shipping samples, follow the guidelines in the study's lab manual. If no guidelines are provided, follow IATA regulations.
  - When shipping items in aliquot boxes, make sure there is some adsorbent material around the box, lid is secured with a rubber band, and box is sealed in a bag.
  - It is recommended that shipments occur Mon-Wed. Check with study team if shipments are allowed Thursday. Friday shipments should be avoided if possible. Before a batch shipment, there should be some acknowledgement in writing/e-mail that the study team would like the samples to ship out.

Reference:

SOP Title: Batch Shipment	Version: 3
SOP Number: Nexus-27	Effective Date: 03/01/24

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SCTR Research Nexus Laboratory Procedures

Ambient Shipment

- If available, check with the lab manual for study specific packaging guidelines. Study teams are responsible for providing all shipping materials.
- Insert specimen tube(s) into a Specimen Collection 95kPa Bag containing absorbent material. Place bag on flat surface to minimize wrinkles, especially at adhesive sealing area. Remove tape liner and seal the bag.
- Fold and place the shipping documents (requisition forms, manifest, etc.) into the reverse side of the Specimen Collection Bag if slit pouch is present. Alternatively, forms can be placed between packaging and top of box.
- Wrap the specimen bag with protective material, such as gel pack, bubble wrap, or packing materials so that samples are protected and do not shift inside the box.
- If a gel pack needs to be created: Fill a Gel Pak bag to the indicator line with cool tap water. Seal the bag. Lightly press the absorbent pack to expel its contents. Massage the bag until water has been absorbed and a gel material has formed. Expel the air from the Gel Pak and reseal.

Reference:

SOP Title: Nexus Laboratory Ambient Shipping	Version: 5
SOP Number: Nexus-4 (previously CTRC-4)	Effective Date: 02/16/24

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SCTR Research Nexus Laboratory Procedures

Ambient Shipment Continued

- Place the samples in an appropriate shipping container. Containers should be of sturdy corrugated material and have the UN3373 label for shipping biological substances. If the box is small (one dimension 2” or less), it is recommended that the box be placed in an overpack bag.
- Seal the shipping container securely. Tape may be needed to reinforce provided seals.
- If needed, complete and affix the airbill to the designated spot on the box or overpack bag.
- Affix the label with Study PI address on the box. If no label is provided, copy the return address on the airbill or use the lab address.

Reference:

SOP Title: Nexus Laboratory Ambient Shipping	Version: 5
SOP Number: Nexus-4 (previously CTRC-4)	Effective Date: 02/16/24

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SCTR Research Nexus Laboratory Procedures

Generic Frozen Packaging and Shipping

- After the laboratory samples have been collected and processed according to laboratory protocol, the steps below are followed for frozen packaging and shipping:
  - Make sure specimen labels are securely affixed to each aliquot. Place frozen tube(s) into absorbent vial/tube holder(s), cryobox(s) w/absorbent sheet, or wrap each specimen in absorbent paper. Place frozen tube holder(s), box(s), or individually wrapped specimen into specimen 95kPa shipping bag. Seal the bag.
  - Place sealed specimen bag(s) in bottom of the styrofoam frozen shipper box if lab manual does not specify layering specimen between dry ice. Place approximately 6lbs (3kg) dry ice directly on top of the specimen shipping bag(s). For batch shipping, multiple specimen shipping bags or 1-2 cryoboxes may be placed in one shipper depending on size.
  - Place foam lid on insulated frozen shipper. Do not tape the styrofoam box closed. Place the appropriate copy of the shipping manifest or log in a zip-lock bag on top of the styrofoam lid. Secure cardboard shipper flaps with packaging tape. Attach air waybill to outside of the box. Indicate the amount of dry ice and shipper information on the airbill.

Reference:

SOP Title: Nexus Laboratory Generic Frozen Packaging and Shipping	Version: 6
SOP Number: Nexus-7 (previously CTRC-7)	Effective Date: 02/19/24

SCTR Research Nexus Laboratory Procedures

Generic Frozen Packaging and Shipping Continued

- NOTE: If an airbill has not been filled out or pre-printed, indicate “Dry Ice, 9, UN1845, number of packages x weight in kilograms” on the label. In addition, be sure to fill out the black and white striped label (hazard class 9, UN1845, Dry Ice) with the dry ice amount in kilograms and attach this label to the outside of the shipping box. A “UN3373” Diagnostic Specimen sticker on the outside of the shipping box is also required. If not included with the shipper, extra labels are located in the drawer marked “packaging supplies”.
- If samples are shipped on Friday, check the Saturday delivery box on the airbill. Include a “Saturday Delivery” sticker on the outside of the shipping box.
- Shipments on Liquid Nitrogen: The receiving lab will provide a shipper that is pre-charged with liquid nitrogen and has a built-in temperature monitoring device. Samples will be moved as quickly as possible from our own liquid nitrogen or other frozen storage into the packaging that is required by the receiving lab and then placed into the shipping container as specified by the study. The shipper will be sealed as specified by the study, and the temperature monitor will be placed accordingly.
- If shipping internationally, all requisitions, chain-of-custody, and other required forms will be completed, with copies attached to the outside of the shipping package. A copy of all forms will be made for our own records.

