

SOP #1  
Restricted Access Policy

## 1. Introduction

Research involving Magnetic Resonance Imaging (MRI) at high magnetic field strengths presents unique hazards to both research subjects and individuals working within and around the MRI system. Consequently, the potential for serious personal injury is present due to the sheer size and strength of the static magnetic field. The static magnetic field always present. It is important that all those entering the facility be aware of the presence of the field, as it cannot be detected in any way, i.e. magnetic fields cannot be felt, seen or smelled. Ferromagnetic objects brought into the magnet room could quickly become dangerous projectiles, and the magnetic field can also interfere with the operation of certain medical implants.

## 2. Zones (Floor Plan shown in Appendix A1)

The MRI facility is divided into separate safety zones, labeled Zones I–IV as per the ACR standard convention:

- Zone I is accessible to the general public and is unsecured during normal working hours (the Lobby/Waiting room).
- Zone II is located within secured doors and contains research space but does not present any elevated risk.
- Zone III is contained within additional security doors and may contain magnetic fields greater than 5 Gauss and/or permit direct access to Zone IV. People with certain medical implants, such as pacemakers, should not enter areas with magnetic field strengths of 5 Gauss or greater.
- Zone IV are the magnet rooms. The door to these rooms are physically locked with a key and must be kept locked when the scanner is not in use.

## 3. Entry requirements

- Zone I. Unrestricted.
- Zone II. Card access to Zone II is granted to UD personnel as needed. Anyone else who enters this zone must be accompanied by someone who does have access.
- Zone III. Card access to Zone III is granted to Level 1 and 2 users. Anyone else who enters this zone must be supervised by a Level 1 or 2 user.
- Zone IV. All those needing to enter the magnet room must complete a Magnetic Resonance Safety Screening Form (Appendix A2) and have it reviewed and approved by a Level 2 user before entering the magnet room. Research subjects need to fill out a new form each time they are scanned. Auxiliary staff screening forms will be kept on file here and at their home department. It is the responsibility of those individuals to notify their supervisors and the Center Manager of any changes in their MRI-safety related status. Level 1 and 2 users may enter Zone IV unsupervised. Anyone else who enters Zone IV must be supervised by a Level 2 user.

- 4. Access requests** Card access to any of the secure doors must be requested by e-mail to the Manager. Unsupervised access to Zones III and IV will only be granted to personnel who have completed Level 1 safety training.

SOP #2  
Ethics approval

1. All research studies involving human subjects or animals must be approved by the University of Delaware Institutional Review Board (IRB) or the Institutional Animal Care and Use Committee (IACUC).
2. The PI and research team is responsible for administering the consent documents to the research participants.
3. Any event that requires an emergency response or exposed research participants to unanticipated risks must be reported to the Director and appropriate oversight committee (IRB or IACUC) within 24 hours of the incident.
4. Certain uses of the MRI scanner are not classified as research, including demonstrations, course work and quality assurance. Participants in these non-research activities must complete the non-research waiver form (Appendix A3) and not an IRB consent form. Contact the Director if you are not certain whether your planned use of the MRI scanner is classified as research or not.

SOP #3  
User Levels and Safety Training Procedures

**Level 1** Users are trained to safety screen themselves to enter the MR environment and are authorized to independently enter Zones III and IV and to supervise others in Zone III. To be eligible for Level 1, candidates must be screened to enter the MR environment by the MR Safety officer and successfully complete the Level 1 Safety Training:

1. A current and accurate MRI screening form must be on file with the center manager or director.
2. Attend Level 1 safety training session with the CBBI Manager.
3. Completion of the Level 1 written test. The minimum passing grade is 90%
4. The center manager will authorize Level 1 status. Annual retraining and reviews will be required to maintain Level 1 status.

