

UC Davis Imaging Research Center

MRI Safety Manual

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MRI Safety Guidelines for the UC Davis Imaging Research Center

Section 1

Introduction

The use of Magnetic Resonance Imaging (MRI) presents known safety hazards. MRI Safety Guidelines have been developed so that investigators, researchers, students, colleagues, study participants, and associated equipment remain safe in the magnetic environment. All personnel working within the magnetic environment are required to complete MRI safety training (see Section-4). The UC Davis Imaging Research Center (IRC) MRI Safety Committee has developed this guide of general MRI safety information for Research MRI Users.

Components of the MRI scanner system

The Static or main Magnetic field

- The strong magnetic field is always present.
- The risk of the strong magnetic field increases the closer an object is to the bore or opening of the magnet.
- Objects that are ferromagnetic may become projectiles with the potential to cause serious injury.
- Objects that are ferromagnetic may pin someone against the magnet in a life threatening situation.
- Every individual must be screened for potential contraindication to safety PRIOR to entering the magnetic field.
- All equipment must be evaluated for potential risk PRIOR to being safely placed in the magnetic field.

The Radio Frequency (RF)

- Research participants and animals must be protected from potential heating and burns.
- The FDA sets limits to the amount of heating or the Specific Absorption Rate (SAR) that is allowed.
- Equipment and accessories must be used properly and safely to prevent heating or burns to the research participant or animal.

The Gradients or Time Varying Magnetic Fields

- Rapidly changing gradient fields used in MRI have the potential to cause peripheral nerve stimulation (PNS).
- Gradients produce excessive acoustic noise levels for which hearing protection must be provided and worn.

Ancillary equipment used for experiments

- All equipment placed in the magnetic environment must be considered for heating or any other potential safety risk.

Section 2

Purpose

The purpose of this MRI Safety Guidelines is to provide a resource for continued safe MRI practices within the UC Davis Imaging Research Center community. The UC Davis Imaging Research Center MRI Safety Committee developed the MRI Safety Guidelines based on locally accepted standards and the internationally accepted recommendations of the American College of Radiology (ACR). The initial Blue Ribbon Panel of the ACR, lead by Emanuel Kanal, M.D., FACR, first published recommendations in 2002 with revised information in 2004 and 2007. In 2013 the paper: *ACR Guidance Document for Safe MR Practices: 2013* was published and is used as the primary reference for the MRI Safety program at UC Davis Imaging Research Center.

The 2013 recommendations are incorporated into daily practice and policy here in light of continuing reports of accidents in the magnetic environment involving both equipment damage and serious personal injury, including death within the MR community. The MRI Safety Guidelines are reviewed on a regular basis, modified as needed and posted on the UC Davis Imaging Research Center web-site.

The *ACR Guidance Document for Safe MR Practices 2013* recommends that:

- All MRI sites should maintain MR safety policies.
- The MRI Safety Guidelines should be reviewed concurrently with the introduction of any significant changes in safety parameters of the MR environment and updated as needed.
- Site administration is responsible to ensure that the MRI Safety Guidelines are implemented and adhered to at all times by all site personnel.

- Any and all adverse events, MR safety incidents or “near incidents” are reported to the UC Davis Imaging Research MRI Safety Committee and used in continuous quality improvement efforts.

UC Davis Imaging Research Center suggests action consistent with the ACR recommendations to prevent accidents and injuries in the MRI suite. The risk reduction strategies include reference to the ACR guidelines.

Standard of Practice at UC Davis Imaging Research Center

It has been reported by other facilities that any of the MRI related injuries and the few fatalities that have occurred were the apparent result of failure to follow safety guidelines or the use of inappropriate or outdated information. It is required that all UC Davis Imaging Research Center MRI researchers complete safety training prior to obtaining access to the MRI environment. It is expected that all MRI researchers should execute proper and orderly procedures every time studies and or developmental work is performed. UC Davis Imaging Research Center researchers and support staff assigned to work in the MRI area(s) are required to complete safety training and adhere to the MRI Safety Guidelines.

