Safety Guidelines for Conducting Magnetic Resonance Imaging (MRI) Experiments Involving Human Subjects

Center for Functional Magnetic Resonance Imaging
University of California, San Diego

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Introduction

The purpose of this document is to define a set of safety standards and safety procedures for conducting magnetic resonance imaging (MRI) experiments involving human subjects and biomedical studies at the UCSD Functional MRI Center. The manual briefly describes the Center's Facilities, including the imaging modalities available. A brief description of the principles of MR imaging is provided as background to the risks associated with MR experiments. Subsequent sections are organized by topics that must be addressed before an investigator begins work at the Center. The requirements to be met before scanning include: (1) Obtain a fMRI Center Operator Certificate (with current operator and safety training), (2) Obtaining approval of your study protocol from the Center's Human Subjects or Biomedical Applications Review Committees, (3) For human studies, provide the Center with approval letter from the UCSD Human Research Protections Program & an approved Informed Consent form. For animal studies, provide the Center with approval letter from the UCSD Institutional Animal Care and Use Committee. (4) Establish an experimenter research file and subject screening files at the Center's administrative office.

Facilities

UCSD's Functional Magnetic Resonance Imaging (MRI) center is dedicated solely for research. It is not a medical facility. The center houses three imaging systems: two General Electric 3T Signa Infinity Twin-Speed with Excite MR System (14.X software) and a 7T horizontal 21 cm bore system for rodent imaging. All systems are equipped for state-of-the-art high-resolution 2D and 3D structural imaging, dynamic imaging (echo

planar imaging), and magnetic resonance spectroscopy (MRS). On March 28th, 2003 the Food and Drug Administration formally approved the equivalence of the potential hazards of the GE 3.0T Signa Excite System to the Signa 3.0T Magnetic Resonance System, a legally marketed predicate device, permitting General Electric to market the 3.0T Signa Excite System without additional premarket review.

The Center occupies a building on the main UCSD campus on Osler Lane adjacent to the Basic Science Building and the animal vivarium (a map of the location is found in the Appendix of this manual). The building has approximately 7,000 sq. ft (assignable). In addition to four magnet bays, the facility contains: 1) a machine shop for RF and gradient coil construction; 2) an electronics shop; and 3) two animal preparation/holding rooms. The Center also includes: 1) faculty office space for the Director and Associate Directors, 2) offices for three staff scientists who provide support in fMRI/neuroscience applications, pulse sequence development, and small animal imaging; 3) offices for the Administrative Director, the Network Administrator, an Engineer, and three administrative support staff; and 4) work space for post-doctoral fellows and students.

The building is ordinarily open weekdays from 8am – 5pm. Outside these hours access is restricted to approved personnel with card-reader access. To access the fMRI Center outside normal weekday hours, you must be a current center-certified scanner operator. Since there is much more limited help or support available outside normal working hours, operators are expected to have a acquired considerable experience running the scanners during normal working hours before being granted out-of-hours access. Out-of –hours access is not automatic and is granted at the Center Director's

discretion. Note: Outside normal hours the outside doors are to remain closed and locked. Subjects/research assistants are encouraged to use the black phone by the west-entrance to gain access (Phone: 2-0577 (3T west console room), 2-0580 (3T east console room)). Under no circumstances should door be propped open, or entry cards shared.

Principles of MR Imaging

Magnetic resonance imaging (MRI) is a highly flexible technique for making images of the human body. Hydrogen nuclei (protons) behave like small magnets, so that when a subject lies in a magnet the protons tend to align with the magnetic field. When properly excited the protons precess (rotate), producing a measurable signal in a nearby detector coil. The frequency of precession is proportional to the local magnetic field, so by making the field vary across the body the signals arising from different locations can be distinguished based on their frequency. There are three basic components to an MRI system: 1) a large, static magnetic field (e.g., 3 Tesla for the human imagers at the Center); 2) radio frequency (RF) coils that are used as a transmitter to excite the MR signal, and as a receiver to detect the MR signal; and 3) gradient coils that are pulsed on and off to produce linear gradients of the magnetic field for imaging. MRI techniques involve pulsing currents through the RF and gradient coils, so a particular technique is often referred to as a pulse sequence. By varying the pulse sequence, one can produce an enormous range of images with different spatial and temporal resolutions, and with substantially different contrast between tissues in the image.

Functional MRI (fMRI) is used to measure changes in blood oxygenation and blood flow that accompany neural activity. When a particular area of the brain is activated, the local blood flow increases dramatically and the local blood is more oxygenated. This change in oxygenation affects the local MR signal, so fMRI provides a way to map patterns of activation in the working human brain. In a typical fMRI experiment rapid dynamic images are acquired while a subject alternates between experimental and control conditions. The time series of images is then processed on a pixel-by-pixel basis to identify pixels that show a significant correlation with the alternating experimental and control periods.

The main magnetic field (e.g. 3 Tesla) is provided by a large magnet with a cylindrical bore with a diameter of 92.5 cm. Fixed within the bore is the gradient coil, with an inner diameter of 60 cm. A computer controlled bed moves in and out of the magnet bore to position the subject's head at the midpoint of the gradient coil. For brain imaging, the subject's head rests in the head RF coil, with an inner diameter of 38 cm. For functional MRI studies, three types of imaging are used:

1. *Localizer:* Brief images (about 20 seconds each) are acquired in three orthogonal planes in order to identify structural landmarks and choose the locations for imaging in the rest of the experiment. Typical time required is 1 min, although if re-positioning of the patient is necessary additional localizers may be required.