**Level 2** Users are trained to administer MR safety screening to others, may supervise others in Zone IV, and may independently operate the MRI scanner for research studies. To be eligible for Level 2, candidates must already be authorized Level 1 user and successfully complete the Level 2 Safety Training:

1. Watch the Siemens Safety Video focusing on the last 11 minutes (Subject Preparation and Examination, etc.) as well as the Manny Kanal LEVEL II video (both videos CBBI website).
2. Read "Part A: Safety" of the Operator Manual.
3. Read the UD CBBI's Standard Operating Procedures and sign the SOP agreement form indicating that you understand the procedures and agree to adhere to them.
4. Attend a Level 2 training session with the Safety Officer to learn:
  - how to administer the safety screening form (Appendix A2).
  - Hazards (see SOP #4).
  - to explain the MRI-specific language on the informed consent forms and the non-research waiver.
  - how to check for the MRI safety of medical implants
  - how to screen subjects to ensure their MRI safety including the acceptability, or need for removal, of foreign objects.
  - the procedures for incidental findings.
5. Complete the Level 2 Safety Training Test. A score of 90% or higher is required to pass.
6. Shadow and receive supervision from Level 2 user for approximately 5 scanning sessions (adjusted based on past education and experience). This time must include the following tasks:
  - Thorough review of how to screen others to ensure their safety into the magnet room
  - MR system preparation
  - Execution of scanning procedures
  - Research participant registration
  - Starting and Stopping measurements
  - Communicating with participant during scan session
7. The center manager will authorize Level 2 status. Annual retraining and reviews may be required to maintain Level 2 status.

SOP #4  
Hazards

1. **High Static Magnetic Fields.** High static magnetic field strengths are present in Zones III and IV. These strong magnetic fields pose potential risks to those working, volunteering, or touring in the environment.
  - 1.1 All metallic objects have the potential to become projectiles in the MR environment, as they may contain ferrous components. This could potentially cause serious injury to anyone near the magnet, as well as damage to the MRI system.
  - 1.2 No objects or devices should not be brought into the magnet room without prior approval for the Center Manager or Director.
  - 1.3 It is mandatory to remove all personal objects made of, or potentially containing, metal from any person before they cross the 5 Gauss line as marked by the door threshold and on signs on the magnet room door. In addition to any items in pockets, metal items attached to the subjects must also be removed:
  - 1.4 Clothing: Metal studded clothing, belt, steel toe shoes/boots, athletic/sports clothing containing metal (e.g., clothing items made of metal containing fabrics of brands like Athleta, Columbia, Omniheat, Lululemon, and TommyCopper), clothing with excessive zippers
  - 1.5 Accessories: jewelry (including metal body piercings), watch, hair pins, barrettes, wigs and hair extensions
  - 1.6 Any individual with a device classified as "MRI-Not Safe "may not proceed beyond the 5 Gauss line. The 5 Gauss line is marked at the entry door into the magnet room and extends through the observation window at the operator's console. There are also areas exceeding 5 Gauss in the equipment room.
2. **Rapidly Changing Magnetic Fields.** Rapidly changing magnetic fields are generated by gradient and RF coils in the MRI scanner during data acquisition. These fields pose potential risks for volunteers being scanned and for personnel working in the bore during the scan. To minimize the risk of burns it is important to prevent skin-to-skin contact points and the formation of "closed-loops" resulting from body parts in contact with each other. Contact between skin and the transmitting body coil must also be avoided. This can be achieved by using foam padding available on the shelves in the magnet room. Objects with good electrical conductance must not be permitted to rest against the skin of the subject within the region spanned by the body coil and should not be permitted within the body coil unless essential for the successful execution of the study.
3. **Sound.** During certain types of MRI data collection, there exists high, and therefore potentially dangerous acoustic sound pressure levels (SPL). It is mandatory for the subject, and all others who are present in the magnet room during the scan session to wear hearing protection in the form of high rated NRR earplugs and/or headphones.
4. **Electrical Power.** Dangerous and potentially lethal levels of electricity are present in the MRI systems. As such, it is important that all individuals working around the MRI system be aware and knowledgeable regarding the relevant danger and safety issues. There is a risk of electric shock from extremely high voltages, possibly causing severe injury or death, and damage to the MRI system. Only trained personnel should set up hardware in the magnet room and plug in or change the placement of any cables. High currents in wires also pose a risk of fire.
- 5.

