Baylor College of Medicine
Core for Advanced MR Imaging
(CAMRI)
Safety and Operations
Policies and Procedures Manual

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CAMRI Scientific Advisory Committee

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CAMRI Wiki
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CAMRI Website
https://www.bcm.edu/research/atc-core-labs/core-for-advanced-magnetic-resonance-imaging

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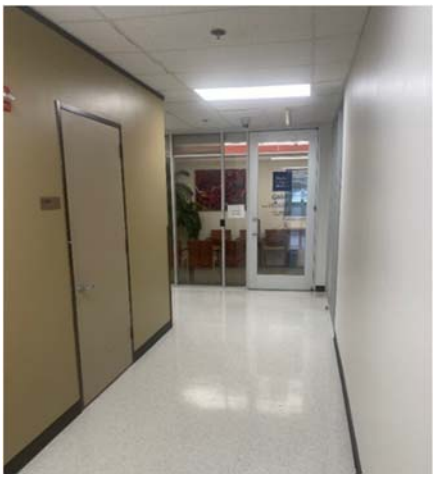
MRI SAFETY ZONES:

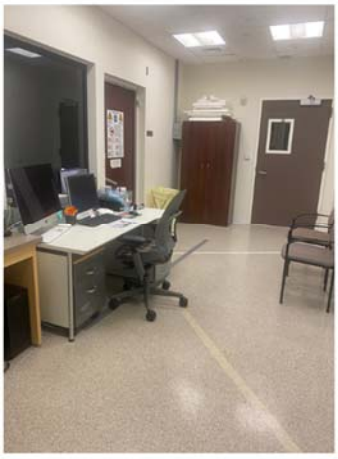
The area where the MR scanner is housed is divided into four safety zones in accordance with the American College of Radiology (ACR) Guidance for Safe MR Practices: 2007.

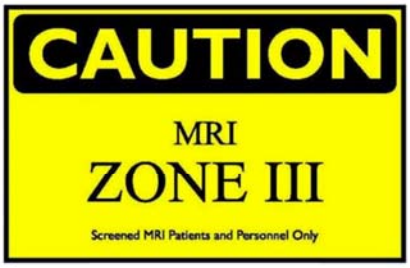
- **Zone 1** includes all areas accessible to the general public (the corridors outside the MRI Suite S104).



- **Zone 2** indicates the interface between publicly accessible Zone 1 and the restricted Zones 3 and 4. The MRI waiting room and CAMRI hallways where participants are greeted and screened before entering the scanner room is Zone 2. Main door badge access is required.

- **Zone 3** is the region in which free access by unscreened non-MR personnel or ferromagnetic objects or equipment can result in serious injury or death. **Zone 3 is strictly restricted.** The MRI Console Room and MRI Equipment Room are Zones 3a and 3b, respectively. Level 2 Advanced User badge access is required to enter Zone 3 & 4.

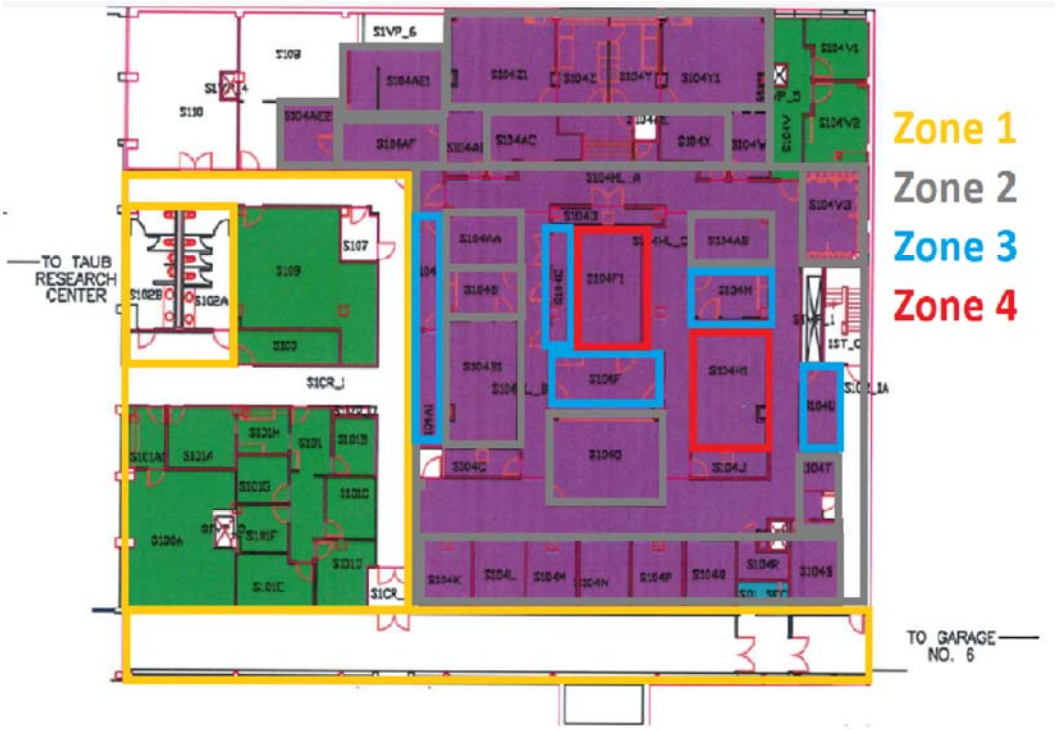




- **Zone 4** is synonymous with the MR scanner room, that is, the physical confines of the room within which the MR scanner is located. Zone 4, by definition, will always be located within Zone 3 as it is the MR magnet and its associated magnetic field that generates the existence of Zone 3.

CAMRI Blueprint

Zone 3 & 4 are S104F, F1, H & H1



Zone Signage

Figure below illustrates signage in place at the entrance to the MRI control room and scan room.

CONTROL ROOM DOOR

SCANNER DOOR

ROLES AND RESPONSIBILITIES:

It is the responsibility of all employees, students, and visitors to conduct activities in a manner that will not adversely impact themselves, other laboratory personnel, Baylor College of Medicine property, the surrounding community, or the environment. The implementation of a comprehensive MRI safety program relies on the support and cooperation of all entities listed in this section.

DIRECTORS OF CAMRI

The Directors provide the necessary support for proper management of maintenance and operations of the MRI Suite and the operation of the facility. Specific responsibilities with regard to the MRI Suite are to:

- Supervise the MRI Technologist and MRI Operators with respect to operation of the MRI Suite.
- Supervise the IT Administrator with respect to CAMRI servers and networking capabilities
- Provide the necessary support for proper management of maintenance and operations of the MRI Suite.
- Ensure compliance with Baylor College of Medicine safety policies and procedures.
- Negotiate and manage research contracts for research and development activities conducted in collaboration with vendors (including specialized sequences), as well as service and maintenance contracts.
- Serve as member of the MRI Policies and Procedures Committee.
- Develop and implement CAMRI policies, with the input of CAMRI and ATC oversight committees.
- Report instances of noncompliance (failure to exercise and implement safety policies and procedures or failure to adhere to IRB protocols)

MRI TECHNOLOGIST

The MRI Technologist works directly with users and study participants to perform structural and functional scans. The MRI Technologist is an ARRT-registered technologist responsible for operating the Siemens 3T MRI scanners, screening participants prior to scanning, preparing participants for their scan, providing immediate medical treatment and assistance when necessary, and responding to incidents and accidents within the MRI Suite.

Specific responsibilities of the MRI Technologist are to:

- Maintain current ARRT certification.
- Maintain Cardiopulmonary Resuscitation (CPR) and (BLS) certifications.
- Restrict access to the MRI Suite to authorized individuals and participants.
- Conduct screening for research participants and guests accompanying participants.
- Conduct MRI Safety, Level 1 & Level 2 training for CAMRI users.
- Respond to after-hours emergencies as needed.
- Perform routine cleaning and maintenance of the MRI facility (includes cleaning floors and surfaces, replacing light bulbs in the ceiling of the MRI scanner room, stocking linen in rooms,

leaving the trash can outside of the facility in the main hallway to be emptied by housekeeping staff)

- Operate the MRI scanner to include routine and experimental setup, modification of scanning parameters to optimize data, and basic troubleshooting of scanner malfunction.
- Greet and interview research participants, document screening interviews, prepare subjects for scanning, converse with subjects during scanning, and remove subjects from the scanner after scanning.
- Serve as member of the MRI Policies and Procedures Committee.
- Respond to any incidents or accidents that occur within the MRI Suite.
- Maintain accurate and appropriate records of the usage of the MRI scanner and of participant studies.
- Support users of the MRI scanner with paradigm implementation and other needed assistance.
- Enforce safety policies in the MRI Suite.
- Organize, archive, and facilitate the transfer of acquired imaging data.
- Monitor and maintain temperature requirements for the scanner (water and helium levels).