2. *High resolution anatomical images:* A 3D imaging sequence is used to acquire images of the entire brain at high resolution (e.g. 1x1x1 mm). The pulse sequence typically used is a 3D gradient echo, usually with an inversion preparation, which often typically requires 6-8 min.

3. *Rapid dynamic imaging:* Dynamic images are acquired while the subject performs the chosen task. Typically the pulse sequence used is an echo planar imaging (EPI) method with in-plane resolution of 3-4 mm, and a slice thickness of 3-6 mm. Typically each image is acquired after a single RF pulse, and the maximum image acquisition rate is about 12/sec. Each run of a dynamic series lasts from 3-8 min.

A full fMRI experimental session then consists of a localizer, one or more high resolution anatomical scans, and typically 3-6 dynamic imaging runs. Total time for the session ranges from 45-90 min.

Only individuals who have successfully gone through the Center's training program may perform MR scanning. This program consists of about 12 hours of lectures and supervised individual training, emphasizing safety as well as the basic operations of the scanner. Graduates of the program receive a Center-Certified Operator Certificate. Ongoing safety training is provided via an annual web-based quiz which is retaken annually. In addition operators must be current with scanner policies and operating procedures within the prior 4 months. During MRI research studies the Center-Certified Operator has the on-site responsibility to implement the safety guidelines. The Center-Certified operator for a study must also be named in the web-based scanner schedule. If the operator changes, the record must reflect this.

Potential Risks

The primary established hazard associated with MR imaging is that the magnet exerts a strong force on ferromagnetic objects. For this reason, ferromagnetic objects are excluded from the vicinity of the magnet so that they will not become projectiles. In

addition, each subject undergoes a standard screening procedure to determine whether they have any implanted materials that may pose a risk (see checklist at the end of this document). If there is any doubt about the nature of any implanted material, the subject will not be scanned. No ionizing radiation is used with MRI.

Although no other risks have been established for MRI, there are four areas of potential concern for which the FDA recommends prudent limits:

1) Exposure to a static magnetic field:

The FDA guideline is that magnetic fields up to and including 8 Tesla pose no significant risk. The limit of 8 Tesla is based not on known risks at higher field, but rather simply a lack of long-term data at those fields. Such higher field studies are underway at a few institutions. The Center's 3T magnetic fields are within the guidelines provided by the United States food and Drug Administration for clinical imaging and fall within the category of no significant risk. In high magnetic fields, rapid motion of the head can cause dizziness, vertigo, nausea, or a metallic taste. For this reason, the scanner bed moves slowly into the magnet bore and the subject is encouraged to remain still while in the region of the static magnetic field. The Operator will insure that rapid movements on the subject's part are minimized as the subject enters and exits the vicinity of the magnet. During the scanning, head motion is restrained by padding inserted between the subject's head and the head RF coil or other similar support. GE magnet sites often distinguish a Security Zone, defined by magnet room and its walls, from an Exclusion Zone defined by the five gauss line, which might extend beyond the magnet room. At the Center the 5 gauss line is inside the magnet room so that the Security and Exclusion Zones are the same. No pacemakers, metallic implants, neurostimulators, or

loose metal objects are permitted inside the magnet room unless authorized by fMRI Center Engineering team (contact: Larry May or Cecelia Kemper). Metal objects (e.g. limb braces, traction mechanisms, or stereotaxic devices, etc.) should not be placed within the MR magnet.

Quench with Vent Failure

A magnet quench can result in the release of cryogen vapor into the magnet room if the vent fails; white clouds of vapor appear in the magnet room. Cryogens released during a quench can cause asphyxiation, frostbite, or injuries due to panic. Magnet quenches are indicated by a loud noise, warning message, or the tilting of an image on the image screen. It is critical to have a well-planned method to quickly remove the patient and all personnel from the magnet room if a quench should occur.

Use this procedure in case of a sudden cryogen release into the magnet room.

1. Do not panic.
   - Staying calm helps you remain focused so you are able to safely remember and follow your planned method of action.
2. Using the intercom, tell the patient to stay calm and remain on the table.
   - Tell the patient that someone will be in shortly to offer assistance.
3. Turn on the magnet room exhaust fan.
   - Some systems vent automatically and there is no fan to turn on.
4. Prop open the door between the operator room and hallway.
   - This promotes air circulation.
5. Prop open the door to the magnet room.
   - If helium is venting in the room, the magnet room door may not open.
   - If the door cannot be opened, break the window to the magnet room to relieve pressure.
6. Enter the magnet room and help the patient exit.
   - If a gurney or wheelchair is needed to remove the patient, make sure it is a non-ferrous type.
   - When exiting, stay near the floor where the oxygen will be and immediately exit the magnet room.
7. Evacuate all personnel from the area until the air is restored to normal.

(From GE Medical Systems MR 3.0T Signa Excite™ Learning and Reference Guide, 2003)

To reduce electrical resistance, superconductive magnets use cryogens to super-cool the electrical conductor that generates the static magnetic field. Temperatures of the cryogens used might be as low as -269^{o} C (-452^{o} F). Occasionally a sudden boil-off of all of the cryogen or a quench occurs. A quench is accompanied by a loud noise and causes the rapid loss of the magnetic field. Any helium or nitrogen gas that might leak into the magnet room could displace oxygen. The Center's magnet rooms are equipped with vents to properly dispose of cryogen vapors. However if the vents should fail, there is a risk of asphyxiation or frostbite. If the vents should fail during a quench the procedure in the following table should be followed. Essentially, the procedure involves turning on any remaining working fans and opening doors to the operator room and to the magnet room to permit the ventilation of helium or nitrogen gas from the magnet room. Next the subject should be removed from the magnet.