SOP #5  
Medical Emergency Procedure

1. A medical emergency is defined as a situation in which a person requires immediate medical attention, because of an acute injury or illness that poses an immediate risk to a person's life or long-term health. Medical emergencies encountered in the MRI environment may include stroke, cardiac arrest, impaled objects, crush wounds or burns.
2. If a medical emergency arises, the procedure set out below must be followed:
  - 2.1 Immediately STOP the scan (if in progress).
  - 2.2 Remove the research subject from the scanner.
  - 2.3 Either use the "Home" button to advance the bed out of the scanner, or Pull the Emergency Release located under the support frame of the bed to unlock the clutch and pull the bed out manually.
3. Remove the injured person from the magnet room either by aiding them while walking or by using the non-magnetic stretcher as follows:
  - 3.1 Place the stretcher next to the MRI bed.
  - 3.2 Lock wheels in place to avoid movement of the stretcher.
  - 3.3 Slide the person onto the stretcher using the sheet to help you.
  - 3.4 Protect the person's head at all times.
  - 3.5 Raise the side-rails of the stretcher, unlock the wheels and move the stretcher into the control room.
  - 3.6 Close the magnet room door.
  - 3.7 Assess the condition of the injured person. If immediate medical assistance is required:
    - Call UD Security
    - Prop open the Control Room door to facilitate access for the emergency response team.
    - Have someone wait at the entrance to the CBBI to let the paramedics into the facility when they arrive.
    - Provide first aid or help the injured person according to your skills, knowledge and comfort level. Follow instructions of emergency personnel when they arrive.
    - The paramedics or other emergency responders must not enter the magnet room.
4. Once the emergency situation has been responded to, report the incident to the Director, Safety Officer and UD's EHS.
5. All medical emergencies involving human or animal research subjects must also be reported to the applicable ethics review committee (IRB or IACUC) within 24 hours of the incident.

SOP #6  
Emergency Fire Procedure

1. **First Signs of Potential Fire.** In most instances, there are signs of a potential fire present before a fire occurs. Awareness of these early signs can be critical in the prevention of injury to the subject and other research support personnel in the magnet room, equipment room and the control room during a scan.
  - irregular noise, for example a loud popping sound or a sudden stop of the gradients. It is imperative that the operator determine the cause of the irregular noise before continuing with the scan session.
  - subtle odor
  - small amounts of smoke
  - smoke detector has gone off and an alarm is sounding in the magnet room
2. **If any signs of fire are detected:**
  - 2.1 Immediately STOP the scan (if in progress).
  - 2.2 Shut-down the electrical power to the MRI
  - 2.3 If applicable, remove the participant from the scanner
  - 2.4 Quickly investigate the source of the irregular noise, odor or smoke without putting yourself at risk. Limit exposure to potentially harmful chemical smoke
  - 2.5 Contain fire if possible
  - 2.6 The sprinkler system will only activate if there is sufficient heat and smoke being emitted by the fire. If the sprinklers have not yet activated and it is safe to do so, use the non-magnetic fire extinguisher to put out the fire. The non-magnetic fire extinguisher is located to the right as you enter the control room.
  - 2.7 Close the magnet room door to prevent noxious fumes from permeating the rest of the building.
3. **If the fire is uncontrolled** (sprinklers or fire extinguisher have not been able to successfully contain the fire)
  - 3.1 remove all personnel from the magnet room
  - 3.2 close the door to the magnet room
  - 3.3 quench the magnet following SOP #7 "Emergency Quench Procedure".
  - 3.4 Evacuate the building, pull the fire alarm on the way out. They are located in the waiting room near the front door, as well as at each exit
  - 3.5 immediately call UD Security
  - 3.6 UD Security will help guide the Fire Department to the correct location. CBBi address location is 77 East Delaware Ave., Newark, DE.
  - 3.7 Meet UD Security and/or the fire department at the exterior door.
  - 3.8 Give them details regarding the incident including the specific location of the fire and whether or not the magnet has been quenched.
  - 3.9 If the magnet has not been quenched the fire fighters must be informed that the magnet is still on. The fire fighters must not enter the magnet room with their gear donned; doing so could cause serious injury to themselves or anyone near the magnet at the time.
  - 3.10 If the fire fighters deem it necessary to enter the magnet room with their gear donned, the magnet must be quenched following SOP #7 "Emergency Quench Procedure".
  - 3.11 Inform the fire department that there are plastic bottles (phantoms) containing nickel sulfate in the southwest corner of the magnet room. The phantom fluids may produce nickelous aerosols. Notify the Director, Safety Officer and UD EHS.