To maintain safe laboratory practice, at least one UC Davis MRI researcher, student or faculty member that is MRI safety trained must be present with the research participant for all MRI scanning during normal work hours, being Monday through Friday, 8am to 5pm. After normal work hours, weekends, and holidays a minimum of two MRI safety trained individuals besides the research participant being scanned must be present. This means the operator of the scanner and the safety monitor who have both completed MRI safety training. A one-to-one ratio of safety monitors to non-safety monitors must be in the MRI scanning environment after regular hours, holidays, and weekends. For animal studies a minimum of two MRI safety trained individuals should be on site at all times. This applies to all scanning hours including the evenings, weekends and holidays.

Section 3

Definitions

MRI Safety Committee

The MRI Safety Committee is the official committee of the UC Davis Imaging Research Center (IRC) that reviews, develops, and implements MRI Safety. The MRI Safety Committee meets on a bimonthly basis. Members are appointed by the Director of the UC Davis Imaging Research Center. Meetings are conducted by the MRI safety officer.

MRI Safety Officer

The MRI Safety Officer is an American Registry of Radiologic Technologists (ARRT) registered professional with the knowledge and experience to oversee day-to-day operations of the MRI Suite and implement UC Davis Imaging Research Center MRI Safety Program. The MRI Safety Officer's primary function is to support the research activities conducted within the MRI Suite by MRI research users while overseeing the safe operation of the MR Scanner and compliance with all relevant regulations, and UC Davis Imaging Research Center policies and procedures. The MRI Safety Officer is appointed by the Director of the UC Davis IRC.

To ensure safety and compliance with policies and procedures, the MRI Safety Officer will implement the MRI Safety Program. This position has the authority to immediately cease unsafe activities or activities that are out of compliance with UC Davis Imaging Research Center MRI Safety Guidelines and applicable regulations, and will report such instances for further review to the UC Davis IRC MRI Safety Committee at which time will determine a course of action.

MRI Research User

The MRI Research User, hereafter *researcher*, is a Principal Investigator (PI) who has an IRB or IACUC approved protocol and utilizes one or more of the MRI scanners affiliated with UC Davis IRC for research purposes and/or a student, staff member or research assistant for whom the PI is responsible. Researchers must have approval via the UC Davis IRC Protocol Initiation form, and approved IRB or IACUC protocol. Only researchers with approved protocols are allowed to schedule MRI scanner time for research studies.

Research Participant

A research participant is a human subject who is placed into the MRI scanner for research purposes. The research participant must complete and sign both IRB consent and MRI Screening form prior to the MRI scan. The research participant must be treated and cared for within all institutional and federal guidelines and regulations.

MRI Scanner Operator

The MRI scanner operator is an individual who is an UC Davis affiliated personal that has completed the MRI safety training and is specially trained in the operation of one or more of the MRI scanners at the UC Davis IRC. Under grad students or volunteers are not eligible for MRI operator training. It should be noted that the trained UC Davis MRI scanner operators have authority by the MRI Safety Committee to stop any procedure that they feel exceeds safe practices.

MRI Scanners

The available MRI scanners as of 1/01/2015 at the UC Davis Imaging Research Center are:

- Siemens 3T TIM TRIO
- Siemens 3T Skyra

- General Electric 1.5T LX 9.1

Section 4

MRI Safety Training Procedure

Safety Training for all MRI Researchers is mandated by the MRI Safety Committee and has evolved to include the steps described below.

Overview

Safety training is required for all scanner operators and safety monitors. This involves an initial on-site training session that includes a lecture, safety video, tour of the MRI suite and a written quiz. Subsequent renewals may be processed online (see below). It is the responsibility of the operator or safety monitor to renew before their MRI safety expires. **Safety training must be renewed annually by all active scanner users and safety monitors. If your MRI Safety training has expired you will need to take the MRI Safety class at the UC Davis Imaging Research Center if you plan to continue to perform MRI research studies.**