Reference:

SOP Title: Nexus Laboratory Generic Frozen Packaging and Shipping	Version: 6
SOP Number: Nexus-7 (previously CTRC-7)	Effective Date: 02/19/24

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SCTR Research Nexus Laboratory Procedures

Sample Destruction:

- The Research Nexus Lab must receive written instruction from the protocol PI requesting that samples be destroyed, and the instruction must indicate specifically which samples are to be discarded (i.e., protocol XXX plasma samples, protocol XXX biomarker samples).
- The MUSC principal investigator (PI) must complete, sign, and date the Nexus Lab Sample Destruction Form.
- The destruction of samples will be witnessed by a second Lab Technician or Lab Manager, who will also sign and date the Nexus Lab Sample Destruction Form.
- All samples for destruction are discarded according to MUSC Institutional Policy. Once the Nexus Lab Sample Destruction Form is completed, the MUSC PI's written destruction request is attached to the Nexus Lab Sample Destruction Form. The documents are placed in the appropriate protocol file and retained for a minimum of three years per MUSC Institutional Policy.

Reference:

SOP Title: Nexus Laboratory Sample Destruction	Version: 3
SOP Number: Nexus-8 (previously CTRC-8)	Effective Date: 03/13/15

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SCTR Research Nexus Laboratory Procedures

Temperature Monitoring System

- The chart to the right is the list of “input” numbers with descriptions and temperature ranges for equipment monitored in the Nexus Laboratory: (An “input” is each individual piece of equipment being monitored (e.g., each freezer or refrigerator).)
- Note: The LN2 freezer depends on a separate LN2 supply (large LN2 tank); should that supply be interrupted and the LN2 in the freezer drop below the minimum level, the freezer will alarm without triggering a Rees alarm and/or notification.
- The Rees Centron SQL system is designed to provide high-security environmental monitoring. Centron monitors inputs, analyzes for trouble, and ensures that the appropriate people are notified in a timely manner. Centron also provides detailed records of all events. Information and calibration is updated annually and located in the Rees Validation Protocol binder stored in CSB 217 near the central computer. An updated digital copy of the calibration summary is also located on the Nexus Shares drive: \NexusShares\CTRC\Lab\Equipment Maintenance Records\Lab Equipment\Rees Scientific.

Rees Input Number	Equipment and Description	Temperature Range (High to Low)
1	-80°C Freezer B	-90°C to -70°C
3	2 - 8°C Glass Refrigerator	1°C to 8°C
4	-80°C Freezer D	-90°C to -60°C
6	-80°C Freezer C	-90°C to -70°C
7	-80°C Freezer A	-90°C to -70°C
8	-20°C Freezer	-40°C to -15°C
9	-20°C DNA Freezer	-30°C to -10°C
13	-80°C Freezer E	-90°C to -70°C
31	LN2 Liquid Phase (Old tanks)	-200°C to -135°C
32	LN2 Vapor Phase (Old tanks)	-200°C to -135°C
37	LN2 Freezer Liquid*	-200°C to -135°C
38	LN2 Freezer Vapor*	-200°C to -135°C
39	-80°C Freezer G	-90°C to -60°C
41	2 - 8°C Skinny Refrigerator	1°C to 10°C
132	Monitoring of Inputs 1-16	N/A
133/135	Battery Watch	N/A
134	Monitoring of Inputs 17-32	N/A

Reference:

SOP Title: Nexus Laboratory Rees Temperature Monitoring System	Version: 8
SOP Number: Nexus-6 (previously CTRC-6)	Effective Date: 02/16/24

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SCTR Research Nexus Laboratory Procedures

Temperature Monitoring System Continued

- The Rees Centron SQL system functions as a full-capability workstation, allowing view and program of all nodes. The local workstation is in CSB 217 along the right-side wall, or it can be viewed via remote connection (http://rsc-03745-csb217.csb.musc.edu/index.htm).
  - Each Centron “node” has its own built-in telephone alarm system that issues phone calls in the event of an alarm. (A “node” is the overall system which covers both the Nexus Laboratory and the SCTR Biobank.) The phone numbers called and the order in which they are called have been customized for the Nexus Laboratory as follows:
  - The phone message sent lists the details of the alarm in a voice synthesized message. Rees continues to call the supplied list of phone numbers until an acknowledgement is made, or the alarm condition returns to normal.
  - The Centron can be called at any time to check on any input's status. After the user-programmed number of rings the node will answer and respond with an easy-to-understand voice menu.

