Stanford Center for Cognitive and Neurobiological Imaging (CNI)

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Section 1 - Introduction

Mission of CNI MRI Center

The center for Cognitive and Neurobiological Imaging (CNI) at Stanford University is a shared facility, dedicated to research and teaching in cognitive neuroscience. The center is located on the lower level floor of Jordan Hall in the same building as the Psychology Department. The CNI provides neuroimaging facilities and related resources for researchers and students in the cognitive and neurobiological sciences. The CNI mission is to develop and disseminate cognitive and neurobiological imaging methods. The unique intellectual focus of the CNI is to help scientists in different disciplines integrate their findings by using quantitative methods that span a wide range of spatial and temporal scales and imaging technologies. The core facility provided by the CNI is a research-dedicated 3T MRI.

Purpose of Manual

The purpose of this document is to provide a resource for the safe operation of a Magnetic Resonance (MR) facility and to outline the research imaging policies and procedures for the Stanford CNI.

The policies and procedures discussed in this manual were developed to be consistent with the requirements of the Environmental Health and Safety policies and with the Human Subjects Research policies at Stanford University. This manual is available in the MRI Suite located at the CNI and is posted on the CNI website. The contents of this manual are reviewed annually and revised as necessary to reflect changes in MRI safety and operations.

Section 2 – Purpose of Policies and Procedures

The Stanford Center for Cognitive and Neurobiological Imaging (CNI) Committee uses the internationally accepted recommendations from the American College of Radiology, as described below, to establish Research MR Safety Policies and Procedures. These are general rules pertaining to safe operation of research MR. These policies and procedures will be reviewed on a regular basis and modified as needed.

Violations of these policies and procedures will result in a review of the incident or event with the CNI research MR safety committee (described below), the Principle Investigator, and the responsible individual.

American College of Radiology ACR

In 2002 the ACR commissioned a Blue Ribbon Panel on MR Safety. The purpose was a review of the safety practices in light of continuing reports of accidents in the magnetic environment involving injury, including death. The result of the study was a white paper publication intended to be used as a template for MR facilities to use to develope an MR Safety Program. Initially published in the American Journal of Roentgenology in June 2002, updated in May 2004, and then markedly expanded and updated in March of 2007 (for June, 2007 publication in the AJR), the “ACR Guidance Document for Safe MR Practices: 2007" addresses numerous MR safety related topics. The recommendations of these authorities are being incorporated into daily practice here.

Standard of Practice at CNI

Many of the MR 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 related to the safety aspects of biomedical implants and devices. The Reference Manual for Magnetic Resonance Safety, Implants and Devices: 2010 Edition will be available at the scanner at all times and all implants will be checked with this book and/or directly with the device manufacturers. The CNI staff will ensure that all users of the CNI research MR facilities will be well acquainted with these policies and procedures to ensure a safe standard of practice. It is expected that all users of the research MR facility will execute proper and orderly procedures every time experiments and/or developmental work is performed.

For research studies involving human subjects, it is recommended but not required, that two operators be present at all times while the magnet is in use during business hours (9:00AM to 5:00PM Monday through Friday) while CNI staff are present in the facility. It is a requirement that two operators be present when scanning human subjects outside of business hours. The CNI website has a scan-buddy sign-up page to help small labs find scan partners. For phantom studies, one operator is sufficient at any time.

Researchers requesting authorization to use the scanner for human studies will submit their request along with a valid IRB approval for the study. Permission to use the scanner for non-human subject research must be approved by Research Director on a case-by-case basis. Please contact the Facility Manager with safety concerns or questions.

Safety Committee Contacts
Facility Manager, Laima Baltusis (laimab@stanford.edu cell phone 408 529 2238) is the primary contact for equipment related questions, safety training and operational questions.

Research Director, Robert Dougherty, (bobd@stanford.edu cell phone 650 315 3731) for all research, IRB concerns and questions.

CNI Co-Directors:
Professor Anthony Wagner – awagner@stanford.edu
Professor Brian Wandell – wandell@stanford.edu

The above personnel have the authority to stop any scan procedure that is deemed unsafe for the volunteer or detrimental to the scanner.

Additional resources for safety are:
Dr. Frank Shellock’s website devoted to MRI safety: http://www.mrisafety.com/

Dr. Emanuel Kanal’s website devoted to MRI safety: http://gecommunity.gehealthcare.com/geCommunity/interest_groups/res_corner/rescorner_kanal.jsp

The FDA site for Medical Devices - Device Advice: Device Regulation and Guidance: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072686.htm
Section 3 – Overview of Magnetic Resonance

Using Magnetic Resonance (MR) scanner systems for research studies requires the adherence to prescribed procedures so that the working environment remains safe. This includes the safe handling of human subjects, personnel, and equipment. All personnel working with MR in any capacity should be aware that there are basic safety concerns that apply. The components of the MR scanner system(s) that present potential safety risks are:

1. The static or main magnetic field of the system inside the scanner room
   • The magnetic field is always present. Once the MRI system is ramped up the system is always on.
   • 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. e.g. scissors, keys, pens
   • Objects that are ferromagnetic may pin someone against the magnet in a life-threatening manner. e.g. wheelchairs, stretchers, oxygen tanks.
   • Everyone will be screened for potential contraindication to safely entering the magnetic field.
   • All equipment must be evaluated for potential risk prior to being safely placed in the magnetic field. A small magnet should be kept in the control room to check all items before they are allowed into the MR room.

2. The Radio Frequency (RF) that is produced when the scanner is operating
   • Human subjects 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 must be used safely to prevent heating or burns to the subject

3. The Time Varying Magnetic Field Gradients
   • Gradients produce excessive acoustic noise levels for which hearing protection must be provided
   • Rapidly changing gradient fields used in research have the potential to cause peripheral nerve stimulation

4. Ancillary equipment used for experiments
   • All equipment placed in the magnetic environment must be considered for heating or any other potential safety risk.

Section 4 - Definition of MR Users

The CNI safety staff has defined three levels or categories of MR Users. MR users are required to receive training on MR policies prior to engaging in MR research at the CNI and are required to review the policies annually. The level of training is described below.

Level 1:
MRI Peripheral Area User – This individual works with a Level 3 MR operator and may enter the magnet room to assist. Level 1 investigators must have passed Safety Training, but they need not have experience operating the scanner; Level 1 investigators
cannot schedule or operate the scanner.

The Peripheral Area is defined as the area within the restricted access zone but outside the magnet room itself. It is in this area that the answers to MR screening questions, subject histories, etc are typically obtained.

To become a Level 1 user you are required to:
  • View the Safety Video http://mrisafetyvideo.com/MagResProcs1HrSo.htm
  • Attend the MR Safety Screening Class
  • Complete the Level 1 Safety written test

Level 2:
Magnet Room User/ Apprentice Operator - This individual may enter the Magnet room to assist setting up the equipment, and for instructing and positioning volunteers. A Level 2 investigator may only operate the MRI scanner under the supervision of Level 3 personnel for human studies. Level 2 users may perform unsupervised studies on phantoms. Principal Investigators/Researchers are expected to complete a minimum of Level 2 training.

To become a Level 2 user you are required to:
  • Fulfill requirements for a Level 1 user
  • Complete Level 2 Safety written test
  • Attend an orientation session for the MR Scanner

Level 3:
Magnet Room Operator - This individual has permission to run the MRI Scanner when CNI staff are not present and to supervise Level 2 and Level 1 personnel. Level 3 investigators must have at least 10 hours of experience at Level 2, and then have passed a hands-on test administered by the Facility Manager. Level 3 operators are given full privileges to the facility and can come in whenever they have scheduled time for use of the facility.

To become a Level 3 user you are required to:
  • Be certified at Level 2 with at least 10 hours of Level 2 scan hours
  • Complete Level 3 Safety written test
  • Successfully complete a practical exam of scanner operation
  • Complete refresher training and review once per year

All MR operators should become familiar with the contents of this Magnetic Resonance (MR) Safety and Research Imaging Policies and Procedures Manual and use it for reference as needed.