PRINCIPLE INVESTIGATOR (PI)

PIs are responsible for overseeing the activities of all Research Assistants, students and visitors assigned to execute their MRI experiments. It is the responsibility of the PI to follow MRI policies and procedures and to ensure that personnel training is completed. Specific responsibilities of PI are to:

- Ensure that all projects for which they are responsible comply with relevant regulations, policies, and procedures for use of the MRI and for human subjects' research.
- Obtain the appropriate approval from the IRB for conducting research in the MRI scanner.
- Ensure that all MRI operators involved in their research maintain training requirements and follow all relevant MRI policies and procedures and IRB requirements.
- Communicate instances of accidents and unsafe work conditions to the CAMRI and the IRB.
- Communicate issues with equipment or data quality with CAMRI staff
- Inform personnel of potential hazards associated with MRI research and provide access to the MRI Policies and Procedures Manual.
- Follow additional MRI Operator responsibilities as outlined below.

MRI OPERATORS (Level 2 and Level 1)

It is the responsibility of all MRI Operators to conduct MRI research in a manner that will not adversely impact themselves, other personnel, the surrounding community, or the environment. Specific responsibilities of MRI Operators are to:

- Be familiar with and abide by the contents of this manual.
- Maintain appropriate training for their designated operator level.
- Limit operations within the MRI Suite in accordance with their designated operator level.
- Report incidents, accidents, and near-miss events occurring within the MRI Suite to their supervisor and CAMRI staff.

- Follow all policies and procedures for MRI safety and operations and human subjects research.

MRI Operators should be knowledgeable of the following:

- Suite-specific emergency procedures, contact information, evacuation procedures.
- Suite-specific procedures for managing participants, operating the scanner, recordkeeping, data management, and maintenance reporting.
- Location, use, storage, and maintenance of personal protective equipment, MRI coils and other ancillary equipment in the suite.
- Access restrictions and the need to challenge unknown persons entering the facility.
- Report issues with data quality and equipment or other concerns to CAMRI staff.
- Follow all policies and procedures for MRI safety and operations and human subjects research.
- Follow all policies and procedures for their study according to IRB approval (e.g., HIPAA compliance)

SECURITY AND ACCESS

The only instances of fatality due to MRI were because of an untrained individual bringing a metal object into a scanner environment where they should not have had access. Unauthorized access to the MRI Suite and scanner magnet can result in injury to those who may have conditions that are unsafe for the MR environment, damage to personal items that can be affected by the magnetic field, and damage to the scanner and injury resulting from a ferromagnetic object being pulled into the bore of the magnet. For this reason, **the MRI Suite is a Restricted Room.**

When an individual meets the training requirements (described below), CAMRI will request that they be given access to the appropriate areas in the CAMRI suite. This access is granted by BCM security and can also be taken away if the individuals are not in compliance with either BCM policies or CAMRI policies. CAMRI's top priority is to maintain a safe scanning environment for all users and participants, and individuals who have met the training requirements but put others at risk will have their access removed.

Access to the MRI Suite and scanner rooms are controlled by electronic card access. Access to mechanical space is controlled by manual key access. Unsupervised access is restricted to those individuals certified to operate the scanner (level 2); those who may need to enter the console, equipment, or scanner rooms in the event of an incident or emergency; and authorized individuals who may need to provide access to service personnel. No one is permitted supervised or unsupervised access without appropriate notification of the potential risks associated with the magnet. Keys and electronic access to the MRI Suite must be kept in a secure location and may not be shared or loaned to other personnel.

OPERATOR LEVELS AND ACCESS

The operator levels outlined below define access and scanning privileges for the MRI Suite. Personnel who wish to work in the MRI Suite must be involved in an IRB-approved MRI research study and meet all the eligibility and training requirements for the operator level they wish to attain. Badge access will be issued indicating an individual's operator level. No one should be in the MRI Suite without a badge, unless they are a research participant or a visitor, in which security will provide a temporary badge. Personnel certified at Levels 2 will be given electronic access to the MRI Suite and control room.

MRI training is broken down into 4 stages:

- Introductory stage (Mandatory for all users working in CAMRI)
- Level 1 Training (Supervised)
- Level 2 Training (Advanced training)
- Level 2 Operator (Independent/Unsupervised user)

Introductory stage - 1 hour MRI Safety Course

The MRI Safety Course training is required for anyone working around the MRI suite or who will have access to CAMRI. It provides an understanding of MRI hazards, safety policies and procedures for the MRI Suite, general operating procedures, and emergency response within the MRI Suite. MRI safety course is taught once per month. Arriving more than 15 minutes late will require you to reschedule course for another date. All participants will fill out screening forms to ensure they are safe to work in the MRI environment. Any changes in medical status or implanted devices should be reported to CAMRI as soon as possible. Most people will immediately schedule a Level 1 training course at the completion of the MRI safety course.

After completion of the course and quiz, personnel are:

- Able to observe scanning in CAMRI under the supervision of Level 2 Operator or CAMRI Staff.
- Qualified to continue with Level 1 training course
- Allowed badge access to the CAMRI main doors

Level 1 Training Course (Supervised)

Level 1 training consists of 1-1.5 hours training in the MRI scanner to learn hardware, safety and screening procedures, and review MRI safety course materials. PIs, postdoctoral fellows, research assistants, undergraduate and graduate students are eligible to become Level 1 operators. During Level 1 training, personnel are:

- Permitted in the scan room with a Level 2 operator.
- Observe and assist Level 2 operator during scan session.
- Not able to operate scanner, screen participants, or be left alone in Zone 3 or 4.

This is the appropriate training level for individuals who will be, for example…

- Running behavioral testing in the CAMRI suite, and then escorting their participants to scans that will be run by CAMRI staff or a Level 2 trained member of their lab
- Running the fMRI task stimulus for experiments while CAMRI staff or Level 2 trained member of the lab operates the scanner
- Escorting participants or their families in the CAMRI suite for studies that use the scanner

To obtain Level 1 completion certification, personnel must:

- Successfully completed the MRI safety course and the level 1 training session.
- Maintain one's own safety in a limited set of conditions. Level 1 trainees are not responsible for participants and cannot be left alone in the scan room or control room with a participant.
- Be supervised by a level 2 operator user at **ALL TIMES** in zones 3 & 4!

Level 2 Training (Advanced Training)

Level 2 training consists of some supervised time on the scanner with MR Technologist and some unsupervised time at scanner working on mastering the protocols used for said research.
Level 2 trainees are permitted unsupervised access to the MRI Suite to conduct scans of inanimate objects or phantoms. They may **not** operate the scanner for scans of research participants unless under direct supervision of a level 2 operator. During this training, personnel may observe or assist another operator during scan sessions.

Level 2 trainees must:

- Successfully completed the MRI safety course and the Level 1 training session.
- Complete the initial level 2 training session and practice scanning with a Level 2 operator until they feel confident to perform ALL scanning steps on their own (Including stimulus and functional tasks).
- Complete written test and a mock scan to demonstrate scanning skills and safety procedures. 80% or better on both testing areas is required to successfully pass level 2 training. If a trainee fails either part of the test they will need to log at least 3 scanning sessions with a Level 2 operator before they can retest. A mock test is also required if trainee failed previously. Failure of 2 consecutive exams requires repeat training at the discretion of CAMRI staff.

Level 2 Operator

Level 2 operators are highly trained and experienced personnel that have successfully completed all training and are able to perform MRI scanning sessions unsupervised. Badge access to CAMRI and the MRI scan rooms will be approved at this level, and Level 2 operators will be granted access to schedule their own research participants in iLab.

Level 2 Operators must:

- Work constantly in the MR environment to maintain certification. Recertification testing of level 2 is mandatory once a year. Review courses and recertification tests will be taught once every quarter. Check wiki and contact Lacey DeLay to sign up. Periods of extended non-scanning (6 months) will require recertification to ensure scanning efficiency/safety.
- Be able to supervise and train others in Level 1 or 2 training phases.

SAFETY AND ACCESSIBILITY TO SCANNERS

POLICY REGARDING DOOR SECURITY

Scanner and control room doors should NEVER be left open unattended. Make it a habit to close the door after you. Only level 2 users will have access to the scan room doors. Do not let someone use your badge to access the scanner. ANYONE that is not level 2 is not allowed to be in either the control room or the scan rooms unattended for any reason, a trained individual must accompany them. Do not prop control room doors open unattended and always keep door to the scanner closed when not actively accessing the scanner.