Call Out Order	Phone Location/Description
1st	Nexus Laboratory phone #1
2nd	Nexus Laboratory phone #2
3rd	Nexus Lab Manager office phone
4th	Nexus Employee cell phone (if applicable)
5th	Nexus Employee cell phone (if applicable)
6th	Nexus Employee cell phone (if applicable)
7th	Nexus Lab Manager Cell Phone

Reference:

SOP Title: Nexus Laboratory Rees Temperature Monitoring System	Version: 8
SOP Number: Nexus-6 (previously CTRC-6)	Effective Date: 02/16/24

MUSC Medical University of South Carolina Research

SCTR Research Nexus Laboratory Procedures

Temperature Monitoring System Continued

- The Centron node provides records that show periodic readings when conditions are normal. In the event of an alarm, Centron records the time of the alarm, the nature of the alarm, the phone number contacted to report the alarm, and the time when the alarm was corrected.

- Any user who inhibits, enables, or resets an alarm, or changes the program, will be identified by name in the audit log. Nexus Laboratory employees have permission levels to inhibit alarms for up to one hour (or longer at the discretion of the manager). The manager may inhibit the system for any length of time, providing justification as well.

- If inputs are inhibited via computer, comments to document the changes, alarms, etc., must be added to the log, along with the name of the person making the entry, the time and the date. This information should also be recorded in the Freezer Incident Tracking Log stored in the Nexus Lab folder (\NexusShares\CTRC\Lab\Equipment Maintenance Records).

Reference:

SOP Title: Nexus Laboratory Rees Temperature Monitoring System	Version: 8
SOP Number: Nexus-6 (previously CTRC-6)	Effective Date: 02/16/24

MUSC Medical University of South Carolina
Research

Version Date: 24-Feb-2025
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SCTR Research Nexus Laboratory Procedures

Equipment Maintenance

- All equipment/instrumentation in the lab will be kept on a preventative maintenance/ calibration schedule, with the exception of equipment deemed Out of Service (OOS). (OOS equipment will have maintenance performed when back in use).
  - PM/calibration will be performed by either the state-contracted vendor or equipment vendor if state vendor is unable to perform the required maintenance.
  - Equipment will reflect current PM/calibration status, typically a sticker located on the instrument showing last calibration date and/or calibration expiration date. Out of Service equipment will be labeled as such.
  - Documentation of calibration for temperature-monitored equipment, e.g., freezers and refrigerators, centrifuges and pipettes, will be kept on file as provided by vendor.

Reference:

SOP Title: Laboratory Equipment Maintenance	Version: 2
SOP Number: Nexus-17	Effective Date: 05/15/18

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SCTR Research Nexus Laboratory Procedures

Equipment Maintenance Continued

- Equipment PM/Calibration/Certification Schedule:

Vendor	Equipment Name	Brand	Serial Number	Total for Calibration	Asset #	Month Due	Schedule
Remi Group; 866-296-4847	Autopure (service through 2020)	Qiagen	14040	1	83170280	Jun	Annual
Pipette Repair Service, Inc.	Single Channel Pipettors (P200, P1000, P20, P10, P100); Multichannel P200	Eppendorf	N/A	16	N/A	Jun	Bi-annual
Coastal Biomed	Refrigerated Centrifuge	Beckman Coulter Allegra 6R	--	1	83170286	Feb	Annual
	Refrigerated Centrifuge	Beckman Coulter Allegra X-14R	--	3	83192058, 83193944, 83193781	Feb	Annual
	Refrigerated Centrifuge	Eppendorf	5702R	2	N/A	Feb	Annual
	Microcentrifuge	Fisher Scientific Accuspin Micro17	ENV ID # 40929853	2	N/A	Feb	Annual
	Microcentrifuge	Beckman Coulter Microfuge 16	MBA13M024	1	N/A	Feb	Annual
	Refrigerated Microcentrifuge	SCILOGEX	--	1	N/A	Feb	Annual
	Forced Air General Incubator	VWR, 414005-120	11000091481004	1	N/A	Feb	Annual
Thermo Fisher	Microplate Washer	Thermo, Wellwash Versa	888-4748B	1	83193354	Jul	Annual
Thermo/ Nanodrop	Nanodrop Spectrophotomer (ships to site)	Nanodrop/Thermo	606	1	83110328	Oct	Annual
Promega	Maxwell Purification System	Promega	27521109	1	83110248	Oct	Annual
Tecan	Infinite F200 Pro	Tecan	1705009508	1	83193851	Jun	Annual
Rees Scientific (for monitoring system)	Ultra Low Freezer A (Input 7)	Fisher Scientific, U86-13A41	ULT286-35I-A36	1	83110240	Jan	Annual
	Ultra Low Freezer B (Input 2)	REVCO, ULT2586-4-A48	0129360501100929	1	83193459	Jan	Annual
	Ultra Low Freezer C (Input 6)	Revco, ULT1386-9-A40	S08R-230492-SR	1	83091121	Jan	Annual
	Ultra Low Freezer D (Input 4)	Thermo Scientific, 165AT0V01A	184876	1	83194053	Jan	Annual
	Ultra Low Freezer E (Input 13)	New Brunswick U9280-0000	F700CG900331	1	83191195	Jan	Annual
Bear Mechanical Services, 843-747-8100, Chris Sweat (for maintenance and repair)	Ultra Low Freezer F (Input 1)	Revco, ULT2586-4-A46	0128801601091214	1	83193459	Jan	Annual
	-20C Freezer (Input 8)	VWR Symphony, 97025-008	N/A	1	N/A	Jan	Annual
	Refrigerator (Input 10)	GDM-47	6835459	1	N/A	Jan	Annual
	Glass Refrigerator (Input 3)	VWR, FRU17B2JW5	WA32202041	1	N/A	Jan	Annual
	LN2 28L Liquid Phase (Input 31) / Vapor Phase (Input 32)	Arctic Express/Thermo	--	2	N/A	Jan	Annual
MUSC Risk Mgmt. 2-3604	Biosafety Cabinet	Labconco, Class II Type 2	110339012C, 180456681B	2	83190399, 83194309	Sep	Annual