Annual Safety Training Renewal Instructions

1. Review the MRI Safety presentation (pdf document).
2. After completing the presentation, download the password-protected Safety Questionnaire and Quiz (Word document, username is "safety"; you should have received the password from the MRI Safety officer).
3. On the "Safety Questionnaire" complete the following fields:
 - a. Name
 - b. Dept/Faculty Advisor
 - c. Student/Employee ID Number
4. Select only one box (Y or N) for each question. On question #1 if you have implant(s) list the name of the implant next to "explain".
5. Complete the "Self-Assessment of UC Davis IRC MRI Safety Practices". Answer either "Yes" or "No".
6. Continue with the "MRI Safety Quiz". Complete the Name and PI fields. There are approximately 30 questions and you must pass with 80% to renew.
7. There is only one correct answer for each question on the "MRI Safety Quiz". If you mark more than one box it will be deemed an incorrect answer.
8. After completing both the "safety questionnaire" and the "MRI Safety quiz", save the document.
9. Send your completed document as an email attachment to the MRI Safety officer:

10. The MRI Safety officer will email you a certificate providing you have passed the MRI Safety quiz.

Training includes discussions on, but not limited to the following:

- Indications for use of the MRI system
- Restrictions on use of the MRI system
- Contraindications for use of the MRI system
- Use of visual hazard warning signs
- Burn hazards (including precautions on patient positioning, precautions for larger patients, effective use of patient comfort monitor, precautions on using surface coils, warnings associated with using EKG pads and electrodes, and warnings associated with using peripheral pulse hemodynamic gating)
- Radiofrequency (RF) heating
- Warnings associated with body temperature increases during scanning
- RF power deposition considerations, including face and eye hazards associated with cosmetics and exposure to metal slivers
- Magnetic fringe field warnings and hazards
- Acoustical noise hazards during scanning
- Psychological hazards associated with MR scanning (e.g. claustrophobia)
- Precautions associated with scanning pregnant or infant patients
- Biomagnetic hazards such as subtle genetic or molecular changes,
- Precautions associated with scanning high risk participants (such as those likely to develop seizure or claustrophobic reactions, participants greater than normal risk of cardiac arrest, unconscious, heavily sedated, or confused participants with whom no reliable communication can be maintained)
- Problems associated with the operators limited view of the participant while the participant is in the MRI system.

Additional training is provided in MRI emergency treatment and prevention, such as how to inform the participant about the risks of the procedure, how to explain to the participant the use of the alert system within the MRI system, reviewing the procedures to follow in the event that the participant requires medical emergency attention during the scanning session, reviewing the procedures in the event that the magnet quenches or that the cryogen venting system fails. The call button alert system, and the magnet bore temperature monitor within the system, is provided to aid the researcher in the assessment of acute participant distress. Finally, a review is done of situations requiring immediate action on the part of the researcher, e.g. an MRI system failure that risks participant well-being, an acute medical condition of the participant such as a heart attack, or a life threatening situation such as the participant becoming pinned

against the magnet by a ferromagnetic object, requiring an emergency “controlled rundown” of the main magnetic field known as a quench.

Section 5

MRI Safety Screening

General Procedure

Each individual must be checked for safety and pre-screened prior to entering the magnetic environment of the scanner room. A standardized MRI screening form is used for evaluating the safety of an individual BEFORE that individual is permitted within the magnetic environment. MRI Safety Screening Training is a segment of the requirement for MRI researchers.

The MRI environment

The MRI environment is that area passed the security doors requiring an electronic key card. The establishment of thorough and effective screening procedures for research participants and other individuals is one of the most critical components of a program to guard the safety of all those preparing to undergo MRI procedures or to enter the MRI environment. An important aspect of protecting individuals from MRI system-related accidents and injuries involves an understanding of the risks associated with the various implants, devices, and accessories which may be present within or adjacent to the individual. Risks of other objects that may cause problems in this setting must also be evaluated. This requires obtaining information and documentation about these objects in order to provide the safest MRI environment possible. In addition, because many MR-related incidents have been due to deficiencies in screening methods and/or lack of proper control of access to the MRI environment, (especially with regard to preventing personal items and other potentially problematic objects from entering the MRI room) it is crucial to establish procedures and guidelines to help prevent such incidents from occurring.