Section 5 - Static Magnetic Field
The most common breaches of MR safety occur due to an object being attracted to the Static Magnetic Field. An individual may be struck, injured or trapped against the magnet by the object. Equipment may be damaged by slamming into the magnet or being struck by another object that is accelerating rapidly due to the strong attraction of the magnetic
The Static Magnetic Field is the main magnetic field of the scanner that is always present once the magnet is ramped up to the designated field strength. The field increases non-linearly as one approaches the bore of the magnet and the field map depends on the particular magnet configuration. The static magnetic field strength within the bore of the magnet is described in units of Tesla (T) with 1 T equal to 10,000 gauss. The CNI scanner is a 3 Tesla system. The zone around the magnet where the field strength drops to 5 gauss or below (the 5-gauss line) is deemed to be safe for general public access and use of any non-MR compatible equipment. At the CNI, the 5-gauss line is contained within the scanner room, so all other areas of the CNI MR suite are outside the 5-gauss line and thus deemed safe for access by people who have not been screened for MR safety and for use of non-MR compatible equipment. The area within the scanner room that is within the 5-gauss line is called the fringe field. The MR user entering the scanner room must be aware of the fringe field and which objects and devices are safe to move into the static magnetic field.

**Projectile Effect**

Items that are ferromagnetic have the potential of becoming projectiles when brought into the magnetic field. Depending on the mass and property of the object, serious injury could result as the object is attracted by the static field into the bore of the magnet. It must be noted that objects accelerate extremely rapidly when captured by the magnetic field and the path of travel is unpredictable once within the strong field.

Projectiles have the potential of causing serious injury including death, to anyone who may be in the path of the object as it accelerates toward the magnet. Projectiles may cause an individual to be pinned to the magnet. Equipment may be irrecoverably damaged by becoming a projectile or by being struck by one. Reports indicate that projectiles continue to be a persistent safety concern for all MRI centers. It is expected that all MR operators will exercise extreme caution when working in or near the magnet to prevent any possible projectile incident.

**Torsion and Translation Forces**

Ferromagnetic objects or devices, including those within the human body, will attempt to align with and will be attracted to the main magnetic field. This includes metal fragments within the eyes, ferromagnetic brain aneurysm clips and other implanted medical devices. All material and equipment must be tested for ferromagnetic properties with a hand held magnet outside of the fringe field before being brought within the scanner room and all human subjects must be screened to ensure that any implants are MR-compatible.

**Magnetohydrodynamic Effects**

Magnetohydrodynamic effects are those relating to phenomena arising from the motion of electrically conducting fluids in the presence of electric and magnetic fields. It is believed that some effects such as vertigo, nausea, and phosphenes (visual sensations arising from mechanical or electrical stimulation of the eye), may be related to magnetohydrodynamic phenomena. They are known to become more evident with increase in static magnetic field strength.

These effects are likely only to occur during quick movements of the head within the field.
Moving the subject slowly in and out of the scanner and restricting head movement should eliminate these sensations. It is recommended that MR users or subjects, who may be experiencing magnetohydrodynamic phenomena also restrict side to side head movement and move more slowly near the scanner.

Section 6 - Radio Frequency (RF) Electromagnetic Fields
Safety risks from RF include potential tissue heating and burns to the subject. RF may damage electronic or implanted medical devices. (See Personnel Training and Pre-Screening Subjects for MR Studies.) Equipment that is not RF shielded may be damaged or may cause spurious signals when operated in the magnetic field.

Tissue Heating
MR systems require the use of RF pulses to create the MR signal. This RF energy is transmitted readily through free space from the transmit RF coil to the subject. When conducting materials are placed within the RF field, the results may be a concentration of electrical currents sufficient to cause excessive heating and tissue damage. Absorption of RF power by the tissue is described in terms of Specific Absorption Rate (SAR), which is expressed in Watts/kg. In the US, the FDA sets guidelines for MR imaging. Measurements or estimates of SAR are not trivial, particularly in human subjects. The SAR that is produced during an MR procedure is a complex function of numerous variables, including the frequency (determined by the strength of the static magnetic field of the MR system), the repetition time, the type of RF coil used, the volume of tissue contained within the coil, the configuration of the anatomic region exposed, and the orientation of the body to the field vectors, as well as other factors.

The general guideline used by the FDA to establish allowable RF energy deposition is based on levels that produce a maximum change in tissue temperature of 1°C. According to the specific FDA criteria for SAR limits, the SAR must be no greater than (a) 4 W/kg averaged over whole body for any 15-minute period, (b) 3 W/kg averaged over the head for any 10-minute period, or (c) 8 W/kg in any gram of tissue in the head or torso or 12 W/kg in any gram of tissue in the extremities for any period of 5 minutes.

Note: Pulse sequences with 180° refocusing pulses (such as spin-echo EPI and inversion-recovery prepped flow sequences) have much higher RF power deposition than sequences without 180° pulses, such as gradient recalled echo planar imaging, GR-EPI.

MR operators will be aware:

- that the potential of tissue heating during MR increases with a number of imaging factors, including the strength of the magnetic field, the repetition time, the type of RF coil used the volume of tissue contained within the RF coil as well as subject thermoregulation factors.

- that the SAR is regulated by FDA guidelines and that scanning protocols must be designed to perform within those limits.

Burns
RF fields can cause burns by producing electrical currents in conductive loops. When using equipment such as radiofrequency coils, physiologic monitoring, electronically activated devices, and external accessories such as ECG or EEG leads, the investigator
must be extremely careful not to allow the wire(s) or cable(s) to form a conductive loop with itself or with the subject. Coupling of a transmitting coil to a receive coil may also cause severe burns. (See Coils below) Note: Investigators and researchers must avoid creating the potential for burns by:

- Screening all subjects to exclude those that have metal devices or wires implanted within their bodies and ensure that subjects remove all metal prior to entering the scanning room, including jewelry such as necklaces, piercings and earrings.
- Making sure that any wire leads, such as ECG, EEG, EMG do not form closed loops and are insulated with proper material from touching the bare skin of the subject.
- Placing insulating material between the subject’s skin and transmit RF coil. This is especially important for those MR studies that use the body coil or other large RF coils for transmission of RF energy. Be sure to place pads between the arms/body of subject and the sides of the scanner when scanning all volunteers.
- Using only electrically conductive devices, equipment, accessories and materials that have been thoroughly tested and determined to be safe and compatible for MR procedures.
- Checking the integrity of the insulation and /or housing of all components including surface RF coils, leads, cables and wires before using any electrical equipment.
- Removing all non-essential electrically conductive materials from the MR system bore, including unused RF coils, cables and wires.
- Keeping all other electrically conductive materials that must remain in the MR system:
  - From contacting the subject directly.
  - From forming conductive loops.
  - From forming a cross point.
  - From touching the sides of the bore.
  - From positioning over a metallic prosthesis or similar device.
- Having only properly trained individuals operate devices and monitoring equipment in the MR environment.
- Following all manufacturer instructions and removing non-operating equipment from the subject or scanner immediately.
- Monitoring subjects closely while they are participating in the MR study.
- Correcting RF coil decoupling failures immediately to minimize local RF power deposition levels from reaching excessive levels.

Dental hardware
Most dental hardware is generally safe in the MR environment. However, functional imaging studies will mostly likely be degraded from the severe artifact that will likely occur from orthodontic appliances, permanent bridge work and extensive metallic dental work. Subjects with magnetically activated implants must be excluded from participating in a MR study to prevent damage to the device(s).