Reference:

SOP Title: Laboratory Equipment Maintenance	Version: 2
SOP Number: Nexus-17	Effective Date: 05/15/18

MUSC Medical University of South Carolina Research

Version Date: 24-Feb-2025
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SCTR Research Nexus Laboratory Procedures

Emergency Plan for Power Outage or Equipment Failure

- Emergency Plan for Power Outage or Equipment Failure:
  - Each refrigerator and freezer located in the Nexus Laboratory is monitored for temperature continuously via Rees system.
  - All critical equipment is on emergency power and connected to a generator in the event of a floor-wide, building-wide, or campus-wide outage. In addition, MUSC has a contingency plan for onsite oil trucks, and the Research Nexus Lab would be provided emergency power via these trucks.
  - Each freezer or refrigerator is equipped with a Rees sensor, which will begin to call out via phone to appropriate personnel. The Research Nexus Lab personnel contacted by Rees must verify that freezer or refrigerator is without power or that temperature is rising, indicating that contents must be relocated until power returns or equipment is repaired, and the temperature returns to within range. Additionally, the personnel must inhibit the affected freezer/refrigerator and notify the Research Nexus Lab Manager of a power outage or equipment failure.
  - Affected freezer/refrigerator contents are moved to appropriate storage (2-8°C, -20°C or -80°C) in CSB room 217 or other location (MUSC will provide location) until power and/or appropriate temperature is restored or repair is made to the affected unit.

Reference:

SOP Title: Nexus Laboratory Emergency Plan for Power Outage or Equipment Failure	Version: 7
SOP Number: Nexus-5 (previously CTRC-5)	Effective Date: 02/16/24

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SCTR Research Nexus Laboratory Procedures

Emergency Plan for Power Outage or Equipment Failure Continued

- Samples/Protocols potentially impacted during the power outage/equipment repair period will be noted in the Reese documentation and in the Freezer Incident Tracking Log.
  - Using documentation of protocols located within each freezer, Freezerworks (where all samples have documentation including patient information, protocol, and time stamps) can be searched and used to create a list of samples/aliquots stored during this outage timeframe.
- For the liquid nitrogen (LN2) freezer, samples are stable even in a power outage; at maximum level the temperature should remain constant for at least 12 hours. LN2 levels should be checked with a yardstick and manually filled if needed with the hose while the power is out. The LN2 level should never be above the bottom of the lowest box in a rack to avoid compromising sample cryovials and potentially contaminating the freezer.

Reference:

SOP Title: Nexus Laboratory Emergency Plan for Power Outage or Equipment Failure	Version: 7
SOP Number: Nexus-5 (previously CTRC-5)	Effective Date: 02/16/24

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SCTR Research Nexus Laboratory Procedures

Sample Destruction Procedures:

- The Research Nexus Lab must receive written instruction from the protocol PI requesting that samples be destroyed, and the instruction must indicate specifically which samples are to be discarded (i.e., protocol XXX plasma samples, protocol XXX biomarker samples).
- The MUSC principal investigator (PI) must complete, sign, and date the Nexus Lab Sample Destruction Form.
- The destruction of samples will be witnessed by a second Lab Technician or Lab Manager, who will also sign and date the Nexus Lab Sample Destruction Form.
- All samples for destruction are discarded according to MUSC Institutional Policy. Once the Nexus Lab Sample Destruction Form is completed, the MUSC PI's written destruction request is attached to the Nexus Lab Sample Destruction Form. The documents are placed in the appropriate protocol file and retained for a minimum of three years per MUSC Institutional Policy.

Reference:

SOP Title: Nexus Laboratory Sample Destruction	Version: 3
SOP Number: Nexus-8 (previously CTRC-8)	Effective Date: 03/13/15

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MUSC Policies, SOPs & Guidelines

The table below is a list with links to MUSC's public-facing research-related policies, Standard Operating Procedures (SOP), and guidelines.