REDUCTION OF RISKS

The chief risk exposure in the lab is to entering personnel who are unfamiliar with the equipment and its hazards. Personnel working in the facility must be constantly vigilant of who is entering the console or scan room areas. Especially in emergency situations, you must ensure that no one without proper training enters any of the scanner rooms, and even then, that they have adequately checked themselves for possible hazards such as projectiles.

Many objects in the scanner control rooms and equipment rooms are **NOT MR compatible** and may become projectiles in the MR scanner rooms. You must never move any object from these rooms into the MR scanner rooms unless you are absolutely certain that the object is MR safe.

Similarly, some objects in the MR scanner rooms may only be safe when kept at a distance from the MR scanner. **Only personnel explicitly authorized to do so should move objects in the scanner room that are labeled "Not MR safe".** Only objects that are not ferromagnetic should be labeled with a "MR safe" label and this safe label should not be in red or orange. Unlabeled objects should be assumed **NOT** safe to move unless they are clearly non-metallic.

VISITORS, TOUR GROUPS and CLASS SESSIONS

VISITORS

Visitors who wish to tour the MRI Suite must be escorted by appropriately-trained personnel. All tours must first be approved by CAMRI staff. Prior to entry into the console room, visitors must be briefed regarding hazards associated with the MRI and must complete the Safety Screening Form. Visitors may not enter the scanner room. **At no time should a visitor be left unattended while in the MRI Suite.**

To protect the privacy of research participants and to limit the potential distractions for operators, tours should be conducted when the scanner is not in use. If a tour is conducted during a participant scan, the participant must give permission for the tour in writing. All forms must be given to CAMRI Staff.

If a professor wishes to conduct a session as part of a class demonstration, the session must be scheduled in iLab and all students must be prescreened by the MRI technologist or level 2 user in attendance. If the professor has included MRI safety in a prior class, the CAMRI safety training may be waived at the discretion of the MRI Technologist or Operations Director.

RESEARCH PARTICIPANTS

Research participants must be escorted in the MRI Suite **at all times** by a qualified operator and may never be left unattended. (This is both a CAMRI rule and a BCM rule. Failure to comply may result in BCM security revoking badge access.) Research participants are escorted into the control room and the scanner room by a Level 2 operator only, and only after they have completed the MRI screening form.

SAFETY SCREENING

POLICY FOR SUBJECT SCREENING

Anyone preparing to enter an MR scanner room must complete a metal screening form, and this form must be reviewed before access to the scanner room is granted. Individuals who are safety certified at CAMRI are not required to personally complete a formal written metal screening form about themselves but are responsible for verifying that they are personally safe to enter the scanner room.

If there are any doubts regarding the metal screening responses, **do not allow the individual to enter the scanner room**. The fact that the individual has been scanned in an MR scanner previously (even at CAMRI) is **never** a sufficient basis upon which to conclude that the subject can enter the scanner room safely, since risks vary according to magnetic field strength. Dental fillings and orthodontic braces do not constitute significant risks (though the latter may produce unacceptable

artifacts) and do not preclude scanning. Subjects with tattoos or permanent eyeliner should be advised of the small risk of local redness or irritation and asked to report any discomfort immediately. Scanning should be stopped immediately if such discomfort develops.

Some implanted metal devices have been established as safe for MR scanning. A recent copy of Shellock's book cataloguing implanted medical devices is available in the MR suite and up-to-date information is always available on the website http://www.mrisafety.com. If, in reviewing these resources, you believe that it is possible to safely scan your subject, you should contact Krista Runge or Lacey DeLay to request authorization to scan the subject. Even if you are certain that the implanted metal does not constitute a risk**, do not allow the individual into the scanner room unless you have obtained explicit authorization to do so**. It is better to ask these questions before your research subject arrives to prevent cancellation at the last minute and inability to scan.

Before entering the scanner room, subjects and staff must remove all objects from their person that might constitute a risk in the MR environment. It is the responsibility of the level 2 individual to assure that this has been done. Subjects should be asked to turn pockets inside out to demonstrate that no potentially hazardous objects have been overlooked. Gold and platinum jewelry is not ferromagnetic. Nonetheless, subjects should remove ALL jewelry before going in the scanner since these metals can still conduct electricity and therefore pose a risk for burns in the presence of time-varying magnetic fields. Jewelry that forms large loops is particularly hazardous. All subjects must remove their shoes in the control room prior to being scanned. Do not remove them in the scan room as they have the potential to be attracted to the magnet once removed if metal is present.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY SCREENING

All individuals, including operators, researchers, staff, students, research participants, and visitors must be screened prior to entering the MRI Suite. A standardized form (BCM MRI Safety Screening Form) is used to evaluate the safety of each person before that person is permitted in the MRI Suite. See APPENDIX A

Screening Researchers, Staff, and Students

Operators, researchers, staff, and students who intend to enter the MRI Suite are screened by the MRI Technologist prior to attending MRI Safety Training. Screening for all users must be updated on an annual basis during the review/recertification sessions. Additionally, it is the responsibility of these individuals to notify the MRI Technologist if a change in the screening questions (such as pregnancy, surgery, or injuries involving ferromagnetic material) that could prevent them from entering the scanner should arise.

Safety Screening of Visitors

Baylor College of Medicine recognizes two types of visitors to the MRI Suite: 1.) Research participant or family members of research participants who will enter the scanner room with the participant, and 2.) Individuals who come to view or observe as part of a guided tour.

Screening Minors as a Participant
Anyone under the age of 18 who requires a screening must have a parent or legal guardian present at time of screening and signature required on the screening form.

Safety Screening of Research Participants
Research participants are screened a minimum of two times. Safety screening may be performed in person or over the phone before the scan is booked. It is then completed again at the time of the scan. Both safety screens must be completed every time a research participant prepares to undergo an MRI scan.

The preliminary screening is conducted prior to scheduling the participant for a scan. The individual conducting the screening must be on a current IRB protocol and have completed IRB-approved research ethics training and attended an MRI safety course.

If the research participant has any conditions listed in Appendix B, *Exclusionary Criteria*, they are automatically excluded from participating in an MRI study at Baylor College of Medicine. The PI may also decide to exclude participants that experiences claustrophobia or has a condition that makes it difficult for the participant to lie still for the duration of the scan. CAMRI is not able to provide sedation for such participants.

If the research participant has had any type of surgery or has any of the implants or devices listed in Appendix C, *Criteria that May Exclude Research Participants*, the PI or CAMRI staff can make a recommendation to approve or exclude the research participant. All implants and devices, whether MR safe or not, must be documented on the screening form, and the following information must be collected for each device or implant:

-Date of surgery or procedure
-Name of implant and manufacturer information
-Type of surgery or procedure performed

For surgical implants, this information may be provided in a Material Identification Card. If the research participant is willing to provide a surgical report, this information may also be collected. Information must be sufficient to verify the compatibility of the implant with the MR environment. Do not assume a device is clear to be scanned if the participant has had an MRI at another facility since the device was implanted. Our magnets are 3T and not all devices are safe at this magnet strength vs other MRI machines. The PI is responsible for forwarding the necessary information to CAMRI staff for review before the scan session.

Please note that a MRI Screening form must be signed and dated by the participant no more than 5-7 days of the scan and signed by the MRI technologist/level 2 operator on the day of the scan after reviewed with participant. This second screening is conducted by the MRI Technologist or MRI Operator on the day of the participant's scheduled scan to ensure nothing has changed and that everything has been included. The MRI Technologist may cancel or postpone a scan if the research participant's second screening raises suspicion about the suitability of the participant for the MRI environment. Even when the Level 2 operator "knows" that the participant is cleared for the MRI (e.g., a repeat scan or a scan of a lab member), the screening form needs to be filled out and filed with CAMRI.

SCHEDULING

SCHEDULING IN ILAB

To schedule time on the scanner, you must use the iLab website: https://bcm.corefacilities.org/service_center/show_external/3684.

Evening and weekend hours are available upon request for Level 2 Operators only. Each person without a BCM badge that will be present at the scheduled scan need to have security clearance to enter the BCM campus. All requests under 24 hours will automatically be denied.

Email should be sent to CAMRI email alias (camri-staff@listserv.bcm.edu) at least 24 hours prior to scheduled scan. The following information below should be filled out and sent in the body of the email so that security requests can be compiled and submitted to security by CAMRI staff. Approval by BCM security will be forwarded to the requesting user.

Human Research Subject Visitor: Core for Advanced Magnetic Resonance Imaging (CAMRI)
Subjects Name:
DL # of subject:
Accompanying visitor (if any) name:
DL# of accompanying visitor:
Date & Time at BCM:
CAMRI Location: S104
Investigator's name and escorting visitor to CAMRI: (name and ID #)
Investigator:
Person escorting visitors:
Level 2 operator to use scanner:

NOTE: This subject is participating in a research study.