2) Exposure to the RF field causes tissue heating:

The Radio Frequency (RF) fields used in MRI are non-ionizing electromagnetic radiation, and so do not pose the same type of risks as x-rays and radioactive tracer techniques. However, the RF fields do cause tissue heating. The FDA guideline is that there is no significant risk if the specific absorption rate (SAR) is:

a. Less than 4 W/kg whole body for 15 minutes,

b. Less than 3 W/kg averaged over the head for 10 minutes,

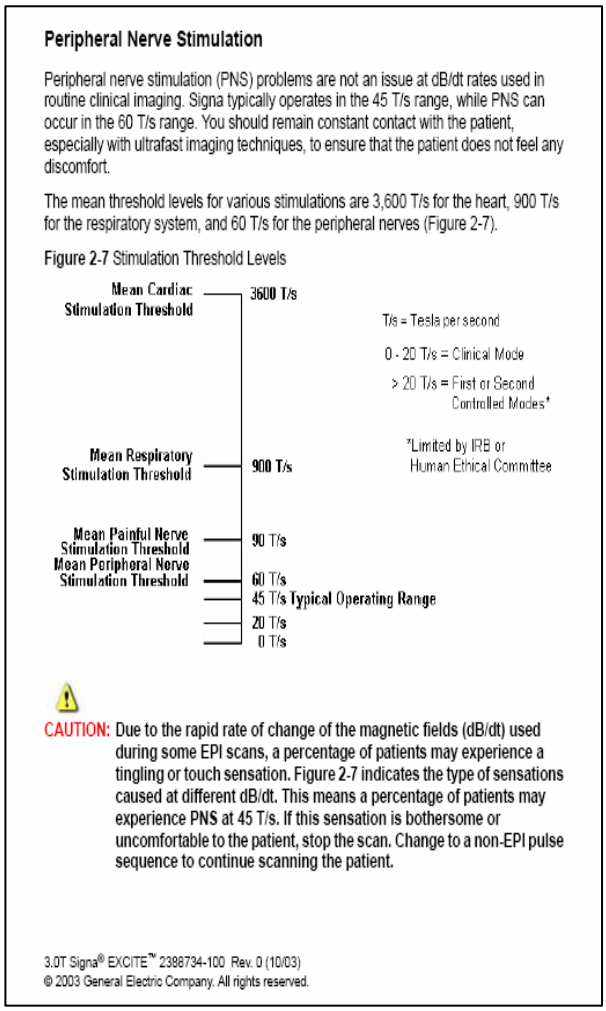
c. Less than 8 W/kg in any gram of tissue in the head or torso for 15 minutes, or

d. Less than 12 W/kg in any gram of tissue in the extremities for 15 minutes.

The pulse sequences used at the Center are similar to standard clinical pulse sequences, with minor modifications, and in these studies we will insure that the radio frequency energy loss in the tissues is below these federal guidelines. In addition, the scanner software calculates the amount of heating expected during the scan and compares the estimate against predetermined levels. If the estimate exceeds the levels, the system adjusts scan parameters. **The complete estimate of excessive heat exposure is based on the subject's weight.** Consequently each subject's weight must be accurately entered into the system before scanning. However, incorrectly entering a person's weight will not expose the patient to excessive SAR. Inadvertently setting weight low trips the power monitor below the SAR limit. Inadvertently setting weight high reduces the maximum number of slices/images that can be acquired per unit time. There is a sensor inside the magnet's bore to monitor temperature. The GE "Working Safely" manual recommends that the room temperature be no greater than 70^0 F (21^0 C) during scanning (GE Medical Systems MR 3.0T Signa Excite^{TM} Learning and Reference Guide, 2003, p. 2-22). Center imagers are equipped with a Signal power monitor system that tracks both instantaneous (peak) and time-averaged (1 sec) RF power delivered to the RF transmit coil. With this system the limit on power delivered to the RF coil can be set to insure that the pulse sequence does not exceed the FDA guidelines even if equipment fails. However, subjects should not be scanned if they have damp clothing, come in direct contact with expose circuitry in the the RF transmit coil surface, come into contact with a looped wire, or if unconnected receive coil or other cables have not been cleared from within the RF transmit coil. Finally, subjects with reduced circulatory function (e.g. those with hypertension or

impaired cardiac output), diabetes, obesity, old age, fever, or impaired ability to perspire may have a reduced capacity to disperse heat and should be studied with care only under IRB approval.