Exclusions of Individuals and Research Participants

Individuals and research participants with cardiac pacemakers, implanted neural stimulators, or with attached or implanted electronic devices, with brain aneurysm clips, are specifically excluded from having MRI scans. All participants that have other types of implanted devices must have approval by the safety officer and/or the MRI safety committee even if a medical doctor approves the implanted device safe for MRI scanning. The MRI operator must notify the PI of a participant’s implanted device prior to scheduling for further evaluation of a participant’s compatibility to be scanned. **(Refer to Appendix: Procedure for approval of MRI scanning with implants.)**

Individuals

All individuals, including researchers, employees and students, who work within the magnetic environment, must be trained according to UC Davis IRC policy and screened for personal safety prior to entering the magnetic field. In addition, employees and researchers who have responsibility to recruit subjects, and/or screen subjects for MRI safety who are not MRI safety trained are required to have an MRI safety trained individual involved with the specific MRI research study to verify that the participant is safe to scan. MRI Safety trained individuals must participate in an Annual Renewal of MRI Safety.

To work unescorted in the magnetic environment, it is mandatory to complete the required MRI safety training. This includes all scanner operators and individuals who are assisting as MRI safety monitors with MRI research studies. Operators who will be scanning research participants or animals must complete operator on-site training. Non-UC Davis personnel may not be trained to operate the MR scanner, without specific approval of the Director. Undergrads or volunteers are not eligible for MRI operator training. Any individual who has a need to enter the magnet room, i.e. facility maintenance employees, site visitors, etc. must be screened on a case by case basis.

Pregnancy

Individuals who are or may be pregnant are not allowed to remain in the MR scanner room while the RF and gradients are operating. Pregnant individuals may remain in the control room and enter the magnet room between scans, during the study. This includes staff or individuals accompanying the research participant.

Female research participants that are pregnant are not eligible to participate in an MRI scan. If a research participant suspects pregnancy, the MRI scan will be postponed until the research participant is able to confirm that she is not pregnant.

Research Participants

The preservation of a safe MRI environment requires constant attention to the care of research participants and individuals with metallic implants and devices, because the variety and complexity of these objects constantly changes. With the continued advances in MRI technology and the development of more sophisticated implants and devices, there is an increased potential for hazardous situations to occur in the MR environment. Therefore, to prevent incidents and accidents, it is necessary to be aware of the latest information pertaining to MR biological effects, to use current evidence-based guidelines to ensure safety for research participants and staff members, and to follow proper recommendations pertaining to biomedical implants and devices.

Preliminary screening of research participants for MRI procedures should take place during the scheduling process. This must be conducted by an individual who is involved with the research study and able to recognize:

1. The potential hazards and issues associated with the MRI environment and MRI procedures.
2. The information contained on the screening form for research participants and individuals that are contraindications for MRI.
3. When to contact an MRI safety trained individual, MRI safety officer, or the UC Davis IRC MRI Safety Committee for further evaluation of a participant's compatibility to be scanned.

Preliminary screening helps to prevent scheduling of research participants who may be at risk for safe MR imaging.

At the UC Davis Imaging Research Center, it is mandatory for every research participant to undergo comprehensive MRI screening in preparation for the MRI study. Comprehensive MRI screening involves the use of the approved UC Davis IRC MRI screening form to document the screening procedure, a review of the information on the screening form, and an oral interview to verify the information and allow discussion of any question or concern that the research participant may have. All sections of the UC Davis IRC MRI screening form must be completed, and include date and signatures of the reviewer and research participant. An individual who has completed MRI safety training must conduct this aspect of research participant MRI screening.

It should be noted that having undergone a previous MRI procedure without incident does not guarantee a safe subsequent MRI examination. Various factors (e.g., static magnetic field strength of the MR scanner system and orientation of a metallic implant or object) can substantially change the scenario. Therefore, a comprehensive screening procedure must be conducted every time a research participant prepares to undergo an MRI procedure. This is not an inconsequential matter, because a seemingly unrelated event may have occurred that could affect the safety of the research participant entering the MRI environment.

To summarize, each research participant considered for an MRI procedure should be screened a total of three times:

1. By the individual scheduling the procedure.
2. By the individual greeting the subject upon arrival at the site.
3. By the individual who is conducting the study or operating the MR scanner.