CANCELLING A RESERVED TIME IN ILAB

After a reservation is made, users have 24 hours to modify or cancel it without charge. If reserved time is not used for any reason (including subject no-show, subject failure to meet screening criteria, experimental difficulties, or any other reason) users will be charged the full rate for the unused time, unless the user reports the cancellation at least 24 hours prior to the start of the reserved time (allowing other users a chance to use the time) in which case the user will be charged at half the normal rate. Canceled time can be paid with the usual payment methods or a user's accrued pilot time.

PILOT HOURS

CAMRI has a pilot time program to reward frequent users and allow for the collection of preliminary data for new projects. For any user (BCM or non-BCM) who scans at CAMRI, pilot time hours are automatically granted based on the amount of paid scanner time used at a ratio of 5 to 1. For every 5 hours of paid scanner time, the user receives 1 hour of free pilot time. No pilot time is awarded for phantom scanning.

To redeem pilot hours, email camri-staff@listserv.bcm.edu '''PRIOR TO''' scheduled scan time to request pilot time usage for appropriate scan type classification (pilot time vs. billable time). Pilot time **cannot** be adjusted once scan is complete. If a pilot hour is requested and the scan is cancelled then the pilot hour is lost.

Pilot time expires at the end of each BCM fiscal year (July 1st-June 30th) but up to 5 hours of unused pilot time may be rolled over to the next fiscal year.

General Information

Risks associated with the MRI:

Used properly, the magnetic resonance imaging equipment contained within CAMRI is quite safe, however, it poses serious risks to the unwary. CAMRI users should be completely familiar with this manual and with the procedures for protecting others from hazards. To minimize risks to subjects and other members of the research team, **only personnel who have successfully completed the full CAMRI safety certification process are allowed access to the MR scan rooms, control rooms or equipment rooms.** Observers who have not been safety trained are **not permitted** to enter the MRI suites without special prior arrangements.

The main hazards in the lab are:

- The “projectile effect” when heavy, sharp, or dangerous objects are hurled into the scanner. Even seemingly innocuous objects, such as hand tools, can be *lethal*.
- Pacemaker damage. Certain cardiac pacemakers can be damaged by exposure to magnetic fields, causing direct hazards to subjects. Under no circumstances should persons with pacemakers enter the MRI suites at CAMRI.

- As in many laboratories, the MRI lab contains wiring and circuitry that operate at dangerous voltages. Under no circumstances should users touch any exposed wiring, or any exposed terminals in the equipment cabinets.
- Grossly improper scanner operation could result in excessive heating of the subject due to RF energy being deposited. This is easily avoided by operating the equipment according to the guidelines contained in the user manuals and set by the individual instructors.
- Suffocation: in extreme cases, the imaging magnet may release large volumes of helium gas that can rapidly force all air out of the scan room. Normally, the helium gas would be vented through the roof. However, there is a small but significant risk that the venting system could fail.

SAFE AREAS

There are no areas in the MR suites that can be considered completely safe. The control rooms, scanner rooms, and equipment rooms all have risks associated with magnetic fields and/or electrical equipment. CAMRI safety certification is required for personnel to enter any of these areas.

MEDICAL CRASH CART

We do not have a MD here at CAMRI and we do not have a medical crash cart. For these reasons individuals that are high risk, or any other safety concern should not be scanned here at CAMRI. CAMRI currently does not do contrast studies because we do not have an active MD on site or crash cart. In case of an emergency, you should dial 911 and remove the individual from the scanner before they arrive. If dialing 911 from a scanner land line please dial a 9 first. (9-911)

POLICY REGARDING CHILDREN

Children may only enter the scan rooms as participants in an IRB approved research study of children. Children not involved in the research study (e.g, the child or sibling or a research subject) may not enter the scan room and should be monitored at all times.

All safety precautions applicable to adult subjects are applicable and if anything, more important in children. Careful metal screening, accurate entry of age, sex and weight, and use of “Standard Mode” scanning options whenever possible are important steps in minimizing risks to this population. Ensure constant communication of pediatric subjects while they are in the scanner and explain procedure before their session. Be especially certain that hearing protection is adequate, as children may not be able to communicate when a problem is occurring. All children must be supervised and never left alone while at CAMRI.

POLICY FOR HEARING PROTECTION

Anyone in the scanner room while the scanner is in operation **MUST** be provided with and must use hearing protection in the form of earplugs and/or headphones to avoid hearing injury from the acoustic noise generated by the scanner. We provide both ear plugs and headphones in each of our rooms here at CAMRI. Your lab is welcome to provide your own ear protection if they have been cleared by CAMRI staff to meet minimum decibel requirements and safety. Hearing protection is mandatory.

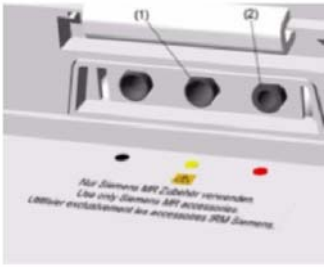
Sources of acoustic noise:

When the scanner is not acquiring images, the only source of acoustic noise is the chirping of the compressor pump used to circulate cold water. Different studies have report this noise to be in the 65-80 dB range, below the OSHA standard necessitating the use of a hearing protection device (HPD). **Make sure that you always hear this chirping sound before you start scanning.**

The time-varying gradient magnetic fields are the primary source of acoustic noise during MR imaging. The rapid rise and fall of currents within the gradient coils in the presence of the static magnetic field create strong Lorentz forces that cause the gradient coils to move against their mountings. The vibration of the coils and the vibration and flexing of their mountings cause the loud tapping and knocking noises during imaging. All participants or individuals that are in the magnet room while scans are running MUST have hearing protection.

POLICY REGARDING SQUEEZE BULB

The scanners are both equipped with a squeeze bulb that allows the subject to set off an audible alarm to attract the operator's attention. The squeeze bulb should be made available to subjects unless some alternative method of constant monitoring (e.g., another person in the scanner room) is in effect. Subjects should be advised to squeeze the bulb if they experience anything that needs immediate attention. It is best to inform subjects that if they need to contact you and it is not immediate than to do so in between scans when the scanner is quiet. All users should stay in constant communication with their subjects throughout the scan session. Use of the squeeze bulb or some comparable form of continuous subject monitoring is **MANDATORY** if you are operating the scanner. The squeeze bulb plugs into the red connector at the foot of the bed. You can verify that the squeeze bulb is connected by noting that the squeeze bulb LED lights up when you press the talk button on the intercom. If the subject squeezes the squeeze bulb, a continuous audible alarm is emitted via the intercom and the intercom squeeze bulb LED lights up.



Squeeze ball connector can be found at the foot of each table. Attach hose to color coded plug if it becomes disconnected.

The silence alarm button for the emergency squeeze ball is labeled (1). The emergency table stop button is labeled (2).

(INTERCOM IN THE PRISMA SCANNERS)

Responding to a squeeze bulb alarm

1) If a scan is ongoing, press the "Stop" button on the CONSOLE screen under your active sequences using the mouse. (You will need to do this because the scan is not stopped when the participant squeezes the emergency ball, it only alerts you that it has been squeezed).

   This is especially important if you are scanning in "Level 1" mode rather than standard mode since the subject may have triggered the squeeze ball in response to magnetostimulation or excessive heating.

2) Press the appropriate intercom talk button to stop the audible alarm. (If you have not stopped the scanner first than you will hear the scanner noises and you will not be able to hear the subject talk)

3) While holding down on the intercom talk button, speak to the subject to determine why the squeeze bulb was pressed. *Make sure that the volume is turned up so that you can hear the subject's response.*

4) If necessary, enter the room to further investigate and/or correct the problem.

POLICY REGARDING ACCURATE ENTRY OF SUBJECT HEIGHT, WEIGHT, AGE AND SEX

The scanners require that the subject's height, weight, age and sex be entered before scanning. Accurate information regarding height and weight **MUST** be provided to ensure that FDA limits for energy deposition are not exceeded. Weights should be correct to within five pounds. Height should be correct within 3 inches. Incorrect weight should **never** be entered in an effort to get the scanner to conduct a study that it otherwise would not perform because FDA limits would be exceeded. There is a scale with a height bar on it in the hallway by the stairs for users to ensure accurate height and weight measurements.

Since CAMRI is a research facility, we must not use patient identifiers for HIPAA violations and patient names should be anonymized. Research identifiers should be used as the patient name and patient ID. You should NEVER use the subject's name when registering the subject for a scan at CAMRI. All experiments should have a subject number used in place of the subject's name and patient ID. Similarly, anonymized birth dates should be used (generally, Jan 1). Accurate sex, height and date of birth is independent to the PIs preferences. Accurate sex and birth year are up to the discretion of the PI but are recommended in the event the scan is read by a physician for an incidental finding.