Tattoos
Recent tattoos will usually be with natural dyes that are safe in the scanning environment. If the tattoos have a great deal of red color (which can contain iron oxide) and were done more than 10 years ago then the subject will need to be instructed that if they feel heat in that area to squeeze the emergency ball and let the operator know. Ice packs can be
placed on the area during the scan if needed. This will decrease the potential for RF heating of tattooed tissue especially if high duty cycle RF sequences are to be used.

**Coils**

Coil is the term used to describe the devices that transmit and receive the RF fields. These coils can be produced in a variety of configurations. The investigator must have some basic knowledge of coil technology to properly conduct the MR experiment. Safety issues can occur as follows. Transmitting RF energy through a receive-only coil may damage or ruin the device. Transmitting more RF power than the coil was designed to manage can damage or ruin the device. Twisting, looping or crossing cables may cause current to be induced, resulting in damaging the coil, abnormal heating or potential arcing. Damaged or ruined devices have the potential for sparking or at the very least malfunctioning.

Frayed cables, loose connectors or other broken components will increase the risk of personal injury and equipment damage. **Researchers should be able to identify the coil for any given experiment and report any malfunctions or defects discovered while using to the Facility Manager. Coil manuals are available at the scanner and should be read before using specified coils.**

**Section 7 - Time Varying Magnetic Field Gradients**

The two safety concerns resulting from the use of the time varying magnetic field gradients are peripheral nerve stimulation and acoustic noise.

The gradients are produced by resistive electromagnetic coils. The gradients are weaker than the main static magnetic field, are transient and enable the nuclear spins to be spatially encoded. The strength of these gradients is measured in milli-Tesla (mT) per meter (m). The change in the magnetic field (dB) occurs over time (dt) and is measured in units of dB/dt.

**Nerve Stimulation**

The transient application of magnetic field gradients (dB/dt) can induce current in conductive materials, including nerve or muscle tissue. The induced current generally does not deeply penetrate tissue and thus is greatest in peripheral tissue. Mild skin sensations and involuntary muscle contractions, which are thought to be the result of direct peripheral nerve stimulation, have been reported and should not be ignored. These sensations may escalate to unpleasant or painful levels at higher levels of dB/dt. The scanner hardware follows FDA guidelines that limit dB/dt to levels insufficient to influence cardiac function. Thus, while the effects of peripheral nerve stimulation may be unpleasant and may require a research scan to be terminated, they are not a safety hazard to the scan subject.

To reduce or avoid peripheral nerve stimulation, subjects should be instructed to not clasp their hands, cross their legs, or in any other way form a closed loop with their extremities. Phase and Frequency encoding directions may be selected carefully to avoid peripheral nerve stimulation. Subjects should be instructed to report any sensations so that corrective action can be implemented.

Researchers will continuously monitor subjects participating in a study and will stop
scanning immediately if the subject complains of painful or uncomfortable peripheral nerve stimulation and will attempt to correct the situation by adjusting the scan protocol and/or the subject position.

**Acoustic Noise**

Problems associated with acoustic noise for subjects and health care workers include simple annoyance, difficulties in verbal communication, heightened anxiety, temporary hearing loss, and, potentially, permanent hearing impairment. Acoustic noise may pose a particular hazard to specific subject groups who are at increased risk. Subjects with psychiatric disorders, the elderly and pediatric subjects may be confused or experience heightened anxiety. Certain drugs are known to increase hearing sensitivity. Neonates with immature anatomic development may have an increased reaction to acoustic noise.

Various techniques have been described to attenuate noise and, thus, prevent problems or hazards associated with exposure to MR-related acoustic noise. The simplest and least expensive means is to use disposable earplugs or commercially available noise-abatement headphones. Earplugs, when properly used, can decrease noise by about 20-40 dB, which affords adequate protection for MR environments. Regardless of the technique used, facilities operating with MR systems that generate substantial acoustic noise should require all subjects undergoing an examination to wear a protective hearing device. Exposure of staff members and other individuals (e.g., relatives, visitors) to loud MR systems is also of concern. Therefore, these individuals should likewise be required to use an appropriate means of hearing protection if they remain in the room during the operation of these units.

*Every subject must be supplied with hearing protection to meet these guidelines, either the foam earplugs or a head set system. Any researcher or staff person who remains in the scanner room during data acquisition must also have hearing protection.*

*The intercom and auditory stimulus must be adjusted to not exceed safe dB levels for the subject.*

**Section 8 – Personnel Training and Pre-Screening Subjects for MR Studies**

The MR environment is that area within the scanner room where the magnetic field exceeds 5 gauss. The establishment of thorough and effective screening procedures for participants and other individuals is one of the most critical components of a program to guard the safety of all those preparing to undergo MR procedures or to enter the MR environment. An important aspect of protecting individuals from MR system-related accidents and injuries involves an understanding of the risks associated with the various implants, devices, accessories, and other objects that may cause problems in this setting. This requires obtaining information and documentation about these objects in order to provide the safest MR environment possible. In addition, because many MR-related incidents have been due to deficiencies in screening methods or lack of proper control of access to the MR environment, especially with regard to preventing personal items and other potentially problematic objects from entering the MR room, it is crucial to establish procedures and guidelines to help prevent such incidents from occurring.
**Personnel**

All personnel, including investigators, employees and students, who work within the magnetic environment, must be trained and screened for personal safety prior to entering the magnetic field. To work unescorted in the magnetic environment, it is mandatory to complete Level 2 training and complete the written safety test. This includes all personnel who are conducting or assisting with MR research studies. All operators of the MR scanner will complete Level 2 training to scan phantoms. Those operators who will be scanning human subjects must complete Level 3 training. Any personnel who have need to enter the magnet room, i.e. facility maintenance employees, site visitors, etc., all must be screened on a case-by-case basis. (See attached screening form.)

All personnel who have responsibility to recruit subjects, screen subjects for MR safety and/or perform MR research studies are required to attend the MR Safety Screening class and participate in an annual renewal.

It is expected that new personnel will complete the appropriate training prior to accessing the scanner area unescorted. All personnel will participate in an annual renewal process to maintain access to the MR environment.

**Human Subjects / Participant Scanning**

The preservation of a safe MR environment requires constant attention to the care of participants and individuals with metallic implants and devices, because the variety and complexity of these objects constantly changes. Therefore, to guard against accidents in the MR environment, it is necessary to periodically revise information on biologic effects and safety to reflect changes that have occurred in MR technology and current guidelines for biomedical implants and devices.

With the continued advances in MR 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 biologic effects, to use current evidence-based guidelines to ensure safety for subjects and staff members, and to follow proper recommendations pertaining to biomedical implants and devices.

Certain aspects of screening participants for MR procedures may take place during the scheduling process. This must be conducted by a worker who is trained to understand the potential hazards and issues associated with the MR environment, and who is familiar with the information contained on the screening form. Preliminary screening helps to prevent scheduling of participants who may be inappropriate candidates for MR imaging.

At the CNI MR facility, every participant will undergo comprehensive screening in preparation for the MR examination. Comprehensive screening involves the use of a printed 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 individual may have. A person trained in MR safety must conduct this aspect of participant screening.

To summarize, each individual considered for participation in a MR procedure should be screened a minimum of three times:
1. by the person scheduling the study
2. by the person greeting the subject upon arrival at the site
3. by the person who is running the study or operating the system

It should be noted that having undergone a previous MR procedure without incident does not guarantee a safe subsequent MR examination. Various factors (e.g., static magnetic field strength of the MR 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 participant prepares to undergo an MR procedure. This is not an inconsequential matter, because a seemingly unrelated event may have occurred that could affect the safety of the participant entering the MR environment.

MR operators must carefully screen subjects using the three point recommendation above, BEFORE those individuals enter the magnetic environment. All persons must be thoroughly screened BEFORE entering the magnetic environment. All human subjects who are to be positioned inside of the magnet bore must be screened for safety, each and every time they are scanned. There are NO exceptions to this policy. This includes those individuals who participate in multiple studies.