Implants and devices

Implants and devices are evolving rapidly and must be thoroughly investigated if potential participants or individuals who will enter the magnetic environment indicate their presence. Implants that are approved to scan at 1.5T are not necessarily safe to scan at 3T. Before scheduling a participant that has an implanted device, both the PI and the safety officer must be notified to confirm compatibility of the implanted device with the magnetic field

strength that will be used to perform the MR scan. If the individual knows or has documentation as to the specific manufacturer and type of device, then the following steps are implemented:

- Look up the item by the manufacturer in the current ***Reference Manual for Magnetic Resonance Safety, Implants, and Devices*** by Frank G. Shellock, Ph.D. or on the web site: <http://www.mrisafety.com>

- If the device or object is not listed there or has not been tested at 3 Tesla, then contact the manufacturer for the following information and written documentation:
 - Have the manufacturer fax the text that states the device is MRI safe and at which magnetic field strength(s), and conditions, it is safe.
 - The text sent should include the FDA date stamp that verifies the device is MRI safe at 3 Tesla or the specific conditions which must be adhered to for the field strength the individual will be entering.

The assurance of safety needs to be verified BEFORE the participant or individual is brought to the MRI scanner so that the operator has adequate information to ensure the safety of the individual they are placing or leading into the magnetic environment.

For research participants, include the device information with the consent and MR safety screening form so there is documentation that the safety of the subject was investigated before the MRI study was performed.

Screening Patients and Individuals with Metallic Foreign Bodies (Frank Shellock)

All participants and individuals with a history of being injured by a metallic foreign body such as a bullet, shrapnel, or other type of metallic object should be thoroughly screened and evaluated prior to admission to the area of the MR system. This is particularly important because serious injury may occur as a result of movement or dislodgment of the metallic foreign body as it is attracted by the magnetic field of the MR system. In addition, heating may occur, although this tends to only happen if the object forms a resonant conductive loop.

The relative risk of injury is dependent on the ferromagnetic properties of the foreign body, the geometry and dimensions of the object, the strength of the static magnetic field, and the strength of the spatial gradient of the MR system. Additionally, the potential for injury is related to the amount of force with which the object is fixed within the tissue (i.e., counter-force or retention force) and whether or not it is positioned in or adjacent to a particularly sensitive site of the body. These sensitive sites include vital neural, vascular, or soft tissue structures.

The use of plain film radiography is the technique of choice recommended to detect metallic foreign bodies for individuals and research participants prior to admission to the MR environment. The UC Davis IRC does not provide plain film radiography, and therefore a participant should not be admitted to the MR environment until they have had plain film radiography documenting that there is not any potential danger to the participant. This includes screening individuals and participants for the presence of metallic orbital foreign bodies. The inherent sensitivity of plain film radiography is considered to be sufficient to identify any metal with a mass large enough to present a hazard to an research participant in the MR environment.

Orbital foreign body screening guidelines

The procedure to follow with regard to an individual or research participant suspected of having an orbital foreign body involves a clinical screening protocol that entails asking the individual or research participant if he or she has had an eye injury. If an eye injury from a metallic object was sustained, the individual or research participant is asked if they have had an MRI scan that was cleared by conventional radiography (x-rays) after the eye injury. If the individual or research participant indicates that they have had an MRI scan after the eye injury that has been cleared of metallic objects by x-rays, then the individual or research participant may proceed with the MRI scan. If the individual or research participant has had an ocular injury, but has not been cleared of metallic objects sustained to the eyes, then the individual or research participant must have x-rays to confirm that there are not any metallic objects in the eyes. The MRI scan must be postponed until documentation has been received indicating that there are not any metallic objects in the eyes.

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. According to the Siemens documentation, if you are using the Siemens headphones you **MUST** also provide the subject with earplugs for additional hearing protection.

Claustrophobia Screening

Statistics indicate that about 10% and up to 20% of the general population is claustrophobic to some degree. In many cases research participants who think they are claustrophobic are able to go through an MRI study with some reassurance.

Medical Status Screening

Research participants must be evaluated for medical status or issues that may prevent them from lying flat or holding still for long periods of time. Research participants who are dependent on continuous medication via external or internal devices should be excluded from research MRI studies. Research participants who do not understand directions or cannot cooperate with the researchers to ensure a successful study should be excluded. In addition, research participants that are unable to ambulate on and off of the MRI table with minimal assistances may be excluded from an MRI research study.