POLICY REGARDING TEMPERATURE CONTROL

In regulating energy deposition in the subject's body in accordance with FDA guidelines, the scanners assume that the ambient temperature in the room does not exceed 72° and that the relative humidity does not exceed 60%. Consequently, the thermostat should never be set for a room temperature higher than 72°. Please note that only cotton, linen or paper should be used for bed covering or blankets since radiofrequency energy may cause heating of synthetic sheets or blankets. We do not provide blankets at CAMRI due to the inability to launder them after each participant.

POLICY REGARDING OBESE OR LARGE SUBJECTS

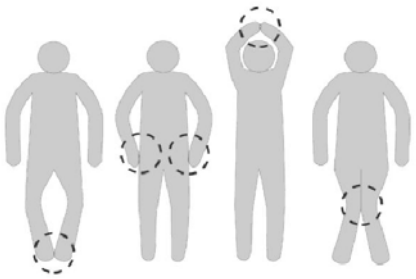
Subjects weighing more than 340 pounds should not be scanned at CAMRI. The PRISMA 3.0 Tesla scanner bed is designed to support weights up to 440 pounds. Even subjects weighing substantially less than 300 pounds should never be allowed to sit at the distal end of either of the scanner beds, since they are not designed to support the full weight of a large subject applied at full mechanical advantage. The Bore size is 60cm so many patients around 300 lbs may not fit in our bore depending on the patient's body habitus.

To avoid burns or peripheral nerve stimulation, a minimum distance of 5 mm should be maintained between the subject's body and the wall of the scanner tunnel. MR pads or cotton sheets available in the MR scan rooms can be used to assure this distance is maintained or that skin to bore contact is not being made.

HANDLING SUBJECT TINGLING OR MUSCLE TWITCHES

Tingling or muscle twitches are potential physiologic effects of time varying magnetic fields. Such effects are particularly likely to occur with echo-planar imaging in fMRI studies (e.g., fMRI and diffusion imaging). To minimize the likelihood of such magnetostimulation, operate the scanner in "Standard Mode". In this mode, only 1% of subjects should experience such effects. However, the scanner may refuse to scan certain subjects with certain pulse sequences in "Standard Mode". If you operate in "Level 1" operating mode, up to 50% of subjects may experience magnetostimulation with certain pulse sequences. Note, operating in "Level 1" rather than "Standard" mode is something that should have been approved for your study in your IRB.

Complaints of tingling or muscle twitches should prompt rescreening for any metal objects that might have been previously overlooked and verification that subject positioning does not form potential loops. For echo planar imaging, selecting a phase encoding direction that is anterior-posterior (when this is an option) should reduce the likelihood of magnetostimulation. Note that the sensory input associated with magnetostimulation will pose an unwanted confound in fMRI studies.



Subject positioning loops that predispose to magnetostimulation or burns

HANDLING PERSPIRATION AND INCREASED PULSE AND SUBJECTS WITH CONDITIONS ASSOCIATED WITH IMPAIRED THERMAL REGULATION

Perspiration and an increased pulse rate may result from energy deposition in the body during scanning. Energy deposition in the body is carefully regulated by the scanner in accordance with FDA guidelines. If your subject develops these symptoms, you should verify that the subject's age, height and weight were entered correctly when registering the patient, since these parameters may influence the calculated energy deposition. You should also verify that the room temperature does not exceed 72° and the humidity does not exceed 60% since the calculated energy deposition limits assume that they do not. The scanner will measure the temperature and may refuse to scan certain sequences if the temperature exceeds 71.6°.

If your study requires you to scan in "Level 1" mode, you should screen for any conditions that may impair thermal regulation (such as fever, diabetes, pregnancy, or cardiovascular disease),

and be particularly cautious with any subjects endorsing these conditions. Children or elderly subjects are also at increased risk of overheating. For all participants, you should be attentive to signs or symptoms of overheating and stop the scan if overheating is suspected. “Level 1” mode should not be used in subjects who are unable to communicate reliably (e.g., children, sedated subjects, stroke patients). Adjusting the fan in the scanner may be helpful in reducing the likelihood of overheating in subjects.

LASER LIGHT LOCALIZER HAZARDS

On both of our 3.0 Tesla PRISMA scanners, a laser is available for landmarking the patient’s position in the scanner. Subjects should be instructed to keep their eyes closed while the laser light is turned on to avoid eye injury. If the laser light appears as a spot rather than as crosshairs, it should be turned off immediately, and you should notify one of the designated CAMRI staff that it is in need of repair.

MRI PHANTOM LEAK HAZARDS

The MR phantoms used to calibrate the scanners are sealed and should not show any evidence of leakage. The contents of some of the phantoms is potentially hazardous. If a phantom develops a leak, protective clothing (gloves, labcoat, goggles and, if the contents have become aerosolized, a face mask) should be worn while cleaning the leak. The contents should be disposed of as hazardous materials (i.e., not simply poured down the drain).

ECHOPLANAR (fMRI) IMAGING HAZARDS

Echoplanar imaging, used in fMRI, utilizes rapidly changing gradients and is associated with higher voltages than many other MR imaging modalities. The risk of magnetostimulation is increased with echoplanar imaging. The risk of magnetostimulation can be reduced by choosing a phase-encoding direction that is oriented anterior-posterior when this is an option.

Rules of CAMRI MRI Imaging Core

MRI SUITE

The MRI Suite is a shared resource. Any action that inhibits or has the potential to inhibit the ability of others to utilize these resources will be considered a policy violation. Operators are expected to use good judgment in their use of the MRI Suite, and to follow the policies and procedures put forth in this manual for the MRI Suite.

The following rules must be followed by all operators in the MRI Suite:

- No follow-up scanning of clinical sequences permitted unless it is specifically designated within a PI's protocol.
- Doors to the MRI Suite (console, scanner, and equipment rooms) must be kept closed and secured at all times.
- No eating, drinking, use of tobacco products, or storage of food and beverages is permitted in the MRI Suite. Currently we allow food and drinks in the control room but they must be disposed of in the control room trash can and the user must put trash can in the hallway for housekeeping.
- Access to the MRI Suite is restricted to authorized individuals.
- Before entering the scanner room, personnel must remove the following items: hearing aids, keys, beeper, cell phone, hairclips, barrettes, pins, jewelry, watch, wallets, credit cards, bank cards, pens, pocket knife, nail clips, or any other objects that contain ferromagnetic material or that may be damaged by the magnetic field.
- Any equipment to be used in the scanner room must be approved by MRI Technologist or Operations Director. All equipment must be tested for ferromagnetic properties with a handheld magnet before being brought into the scanner room and labeled MRI safe or unsafe.
- The MRI Operator has the authority to stop MRI procedures deemed by them to be unsafe.
- For scans involving human research participants:
  - Ensure participants sign a consent form before entering the scanner and remove all items that are not MR-compatible (keys, cards with magnetic strips, etc).
  - Instruct participants not to cross their arms or legs or in any way form a closed loop with their extremities. This will reduce or avoid peripheral nerve stimulation.
  - Instruct participants on how and when to use the emergency squeeze ball.
  - Instruct participants to inform the operator if they experience the following: excessive perspiration, rapid heart rate, difficulty breathing, tightness of chest, pain or discomfort to including warming of the skin, muscle tingling, etc.
  - Provide hearing protection to the research participants and any visitor who will remain in the scanner room during the scan, and instruct them on its proper use, ensuring that hearing protection is properly placed.
  - Maintain verbal contact with the research participant. Immediately investigate a research participant who does not respond verbally to ensure their well-being.
  - Stop the scan if an individual becomes ill or injured. Remove the participant from the magnetic environment immediately and follow incident response procedures. Provide a reportable information/incidents form to the IRB within five business days.

- Properly clean all surfaces that have come into contact with a research participant before the next MRI scan is conducted.
- Lights to both the scan room and control room should be turned off upon departure.
- Report all incidents and near-incidents, including equipment malfunctions, projectile accidents, security or safety breaches, or injury to personnel or research participants, to the PI and CAMRI staff within 24 hours of incident.

Accident Reporting

Accidents, Injuries and Incidents

Any accidents causing injury to an individual or research participant must be reported to CAMRI staff by the researcher conducting the study immediately. In case of an accident or injury when the principal investigator (PI) is not present, the researcher present must also report to the PI.
In addition to reporting to CAMRI staff, the event may need to be reported by the PI to the Institutional Review Board; and / or the Institutional Animal Care and Use Committee.