Guidelines for orbital foreign body screening
The procedure to follow with regard to a person suspected of having an orbital foreign body involves a clinical screening protocol that entails asking the person if he or she has had an ocular injury. If an ocular injury from a metallic object was sustained, the person is asked if a medical examination was conducted at the time of the injury and if he or she was informed by the doctor that the object was completely removed. If (a) there was no injury, (b) the individual was informed that the ophthalmologic examination results were normal, or (c) the foreign body was removed at the time of the injury, the person can then proceed to MR imaging. Individuals with suspected metallic ocular injury will only be investigated if they have been specifically cleared for MR studies by a medical doctor.

Claustrophobia
Statistics indicate that about 10% of the general population is claustrophobic to some degree. In many cases individuals who think they are claustrophobic are able to participate in a MR study with some reassurance. For research studies, individuals who are known to be severely claustrophobic should generally be excluded. Exceptions may be evaluated on a case-by-case basis.

Medical Issues
In general, subjects with medical issues that may prevent them from lying flat, holding still for long periods of time, or that require continuous medication via external or internal devices should be excluded. Exceptions may be evaluated on a case-by-case basis.

Magnetic field-related issues
Magnetic field-related translational attraction and torque are known to present hazards to individuals with certain implants or devices. Most previous ex vivo tests performed to assess objects for MR safety used units with a static magnetic field of 1.5T or lower. Therefore, it is possible that an object that displayed “weakly” ferromagnetic qualities in a 1.5T MR system may exhibit substantial magnetic field interactions with an MR system operating at a stronger static magnetic field strength, such as 3T.

All MR operators must be aware of the static magnetic field being used and that subjects recruited for experiments must be carefully screened for any metallic or MR incompatible...
devices. The list for 3T system compatible implants is getting more extensive. However, it is important to research the manufacturer and check the implant cards if available. All MR operators will investigate potential implants and devices associated with their subjects for MR safety. All ancillary equipment will be tested for the magnet configuration being used by the CNI staff.

**Equipment**

All equipment used for research MR studies, including projectors and stimulus producing apparatus, must be tested for MR safety and compatibility BEFORE entering the fringe field (see static magnetic field). MR researchers are cautioned to NEVER take equipment into the magnet room without prior testing for magnetic attraction. A hand held magnet is available in the control room to test for magnetic attraction. MR researchers are cautioned to NEVER implement the use of equipment with human subjects before testing with a phantom or other method that will not potentially cause harm to another 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.

MR compatible equipment is developed for specific magnetic field strengths and MR system configurations. Equipment that may operate safely within one 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.**

*It is the responsibility of every researcher to note and report any equipment failure to the MR Facility Manager. This includes broken cables, loose connectors, arcing or sparking of devices, leaking of fluids and any other malfunction or suspected malfunction.*

**Section 9 - MR Safety Screening Forms**

The MR operator is required to have every subject or visitor who will enter the scan room fill out an MR screening form. The MR operator should carefully examine the completed screening form to ensure that the subject or visitor is safe to proceed BEFORE that individual is permitted into the magnet area. (This form is appended to this document.) The form is used to screen human subjects who will be entering the magnet area and the MR scanner. This same form is also to be used to screen visitors who may enter the magnet area, even if they are not being scanned (e.g., a parent accompanying a child during a scan).

As part of the user training program, all MRI operators will be required to watch a safety video. A section in the video describes a range of implants and devices and their compatibility with MRI scanning. There will be a short user orientation class after the video has been viewed to discuss the screening form. If a subject has checked off any of the items in the list on the first page, they will not be scanned. The list on the first page includes the following:

- Aneurysm clip(s)
- Cardiac pacemaker
- Implanted cardioverter defibrillator (ICD)
- Electronic implant or device
Magnetically-activated implant or device
Neurostimulation system
Spinal cord stimulator
Internal electrodes or wires
Bone growth/bone fusion stimulator
Cochlear, otologic, or other ear implant
Insulin or other infusion pump
Implanted drug infusion device

If a subject has checked off any item on the second page, these items will be discussed with the subject and cross-checked with the Reference Manual for Magnetic Resonance Safety, Implants, and Devices: 2010 Edition to determine if that subject may be scanned. Some implants and/or devices are MRI compatible and some are not. The form is an aid to both identify and to determine MRI compatibility of all identified devices and implants.

The list of items on the second page of the screening form include:
- Any type of prosthesis (eye, penile, etc.)
- Heart valve prosthesis
- Eyelid spring or wire
- Artificial or prosthetic limb
- Metallic stent, filter, or coil
- Shunt (spinal or intraventricular)
- Vascular access port and/or catheter
- Radiation seeds or implants
- Swan-Ganz or thermodilution catheter
- Medication patch (Nicotine, Nitroglycerine)
- Any metallic fragment or foreign body
- Wire mesh implant
- Tissue expander (e.g., breast)
- Surgical staples, clips, or metallic sutures
- Joint replacement (hip, knee, etc.)
- Bone/joint pin, screw, nail, wire, plate, etc.
- IUD, diaphragm, or pessary
- Dentures or partial plates
- Tattoo or permanent makeup
- Body piercing jewelry
- Hearing aid (Remove before entering MR system room)
- Other implant ______________________
- Breathing problem or motion disorder
- Claustrophobia

Section 10 - MRI Facility Design and Safety Zones
Safety Zones
The MRI Facility in the CNI is divided into four safety zones as indicated in Figure 1 (CNI MRI Safety Zones). Zones are labeled 1-4 and each Zone represents a progressively greater level of access restriction.

Zone 1 is the hallway outside of the CNI MR facility and is freely accessible to the general public.
Zone 2 is the Interface between public areas Zone 1 and restricted areas Zones 3 and 4. Zone 2 includes a reception/waiting area and a rest room, behavioral testing area, mock scanner room, conference room and CNI staff offices. Zone 2 is behind controlled access doors. Individuals who have been granted access to the CNI center must escort visitors and volunteers into Zone 2.

Zone 3 is a restricted area. All visitors and volunteers in Zone 3 must be escorted by authorized personnel at all times while in this zone. Zone 3 contains the MR control area. While this zone is free from risk, persons in Zone 3 have free, physically unrestricted access to Zone 4, an area that does pose risk. Zone 3 is behind controlled access doors. Zone 3 is also referred to as the MRI control room and includes the adjacent changing room.

Zone 4 contains the 3T MRI Scanner Room and Equipment room. Zone 4 is a potentially hazardous zone where magnetic fields are greater than 5 gauss. All persons entering Zone 4, including researchers, volunteers, and special visitors must fill out and sign appropriate screening forms. Authorized personnel must accompany all volunteers and visitors into Zone 4. Zone 4 is behind a keyed access door.

The combined area of Zone 3 and Zone 4 is defined as the MRI suite.

Small metal objects are prohibited in the MRI scan room, Zone 4. Pens, bobby pins, hairclips, etc. must be carefully screened because they can become projectiles that can injure subjects and staff, and damage the MRI equipment. Watches cannot be brought into the MRI scan room Zone 4, as the magnetic field will render them inoperable. Devices with magnetically recorded information such as credit cards, bankcards, or data stored on magnetic tape will be erased if brought into Zone 4. Volunteers and visitors will be provided with storage areas to store personal items such as watches, wallets, and jewelry in the control room, Zone 3.

Large metal objects may not be brought into the MRI scan room, Zone 4, unless they have been certified as MR safe by the CNI staff. Objects such as floor buffers, oxygen tanks, and toolboxes may become attracted to the magnet with sufficient force as to cause severe trauma to subjects and staff. These incidents can also cause significant and costly damage to the MRI equipment.

Warning signs are posted at all entrances to the magnetic security zone. These signs state that a strong magnetic field is in use and that the entrance is restricted to authorized personnel only.

A study director or associate initially screens prospective MRI volunteers/subjects for contraindications. Participants are asked during the screening process if there is any
chance they may be pregnant. If they indicate a possibility of this, they are excluded from the study. Additionally, participants are warned on the consent form that they should not participate if they could be pregnant.