Exceptions may be evaluated on a case by case basis depending on the purpose of the MRI study.

Magnetic field-related issues and Screening

Magnetic field-related translational attraction and torque are known to present hazards to individuals and research participants with certain implants or devices. MR systems used in clinical and research settings operate with a static magnetic field that ranges from 0.2T and higher. Most previous ex vivo tests performed to assess objects for MR safety used units with a static magnetic field of 1.5T or lower. Accordingly, this could present problems, insofar as it is possible that an object that displayed “weakly” ferromagnetic qualities in association with a 1.5T MR system may exhibit substantial magnetic field interactions with an MR system operating at a stronger static magnetic field strength. The magnetic field strength currently used for research participants at UC Davis Imaging Research Center are 1.5T and 3.0T. If implants or devices are safe for 1.5T, this does not necessarily mean that they are safe for 3.0T. Documentation must be obtained from the manufacturer as to the safety of a particular device at 3.0T before it is allowed or brought into the magnetic environment.

Equipment Screening

Any additional equipment to be used that is not currently in use within the magnet room must be approved by the UC Davis IRC MRI Safety Committee. Researchers are cautioned to NEVER take equipment into the magnet room without prior testing for magnetic attraction. Researchers are cautioned to NEVER implement the use of equipment with research participants before testing with a phantom or other method that will not potentially cause harm to a research participant or to related equipment. Equipment operating within the magnetic environment must be monitored for any spurious signals that may cause artifacts on images or acquired data.

MRI safe equipment is developed for specific magnetic field strengths and MRI system configurations. Equipment that may operate safely within a magnet room is NOT necessarily safe to operate in another magnet room even if the magnets are the same static field strength. Routine inspection and maintenance of equipment must be performed. Broken or malfunctioning equipment must be identified and reported to the IRC Tech support team.

Incidental Findings

Incidental findings are described as abnormal anatomical structures displayed on the MRI images of the research participant’s MRI scan that is observed by the MRI researcher. MRI research operators will report any incidental findings to one of the following: Director, Technical Director or Safety Officer. The images will be reviewed by the Director, Technical Director and/or the Safety Officer. If the incidental finding is remarkable, the research participant will be notified of the incidental findings and the action that should be followed to further investigate the incidental finding.

Section 6

Emergency Safety Procedures

General Procedure

In an MRI environment emergency, orderly and proper procedures ensure the safety of individuals, researchers and the research participant. If an emergent event occurs, the procedure is to call 911 and state the reason for the emergency and the location. Furthermore, emergency personnel must be met at the locked electronic doors and advised that a strong magnet field is present and precaution must be observed.

Research Participant Scanning

It is essential that there is constant communication between the research participant within the MRI scanner and the scanner operator. Every research participant is given a signal squeeze ball that will alert the scanner operator of a difficulty even when the scanner is running and producing loud noises. During the quiet times of the study the scanner operator should maintain verbal contact with the research participant. A research participant who does not respond verbally requires immediate investigation to ensure the research participant's well being.

Medical Emergency

If the research participant has a medical emergency, they must be removed from the magnet room and into the control room to prevent a potential accident due to ferromagnetic projectiles in the event emergency personnel enter the magnetic room with equipment. If the medical emergency is due to the individual being trapped in or on the magnet and is in a life threatening situation, it may be necessary to quench the magnet to rescue the injured individual. The event must be reported to the Principal Investigator and the UC Davis IRC MRI Safety Committee.

Emergency Stop

If there is an emergency such as an equipment failure that could cause injury; sparking of equipment, a flood or a fire, the scanner operator or safety monitor should immediately press the emergency stop button.

Magnet Emergency

If an individual or research participant is restrained or pinned by a ferrous object to the magnet: Assess if the situation is life threatening, if YES an emergency rundown to quench the magnet can be performed by an authorized person (see emergency quench below). If an individual or research participant is restrained by a ferrous object to the magnet and is NOT in a life threatening situation, call a member of the IRC tech support team during normal business hours or Siemens Online support to determine the optimal way of releasing the individual or research participant from the magnetic field. If a

quench is necessary proceed as above. It is the responsibility of the scan operator to document the accident within 24 hours and submit a written explanation of the accident to the MRI safety officer.