Education and Training Requirements for Individuals Involved in Human Research	Principal Investigator Responsibilities - Supervision of Staff and Protection of Subjects	Research Involving Non-English Speaking Subjects
Electronic Medical Record Access for Research Monitors/Sponsor Auditors	Principal Investigator Responsibilities - Recordkeeping and Record Retention Requirements	Research Involving Persons with Impaired Decision Making Capacity
Equitable Selection of Subjects	Privacy and Confidentiality	Site Signature and Delegation of Authority Standard Operating Procedure (SOP)
Human Research Audit	Protocol Deviation	State Laws Affecting Human Subjects Research
Informed Consent to Participate in Research	Relying on an External IRB	Statement on Epic Compliance with 21 CFR Part 11
Investigational Drug Services*	Research Data Ownership and Record Retention	Unanticipated Problems and Adverse Events
Management of Reporting Events in Multi-Site Research Studies	Research Documentation in the Legal Medical Record*	Additional MUSC IRB policies are available at https://research.musc.edu/resources/ori/irb/policies
Medication Orders	Research Involving Children	

For questions related to other research-related policies, SOPs and guidelines, contact the OCR/ROC team at ResearchOppCollab@musc.edu.

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Electronic Signatures

MUSC FDA Non-Repudiation Letter for Electronic Signatures

MUSC
Medical University
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Kathleen T. Brady, MD, PhD
Distinguished University Professor

Vice President for Research

Director and Principal Investigator
South Carolina Clinical & Translational Research (SCTR) Institute

Colcock Hall
179 Ashley Avenue
MSC 002
Charleston, SC 29425-0002

Tel 843 792-5205
Fax 843 792-4817
bradykt@musc.edu

April 6, 2020

FDA
Office of Regional Operations (HFC100)
5600 Fishers Lane
Rockville, MD 20857

Dear Sir or Madam,

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that Medical University of South Carolina intends that all electronic signatures executed by our employees, agents, or representatives, located anywhere in the world, are the legally binding equivalent of traditional handwritten signatures. This certification applies to all current and future use of electronic signatures, unless otherwise notified through formal notification to your agency.

Respectfully submitted,

Kathleen T. Brady, MD, PhD
Distinguished University Professor
Vice President for Research
Director, South Carolina Clinical & Translational Research (SCTR) Institute

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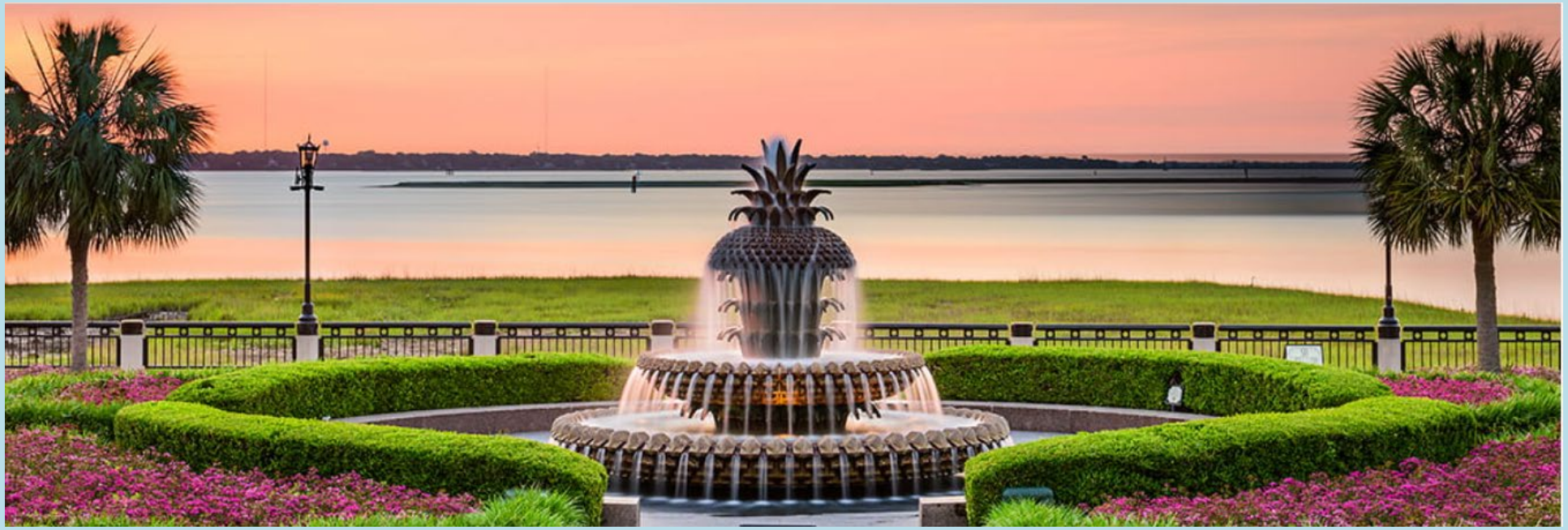

Visitor & Campus Information

For a virtual tour of the MUSC Charleston campus, visit https://virtualtour.musc.edu/.