Upon successful completion of initial screening an MRI scanning session appointment can be made for the volunteer/subject. Before entering Zone 4, the operator will administer and review the subject screening form with the participant item by item, to satisfy himself/herself that the participant has thoughtfully considered each item and that there are no contraindications to scanning. The operator will then witness the subject signing the MRI safety and Consent forms in the appropriate spaces, and will make clear to the participant that emergency medical services are not available onsite. Screening will be conducted each time a participant is scanned, regardless of being a repeat participant in an ongoing study.

Some studies include participants under the age of 18. In such cases, participants will be required to turn all of their pockets inside out and will be checked using an appropriately sensitive ferromagnetic-detector wand to ensure redundancy in the screening process.

Subjects, operators or staff are not permitted in the MRI scan room (Zone 4), if they have a cardiac pace maker, epicardial pacemaker wire, automatic cardioverter defibrillators, cochlear implants, bone growth stimulators, internal infusion pumps, or any other electrically, magnetically, or mechanically activated or controlled biomedical system.

Certain minor contraindications are permissible for MRI scanning. Tattoos below the shoulders, most permanent dental retainers, and orthopedic devices in limbs are generally considered safe. If there is any question regarding a possible risk to the subject owing to an implant or medical history the Facility Manager is to be consulted. The Facility Manager has a listing of suitable devices and implants for MRI scanning and uses the Reference Manual for Magnetic Resonance Safety by Frank G. Shellock, Ph.D. to determine the safety of most contraindications.

If the implant or device is not listed in the above reference manual, the Facility Manager will do an Internet search or contact the Lucas Center MRI Department to confirm safety of the device. The subject must not be scanned until the Facility Manager has confirmed that the device, implant, and medical history are safe.

It is policy of the CNI Center to defer scanning if there is any possibility of causing injury to a subject or staff. As a final check, the designated operator must conduct a visual inspection for metallic objects and make a verbal inquiry regarding contraindications before entering the scan room.

**Shielding**
Copper and steel shielding built into the walls of Zone 4 contains the magnetic field so that Zones 1, 2 and 3 are free of interfering magnetic field. The 5 gauss (0.5 mT) line is contained in the MRI scanner room (Zone 4).

**Ventilation**
The MRI Suite has unidirectional laboratory ventilation. In the event of a quench, released helium is vented to the building exterior rooftop to prevent the creation of a hypoxic environment. The helium released to the outside air is not toxic or harmful. The
suite also has an auxiliary exhaust system that is automatically activated by a low oxygen level in the scanner room.

**Signage**
A sign is posted on the door to the scanning room (Zone 4) warning of the high magnetic field and prohibition of anyone with a pacemaker or other electronic implant to enter the room. There is also a rug placed in front of the door to the MRI scanner room conveying the message that the magnet is always on.

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WARNING
3.0T MAGNET

STRENGTH MAGNETIC FIELD

NO PACEMAKERS
NO METALLIC IMPLANTS
NO NEUROSTIMULATORS
Patients with pacemakers, neurostimulators, or metallic implants must not enter this area. Serious injury may result.

NO LOOSE METAL OBJECTS
Hair, fiber, and other hazardous materials must not be taken into this area. Serious injury or property damage may result.
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**Labeling Requirements for equipment and devices**
Equipment, instruments, and devices should be clearly labeled to indicate their safety in the MR environment. Three types of labels can be used to indicate if an object is safe for the MR environment (MR safe), safe under specific conditions (MR conditional), or unsafe (MR unsafe). MR safe is defined as an object that poses no known hazards in all MR environments. MR safe can only be applied to objects that are 100% safe to be taken, used, or placed within all MR environments without any risk or potential harm. MR conditional is defined as an object that is safe when used in a specific manner within specific MR environments. Most objects will receive this rating. An object with this label warns the user that there are limitations to the usability or to the testing that was performed on it. In other words, the object may have been tested for a 1.5T system, but not for a 3T system. The conditions should be included on the object; in its packaging, or its accompanying instructions. MR unsafe is defined as an object that poses a known threat or hazard in all MR environments.

**Assurance of MR Safety of ancillary devices in the MRI scanner room (Zone 4)**
Some studies require additional items to be brought into the scanner room. The Facility Manager or Research Director must clear these items for use. If these items require extensive assembly and disassembly in the scanner room, the PI conducting the study must designate a person from his/her lab who will be responsible for setting up,
disassembling, and removing the equipment from the MRI scanner room for each scanning session. The designated person must be trained and approved by the Facility Manager.

Some studies involving children may require that certain toys be brought into the scanner room in order to make the child feel more at comfortable and at ease. In order to maintain MR safety assurance for these items, the PI conducting the study must designate a single person from his/her lab to screen these toys prior to the study date. This person will use a strong magnet to verify that the toys are non-magnetic and will examine the toys to verify they contain no electrical components. This person will also be responsible for checking the toys again immediately before the study and prior to entry into the scanner room. The designated person must be trained and approved by the Facility Manager.

The construction and use of mirror devices on head coils will follow the following guidelines. Mirror devices will be built and their use demonstrated by qualified outside vendors, such as [http://www.magconcept.com/MRI/](http://www.magconcept.com/MRI/), who are familiar with safety issues related to these devices. Additionally the Environmental Health and Safety Office will be used as a resource. Their current recommendations regarding use of mirrors in headgear is as follows:

Regarding mirror fabrication - The use and application of the thick plastic/Lucite type backing is appropriate and appears to be adequate to prevent recurrence of mirror breakage. The mirrors, as configured, with the solid plastic base are resistant to fracturing when contact with the plastic backing plate is made. The rigidity of the plastic backing plate prevents forces on the mirror that would cause such fracturing. It is recommended that that edge of the mirror on top and sides be maintained at least 2 mm from the edge of the plastic/Lucite backing. This will ensure that any leading edge of the structure that comes into contact with the surface of the tunnel is solely that of the plastic itself, thus minimizing the probability that that the mirror will fracture.

In summary, The Facility Manager or Research Director must approve all new non-MRI ancillary devices for magnetic and electrical properties. All devices must be non-ferromagnetic, must not produce radio frequency/electrical noise, and must not interfere with scanner operation in any way. All devices will be checked for MR compatibility by the Facility Manager by careful visual inspection and by testing the device using a powerful hand-held rare-earth magnet. MR interference will be assessed empirically with phantom scans.

*Equipment for cleaning and safety*

The MRI Suite is equipped with MR safe supplies for housekeeping, an MR safe ladder, and MR safe fire extinguishers.

**Section 11 - Facility Maintenance and Security**

**MRI Scanner Maintenance**

GE Healthcare performs all 3T MRI scanner maintenance. The Facility Manager has the resources to maintain all necessary service contracts for the MRI Suite. The Facility Manager oversees scheduling of service and maintenance. The chiller and HVAC systems are serviced per the GE Healthcare service contract. Preventative maintenance
is scheduled per the GE Healthcare service contact. Helium fills are performed as needed.

The magnet and associated coils are tested weekly with quality assurance tests to confirm they are safe for use. Operator manuals are available for both the MRI system and for all associated coils. These manuals provide information regarding best practices for usage and maintenance of the equipment.

*Adequate Oxygen Concentration Monitoring*
The scan room is equipped with an oxygen sensor at all times. The Facility Manager monitors the sensor weekly. The sensor is replaced as indicated by the equipment.

*Ancillary Equipment Maintenance*
All ancillary equipment is maintained, updated and serviced by CNI staff. Researchers along with their labs will be asked to maintain ancillary equipment specific to their research group’s requirements.

*Housekeeping*
Housekeeping duties for Zone 4 (sweeping and mopping floors, and cleaning) are performed by the CNI Staff. Floors are swept and mopped weekly. In addition, the scanner table and coils are cleaned after use. Stanford Housekeeping launders sheets and blankets for research participants’ comfort. Delivery of cleaned sheets and blankets is to Zone 3.