3) Exposure to rapidly switched magnetic fields can produce nerve stimulation: The gradient coils used for imaging produce time-varying magnetic fields (slew rate in dB/dt). Such fields, if sufficiently strong, can produce peripheral nerve stimulation. Stimulation can occur in peripheral nerves, muscle, and blood vessels. The FDA guideline is that switched gradient fields pose a significant risk if dB/dt is sufficient to produce severe discomfort or painful stimulation. The mean pain nerve stimulation threshold, the level at which half of subjects are likely to report painful stimulation, is 90 Tesla/Second. The mean peripheral nerve stimulation threshold, the level at which 50% of subjects might report a tactile sensation or metallic taste is 60 Tesla/Second. The slew rate of a typical scan is 45 Tesla/Second (see table above). Gradient switching rates are limited in the pulse sequence software used for fMRI to insure that there is no discomfort for the subject. On the GE 3.0 T Signa Excite systems once if the pulse sequence involves a slew rate greater than 20 Tesla/Second, the operator is prompted with the question:



Peripheral Nerve Stimulation

Peripheral nerve stimulation (PNS) problems are not an issue at dB/dt rates used in routine clinical imaging. Signa typically operates in the 45 T/s range, while PNS can occur in the 60 T/s range. You should remain constant contact with the patient, especially with ultrafast imaging techniques, to ensure that the patient does not feel any discomfort.

The mean threshold levels for various stimulations are 3,600 T/s for the heart, 900 T/s for the respiratory system, and 60 T/s for the peripheral nerves (Figure 2-7).

Figure 2-7 Stimulation Threshold Levels

CAUTION: Due to the rapid rate of change of the magnetic fields (dB/dt) used during some EPI scans, a percentage of patients may experience a tingling or touch sensation. Figure 2-7 indicates the type of sensations caused at different dB/dt. This means a percentage of patients may experience PNS at 45 T/s. If this sensation is bothersome or uncomfortable to the patient, stop the scan. Change to a non-EPI pulse sequence to continue scanning the patient.

“Attention, Possible patient nerve stimulation. OK”. If a pulse sequence is prescribed that would exceed the maximum value set by the appropriate governing board (UCSD Institutional Review Board) the software will not accept the value and prompt the user to set a lower value.

Following each scan session in which a subject reports any somatosensory, painful or motor stimulation, the subject should complete a peripheral nerve stimulation form (Forms are available electronically from the fMRI Center’s website, in as paper copies each scan room).

4) Acoustic noise. When current is pulsed through a gradient coil sitting in a magnetic field it acts somewhat like a loudspeaker, creating a sharp tapping sound at the characteristic frequency of gradient pulsing (around 1 kHz). The sound levels are most intense during dynamic imaging that requires rapid gradient switching. Sound pressure levels at the center of a head gradient coil were measured to be in the range from 122-131 dB SPL for a 3T scanner during echo planar imaging (Foster, et al 2000). The FDA guideline is that the acoustic noise poses a significant risk if peak acoustic noise is over 140 dB. For the pulse sequences used on our scanners the acoustic levels are below this limit. In addition, all individuals entering the magnet bore must be provided adequate sound protection. The ear-plugs we use are rated to reduce acoustic noise by 30 dB. Earplugs must be used when scanning on the GE 3.0 T Signa Excite system to keep sound exposure less than 99 DbA (GE Medical Systems MR 3.0T Signa Excite™ Learning and Reference Guide, 2003, pp. 2-21, 2-22). The subject always has the right to end the study at any time if the acoustic noise is not tolerable.

Risk Management

Operators must be trained and demonstrate competence in the operation of the MRI scanner. They must also be trained and demonstrate knowledge in risks of MRI and be able to respond appropriately to emergency situations should they arise.

Each examination will last approximately 1-1.5 hours. Prior to arriving at the Center, each subject is screened to make sure that there are no counter-indications for MRI (see checklist at the end). We recommend that subjects are screened 3 times; (1) When the subject is first recruited for a study, the subject is initially screened for any contraindication to MRI. This early screening provides adequate lead time to investigate any “yes” responses on the screening form. It also prevents cancellation of scanner sessions due to subject incompatibility (which incur penalties). (2) When the subject arrives at the Center, before entry into the magnet room every subject will again be carefully screened for any implanted material that could constitute a risk in the scanner. The subject will be asked to fill out a checklist again under the supervision of the Operator, and then each item will be verbally confirmed. If the subject is not sure about the answer to any of the checklist questions, they will not be scanned. No one may enter the magnet room unless they have completed a screening form. Subjects attending for repeat investigations need to complete a new screening form (the form only remains valid for 24 hours). (3) Finally, immediately prior to taking the subject into the scan room, a third pre-procedure checklist is completed. This form is an *“aide memoire”* for the operator and re-lists the absolute contraindications to MRI, as well as a checklist to clear the subject of any metal objects about their person / in pockets. Any

subject with diminished cognitive competence will be screened with a hand-held metal detector to determine if they have overlooked metal on their person.

Pregnant women will be excluded from studies at the Center. Although “to date there are no known deleterious effects related to the use of MR procedures during pregnancy” (Sawyer-Glover and Shellock, 2000), the FDA guidelines indicate that the safety of MR for imaging the fetus has not been established. Women of child-bearing age will be scanned only if the project was approved by the UCSD Institutional Review Board. Age range and gender distribution of subjects should be provided in the IRB application, along with methods to exclude pregnancy (questionnaire, pregnancy test, gender/age restriction…. etc.).

Any behavioral, physiological, or other equipment to be brought into the magnet room must be approved for MR compatibility by the Center Engineering team. MR compatibility must be documented on the Center’s MR compatibility form, and the device must bear a tag to demonstrate that it has been approved (Appendix). Approved devices are positioned in the MRI scan room BEFORE the subject enters the scan room.