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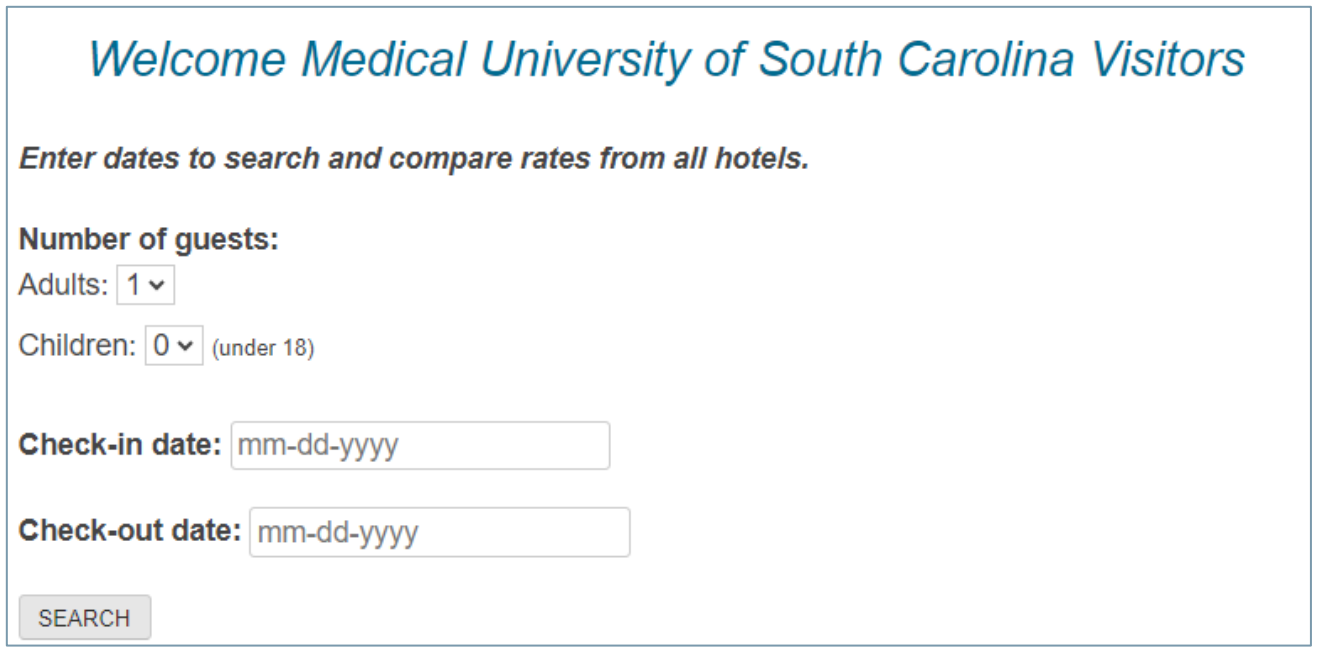
Hotel Accommodations

When visiting MUSC, please choose from our list of preferred hotels. The list and access to the hotel websites can be found at http://www.campustravel.com/university/musc/visit_musc.html.

To compare rates at these different hotels, use the link below to enter the check-in and check-out dates.
https://campustravel.com/university/medical-university-of-south-carolina/medical-university-of-south-carolina-search/



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Parking Locations & Directions

There are four parking garages on the MUSC Charleston campus. For more information, visit http://www.muschealth.org/patients-visitors/patient-information/parking.html.

For **Ashley River Tower** and the **Shawn Jenkins Children's Hospital and Pearl Tourville Women's Pavilion:** McClellan Banks Garage

21 McClellan Banks Drive (The entrance can be accessed via Bravo Street, Charleston Center Drive, or McClellan Banks Drive from Calhoun Street.)

For the **Medical University Hospital**, **Rutledge Tower**, and the **Storm Eye Institute:** Ashley-Rutledge Garage

158 Ashley Avenue (Entrances are located on Ashley and Rutledge Avenues and have a 6'8" clearance.)

Patients or visitors with disabilities may use the Rutledge Tower Surface Lot at 135 Rutledge Avenue.

For the **Institute of Psychiatry**, **Hollings Cancer Center**, the **Clinical Sciences Building**, and the **Adult or Pediatric Emergency Rooms:** Jonathan Lucas Street Garage

97 Jonathan Lucas Street (The entrance is located at President & Doughty and has a 6'8" clearance.)

For the **James B. Edwards Dental Clinic:** President Street Garage (E-lot)

91 President Street (The entrance is located at the corner of Bee and President Streets.)

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Campus Information

Visitor Badge

Visitors over the age of 16 are required to obtain a visitor badge upon entering the hospital. Obtain a visitor badge at the Information Desk, located at the hospitals' entrances; a valid photo ID is required.