*User Access & Training*
The MRI Suite is a restricted room. Access to the MRI Suite is controlled by electronic card access. Access to the scanner room and mechanical space is controlled by manual key access. Access to the facility for operators is via the CNI ID card and is arranged with the Facility Manager, following designated training. Unsupervised access is restricted to trained individuals. 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.

The CNI imaging facility is available to researchers by arrangement with the Facility Manager. Each individual investigator entering the MRI Suite must obtain training to enter the MRI Suite and must obtain additional training to use the MRI lab and to operate center equipment.

Access status is broken up into three categories, and has been described previously (see Section 4).

- **Level 1: MRI Peripheral Area User.** This individual works with a Level 3 MR operator and may enter the magnet room to assist. Level 1 investigators must have passed Safety training, but they need not have experience operating the scanner; Level 1 investigators cannot schedule or operate the scanner.
- **Level 2: Magnet Room User/Apprentice Operator.** This individual may enter the Magnet room to assist setting up the equipment, instructing and positioning volunteers. A Level 2 investigator may only operate the MRI scanner under the supervision of Level 3 personnel.
• **Level 3: Magnet Room Operator.** This individual has permission to run the MRI Scanner when CNI staff are not present and to supervise Level 1 and Level 2 personnel. Level 3 investigators must have accumulated experience at Level 2, and then have passed a hands-on test administered by the CNI Facility Manager. Level 3 operators are given full privileges to the facility and can enter the facility at any time.

For research studies involving human subjects, there must be one Level 3 investigator present at all times. During business hours (9:00AM to 5:00PM Monday through Friday), it is strongly suggested, but not required, that there also be a second investigator present; this investigator must be trained to at least Level 1 status. It is a requirement that a second investigator trained to at least Level 1 be present when scanning outside of business hours. The CNI website has a scan-buddy sign-up page to help smaller labs find appropriately trained scan partners. For phantom studies, one Level 3 status investigator is sufficient at any time.

**Visitor and Tour Group Access**
Appropriately trained personnel must escort visitors who wish to tour the MRI Suite. Prior to entry into the console room, visitors must be briefed regarding hazards associated with the MRI. 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 possible. If a tour is conducted during a participant scan, the participant must give permission for the tour.

**Research Participant Access**
Research participants must be escorted throughout the MRI Suite at all times by a qualified Level 1, Level 2, or Level 3 operator and may never be left unattended while in zones 3 or 4.

**Restricted Access for Ancillary Personnel**
The MRI Suite is a restricted area. Housekeeping staff and maintenance personnel are not permitted to enter Zone 4. Trash is placed outside the MRI scanner room for pickup. Light bulb changes, mopping, etc., are performed by the CNI staff. Trained service contractors are escorted while conducting working in the suite.

**Section 12 - Rules of Etiquette in the MRI Suite**
The MRI Suite is a shared resource. Any action that inhibits or has the potential to inhibit the ability 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.

All operators in the MRI Suite must follow the following rules:
  • Doors to the MRI Suite (console, scanner, and equipment rooms) must be kept closed and secured at all times.
  • No eating, drinking, or storage of food and beverages is permitted in Zone 4 (the MRI scanner room and equipment room).
  • Food and drinks are permitted in the console room, but must be kept away from the computer equipment. Users must also carefully clean up after themselves.
  • Access to the MRI Suite is restricted to authorized individuals.
  • It is required that two appropriately trained MRI operators must be present to
operate the MR scanner during weekday off-hours and weekends for human studies. It is recommended that two appropriately trained operators be present to operate the MR scanner during normal business hours.

Research participants traveling to the CNI Center should be provided directions to the campus and basic information regarding their scanning session to facilitate their visit.

• Upon Arrival: Participants should be instructed to wait in the lobby of Jordan Hall until they can be escorted to the MRI Suite. An investigator should meet the participant in the lobby to escort them through the building.
  • Arrival Time: Research participants should be instructed to arrive with sufficient time to complete safety screening and to prepare for the scan. The amount of time required may depend upon the conditions of each particular study. If the participant is running late, consideration must be made for any studies scheduled after that participant. In some cases, the participant may need to be rescheduled.
  • Confidentiality: Policies regarding privacy for research participants are clearly outlined in the IRB; and it is the responsibility of the PI to ensure these policies are followed.

Section 13 - Infection Control
The safety guidelines here aim to prevent the transfer of infectious material from human subjects to or from another subject or employee.

During a scan session, all surfaces that typically come in contact with a human subject (including all padding) are covered with linens. Before a scan session, the scan operator will prepare the scanner by covering these surfaces with clean linens. After a scan is complete, the operator should place the used linens in the laundry bin that is available in the MR suite.

The scanning bed and any other surfaces that have come in contact with a human subject may be cleaned before placing another human subject on the scanning bed using a disinfectant wipe such as PDI (Professional Disposables International, Inc.) Super Sani-Cloth Germicidal Disposable Wipe, which will be available in the MR suite.

When scanning subjects who may be incontinent or at risk of nausea, the MR operator should place disposable dry-pads (such as Chux) under the linens to catch any bodily fluids. These pads are available in the MR suite. In the event of an accident involving bodily fluids, it is the responsibility of the researcher to clean up ALL substances (blood, hair, urine, feces, secretions, tissue) from all contact surfaces. This includes: the scanner table, inside and outside of all RF coils, counters and work surfaces. Appropriate cleaning solutions, gloves and towels are available in the suite for this purpose. The MR operator should also notify the Facility Manager as soon as possible if such an incident occurs.

Section 14 - Post-Scanning
Upon completion of the study the researcher must ensure the following:

• All equipment is restored to normal working order. If there is a problem with a piece of equipment you must report this to the Facility Manager immediately.

• Return to standard usage or as directed for each specific system: coils, shim files,
configuration files, and all computers. Check to see that all accessories and/or devices are turned off properly, cords and cables wound, and returned to their designated storage area.

- All used linens must be placed in the appropriate laundry bin.
- Any spills or bodily fluids must be cleaned thoroughly with a disinfectant solution.
- Report any supplies that appear to be running low to the Facility Manager so that the stock may be refilled, especially if you have used the last of the item.

Section 15 - Project Review and Approval

All users must have IRB approval for research projects, and must be funded via a grant for billing purposes. Information about the procedures and policies related to obtaining IRB approval for research projects conducted at Stanford University is at the web site for Human Subjects Research at [www.humansubjects.stanford.edu](http://www.humansubjects.stanford.edu).

Projects cannot be initiated without relevant IRB approval. Ongoing projects will be suspended when IRB approval expires. PI's must provide written documentation of the initial IRB approval(s) and annual IRB renewal(s). The PI must make sure that the protocols list all personnel who will be conducting MRI research.

Section 16 - Scheduling MRI Scanner Time

All scanner time is booked via the CNI web-based on-line scheduling system for approved users.

After receiving IRB approval, PI's initiate the creation of a Scanner Account by contacting the CNI and providing the following information:

- Project title (ex. Neural Basis of Visual Pattern Appearance)
- Funding source (ex. NIH, NSF)
- Grant number(s) (as per funding source)
- Grant Expiration Date
- IRB approval dates
- Abbreviated title: one or two word description. (This will be used along with the PI name and funding source to allow appropriate users to select a project when scheduling scanner time on the web-based scheduler, e.g., Smith- NIH Pattern).
- A list of researchers associated with this project

The Facility Manager will contact the PI via email once the account has been set up.