Emergency Quench

A quench includes the rapid release of cryogenics and results in the loss or significant decrease of the magnetic field. A quench should ONLY be performed by authorized personnel in dire emergency that involves a serious personal injury or life threatening situation. Sudden loss of the magnet field in a quench situation could cause debris and freezing gases to enter the room. Also, this rapid loss of cryogenics could potentially damage the magnet or components of the system. There is a considerable cost related to quenching the magnet and re-implementing the magnetic field. The strong magnetic field will dissipate in about a minute, releasing the individual.

Note: in extraordinary circumstances such as an earthquake or explosion, resulting in an uncontrolled quench, the oxygen level in the magnet room may significantly decrease possibly making breathing difficult.

Section 7

MRI Screening Form

The MRI Screening Form for Human Subject Participants in use at UC Davis IRC is:

- A standardized form that will ensure safety of UC Davis IRC research participants and individuals.
- The only approved MRI screening form that will be used for screening of research participants or individuals at the UC Davis IRC. Any modification to the UC Davis IRC MRI screening form without review and approval by the MRI Safety Committee is strictly prohibited.
- Available on the UC Davis IRC web site.
- Available in original form at <http://www.mrisafety.com>.

Components of Standard MR Screening Form

The following describe the various parts of the MRI Safety Screening form (see appendix) and why all of the detailed questions are necessary to ensure safe practices. The top of the form asks about:

- Principal Investigator name
- Date
- Demographic information

This information is necessary to be able to contact the participant in the future should need arise. The forms are retained with other records by UC Davis Imaging Research Center so that the information remains within HIPAA compliance.

The first three questions ensure the research participant or individual is free from ferromagnetic, electromagnetic or other objects or devices that may have entered the body through surgery, accident, or other means.

1. Have you ever had surgery or similar invasive procedure in which medical devices may have been implanted?

A history of surgery or operative procedures must be investigated to ensure that there is no metal or implanted devices within the body which could risk the safety of the research participant or individual. Identification of all devices or implants must be made to ensure the safety of the participant and to avoid damage to any device. Metallic objects may cause distortion of data even if they are determined to be MRI safe.

2. Have you had any previous MRI imaging studies?

A participant who has had previous MRI studies either clinically or for research will be potentially more comfortable with the study. If the participant has been rejected for a prior MRI study, this may indicate a safety incompatibility. Other diagnostic studies are usually not relevant to the MRI research study.

3. Have you ever worked with metal (grinding, fabricating, etc.) or had an injury to the eye involving a metallic object (e.g., metallic slivers, shavings, and shrapnel foreign bodies)?

Any injury to the eye must be investigated. Serious injury to the individual may occur if there is ferrous material in or near the eye. It is recommended that adolescents be questioned separate from parents or guardians to have accurate information about possible foreign bodies. (See previous detailed information: Section 5: UC Davis IRC guidelines for orbital foreign body screening).

For female subjects only:

Questions 4 - 8 will help to determine that the participant is not pregnant or nursing. Pregnant research participants are excluded from research MRI studies. Pregnant individuals who are staff or may accompany a participant are not allowed in the MR scanner room while the RF and gradients are operating. A participant that is nursing will not receive Gadolinium contrast media.

9. Are you currently taking or have you recently taken any medication?

Use of certain medications or drugs may exclude the individual from participating in the study or may be reflected in the data collected. The recent use of medication may indicate a low tolerance for the MRI study due to pain, acute illness, chronic disease or substance abuse.

10. Do you have anemia or any disease(s) that affects your blood, a history of renal disease, or seizures?

A study participant with a history of renal disease needs to be tested and evaluated BEFORE receiving intravenous gadolinium based contrast media. The medical director of the study should be consulted.

11. Do you have a history of seizure disorder or epilepsy?

A study participant with a history of seizure disorder is a warning that the scan operator and/or safety monitor carefully observe and communicate with the participant for any change in behavior or sudden body contractions.

8. Do you have a history of asthma, allergic reaction, respiratory disease, or reaction to a contrast medium or dye used for an MRI or CT examination?