If there are no counter-indications for MRI, the subject will lie on the bed just outside the opening to the magnet and be positioned in the head coil. A step-by-step description of patient placement is found in the Appendix. A synopsis is presented here. Foam pads or towels will be placed around the subject’s head for stabilization. Alternative head movement constraints may be used as long as the comfort of the subject is maintained. The subject will be given ear-plugs and instructed in their proper use. For some studies the subject may also wear headphones. Usually a button-press

response box or a joystick will be positioned where it can be manipulated by the subject. No cables should touch the subject's skin. Looped cables should not be placed near the subject. Any unused cables, transmit or receive coils, or any other unused equipment should be removed from the bore and from the RF coil. The bed is then advanced into the magnet at a rate of 8 cm/s through a computer-controlled interface.

If, at any time, a subject becomes unable to tolerate the procedure, the exam will be terminated. Subjects will be in constant voice contact with the operator via an intercom system. Subjects who cannot communicate reliably with the console operator should not be studied.

Although there are no known long-term cumulative effects of exposure to the electromagnetic fields used in MRI, it is prudent to limit the number of studies on a single individual. The recommended consent form includes asking the subject to specify the number of MRI examinations (either as a research subject or for medical purposes) they have undergone during the last year. Our recommendation is that investigators should limit studies on one subject to six within any one-year period. For some studies involving unique subjects more studies may be required by the scientific goals of the experiment. In these cases a separate justification for the larger number of studies should be included in the IRB application and in the proposal sent to the Center.

MR is extremely safe and no adverse event is anticipated. As described above, the primary risk is from metallic objects brought into the scanner room that could become projectiles. To minimize this risk, nonessential personnel are excluded from the scanner room to insure that no ferromagnetic objects are brought near the magnet. In each scan room the 5 Gauss field limit is marked on the floor. No one may enter the

magnet room unless they have been screened and checked for metal objects by the Center-Certified Operator running the console. National reviews of the few cases where metal objects caused injury during a scan have found confusion about who had the authority and responsibility to prevent metal objects from entering the scanning room. At the UCSD Functional MRI Center, the Center Certified Operator has the ultimate authority to enforce safety standards.

Given the potential risks of peripheral nerve stimulation and over heating associated with rapid dynamic imaging, the Operator should frequently inquire about the subjects comfort and room temperature. Typically some verbal contact should be made with the subject prior to each scan.

All records will be kept confidential. At the beginning of each study the Principal Investigator will provide the Operator with a subject number for each subject. This number will be recorded in the computer database for that scanner, along with a record of each of the pulse sequences used for the study. This record will be archived. No identifying information will be stored except the number provided by the PI. In this way the subject's anonymity is preserved while allowing the Center to maintain records of the procedures used in each study.

Maintenance service on the system will follow GE guidelines. To reduce risks related to the static magnetic field, gradients, electromagnetic RF fields, and acoustic noise operators should follow the requirements outlined in the Summary of Safety Guidelines listed at the end of this manual.

Emergencies

If a metal object traps a subject in the magnet bore so that removal is not possible without quenching the magnet, press the Magnet Rundown System button on the side wall as one enters the magnet room (See Figure below). In about two minutes the magnetic field will drop to a level where metal objects can be removed. Although this is a measure of last resort, quenching is further justified if a subject has been injured.

The Center is not a medical facility. Emergencies at the Center should be treated as they would in at any other UCSD academic facility.

In the event of a fire, rescue, police, or medical emergency at the Center:

1. **Call 911 or 44357**. This is Campus 911 not the general 911 number. The Operator will call the fire department, campus security, etc. In case the operator does not know the Center's location: **Center for Functional MRI, W. M. Keck Building, North side of Osler lane at the south end fo the basic science building.** Phone: (858) 822-0577 (3T west conosle room), (858) 822-0580 (3T east console room). Directions to the Center and a map are found in the Appendix of the manual.
2. Release the MRI bed from the scanner and roll it into the hallway outside the scan room to insure that emergency

Emergency Magnet Rundown

The **Emergency Magnet Rundown** (Figure 2-15) operates as follows and is located inside the magnet room:

- 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

Figure 2-15 Emergency Magnet Rundown Unit

WARNING: The Emergency Magnet Rundown should only be used to free someone pinned to the magnet 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.

personnel will not go near the magnet. All Center-trained operators must have experience with this maneuver before being certified.

3. Administer CPR as needed. An Automated External Defibrillator is available in the atrium between the two 3T console rooms. A first aid kit is available in the cupboards adjacent to the photocopier. Supplementary oxygen is available from the ceiling vent above the photocopier, or via one of the cylinders in the 3T console rooms.

If a **fire** occurs in the magnet room (1) press the Emergency Off button. This is the red button on the upper left side of the console keyboard (See below). There are also Emergency off buttons on each side of the front magnet facing. Pressing the

button cuts power to the magnet room and removes electrical power to all components of the system other than the static magnetic field and the Magnet Shutdown Unit. (2) Evacuate the subject. (3) Pull the fire alarm and call Campus **911**. (4) Use the fire extinguishers to contain the fire. Notice that the white extinguishers are in the magnet rooms and are magnet safe. The red extinguishers should not be taken into the magnet room. The rule of thumb is to attempt to extinguish a fire that is not as tall as your waist. In the presence of a larger fire, evacuate all individuals to a safe location.