CAMRI POLICY FOR UNEXPECTED EVENT REPORTING

If an unexpected, unusual or untoward event occurs (or nearly occurs) during a scan, please send an e-mail with a brief description of the event to camri-staff@listserv.bcm.edu as soon as possible. This will allow CAMRI to be responsive and proactive in addressing any issues. The e-mail does not need to be lengthy but is required for both scanner-related and subject-related events. Example e-mails:

1. "We were scanning today at 2 p.m., and the patient complained of back pain after 45 minutes, so we had to end the scan early"
2. "In the middle of our third functional scan, the scanner crashed and had to be rebooted"
3. "the BOLDscreen was flickering during our functional runs"

In addition to specific problems that you encounter, we always welcome user feedback on CAMRI operations.

Adverse Event Reporting to IRB

The CAMRI requirement to report unexpected events is distinct from the enduring requirement to notify the IRB of any adverse event occurring to human subjects enrolled in a protocol. An adverse event is defined as "any untoward medical occurrence in a participant, which does not necessarily have a causal relationship with the trial intervention. An adverse event (AE) can, therefore, be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease."

Equipment Damage or Failure

Malfunctions of equipment due to breakage or failure may present a safety risk to individuals and research participants. Damage or failure of equipment needs to be addressed immediately so that repairs or replacements can be made. Failures that prevent normal operation or a safety risk are to be reported to CAMRI Staff via email, this includes broken coils or ancillary equipment. Changes or issues with image quality that may indicate a failure of equipment should also be reported to CAMRI staff for the same reason.

Facility Safety Breach

A facility safety breach presents a risk to individuals, researchers and research participants. Examples of a facility safety breach are failed access points allowing non-trained or non-escorted individuals into the magnetic environment. Open access to the magnetic environment must be addressed immediately to prevent serious injury to individuals or equipment. Other potential safety breaches include: flooding, electrical hazards and obvious structural faults. Individuals and researchers should report any breaches to the CAMRI Staff via email as soon as breach occurs. For immediate reporting of any emergency situation please call cell phone number located in beginning of this manual.

Penalty for not following CAMRI's Policies and Procedures

This manual outlines CAMRI's policies and procedures that should be followed every time a user is on site. If any breach in safety occurs or if any user goes against CAMRI's rules, then they are subject to but not limited to the following reprimands:

a. First offense: 1 warning and an email to the guilty party with the PI cc'd. Offender must take the next scheduled review course & test (within 3 months) and be charged a training rate of $250 for the session.

b. Second offense: Probation for 3 months (length is at the discretion of CAMRI staff depending on severity). Offender will need to retake the review course and pass test. ($500 for level 2 reinstatement and repeat training)

PROBATION: Must be accompanied by another level 2 user and not allowed to be in control room or scan room by themselves. Offender will lose badge access to the control room doors until probation period is over.

c. Repeat offenders- Either permanently confiscate badge or endure a longer probation period (3, 6 or 9 months). At the discretion of CAMRI staff repeat offenders will need to repeat all training and level 2 users will no longer be level 2.

CAMRI SCANNING TROUBLESHOOTING AND SAFETY INFORMATION

3 Principles of MR Imaging:

THE SCANNER IS ALWAYS ON. A serious hazard for MRI safety is allowing an object to become attracted to the static magnetic field. This can result in an individual being struck, injured or trapped against the magnet by the object. Equipment can also become damaged by slamming into the magnet or being struck by another object that is accelerating rapidly due to the strong attraction of the magnetic field. There are 3 main components of the MRI scanner: the static magnetic field, the radiofrequency field, and the gradient or time varying magnetic field.

3.1 Static Magnetic Field

The static magnetic field is the main magnetic field that is always present once the scanner is installed and operational. This field is described in units of Tesla (T) or Gauss (1T = 10,000 gauss). Both of our scanners have a 3T static magnetic field, approximately 60,000 times stronger than the earth's magnetic field that induces a compass to point North. Our active field 5 gauss line starts at entry of the scanner rooms. Do not bring anything ferromagnetic or having the ability to become magnetized into the scan room. Always keep the scanner room door shut when not actively entering the room.

3.2 Radiofrequency Field

The radiofrequency (RF) coil is the heating source within the scanner. This system uses coils as transmitters to excite the MRI signal and as a receiver to detect the MRI signal. It is important to properly use the equipment and accessories of the MRI scanner. Always have equipment checked prior to entry into the scan rooms and be vigilant with patient positioning.

3.3 Gradient/Time varying Magnetic Field

The gradient or time varying magnetic field selects the slices and imaging planes. This particular field is superimposed over the static magnetic field and is the sources of all the acoustic noise. The coils within this system are pulsed on and off to produce linear gradients of the magnetic field for imaging. This allows producing an array of images with different spatial and temporal resolutions, and with different contrast between tissues in the image. Hearing protection is mandatory!

DEALING WITH ERROR MESSAGES & SCANNER ISSUES

When you have a error message on the scanner it will appear in the bottom right hand of the screen as either a yellow or red color. This is what it looks like without any errors:

When there is a error or warning about a particular system, there will be a yellow line through it:

When there is an error in general, there will be a red line:

The two ways to clear an error message that is preventing you from scanning is to do either a routine restart/reboot (7-10 minutes) or a full shutdown (30 minutes). Instructions on how to do these are below.

Performing a Routine Restart or Reboot

A Restart/ Reboot of the MRI scanner initiates a routine electrical reboot should a situation or problem arise. The magnet is still on you are only rebooting the electrical components. Your participant can stay in the scanner for this as long as they give you consent. Make sure you perform an Error Save Log before you reboot or shutdown the scanner. Directions for this are below shutdown procedures. A routine restart/reboot only takes a few minutes to complete and can be done if any of the following occurs:

1. Computer screen is freezing or loading slow.

2. The scanner table is not responding to controls.

3. An error message has occurred that requires the system to be rebooted. (Error messages will appear at bottom right hand of screen yellow or red line in color.

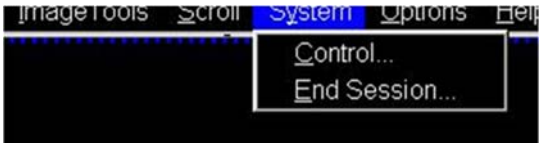
How to do a Routine Start Restart or Reboot

This type of reboot clears most errors and takes approximately 7-10 minutes

1. The subject can stay on the table in the scanner for this reboot if it is ok with them.

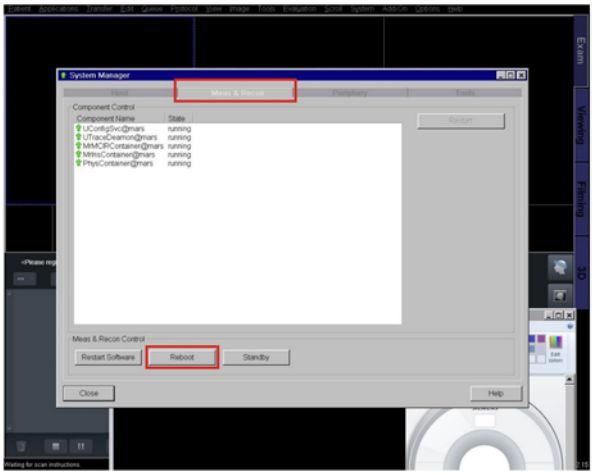
2. Click the “System” tab at the top of the screen

3. Click on “Control”



4. Click the “Meas & Recon” Tab

5. Click “Reboot”



If the error message is still present and preventing you from scanning after the restart/reboot procedure, then you will need to perform a full shutdown of the system. (Full shutdown is only the electrical components, the magnet will always remain on)

PERFORMING A FULL ROUTINE SHUTDOWN

A full shutdown of the MRI scanner initiates a routine electrical shutdown should a problem arise. The subject is not allowed to stay in scanner for this and the bed should be brought out to the home position (all the way up and out). The full shutdown process takes approximately 30 minutes and should be done if any of the following occurs:

1. Reboot/Restart did not fix error messages.
2. There are visible alarms that revealed that the magnet has quenched or that helium levels are low.
3. You do not hear the chirping sound or Siemens advises you to turn it off.
4. An error message occurred that requires a full shutdown of the scanner.

Full Routine Shutdown Procedure: (30 minutes)

1. Along the top of the system is a bar of various commands. Select “System”.

2. From “System” <End Session>:

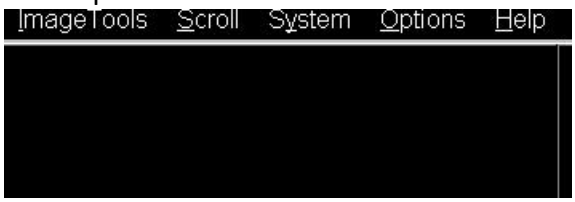
3. Then select <Shutdown System>

This is used when the Restart/ Reboot does not fix error message. If error still persists after full shutdown, contact Siemens. If you contact Siemens prior to the restart and full shut down, then they will require you to do so before they are able to assist you. Anytime you contact Siemens you will be require to provide them with the functional location number of the scanner you are using. These numbers are hung up in each control room by the list of safety numbers.