The smallest booking increment is 30 minutes. An individual must be registered in the system in order to book time. A confirmation email will be sent to the MRI user specifying the date and time of the scan once the requested time is entered to the calendar. *Reminder emails will not be sent.* The Name of operator will be listed on the schedule.
Section 17 - Billing and Cancellation Policies

Billing
Scanner time is compiled from the web-based scheduling system and charged on a monthly basis. The Facility Manager will send an e-mail at the beginning of each month to all users including each PI containing all the hours scanned for the previous month and the accounts used. PI’s must verify that the information is correct and send a reply, or charges will automatically be submitted at the end of the month. Users also have an opportunity to dispute charges during this time. Changes to charge reports will not be made after the end of the month, so it is crucial for each PI to review his/her charge reports for accuracy and dispute any charges as soon as possible.

Once the Facility Manager has received confirmation from the PI, charges to Accounts Payable for that month will be put through. No e-mail response from the PI will indicate that all charges are correct. At the end of the month the Facility Manager will issue the scanner charge report to each Principle Investigator. This charge report will contain any additional information regarding canceled scanning sessions and accumulated credits.

Rates and rate categories are subject to change depending on the financial conditions of the center; the current rates and rate categories are posted on the CNI website.

Cancellations
CNI users will be able to cancel their scanning sessions 20 hours or more in advance of their scheduled scanning time without penalty. When a scanning session is canceled with less than 20 hours of the scheduled time, the session will be removed from the scheduler (calendar) but a record of it will be retained. If nobody uses the time, then it will result in a charge. It is in the CNI user's best interest to notify the other users that the scanning session has been canceled and the time slot is now free. This will increase the likelihood that someone else will book the time, thereby avoiding the pending charge.

If a scan must be terminated prematurely, the user cannot edit the schedule. In this case, to avoid being charged for the time, the user must contact the Facility Manager by sending an email with specific information as to the cause, such as subject withdrawal due to claustrophobia. If the session is terminated due to equipment failure, the user should contact the Facility Manager immediately so that the equipment can be repaired and/or subsequent users notified of the problem.

If a user would like to swap a scanning session with another user, they may ask the Facility Manager to alter the schedule after obtaining consent of the other user.

Section 18 - Incidental Findings
On occasion the brain images of a subject that are collected during the course of a study may reveal a potential brain abnormality. The PI and his/her research associates are not trained to perform radiological diagnosis, and the scans performed at CNI are not optimized to find abnormalities. If the protocol produces anatomical images in which the operator thinks there might be a potential abnormality, a qualified neuroradiologist will examine them. The neuroradiologist will determine if the potential abnormality merits further investigation will inform the PI of the action to be taken. If the neuroradiologist indicates that the subject should be informed of a potential abnormality, then the PI must contact the subject in a timely manner. In no instance should a graduate student or postdoctoral fellow be responsible for contacting the subject. When contacting the
subject, the PI will not attempt to explain to the subject what the finding is, nor will he/she offer medical advice on how to proceed. It must be made clear that the report is not an official diagnosis because the research protocol does not qualify as a diagnostic scan. Further, because these scans are not of clinical quality, they should not be offered to the subject and/or their physician. However, the subject may be entitled to their data upon request under the terms specified in the consent form.

The CNI Center will refer all potential brain abnormalities to a neuroradiologist in the Stanford Radiology Department, as per the agreement between CNI and the Radiology Department. The PI must promptly provide a DVD with the scans in question to be read "as is" by the attending neuroradiologist. Subjects are informed of this policy in the Consent Form under the section titled "Incidental Finding".

There are three basic concerns about incidental findings.

1. **Should a neuroradiologist read every anatomical scan?**
   According to current policy, a neuroradiologist is consulted only if/when the investigators notice an abnormality. That is, not all scans are read by a neuroradiologist.

2. **Does the wording of the consent form create an expectation in the subject that nullifies the claim that the anatomical images are not of sufficient quality to be useful?**
   The consent form for any CNI MR study must clearly state that the scans performed are not optimized to find abnormalities and that the investigators are not trained to read the acquired scans for abnormalities nor are they responsible for finding them, but that it is possible to notice a finding that seems abnormal.

3. **Should the subject be contacted by the investigator or by the consulting neuroradiologist?**
   According to the current policy, the subject is initially informed about the finding by the PI (only if the consulting neuroradiologist decides that it merits further investigation). When this occurs, the PI does not attempt to explain what the finding is, nor does he or she offer medical advice on how to proceed. Rather, the PI tells the subject that an incidental finding was observed that merits further investigation and provides the subject with a simple report that has been provided by a neuroradiologist. The subject will be advised to contact their primary care physician or neurologist for a formal follow-up.

The NIH held a workshop in Jan 2005 specifically to discuss the issue of incidental findings during neuroimaging research. A report and summary of their recommendations is available online at: [http://www.ninds.nih.gov/news_and_events/proceedings/ifexecsummary.htm](http://www.ninds.nih.gov/news_and_events/proceedings/ifexecsummary.htm). The current policy described above is consistent with their recommendations.

**Section 19 - Reporting of Incidents and Adverse Events**

If any incidents occur within the MRI Scanner room, regardless of severity, they must be reported to the Facility Manager as soon as possible. The Facility Manager will complete an Incident and Adverse Events report in the facility logbook and will follow-up as necessary. Reports will be maintained indefinitely.
Section 20 - Emergency Procedures

Emergencies, by their nature, are unpredictable and unexpected events that pose a potential threat to health and safety of personnel, property, and the environment. Each emergency event will be unique and will require assessment to determine the appropriate response. Zone 4 in the MRI Suite poses a hazard for emergency response personnel in that they cannot safely enter the suite with typical emergency response equipment. Therefore, emergency response procedures for Zone 4 of the MRI Suite must include MR safe equipment whenever possible, and procedures for removal of injured or ill individuals from the suite.

This section provides general emergency procedures for the MRI Suite. Additional emergency response information for the 3T GE magnet is available in the MRI Console Room - Zone 3.

Emergency Preparation

In preparing for emergencies in the MRI Suite, MRI Operators must know the appropriate procedures for emergencies involving research participants, appropriate steps for safely shutting down the magnet, the location and use of any emergency equipment, emergency contact information, and any necessary follow-up procedures.

The emergency preparedness procedures for the MRI Suite are composed of three elements:

- The Emergency Response outlining specific response procedures provided in the MRI Console Room Zone 3, along with a list of emergency contacts.
- MRI Operators trained on the Emergency Response.
- Four MR safe fire extinguishers located in the CNI Center.

Emergency Button Function & Location

The MRI scanner suite is equipped with three types of emergency buttons:

- the Emergency Stop button,
- the Emergency Off button,
- the Magnet Run-down unit.

Emergency Stop

If you want to stop a scan for any reason you can press the Emergency Stop button, which is located on the keyboard and on both the right and left sides of the magnet enclosure.

The Emergency Stop button disables the following systems:

- RF
- Gradient Power Supply
- Magnet Room Unit
- Table and Patient Support Subsystem

**WARNING:** The Emergency Stop button does not remove the magnetic field, turn off the computer cabinets, operator’s console, or camera.

Emergency Off
The Emergency Off button is located on the wall next to all computer equipment and next to the MR magnet room doors. It removes ALL electrical power from ALL components of the system, including any power sources from uninterrupted power supply (UPS) devices. The Emergency Off button not only stops a scan in a patient emergency, but also in the event of a serious equipment fault or hazards such as fire/water in the vicinity of the MR equipment. The entire MR system is turned OFF except for the static magnetic field. Note that all data from the currently running scan is likely to be lost.

Use this button only in a major emergency in the computer or MR magnet room. For example, use this button when you notice fire, sparks, or loud noises not associated with normal operation of the system.

NOTE: To restore power after emergency stop, the main circuit breaker must be reset before rebooting the system. Always contact a service engineer before restoring power.

WARNING: The Emergency Off button does not turn off the magnetic field. To avoid personal injury or equipment damage, do not bring any ferromagnetic equipment into the magnet room. Assume that equipment is magnetic unless it is clearly labeled otherwise.