Safety Escort Program

The Medical University Department of Public Safety is committed to ensuring a safe environment for all students, employees and visitors at the University. The campus escort service provides personal safety escorts 24 hours a day, 7 days a week and is designed to provide escorts to all MUSC students, employees, visitors, and customers around the University Campus and the surrounding area (normally within two blocks). Special requests will be honored on a case-by-case basis. To access the escort service, call 843-792-2261 or 843-792-4196.

Smoking Policy

Effective March 1, 2012, MUSC was designated a tobacco-free campus. Smoking is not permitted in any areas on campus. This includes the use of chewing tobacco and e-cigarettes. As South Carolina's academic health center and home to the only National Cancer Institute-designated cancer institute in the state, it is a part of our mission to prevent cancer and to lead by example in providing the healthiest environment possible for everyone on our campus.

View the Smoke-Free Medical District Map (PDF)

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Internet Access

MUSC provides free wireless internet access for patients and visitors at the Medical Center campus. This service is provided on an as-is basis and is supported on all wireless devices with standards-based web browsers. This includes Windows laptops, Macs, Linux and iPhones.

To connect to the network:

1. Open your wireless network utility and join the MUSCGuest network.
2. Once you connect, open your browser.
3. You will be presented with MUSC's Terms of Use. Click Accept, and OK.
4. The MUSC Guest Wireless Network page will display. You are now connected to the internet.

Terms of Use for MUSC Guest Wireless Network

This network is the property of The Medical University of South Carolina (MUSC) and may be accessed only by authorized guests of MUSC.

Unauthorized use of this network is strictly prohibited and subject to criminal prosecution.

The data you send and receive over this network is not encrypted and may be viewed or intercepted by others. Use this network at your own risk. Privacy and security safeguards are the user's responsibility; this network does not provide any. MUSC does not warrant or represent that this service will be uninterrupted, error-free, or secure. Users should be aware that there are security, privacy, and confidentiality risks inherent in wireless communications and technology.

The University may monitor any activity or retrieve any information transmitted through this network, to ensure compliance with MUSC policy, and with federal, state and local law. By accessing and using this network, you are consenting to such monitoring and information retrieval by MUSC. Users should have no general expectation of privacy or confidentiality when using this network.

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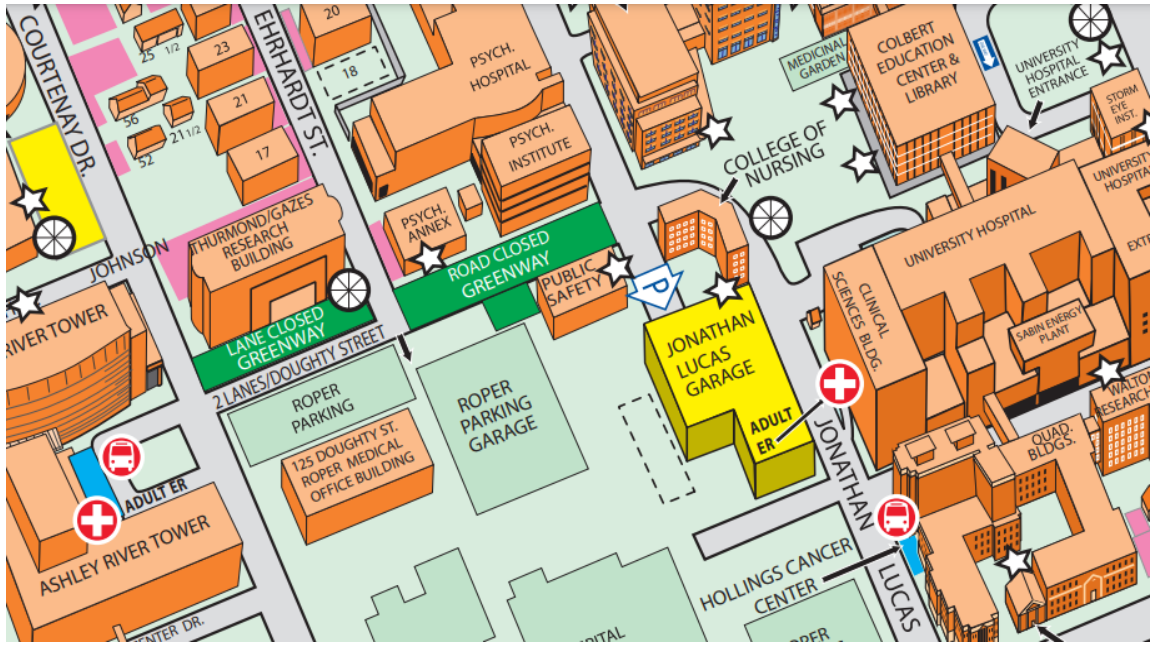
Dining Options

- The **Charleston Medical District Greenway** is located at 105 Doughty St. from President Street to Courtenay Drive and offers food trucks Monday-Friday as well as outdoor dining space.
- MUSC Charleston has three main **cafeteria** dining locations with multiple dining options available. All major credit cards are accepted (VISA, MasterCard, Discover, and American Express).