Detailed instructions on how to do this are below:

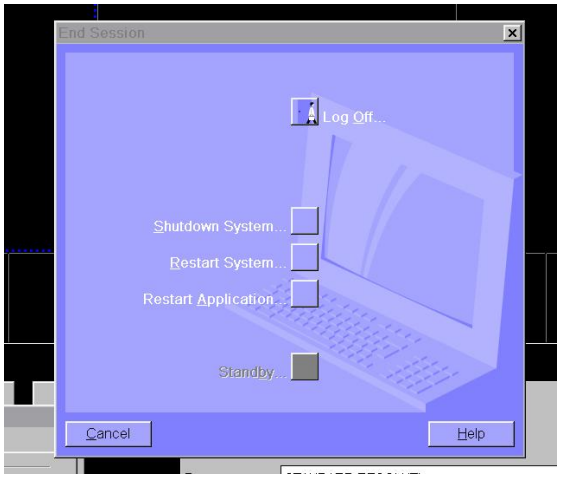
Routine Shutdown Procedure

1. Click the System tab at the top of the screen:



2. Click on “End Session”

3. Click “Shutdown System”.



4. In the confirmation dialog box that appears, click “Yes”

5. It will take approximately 5-10 minutes before you see “It is now safe to turn off your computer” (picture a.) on the MR computer screen. You must then press the blue “system off” button on the Siemens scanner control box (picture b.) located on the wall next to the MR Scanner window.

6. If you are restarting because of an error, wait at least one full minute before turning the scanner back

a.

b.

To turn on the scanner after shutdown:

1. Turn the key on control panel to unlock position and press blue scanner on button.

   Scanner will take about 20 minutes to boot up before you can use it.

   (You will see a red line at bottom of screen while booting)

2. When the scanner is ready to use, it will make 3 beeps/chirps that can be heard through the intercom system. (Prior to this, the computer screen will appear as usual, but there will be a red error line at the bottom of the screen. (The red line will disappear at the same time as the 3 beeps) PLEASE NOTE** If you start moving table or unplugging/plugging in coils before the 3 beeps the scanner might give you an error message and you will need to perform the 30-minute shutdown to resolve this.

MR Scanner Error Save Log

1. If you ever have a scanner problem that requires you to reboot, it is very important to make a MR Save Log entry **BEFORE** you reboot the system

2. This log entry helps the Siemens engineer isolate the scanner problem and expedite the system repair. To make a MR Save Log entry, you must do the following:

• At the top of the screen – click system, then control, then tools

• Click on "Save system log files"

o You will see a box pop up with script on a black background, LEAVE THIS ALONE!

o Another box will pop up where you can input the problem

o Fill out the "User" section and then click OK

o You must wait until the black pop box with script closes before you can proceed to reboot, scan etc

3. Please email camri-staff@listserv.bcm.edu with details of the problem

EMERGENCY PROCEDURES

PERFORMING AN EMERGENCY MAGNET QUENCH

(LIFE THREATING EMERGENCY involving Magnetic field)

Users of the CAMRI facility should only quench the magnet in the event that the magnetic field itself poses an **immediate risk to an individual's life**. Two such circumstances are:

1) A metal object is lodged in the scanner in a way that poses an immediate serious threat to a person (e.g., the person is pinned to the magnet by a metal object that is causing internal injuries).

2) Fire personnel determine that there is ***no other alternative*** to entering the room with axes or other heavy gear when fighting a fire.

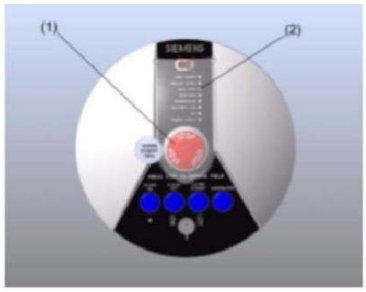
If the absence of a major emergency, facility users should never quench the magnet by themselves, even if they are convinced that a magnet quench will ultimately be necessary (e.g., if a large object has been drawn into the magnet, but poses no immediate risk to a person). If no one is harmed by a metal object flying into the scanner a controlled quench can be performed by a Siemens engineer that will reserve the helium and allow them to bring down the field in a controlled setting.

QUENCH PROCEDURE

1. Locate and press the **QUENCH BUTTON** in the control room or scanner room. The magnetic field will fall to a safe level within 30 seconds. Make sure the door to the scan room is open when you hit the quench button. (closed doors can create a suction when the quench button is hit)

   In the control rooms, quench buttons are located on the top portion of the Siemens wall mounted control boxes located just to the left of the window. Both control room quench buttons are covered by a plexiglass cover labeled "Quench Button For Emergency Use Only". The quench button itself has the word "STOP" printed three times around its perimeter.

In the scanner room, quench buttons are located behind the door and is represented by the yellow image below.



T control room quench button is the button labeled "(1)"

Scan room quench button located behind door

2. When the magnet is quenched, the helium in the scanner boils off. Although the helium should vent out of the room to the rooftop, **you should make sure the door to the scanner room is wide open before quenching the magnet**. If possible, you should remove yourself and the subject from the scanner room before quenching the magnet to minimize the chance of asphyxiation in the event that the helium is improperly vented.

3. If using the landline in the control room, you will need to dial a 9 before 911 to call out. Call 9-911 and request medical assistance as detailed elsewhere in this manual.

4. The helium vent ducts become dangerously cold during a quench. Do not touch them.

5. Immediately notify a CAMRI staff member that you have quenched the magnet. If it is after hours please call the cell phone number for Krista listed under emergency numbers form.

6. At best, it will be at least a few weeks before the scanner can be returned to service. If uninjured, your research subject should be sent home. All accidents (including an quench) must be reported and documented.

PERFORMING AN EMERGENCY ELECTRICAL SHUTDOWN

The following events should prompt an emergency electrical shutdown:

1. You see smoke or fire coming from the scanner, equipment room or console.

2. Flooding has carried or is threatening to carry water into electrical equipment

Electrical shutdowns do not turn off the magnetic field—the magnet is always on unless the magnet has been quenched.

Emergency Electrical Shutdown Procedure

1. Locate and press the large red electrical shutdown buttons in the scanner room or control room. These buttons are clearly labeled. **Make sure that it is the electrical shutdown button, not the quench button.**

The emergency electrical shutdown button is red and it is labeled Emergency electrical shutdown button.

2. Electrical shutdown immediately stops all power to the scanner, the scanner equipment, and the console computers. It does not turn off the lights. However, power to other equipment (e.g. The boldscreens) will not be interrupted, so be aware that electrical or fire hazards may still be present.

3. In the case of fire or medical emergency, call 9-911

4. Remove your subject from the scanner room. The electric brakes on the scanner bed will have been released automatically, so simply pull the bed out of the gantry manually using the handle at the foot of the bed.

5. Notify CAMRI staff that you have performed an Emergency Electrical shutdown.

6. Circumstances that justify an emergency electrical shutdown do not typically justify quenching the magnet. **Do not quench the magnet unless there is a specific reason to do so** (possible reasons for quenching the magnet are discussed elsewhere in this manual).

7. If uninjured, send your subject home. It will take at least a couple of days to restore the scanner to operational status.

PRESSING THE TABLE STOP BUTTON

A table stop is performed when you need the bed to stop because something is being pulled or stuck in the bed tracks. It will release the bed from the guide tracks and allow you manually pull the bed out. The table stop can also be used if you need to manually pull someone out of the scanner if you performed an electrical shutdown, bed is not responding or if power is off

Releasing the table stop

From Scanner: Go into the room and turn the table stop button (on bed) clockwise until it clicks and then press the table up and down buttons in succession. This will reset the table and allow the bed to be used again. (The screen on scanner will walk you through this process)

From the console: Hit the small flashing button on back of intercom and go into room and press the table up and table down buttons in succession. This will reset the table and allow the bed to be used again.

HANDLING MEDICAL EMERGENCIES

CAMRI does not have medical staff. The following procedures are designed on the assumption that a physician or nurse is not immediately available in the MR laboratory at the time of the emergency. If a physician or nurse is present, the medical recommendations may be adjusted as deemed medically appropriate for the subject's condition. However, all non-medical aspects of these guidelines, **particularly those related to removing the person from the magnet or scanner room, must be followed** to avoid unnecessary injury to the subject or personnel.

1. If (**and only if**) the medical emergency involves the subject being pinned to the magnet by a metal object held in place by the magnetic field, quench the magnet following the procedure described elsewhere in this manual.

2. Call 911 (9-911) Describe the event. Advise the person taking the report that the building is a secure building and that you are in CAMRI S104. Baylor security will escort them to you.