*Magnet Rundown Unit (Quench button)*
The Magnet Rundown is located inside the magnet room and is used to quench the magnet. Quenching is a serious operation that involves:
• Rapid reduction of the magnetic field in about two minutes
• Boil-off of cryogens, accompanied by loud hissing sound
• Several days of down time to replace the cryogens

WARNING: The Magnet Rundown should only be used to free someone pinned to the magnet in a life-threatening emergency or to remove a large ferromagnetic object captured by the magnetic field when injury to persons is imminent. A controlled magnet rundown should be performed by a GE Service Engineer in non-emergency situations.

*Emergency Notification*
When an emergency situation arises, contact University Police by dialing 9-911 from a campus phone (911 from a cellphone) with following information:
• Name and telephone number of the caller.
• Nature of the emergency (e.g., medical emergency, technical problem, fire, etc.)
• Specify that this is the CNI MRI Suite with magnetic hazards.
• Special considerations (e.g., hazardous gases present, people trapped, number of people injured and type of injuries, electrical hazards, property damage and access routes to the emergency).

If an emergency arises, the MRI operator scanning at that time is responsible for supervising safe entry of emergency personnel and directing them into the scanner room. Emergency medical personnel
may enter the MRI scan room only if they have been trained and understand the magnetic hazards, or are being directly assisted by CNI staff and/or the MRI operator at the time, who are knowledgeable about magnetic hazards.

Termination of Scanning and Participant Evacuation
MRI Operators must be prepared at all times to handle an emergency involving a research participant, and must be able to identify signs that the participant is experiencing discomfort or distress. MRI Operators should provide the emergency squeeze ball to participants and make sure the participant is comfortable with its use. Operators must also remain in verbal contact with the participant throughout the scan.

Patient Alert System
Squeezing the bulb causes the control box to light up and emit an audible signal. A switch on the control box allows you to set the signal for intermittent or constant light and sound. Your MR system also has an intercom system that enables you to maintain verbal contact with the patient throughout the examination.

Reasons for Terminating a Scan
The MRI Operator should terminate the scan when any of the following occur:
• The research participant requests to end the scan for any reason, such as claustrophobia symptoms, any pain or discomfort, illness, dizziness, or nausea.
• The participant experiences a medical emergency or becomes unresponsive.
• Technical issues such as the following occur:
  o Power outage.
  o Fire alarm.
  o Scanner console freezes (and problem is not resolved by rebooting the scanner).
  o Head coil malfunctions.
  o Gradient errors occur.
  o Cold head is not working.
  o Chiller malfunctions.
A research participant must never be asked to remain in the magnet when experiencing discomfort or distress and should never be kept in the scanner while technical concerns are evaluated.

Emergency Evacuation Procedure for a Responsive Participant
If the research participant is conscious and is able to communicate, follow these steps:
• Press the Emergency Stop button.
• Move the table out of the magnet.
• Lower the table down to the floor as low as possible.
• Have the participant sit up, but do not have them get up off the table right away.
• Assess the research participant.
• If the participant is experiencing a medical emergency, call 9-911 and follow emergency notification procedures described above.
  • If the symptoms subside and the participant feels better, the participant may be escorted from the facility, and a recommendation made to the participant for follow-up
with a medical professional if the symptoms recur.

Emergency Evacuation for a Nonresponsive Participant
If the participant becomes unresponsive at any time during the procedure, scanning should be stopped immediately.

- Press the Emergency Stop button.
- Move the table out of the magnet.
- Detach the table from the scanner.
- Wheel the table, with the participant on it, out of the scanner room into the control room.
- Close the scanner door.
- Open the hallway door and wheel the participant out into the main corridor.
- Call 9-911 and give the operator the location (CNI Center, Jordan Hall lower level)

Table Transport Emergency Release
In an emergency, the patient cradle can be manually pulled out of the magnet. By squeezing the release handle and pulling the cradle, you can move the patient all the way out to the home position. The figure below displays the cradle release handle on movable 1.5T and 3.0T tables.

Cradle Release Handle
The 1.5T and 3.0T patient tables can be detached from the magnet system. The tables can also be lowered and raised. In the event that a patient needs emergency medical attention during the scanning session, use the undock pedal (figure below) or the emergency table lever release for quick transportation of patients outside the magnet room.

Undock Pedal at Foot and Side of Table
To undock the table from the scanner, depress the undock pedal. There are three undock pedals; one at the foot of the table, and one on each side of the table near where the table connects to the bore.

Quench
The MRI scanner is super-cooled with liquid helium. A quench is the rapid boiling off of this liquid either intentionally or unintentionally. An intentional quench is performed in an extreme emergency to rapidly run the magnetic field to zero. A quench of the magnet should only be performed when a person is pinned to the magnet and is unable to free themselves without harm.

Fire
If an electrical fire were to occur in Zone 3 or Zone 4, nonferrous chemical fire extinguishers are located within the MRI Suite to contain the fire. Personnel are not required to fight fires and should evacuate the building immediately in the event of a fire. University Police have the primary responsibility for managing emergencies and must be notified immediately of such situations by calling 9-911 from any campus phone.
Employees may use fire extinguishers to fight small, incipient fires (no larger than a waste basket) only if they have been trained in the proper use of a fire extinguisher and are confident in their ability to cope with the hazards of a fire. In such cases, firefighting efforts must be terminated when it becomes obvious that there is danger from smoke, heat, or flames. If a fire occurs in the MRI Suite or the building fire alarm sounds:

- Stop the scan and remove the research participant.
- Have all individuals in the MRI Suite evacuate the building according to the building evacuation plan, in a calm manner. Never use elevators.
- Congregate at the predesignated assembly area for the building.
- Notify emergency response personnel if you have specific information about the fire and whether or not the magnet has quenched.

If time permits, turn off all electrical equipment, such as computers and other nonessential apparatus. Leave the lights on.

Note: extinguishers are only effective on small fires, such as wastebasket fires, that can be extinguished quickly. Do not fight a fire alone!

Note: How to Operate a Fire Extinguisher:

- P--- Pull Pin
- A--- Aim Nozzle Low at Base of Flames
- S--- Squeeze Handles Together
- S--- Sweep From Side to Side at Base of Fire

Section 21 - Recordkeeping
Records regarding MRI safety and compliance, research participants, scans, equipment maintenance and repair, as well as usage and billing, are maintained by the MRI Facility Manager and PI overseeing research study. A list of records is outlined below:

- Training Records: The Facility Manager maintains safety and compliance training records for all personnel.
- Screening Forms: safety screening forms for research participants are kept on file by the PI overseeing the study.
- Consent Forms: Signed consent forms for each research participant involved in a study are maintained by the PI in accordance with IRB requirements.
- Incidental Findings: The PI's maintain the MRI Incidental Findings Review forms. These forms do not contain identifying information and will follow the naming convention for scanner files.
- Data: It is the jurisdiction and responsibility of the PI to keep their subject volunteer information protected and confidential. They will retain copies of their own volunteer’s signed informed consents and assents, MRI prescreening, and any other documentation related to participation in their study. Once imaging data has been shared with the PI, it becomes their jurisdiction and responsibility to maintain and use the data in a confidential and appropriate manner.
- Data Logs: The following logs are kept by the MRI Facility Manager:
  - Weekly Quality assurance data.
  - Scanner and equipment room filter change dates.
  - Scanner communication log with GE for maintenance and scanner errors.
  - Usage Logs: Accurate records regarding use of the scanner are required for proper billing and reporting to federal funding agencies. These records are
reviewed and maintained by the Facility Manager and are contained in the web-based on-line calendar.

- When signing up for scanner time, MRI Operators must record the following information:
  - Date.
  - IRB number (when appropriate) and study name or description.
  - PI overseeing the project or study.
  - Funding or grant number.
  - Start and end time of scanner use.
  - Comments in the note section that will allow them to easily identify the nature of the scan when reviewing billing confirmations.