- Signs from all hospital entrances provide direction to the cafeteria area.
- Visitors can call the cafeteria MENU line at 843-792-8713 to hear about daily specials.

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Dining Options

University Hospital Cafeteria

Monday through Friday Hours of Operation: 6:15 am to 12:00 am.

Hot Bar
Breakfast**:** 6:15am - 10am
Lunch/Dinner: 11am – 7pm

Grill offers quality grill options, cooked to order.
Breakfast: 6:30am - 10am
Lunch:11am - 2pm
Dinner: 5pm-7pm; 8pm-12am

Starbucks Express: 6:30am – 2pm
Located near the main entrance of the University Hospital.

The Corner Café & Freshens: 11am – 3pm

Chick-Fil-A®: 11am – 2pm and 5pm – 7pm

Subway® : 8am – 12am

Ashley River Tower Cafeteria

(Located on the first floor of the Ashley River Tower (ART))
Monday through Friday Hours of Operation: 6:30 am to 12:00 am

Hot Bar
Breakfast**:** 6:30am - 10am
Lunch/Dinner: 11am – 7pm

Grill
Breakfast: 6:30am - 10am
Lunch/Dinner:11am - 12am

Subway®: 10am – 12am

Shawn Jenkins Children's Hospital and Pearl Tourville Women's Pavilion

(Located on the seventh floor of the Shawn Jenkins Children's Hospital.)
Monday through Friday Hours of Operation: 6:30 am to 12:00 am
Closed for cleaning daily: 10am-11am, 2:30pm-3:30pm

Starbucks Express: 6:30am – 2pm
(Located outside the Shawn Jenkins Children's Hospital cafeteria)

Breakfast**:** 6:30am - 10am
Lunch: 11am – 2:30pm
Dinner: 3:30pm – 8pm

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Dining Options

Nearby off-campus dining:

- Caviar & Bananas (Located across Ashley Avenue from the MUSC Library)
  170 Ashley Avenue
  Charleston, SC 29403
- Fuel Charleston (Located on the corner of Rutledge Avenue and Cannon Street)
  211 Rutledge Avenue
  Charleston, SC 29403
- For more Charleston dining options, visit https://www.charlestoncvb.com/visitors/tripplanner/where_to_dine~2/

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Automated Teller Machines (ATMs)

The following ATMs are conveniently located throughout our hospitals.

Bank of America

- Located near the Cafeteria entrance in the University Hospital.
- Located on the 1st floor of Rutledge Tower.

SC Federal Credit Union

- Located inside the Children's Hospital entrance on the right as you walk in the main entrance.
- Located near the Cafe in the Ashley River Tower (ART).

Wells Fargo

- Located near the Children's Hospital elevators on the 1st floor.
- Located on the 2nd floor of the University Hospital.

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MUSC Industry Research Liaisons

Signe Denmark, MS, CCRP

Associate Director, Research Opportunities & Collaborations (ROC) and Finance

Kristen Clasen DeHart, M.Ed

Research Opportunities & Collaborations Metrics and Evaluation Program Manager

Heather Hopmeier, BS

Research Opportunities & Collaborations Program Coordinator

The Office of Clinical Research's ROC team welcomes feedback or suggestions from our clinical research collaborators.

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Contact Us

ResearchOppCollab@musc.edu

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The Medical University of South Carolina

ABOUT MUSC

Founded in 1824 in Charleston, MUSC is the state's only comprehensive academic health system, with a unique mission to preserve and optimize human life in South Carolina through education, research and patient care. Each year, MUSC educates more than 3,200 students in six colleges – Dental Medicine, Graduate Studies, Health Professions, Medicine, Nursing and Pharmacy – and trains more than 900 residents and fellows in its health system. MUSC brought in more than $300.6 million in research funds in fiscal year 2023, leading the state overall in research funding. MUSC also leads the state in federal and National Institutes of Health funding, with more than $220 million.

For information on academic programs, visit musc.edu.

As the health care system of the Medical University of South Carolina, MUSC Health is dedicated to delivering the highest-quality and safest patient care while educating and training generations of outstanding health care providers and leaders to serve the people of South Carolina and beyond. Patient care is provided at 16 hospitals (includes owned and equity stake), with approximately 2,700 beds and five additional hospital locations in development; more than 350 telehealth sites and connectivity to patients' homes; and nearly 750 care locations situated in all regions of South Carolina. In 2023, for the ninth consecutive year, U.S. News & World Report named MUSC Health University Medical Center in Charleston the No. 1 hospital in South Carolina.

To learn more about clinical patient services, visit muschealth.org.

MUSC has a total enterprise annual operating budget of $5.9 billion. The nearly 26,000 MUSC family members include world-class faculty, physicians, specialty providers, scientists, students, affiliates and care team members who deliver groundbreaking education, research, and patient care.

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