3. If the emergency involves a subject in the magnet:

   A. Stop the scan and go in the room to help subject.

   B. Pull the bed completely out of the scanner bore. ***The scanner bed cannot be detached from the scanner.***

   C. Remove the subject from the scanner room so that emergency personnel can safely assess the subject.

   D. Close the door to the magnet.

Emergency personnel cannot provide care in the MRI scan room. If you are unable to remove the subject from the scan room prior to their arrival then the level 2 individual on site must clear the first responders prior to entering the active magnet.

5. Provide medical assistance in accordance with your training and experience while awaiting arrival of the paramedics. Consider the following options:

   A. Initiate CPR if the person is pulseless or not breathing

HANDLING FIRE EMERGENCIES

1. In case of fire, call 911 (9-911 if calling from CAMRI phone).

   Let them know they are responding to an active magnet that is not quenched.

2. If smoke or fire is coming from the scanner, equipment room or console, perform an emergency electrical shutdown as described elsewhere in this manual. You will need to manually pull the bed out of the scanner because power to the scanner will be lost. The bed should automatically release after emergency electrical shutdown button is hit but if it does not you will need to press the table stop button on the bed. To do this hit the table stop button on bed, this will release the bed from the tracks and allow you to manually pull bed out.

3. If you are scanning and smoke or fire is NOT coming from the scanner, equipment room or console, stop the scan and safely bring your person out of the scanner. If time permits, initiate a routine electrical shutdown by selecting “End” from the “System” menu at the far right at the console.

4. Remove the subject from the scanner and escort the subject out of the building.

5. Do not return to the building until advised by fire personnel that it is safe to do so.

6. Contact CAMRI personnel to advise them that there was a fire in the building.

WE DO NOT HAVE MRI SAFE FIRE EXTINGUISHERS AT CAMRI!!!

HANDLING AUDIBLE ALARMS PROCEDURE

You should never scan while an audible scanner-related alarm is sounding. If you cannot identify and correct the underlying problem, your study should be discontinued. If an audible alarm is sounding, investigate the following possibilities:

1) The alarm might be the building fire alarm. This extremely loud alarm is audible throughout the building, is associated with flashing lights in the hallways, and would be difficult to mistake for a scanner related alarm. Even if you suspect that the fire alarm has been triggered accidentally or as part of a drill, you **MUST** do the following:

   A. If you are scanning, stop the scan.
   B. Go into the scanner room and pull the bed out.
   C. Assist the subject off the bed
   D. Accompany the subject out of the building via the nearest accessible exit.
   E. Do not reenter the building until told that it is safe to do so by fire personnel.

2) The alarm might have been triggered by someone squeezing the squeeze bulb. Look to

see if the squeeze bulb LED on the intercom is lit. If it is, see the separate section regarding the squeeze bulb. You will be able to continue your study if this is the source of the alarm.

The helium level might be low or the magnet might have quenched spontaneously or as a result of someone pressing the quench button. Check the Siemens control box located in the control room immediately to the left of the window. If the magnet stop LED is lit, the magnet has quenched. If the helium level LED is lit, the helium level is low. You can press the alarm silencer 'AUDIO ALARM OFF' to stop the audible alarm, but **do not scan**. Notify CAMRI staff of the problem, and report the level of helium. CAMRI staff will assess the situation and let you know if you are able to scan or if you will need to send your subject home.

Audible Chirping Noise Check:

The scanner makes a **chirping sound**, this sound is perfectly normal and should be heard on all properly functioning scanners while not in use. This chirping sound is produced by the compressor and if you do not hear this sound please contact Siemens and let CAMRI staff know. Siemens will ask for the helium level of the scanner so be prepared to provide them with this information. If the sound is not present it could be the chiller not functioning properly and the scanner may heat up. The scanner will be out of commission for repairs if the compressor is down.

Do not scan if you do not hear the chirping sound!!!!

Appendix A

MRI Screening Form

CAMRI MRI Screening Form for Research Participants

Thank you for your interest in the MRI studies at the Core for Advanced MR Imaging at Baylor College of Medicine. Prior to receiving an MRI scan, we require the information in the form below. Your answers to these questions will improve our research by helping us to better understand our subject population. This will also ensure that your time in the scanner is safe and comfortable, so please provide accurate and complete answers. The answers you provide will remain confidential.

**Please provide explanation for all yes answers.

TO BE COMPLETED BY PATIENT		
**If you have any of the following- STOP and alert the staff now	YES	NO
Heart pacemaker or defibrillator		
Spinal Cord stimulator		
Implanted infusion pump		
Hearing implants		
Other implantable/external electronic devices		
Cerebral aneurysm clips		
Tissue Expanders		
Pill/Cam (Capsule Endoscopy) (in last 48 hours)		
Have you ever had any metal in your eyes?		
Are you a metal worker/ welder?		

If you answered NO to all the above, please continue	YES	NO
Aortic clips		
Brain clips		
Bullet fragments		
Dental braces, retainer or implants		
Heart valves		
Inferior Vena Cava Filter (IVC) filter (umbrella)		
Intrauterine device (IUD)		
Joint replacements		
Limb prosthesis		
Metal mesh		
Metal tracheostomy		
Penile implants		
Piercings that cannot be removed		
Port/Port-a-Cath		
Rods/screws/plates		
Shrapnel Shunts / stents		
Tattoos or Permanent eyeliner		
Colored Contacts		
Are you claustrophobic?		
Is there any chance of pregnancy?		
Do you require eyeglasses to see computer screen while sitting at desk?		
List any surgeries that you have had:		
List any other medical or biomedical devices:		

PLEASE DO NOT BRING INTO SCAN ROOM: Metal objects & electronic devices such as: *phone, wallet- credit cards, hotel room key cards, parking chips, hearing aids, watch, pens, etc.*

Please provide the following subject information:

DOB:_____ Weight:_____ Sex:_____ Ethnicity:_____

_____ _____

Patient Signature Date Print Name

_____ _____

MRI Tech/ Trained User Date Print Name

Appendix B

Note that a subject reporting having had an MRI in the past is not sufficient for clearance. Not all MRI environments are the same (e.g., 1.5 T vs 3T); MRI staff at another institution may have taken precautions that the participant was not aware of (e.g., limiting scan time, alternate coils); exclusion criteria may have happened after the scan; participants may have mistaken CTs or other medical imaging modalities for MRI; etc. Also note that scanning that takes place in CAMRI is for research, not clinical purposes, and so the acceptable risk is lower than in a hospital environment because the scans do not offer direct benefits to the participant.

Exclusionary Criteria

- Participants with any of the following implants or conditions are excluded from participating in MRI studies at CAMRI unless identified as MRI safe at 3T:
- Metal in the eyes or an injury to the eyes involving a metal object or fragment (such as metallic slivers, shavings, or a foreign body).
- A pacemaker or implanted cardioverter defibrillator.
- Eye implants (prosthesis, retinal tack, eyelid wire or spring);
- Magnetically activated implant or device.
- Internal electrodes or wires.
- Tissue expander (e.g., to expand tissue prior to a breast implant. Breast implants themselves are not exclusionary;)
- Vascular access port and or catheter.
- Neurostimulator system, spinal cord stimulator, bone growth/bone fusion stimulator.
- Aneurysm clips.
- Any type of nonremovable pump (pain, drug infusion, insulin, etc.).
- Ear surgeries, implants (cochlear and otologic), stapes, prosthetic ear bone.
- Any implant labeled MR unsafe.
- Any implant labeled MR conditional that is not deemed safe at 3T.
- Any implant for which clear and unambiguous documentation cannot be provided to verify the implant is MR safe at 3T; or
- Pregnancy, unless specifically allowed by the IRB approval for the study and necessary to the research question.
- Piercings and jewelry that cannot be removed

There is equipment, devices, medical implants, etc that are at risk to injury and/or damage if they are brought into the scanner room. This pertains to be within the body or in personal possession. The items that are listed are considered to be potential risk to an individual's safety. Some items on the list are conditional (*), and further information can be founded at www.mrisafety.com

Appendix C

Criteria that May Exclude Research Participants

- Injury involving an object or foreign body, such as a BB, bullet, shrapnel, or shard of metal;
- Joint replacement (hip, knee, etc.);
- Bone/joint pin, screw, nail, wire, plate, etc.;
- Surgical staples, clips, or metallic sutures;
- Artificial limb;
- Wire mesh implant;
- Heart valve prosthesis;
- Shunts (spinal or intraventricular) not recognized as MRI safe.
- For females, IUD;
- For males, penile implant;
- Insulin pump;
- Metallic stents, filters, or coils;
- Other implants not listed above;
- A history of claustrophobia; or
- Medication patches (nicotine, nitroglycerine, contraceptive, pain.