Individuals who have a history as listed in the question may be more sensitive to MRI contrast and thus more susceptible to a reaction.

Back Page of MRI Screening Form

The back page of the MRI screening form asks several Yes/No questions to confirm any possible contraindications which may exclude the research participant from an MRI scan. Any "Yes" responses may require additional investigation, especially to verify the safety of an implant prior to entering the magnetic environment

Required Signatures and Date

The last section of the MRI screening form must have the printed name and signature of the individual that is completing the form and the safety trained individual that is reviewing the MRI screening form. The date must be entered by the individual(s) that complete the form and review the form. The MRI screening form is a medical-legal document and is invalid if printed name, signatures, or date are not included.

Section 8

Facility Design

Safety Zones

The UC Davis IRC building where the MR scanner is housed is divided into four safety zones in accordance with the ACR Guidance for Safe MR Practices: 2013. Zone 1 includes all areas accessible to the general public (the areas outside the electronic doors). Zone 2 indicates the interface between publicly-accessible Zone 1 and the restricted Zones 3 and 4. The MRI screening room where participants are greeted and screened before entering the scanner environment is Zone 1. 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 controlled. The MRI Control Room and MRI Equipment Room are Zones 3a and 3b, respectively. 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 adjacent to Zone 3 as it is the MR magnet and its associated magnetic field that generates the existence of Zone 3. The 5 gauss line is at the door entrance of the Zone 4 (MR scanner room) for the 3T scanners and at the door entrance of the lockers of Zone 3 in the 1.5T scanner.

Ventilation

The MRI Suite has unidirectional laboratory ventilation. In the event of a quench, released helium is vented to the building exterior to prevent the creation of an hypoxic environment. Quench is accompanied by a loud noise, which would startle persons in the facility and surrounding area. The helium released to the outside air is not toxic or harmful.

Security Access to MRI Suite

Access to open the doors to enter the MRI Suite is controlled by electronic key card. The doors must not be left open at anytime. If the doors are left open longer than 30 seconds, an audible alarm will be activated until the doors are closed as a reminder not to leave the doors open.

Restriction of food, beverages, tobacco products

No food, beverages, or tobacco products will be consumed or used in the MRI suites by participants or research personnel. These items maybe stored in provided lockers or in the kitchen.

Section 9

Gadolinium_Contrast

The American College of Radiology (ACR) guidelines on gadolinium contrast agents (2010) will serve as the standard of practice when administering gadolinium contrast agent for clinical trial participants or research participants requiring gadolinium. Please refer to link:

http://www.acr.org/SecondaryMainMenuCategories/quality_safety/contrast_manual/FullManual.aspx

Appendix:

Procedure for approval of MRI scanning with implants:

- If participants have any type of implants (i.e. orthopedic hardware, heart stents, surgery clips, electronic implants, etc.), you cannot proceed with the MRI scan until written documents from the manufacturer, stating the conditions that must be followed to safely scan the participant and has been approved by one or all of the following IRC personal: Jerry Sonico, Cameron Carter and/or Costin Tanase
- If a participant has had an MRI with an implant, never assume that the participant is safe to scan. You must still have approval before scanning your participant.
- When approval of the implant is needed, have the name of the manufacture, name of the implant, model number of the implant, and physician's operative report.
- Always allow a minimum of seven days before appointment to confirm the conditions needed to safely scan the participant with an implant.
- If unable to acquire written documents confirming the conditions to safely perform an MRI scan, the participant cannot be allowed to participate with the MRI scan.
- Violation of this policy are grounds for immediate suspension of the research lab and all scheduled MRI scans will be cancelled until violation has been resolved.

Approval of items to be used during MRI Scan sessions

- Items that are not already in Zone 4 (Scanner room) must **NOT** be brought into Zone 4 without being first approved for MRI safety by the MRI Safety Officer.
- The item will be stored at the respective MRI scanning facility (Davis or Sacramento) until the time of the scan session. This is to confirm that the item is not substituted for a similar item that has not been approved and brought into the MRI scanner.
- If an item is brought with the subject but has not been approved and is brought into Zone 4, this is a direct violation of this policy and the lab will be suspended and disciplinary action will be taken.