**4. After immediate safety concerns have been addressed**

4.1 Notify the Director, Manager, and UD EHS

4.2 Do not resume scanning until integrity of all safety and MRI operation systems have been checked by the Center Manager.

SOP #7  
Emergency Quench Procedure

- Quenching the magnet means to rapidly boil off and evaporate the liquid helium that keeps the magnetic coils cooled below their critical superconducting temperature. While the coils are superconducting, electrical current flows through them without any electrical resistance, generating the magnetic field. Once the coils are raised above this critical temperature, they will lose their superconductivity and exhibit electrical resistance, and the electrical current flowing through them will dissipate. This will rapidly turn off the magnetic field.
- Quenching the magnet is a potentially hazardous situation. The evaporated coolant is extremely hazardous and requires an emergency ventilation system, consisting of a bursting disk and quench pipe through the building's roof. If this ventilation system were to fail, the result would be a rapid pressurization of gaseous helium in the magnet room, displacing the oxygen.
- Quenching the magnet can cause damage to its structural integrity, potentially requiring expensive repairs, and certainly necessitates a costly helium refill.
- Once initiated, a quench cannot be stopped.

There are two situations in which a quench may occur:

- Spontaneously, due to some force or disruption of the magnet system.
- Intentionally, when the emergency quench button is pressed.

### 1. Spontaneous Quench

- 1.1 You will notice the extremely loud noise and might notice the loss of the magnetic field
- 1.2 Immediately abort the current scan
- 1.3 Evacuate the magnet room
- 1.4 Close the door to the magnet room

### 2 Intentional Quench

- 2.2 The emergency quench button must be pressed in the following situations:
- An uncontrolled fire has occurred. Refer to SOP #6 "Emergency Fire Procedure".
  - An individual is pinned, impaled, and in a life-threatening situation because of a large ferromagnetic object and no other method can prevent further injury or free the person.
- 2.2.1 Do NOT attempt to pull large magnetic objects away from the magnet. The object may reorient itself to the magnet field lines and become a projectile, potentially causing further serious or fatal injuries.
  - 2.2.2 If the situation is not life-threatening, it may be possible to have a Siemens Service engineer ramp the magnet down slowly. This might be a better option because the quench itself is dangerous.
  - 2.2.3 If the magnet was quenched because someone was pinned, and they are injured, follow procedures outlined in SOP #5 "Medical Emergency Procedure".



- 2.3** The emergency quench buttons are located:
- 2.3.1 In the Control Room, to the left of the operator console at the center of the Siemens Alarm Panel. The button is red and is labeled STOP. It is covered by a plastic protective guard with a yellow sticker and a “no-magnet” symbol.
  - 2.3.2 In the magnet room, immediately right to the side door in the room. The button is red and is labeled STOP. It is covered by a plastic protective guard with a yellow sticker and no-magnet symbol.

**3** Evacuate the magnet room

**4** Close the door to the magnet room

**After all quenches, notify the Director and Manager, UD Security, and UD EHS.**

SOP #8  
General Experimental Procedures

1. Support by center staff is provided during regular weekday hours Monday through Friday, 8 a.m.–5 p.m. Other times may be available upon advanced request.
2. Operators must log their time on the logbook next to the MRI console computer. No identifying information will be included in the log.
3. No identifying information will be included on the MRI console when registering subjects. Use only the age or year of birth, and not the exact birthdate, and do not use subjects' initials or real names in the subject ID.
4. Scanning sessions need to end punctually so as not to delay the next users. Extensions are permitted if mutually agreed and the operator is available.
5. The following devices must be operational to be able to scan:
  - Call button
  - Audio system
  - Fire extinguisher
  - Smoke detector
  - Oxygen Sensor
6. Any malfunctioning device or peripheral equipment should be immediately reported to the MRI manager or Director so that repairs can be initiated and affected user informed.
7. At the end of a scanning session, soiled linen must be placed in the laundry hamper, and all peripheral devices including RF coils must be returned to the original locations and settings.