When the fire department arrives, center personnel must determine whether firefighters must take ferromagnetic objects into the magnet room. If ferromagnetic equipment must enter the room, quench the magnet by pressing the button on the

Magnet Rundown Unit. The Magnet Rundown Unit is on the side wall as one enters the magnet room.

Contact with Bodily Fluids

The Center's general rule governing contact with bodily fluids is to take Universal Precautions (See Appendix). Universal Precautions begin with the assumption that all research participants harbor a contagious disease and that only trained staff should manage the clean up of bodily fluids. Several Center staff are being trained to clean up and dispose of small amounts of blood, urine, and other fluids. During normal working hours these staff can be contacted through the Center Director's Office. When larger amounts of fluids need to be managed or after hours call Environment Health and Safety at 43660.

Visitors

Visitors are not permitted in the magnet rooms without prior approval of the Center Director.

Summary of Safety Guidelines

I. Manuals

- The UCSD Center for Functional MRI Operator's Manual should be in the control room whenever a subject is run.
- The Center's Safety Manual should be in the control room whenever a subject is run.

II. Certification

- All console operators must complete the center's operator training and safety courses and updates.
- All console operators must earn and maintain a Center Certified Operator certificate.
- To maintain active Certification an operator must maintain safety training via the annual on-line web-based quiz and regularly perform research scans at UCSD (minimum of 4 months currency). The Center Director will monitor operator activity.
- Research assistants who are not operators, but are essential to the running of a research study may enter the scan room, providing they are safety trained – having taken the Center safety lecture, the annual web-based safety quiz and any updates.

III. Line of Authority

- Everyone in the magnet suite has the responsibility to insure safety.
- The Center-Certified Operator running the console has the ultimate AUTHORITY to enforce safety standards.
- The Center-Certified Operator running a study is that operator listed in the web-based scheduling program. Any changes to the operator for a particular study MUST be reflected in the scheduling program.
- No one may cross into the magnet room without approval from the Center-Certified Operator.

IV. Subject Policies

- Specific IRB and the Center Director's approval must be obtained to study Individuals less than 3 years old.

- Only individuals who can be studied without anesthesia may be scanned at the CenterWomen of child-bearing age may be studied at the Center only for protocols that have IRB approval. The submitted IRB protocols must include the proposed age range and gender distribution of subjects to be studied, and the means to establish that a subject is not pregnant.

- Studies involving pegnant women or patients taking fertility treatments must be specifically approved by the IRB and the Center Director.

- All research subjects may be scanned only after obtaining an approved IRB protocol.

- Subjects with metal fragments in brain, eye, auditory canal, spinal cord, or internal organs may not enter the magnet room.

- Subjects who screen positive for shrapnel or bullets outside of the areas mentioned above may be studied after documenting the location of the objects on the anatomical diagrams included in the screening checklist. As with all subjects, these individuals must be monitored for temperature comfort.

- Subjects with whom no reliable communication can be maintained may not be scanned at the center.

- In the event of an accident that might expose any research subject or research personnel to body fluids universal precautions should be followed. Universal precautions stress that all individuals should be assumed to be infectious for blood-borne diseases such as hepatitis B. A description of universal precautions is contained in the appendix.

V. Screening

- Subjects should be screened for the presence of implanted or attached medical devices or other objects. The screening should use approved forms and occur during recruitment into a study and each time a subject enters the magnet room.

- Only a Center Certified Operator should perform the screening prior to a study.

- Any patient with diminished cognitive competence should be screened with a hand-held metal detector to determine if they have overlooked metal on their person.

- Individuals who screen positive for implanted or attached medical devices should not be allowed into the magnet room unless prior approval is obtained from the Center Director and Safety Officer.

- To permit an individual who screens positive for implanted or attached medical devices to enter the magnet room requires the name of the device, its manufacturer, and its part number. After the device is identified, documentation of its MR compatibility and safety is required.

IV. Devices

- The MR Engineering team must review the safety of any behavioral or physiological device entering the magnet room.

- Device approval must be documented using the MR Device Compatibility Form, and tagged to show thay have been approved

- Approved devices must be postioned in the scan room BEFORE any subjects are positioned on magnet table, or in the vicinity of the magnet.

- Special care will be given to positioning of any wires attached to the device. Wires should not touch the research subject. Wires should be kept straight and not contain loops.

- Remove unused transmit or receive coils from magnet bore and bed.

V. Emergencies

- Release table latch and pull subject out of the bore.

- Release MR bed and roll it into the hallway between the 3T scanners. All Center trained operators must have experience with this maneuver before being certified.

- Call 911

- We do not support a crash cart.

- Administer CPR as needed. An AED is available between the 3T console rooms. All operators are encouraged to obtain CPR training.

- Use the Safety Kit to manage minor injuries. Gloves should be used when managing minor cuts.

- Manage fires with the white extinguisher. Turn off electrical power to the scanner with the red emergency buttons on the console, or body of the scanner. Close doors to contain smoke/flames.

- Do not quench ("emergency run down") the magnetic field unless a subject is trapped by a metallic object in the scanner and is injured or in danger of becoming injured.

VI. Visitors

- Visitors are not permitted inside the magnet rooms without permission of the Center Director.

VII. Peripheral Nerve Stimulation and other Sensory Effects

- If the patient complains of pain or discomfort including headache stop the scan immediately. If the pain is not due to a biomechanical cause (awkward placement of body, poor placement of neck or head supports, etc.) terminate the study. If the discomfort is due to a biomechanical cause, the study may continue if the cause is corrected.