SOP #9  
Siemens Prisma Data Handling

1. At the end of each scanning session, the operator will transfer the data to the DICOM database computer. This computer is on a private network with the MRI scanner and is not accessible from the general university network.
2. Data will remain on the MRI console for a minimum of 1 week.
3. Data will remain in the DICOM database for a minimum of 6 months. The DICOM database should not be considered a primary backup source. It is the responsibility of each Investigator to back up their own data.
4. Data in the DICOM database can be exported to a secure network attached storage (NAS) device that has access to both the private network and the university network.
5. Each Investigator will be given a user account on the NAS and is responsible for transferring data to their local systems using sFTP. The NAS should be considered temporary storage just to enable this transfer and is not a primary backup source. Data on the NAS may be deleted at any time.

SOP #10  
Siemens Prisma System Operations

**1. System start-up and shutdown**

**1.1** Powering on the system.

- 1.1.1 The key must be turned to the “on” position on the Siemens control panel.
- 1.1.2 Press the “SYSTEM ON” button located on the control panel.
- 1.1.3 Do not interact with the system hardware or software while the system is booting. This will cause system errors that will necessitate a system reboot.
- 1.1.4 The system is operation and ready for use when:
  - You hear 3 “knocks” from the system
  - A “system online” message will appear in the magnet status window
  - The red line will disappear from the magnet status icon

**1.2** Powering down the system

- 1.2.1 The MRI table should be in the “Home” position
- 1.2.2 Click System < Control < End Session. This will initiate the software shutdown. This process takes several minutes.
- 1.2.3 The MRI display will go dark upon completion of the software shutdown. After this has occurred, press the “SYSTEM OFF” button located on the control panel.
- 1.2.4 Assure the door to the MRI room is closed and locked.

**2. Power loss to the 3T scanner.**

- 2.1 If power is lost to the scanner during the scan, follow these procedures
  - 2.1.1 Remove the subject from the scanner by pulling the emergency release button located under the support frame of the bed to unlock the clutch and pull out the bed manually.
  - 2.1.2 Notify the center manager.

**3. System alarms**

- 3.1 Oxygen sensor alarm. The room is equipped with an oxygen sensor connected to a monitoring panel in the control room.
  - 3.1.1 Ambient oxygen levels are continuously monitored by the CBB staff and campus safety. In the event an unsafe level is detected campus safety will respond, and users will be advised if any action is required.
  - 3.1.2 Occasionally, the sensor may enter an error state, and will emit an audible alarm. This is an indication the sensor may need to be serviced. Notify CBB staff in this event, but no further action is required.
  - 3.1.3 Ambient oxygen levels will only drop to unsafe levels during a magnet quench, in which Emergency Quench Procedures (SOP #7) should be followed.
- 3.2 Compressor alarm. All superconducting magnets are equipped with compressors that recirculate the cryogenics that maintain the magnetic field. In the event of a compressor fault, the cryogenic helium is no longer recirculated, and the system will begin to rapidly boil off helium, putting the magnetic field in imminent risk.
  - 3.2.1 An audible pumping or chirping noise is an indicator the pump is functioning normally.
  - 3.2.2 If this sound is not present, notify the center manager immediately.

- 3.2.3 An audible alarm and a red light will emit from the system control panel located on the wall in the event of a compressor fault. Notify the center manager immediately if this occurs.

#### **4. Quality Assurance Testing, Maintenance and System Errors**

- 4.1 Weekly QA testing is performed by CBBI staff and is recorded in the red binder located in the control room.
- 4.2 The MRI system undergoes periodic preventative maintenance from Siemens to assure system performance.
- 4.3 Occasionally unknown errors are encountered with the system hardware and/or software. In the event of an error such as this, follow these procedures:
  - 4.3.1 Record the error in the error log, located in the red binder
  - 4.3.2 Notify the center manager
  - 4.3.3 Level 2 system operators are encouraged, but not required, to call and report the issue to the Siemens Uptime Service Center. The contact and system information can be found in the red binder.

SOP #11  
Incidental Findings

- 1.** Images acquired at the CBBI generally do not meet the requirements needed for a medical diagnosis. Further, the images are not routinely reviewed by a radiologist or licensed medical provider. Therefore, research subjects should not have any expectations that their MRI scans will have any diagnostic value.
- 2.** Subjects may be shown or given copies of their images for their personal use, but they should be informed that there is a large natural variation and that the images should not be scrutinized for anomalies by untrained persons. Investigators should not make comments about the MRI images nor answer any questions that they are not qualified to answer.
- 3.** If an operator or investigator detects a potential anomaly during a scanning session, the procedure below should be followed:
  - 3.1 Continue the scanning session as usual and do not inform the subject.
  - 3.2 After the completion of the scanning session, notify CBBI personnel. Do not show the potential anomaly to the subject.
  - 3.3 If CBBI personnel concur that further assessment of the scan is warranted, they will send the images to a radiologist for review. The PI will be consulted to see any medical history should be attached to the images.
  - 3.4 The radiologist will determine if additional medical attention or follow up is required.
  - 3.5 If additional attention is required, this information will be conveyed to the PI who will then inform the participant. Otherwise the subject should not be informed.

SOP #12  
Subject Screening process for MRI

1. Before entering Zones III and IV, all human subjects undergoing an MRI will complete an MRI screening form. Subjects must complete a screening form prior to each appointment.
2. All subjects undergoing an MRI must be screened by Level 2 personnel.
3. The screener(s) must conduct a thorough inquiry regarding the research subject's attire. If the subject's clothing is suspicious for containing metal or metallic fibers, the subject must be made to change into MRI safe attire provided by the center.
4. The research subject will be instructed to remove any piercings, hearing aids, bobby pins (or anything in the hair containing metal), medication patches containing foil, or any other items not already described, deemed to be a safety risk by the Level 2 screener(s). Subjects will be provided a secure location to keep their belongings during their appointment.
5. The level 2 screener will conduct a thorough interview with the subject using the MRI Safety Screening Form.
  - 4.4 In the event the subject indicates "no" to all responses on the screening form, no further action is required.
  - 4.5 In the event the subject indicates a "yes" response(s), further investigation is required.
    - 4.5.1 Any "yes" response to questions within the first column of the MRI safety screening form precludes the subject from undergoing an MRI for research purposes. Do not proceed. Under certain circumstances, scans may still be conducted with prior approval from center leadership.
    - 4.5.2 A "yes" response to questions in the second column must be evaluated individually. In many instances, a "yes" response to questions in this category does not preclude the individual from undergoing an MRI. If you are unsure, do not proceed, and contact the center manager.
  - 4.6 Under most circumstances, medical implants of the following types can be permitted, assuming the appropriate procedures are followed: Orthopedic, orthodontic, and dental hardware.
    - 4.6.1 Corrective orthodontic braces, permanent retainers, fillings, caps, crowns, and any other type of permanent dental or orthodontic fixtures are permitted.
    - 4.6.2 Dentures, partials, and bridges must be evaluated on a case-by-case basis. No further documentation is needed.
    - 4.6.3 Orthopedic implants for the purposes of joint replacement (e.g. hip prosthesis) or internal fixation (e.g. plates, screws, nails, pins, rods) are not considered to be unsafe for MRI. However, special consideration should be given to increases in thermal deposition if the tissue is within the region to be scanned (e.g., lumbar spine scan with implanted screws and plates), and an increased likelihood of image artifacts. Documentation is preferred, but not required.
    - 4.6.4 Intrauterine devices. The subject must be readily able to identify what type of device they have. If the subject has an implant card, a copy will be made and be

affixed to their screening form. If the subject does not have an implant card, the device must be cross-referenced using the MRIsafety.com database or the device manufacturer's website. The MRI personnel will print the information from MRIsafety.com and affix it to the screening form. If the subject is unsure of the name of their device, do not proceed.

- 4.6.5 When applicable, as standard practice, all level 2 screeners will make a photocopy of a subject's implant card (when applicable), and/or make a printout of the MRI information provided by either MRISafety.com or the device manufacturer after receiving clearance from the Center Manager. This information will be affixed to the subject's screening form for record-keeping.

*Note: A physician's statement of device safety is not sufficient in determining the MRI safety of an implant but may be used to research the make and model of an implant.*

- 4.7** Subjects with implants categorized as "MRI safe" at 3 Tesla by either MRISafety.com or the device manufacturer can proceed without any further action.
- 4.8** Do not proceed under any circumstances for subjects with implants categorized as "MRI unsafe" and contact center manager.
- 4.9** For implants categorized as "MRI Conditional", prior approval by Center Manager is required.
- 4.10** Level 2 personnel will sign and date the MRI screening form upon completion of the subject interview. Copies of all screening are retained on-site by the center manager.