- If the patient complains of tingling, a light touch sensation, or muscle twitching stop the scan and access the extent of discomfort. If the discomfort cannot be minimized, the study must terminate.

- Use the Report of Patient Peripheral Nerve Stimulation Form to document complaints of unexplained discomfort or pain immediately after the subject has been removed from the scanner room. Copies of the form should be sent to the Center Director and to the Center Safety Officer.

- When giving informed consent and, again, prior to entry into the magnet room, subjects will be informed of the possibility that they should report to the scan operator excessive warmth, visual flashes, dots, scintillations, or tactile sensations during an MR study.

VII. Acoustic Noise

- All individuals entering the magnet bore must be provided adequate sound protection. Earplugs and headphones can attain this standard. (< 99 db of audible noise).

- When earplugs are used to provide sound protection, only center-approved earplugs should be used.

- Dispose of earplugs after each subject is scanned.

VII. Radio Frequency Fields

- Each person's weight must be entered into the appropriate program field before starting a scanning session. **This is a critical safety step**.

- The patient fan should be ON at all times to maintain adequate airflow through the bore.

- The Console Operator should inquire whether the subject is too warm or cold periodically during the study.

- Subjects should not be scanned if they have damp clothing, come in contact with the RF circuitry of an RF coil surface, come into contact with a looped wire, or if unconnected receive coil or other cables have not been cleared from within the RF transmit coil.

- Use non-conducting pads when needed. Position the subject's hands to the side and insure that legs are not crossed.

- Place foam between the subject and the bore.

- When using surface coils place a sheet or pillowcase between the coil and the patient's skin.

- Removable eye makeup must be washed off prior to a scan.

- Subjects with permanent eyeliner or other metallic ink tattoos may be scanned only after obtaining informed consent under an approved IRB protocol. Such subjects must be informed of the risk of skin irritation. Maintain close communication with these subjects during the course of the scan, and be ready to terminate the exam if symptoms develop.

- Jewelry should be removed prior to a scan. On a case by case basis the Console Operator may decide whether rings may be worn during a scan.

- Scans should not be performed if the magnet room is warmer than 21^{o} C (70^{o} F).

- Do not interfere with the performance of the RF power monitor.

- Head studies producing SAR values greater than 3.2 Watts/kg must be approved by the Center Director and have IRB approval.

References

Pulp Sources.

Elmquist C, Shellock, FG, Stoller, D. Screening adolescents for metallic foreign bodies before MR procedures. Journal of Magnetic Resonance Imaging. 1996;5:784-785.

Foster JR, Hall DA, Summerfield AQ, Palmer AR, Bowtell RW. Sound-level measurements and calculations of safe noise dosage during EPI at 3T. Journal of Magnetic Resonance Imaging. 2000;12:157-163.

Kanal, E., Shellock, FG, Talagala L. Safety considerations in MR imaging. Radiology 1990;176:593-606.

Liburdy RP. Carcinogenesis and exposure to electrical and magnetic fields. N Eng J Med 307:1402 (1982).

Shellock FG. Pocket Guide to MR Procedures and Metallic Objects: Update 2000.

Sawyer-Glover, A. M., Shellock, FG. Pre-MRI procedure screening: Recommendations and safety considerations for biomedical implants and devices. Journal of Magnetic Resonance Imaging. 2000;12:92-106.

Shellock FG, Kanal, E. SMRI report. Policies, guidelines, and recommendations for MR imaging safety and patient management. Questionnaires for screening patients before MR procedures. Journal of Magentic Resonance Imaging. 1996;4:749-751.

Woking Safely. GE Medical Systems MR 3.0T Signa Excite™ Learning and Reference Guide, 2003, Chapter 2. (Available in UCSD Functional MRI Center safety manual kept on each console).

E-sources.

International Electrotechnical Commission: www.iec.ch

Shellock/Baccaco MRI Safety website: www.MRIsafety.com

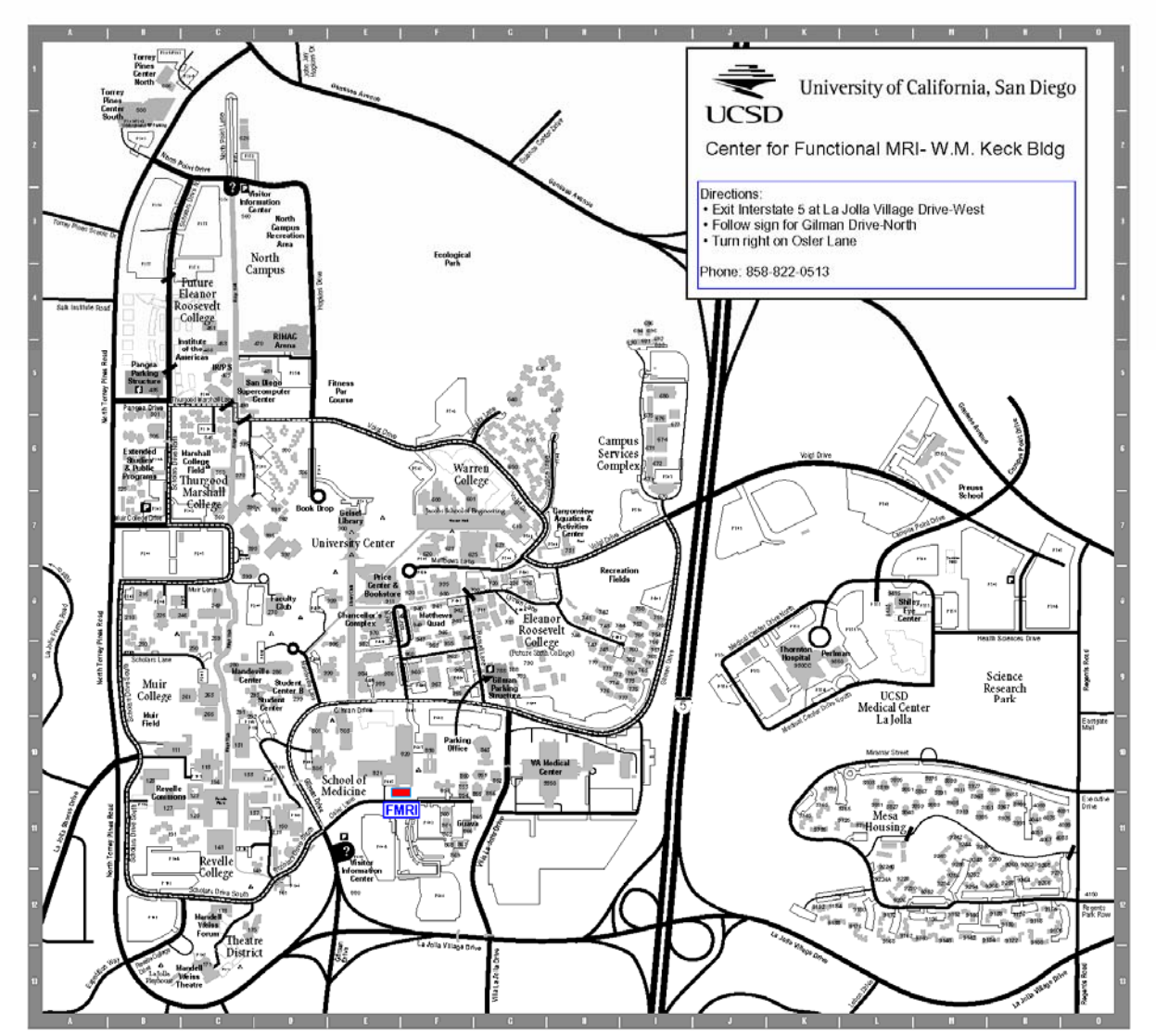
Appendices

1. Patient positioning for surface or phase array coils
2. Center map and directions
3. Comprehensive Pre-Procedure Screening form
4. Magnet room pre-entry screening form (Hazardous Items Checklist)
5. Scan Subject Exit Form
6. Peripheral nerve stimulation form
7. MR compatibility data sheet
8. Descriptions of Universal Precautions
9. Emergency procedures

Patient Positioning

Quick Steps: Position a Patient with a Surface or Phased Array Coil
1. Remove any other coil or unused accessory device from the magnet. 2. Place comfort pads on the table to make the patient comfortable. 3. Place a clean cotton sheet over the comfort pads. 4. Position the patient on the table and the coil in the area of interest on the patient. 5. Use additional pads to immobilize and make the patient comfortable. 6. Provide the patient with the Patient Alert Bulb and give instructions on its use. 7. Provide ear plugs for the patient after all instructions have been given. 8. Instruct the patient to close his or her eyes. 9. Press the Align Light to turn on the red laser light. 10. Plug in the coil. 11. Check to make sure the LED at the coil plug-in is green. 12. Move the table in slowly until the crosshair of the alignment light is over the center of the area of interest. 13. Press Landmark to communicate the region of interest center to the system. 14. Press Move to Scan to move the patient to isocenter (center of magnet). 15. Place thermal pads where the patient touches the bore to help prevent warming. 16. Proceed with the scan prescription, selecting the appropriate coil type and name.

Directions to the UCSD Center for Functional Brain Imaging



Universal Precautions

1. **Barrier protection** should be used at all times to prevent skin and mucous membrane contamination with blood, body fluids containing visible blood, or other body fluids (cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids, semen and vaginal secretions).

   Barrier protection should be used with ALL tissues.

   The type of barrier protection used should be appropriate for the type of procedures being performed and the type of exposure anticipated. Examples of barrier protection include disposable lab coats, gloves, and eye and face protection.

2. **Gloves** are to be worn when there is potential for hand or skin contact with blood, other potentially infectious material, or items and surfaces contaminated with these materials.
3. Wear **face protection** (face shield) during procedures that are likely to generate droplets of blood or body fluid to prevent exposure to mucous membranes of the mouth, nose and eyes.
4. Wear **protective body clothing** (disposable laboratory coats (Tyvek)) when there is a potential for splashing of blood or body fluids.
5. **Wash hands or other skin surfaces** thoroughly and immediately if contaminated with blood, body fluids containing visible blood, or other body fluids to which universal precautions apply.
6. **Wash hands immediately** after gloves are removed.
7. **Avoid accidental injuries** that can be caused by needles, scalpel blades, laboratory instruments, etc. when performing procedures, cleaning instruments, handling sharp instruments, and disposing of used needles, pipettes, etc.
8. Used needles, disposable syringes, scalpel blades, pipettes, and other **sharp items are to be places in puncture resistant containers** marked with a biohazard symbol for disposal.

http://www.niehs.nih.gov/odhsb/biosafe/univers.htm